# MODEL CORE CURRICULUM FOR PHARMACY EDUCATION

-2015 version-

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#### **PREFACE**

Progress in advanced science and technology for the development and application of pharmaceuticals is dependent on the availability of highly skilled pharmacists and pharmaceutical researchers. Pharmacists of the future should have an international outlook and be committed to lifelong learning. University and college faculties and departments of pharmaceutical sciences play a major role in ensuring that pools of such pharmacists and pharmaceutical researchers are available by improving the quality of pharmacy education offered and meeting social responsibilities to uphold the highest standards for their qualification. To achieve those goals, Japanese educators reviewed the curriculum content from the viewpoint of overall pharmacy education and reorganized the courses from a "teacher-centered" to a "learner-focused" format.

The Japanese Ministry of Education, Culture, Sports, Science and Technology (MEXT) compiled the first version of the *Model Core Curriculum for Pharmaceutical Education*, which was published by the Pharmaceutical Society of Japan in August 2002. That volume was used during the period of transition (starting in 2006) of tertiary pharmaceutical science education from a 4-year to a 6-year course. Enrollment in the 6-year course has shown steady growth since its introduction. Evaluations of the new curriculum for the education of pharmacists, which includes practical hospital and pharmacy training, indicated that it represents an improvement over the previous, traditional format.

Approximately 10 years after the initial curriculum was published, the *Model Core Curriculum for Pharmacy Practice Experiences* was separately collected in an additional volume. During and after the transition period in pharmacy education, certain problems in applying the new curriculum became evident, for example: 1) The scientific content had become outdated. 2) The practical training aspects needed to be improved to reflect progress in various medical fields. 3) The content was overabundant, because the curriculum was developed as a stacked system, making it difficult to demonstrate the uniqueness of university education for pharmacists. 4) In addition to training activities, the importance of research also needed to be emphasized. Therefore, MEXT and the Pharmaceutical Society of Japan set up multiple committees to examine revision of the curriculum.

The subsequent revision of the *Model Core Curriculum for Pharmacy Practice Experiences* addressed five main points. 1) The contents were reduced to coverage of the model core curriculum, with 70% equivalent to the number of education courses and the remaining 30% offering specialized educational text. 2) The "Pharmacy Practice Experiences" and "Research" regions were enhanced. 3) The format of the curriculum-based contents focused on the application of an "outcome-based education" system instead of the "ticked-off item system." 4) The 10 required items upon graduation from the 6-year course were grouped under "Professional Competencies for Pharmacists." 5) Learning areas were clearly distinguished under seven major headings.

This *Model Core Curriculum for Pharmacy Education (2015 Version)* was also developed through a process of review and revision, including MEXT approval, and has been used by newly enrolled students

in pharmaceutical science faculties since 2015. Major new features of this curriculum are: 1) The focus was changed to outcome-based education in terms of "Professional Competencies for Pharmacists." 2) To help students acquire the final "Professional Competencies for Pharmacists," general instructional objectives (GIOs) and specific behavioral objectives (SBOs) were set. 3) Text related to Items A to G was edited to minimize the number of pages covering carefully selected contents. 4) The "Pharmacy Practice Experiences" and "Research" sections were limited to actual practices in hospitals and pharmacies and those that can be carried out in all faculties and departments of pharmaceutical science, respectively.

Continuing advances in pharmacist technology and drug development are remarkable, although they are accompanied by rising healthcare costs in developing countries. It is therefore an urgent task to globalize medical education, including that in the pharmaceutical sciences. In recognition of that reality, Japan will continue efforts to ensure that its education system, curriculum content, and knowledge taught meet or exceed international standards. The *Model Core Curriculum for Pharmacy Education (2015 version)* is therefore consistent with the WHO 8-star pharmacist concept for optimum pharmaceutical care and decision making.

#### PROFESSIONAL COMPETENCIES FOR PHARMACISTS

- 1. **Professionalism**: Fulfill the legal, ethical, and professional responsibilities of pharmacists.
- 2. **Patient-oriented attitude**: Respect the rights of individuals and promote the health and welfare of patients and consumers.
- 3. **Communication skills**: Communicate effectively with patients, consumers, and other healthcare professionals to provide necessary information.
- Interprofessional team-care: Collaborate with healthcare teams in hospitals and regional communities.
- 5. **Basic sciences**: Understand the effects of medicines and chemicals on living bodies and the environments.
- 6. **Medication therapy management**: Contribute to the optimal use of medicines through pharmaceutical care.
- 7. **Community health and medical care**: Contribute to public health and pharmaceutical hygiene and enhance community healthcare and home care.
- 8. **Research**: Engage in research on drug development and the appropriate use of medicines to improve the healthcare environment.
- 9. **Lifelong learning**: Continue lifelong professional development in response to the advances in healthcare.
- 10. **Education and training**: Contribute to the development of the next generation of professional pharmacists.

To ensure that pharmacists acquire professional competencies, general instructional objectives (GIOs) and specific behavioral objectives (SBOs) were established.

# A. Philosophical Principles for the Education of Student Pharmacists

#### (1) Mission of Pharmacists

GIO: To fulfill the responsibilities of a pharmacist by learning the history of medical care and pharmacy as well as to understand the roles of the pharmacists in managing public health, providing safe medical services, and preventing drug disaster.

#### 1) As Healthcare Professionals

- 1. To always keep viewpoints of patients/consumers and maintain the attitude of a healthcare professional.
- 2. To have a responsibility to proactively contribute to recovering and maintaining patient/consumer health
- 3. To act responsibly as a member of interprofessional teams to contribute to regional healthcare, medical care, and welfare.
- 4. To communicate personal beliefs on the healthcare professional(s) required by patients, their family, and consumers.
- 5. To communicate personal beliefs on the meaning of life and death.
- 6. To communicate personal beliefs on the meaning and role of each individual in life.
- 7. To communicate personal beliefs on the significance of accepting various senses on life and death, values, and beliefs.

#### (2) Roles of the Pharmacists

- 1. To understand the roles of pharmacists must fulfill for patients/consumers.
- 2. To describe the scope of activities of pharmacists (in healthcare facilities, pharmacies, the pharmaceutical industry, public health administration, etc.) and their roles in the society.
- To describe the role of pharmacists in the appropriate use of pharmaceuticals and pharmaceutical care.
- 4. To describe the probable effects of pharmaceuticals.
- 5. To describe the role of pharmacists in the production of pharmaceuticals (research and development, manufacture, etc.)
- 6. To describe the role of pharmacists in healthcare management, prevention of disease, self-medication, and public health.
- 7. To describe the role of pharmacists in preventing drug abuse and suicide.
- 8. To suggest new roles of pharmacists with demographic changes in society, e.g., an aging society with declining birth rates.

#### (3) Patient Safety and Minimization of Adverse Drug Events

- 1. To keep patients safe by recognizing the risks associated with medications.
- 2. To describe the concept of the WHO patient safety guidelines.
- 3. To describe the pharmacist's duty and responsibility in healthcare risk management.
- 4. To describe the cases of major errors and incidents in pharmaceutical treatment, their causes, and preventive measures.

- 5. To understand and discuss the sufferings of the patients with serious side effects and their families and the preventive measures available.
- 6. To describe the causes, social backgrounds of, and support for victims of major drug disasters, such as thalidomide, SMON, untreated blood products, sorivudine, etc.
- 7. To understand major drug scandals and the mental anguish of patients and their families and to discuss preventative measures.

#### (4) Past and Future of Pharmacy in Japan

- 1. To describe the roles the pharmaceutical science has played in its historical perspective and health care.
- 2. To describe the history and effects of pharmacotherapy on society.
- 3. To describe the history and transition of the role of the pharmacists, including the separation of dispensing and prescribing.
- 4. To understand and discuss the future pharmacists and their roles.

#### (2) Ethical Values Required of Pharmacists

GIO: To acquire the ethical values regarding life and healthcare to proactively behave with consideration of ethical matters and heighten the sensitivity as a healthcare professional.

#### (1) Bioethics

- 1. To describe the sanctity of life in your own words.
- 2. To describe the principles of bioethics (including respect for autonomy, non-maleficence, beneficence, justice, etc.).
- 3. To discuss the ethical issues on life and death and to express your own beliefs.
- 4. To describe the concepts of life transitions in accordance with progress in science and technology and the shifting social mores.

#### (2) Medical Ethics

- 1. To describe the tenets of medical ethics (The Revised Declaration of Geneva, etc.).
- 2. To describe the ethical standards followed by pharmacists (the Code for the Pharmacists, Code of Ethics for Pharmacists, etc.).
- 3. To describe the ethical issues associated with progress in healthcare science.

#### (3) Patients' Rights

- 1. To recognize the importance of considering the patients' sense of value and their humanity.
- 2. To describe the details of the patients' fundamental rights (Declaration of Lisbon on the Rights of the Patient, etc.).
- 3. To describe the significance of patients' right to self-determination and the necessity of obtaining informed consent.
- 4. To respect the confidentiality of patient information, manage it ethically, and to provide appropriate information to patients.

# (4) Research Ethics

- 1. To describe ethical standards governing clinical research (the Declaration of Helsinki, etc.).
- 2. To describe the ethical guidelines governing research involving human subjects.
- 3. To conduct research with due respect for justice, social significance, and integrity, while adhering to legal guidelines and regulations.

# (3) Building Collaborative Relationships among Patients, Pharmacists, and Other Healthcare Professionals

GIO: To understand their mentality, position, and circumstances of others through communication with the patients/consumers and other professionals and to foster relationships of mutual trust.

#### (1) Communication

- 1. To describe elements necessary for transmitting hopes, wishes, and information.
- 2. To describe the importance of both verbal and non-verbal communication.
- 3. To describe adjust modes of communication according to the position, culture, and customs, etc. of individuals.
- 4. To be aware of psychological factors affecting interpersonal relationships.
- 5. To behave with consideration for the mental conditions of others and to remain aware of changes in those conditions.
- 6. To contact others by being aware of your mental conditions.
- 7. To gain an understanding of the thoughts processes and feelings of others by asking appropriate questions and listening carefully to their answers.
- 8. To convey your thoughts and feelings to others using the methods most appropriate for each individual.
- 9. To respect the opinions of others and to work to identify solutions to problems through collaboration.

#### (2) Communicating with Patients/Consumers

- 1. To describe in detail the conditions/diseases and associated care regimens affecting the physical and mental health of the patients, their families, and others involved.
- 2. To behave with the utmost consideration of the physical and mental health, value systems, and beliefs of patients/consumers and their families.

#### (4) Collaboration among Healthcare Professionals

- GIO: To understand the necessity for collaboration among medical, welfare, public administrative, educational, and other relevant professionals and to act as a member of a team.
  - 1. To describe the significance of interprofessional collaborative work among health, medical care, welfare, and nursing care.
  - 2. To describe the roles of pharmacists, healthcare professionals, and government bodies participating in interprofessional collaboration.
  - 3. To describe the roles of pharmacists in contributing to the interprofessional collaborative work, each

- professional, the patients and their families.
- 4. To recognize the limits of your own abilities and to seek support from other professionals depending on the situation.
- 5. To understand the importance of teamwork and sharing information, and endeavor to play a proactive role as a member of a team.

#### (5) Self-Development and Fostering the Next Generation of Pharmacists

GIO: To understand the importance and necessity of life-long learning, and to acquire the willingness and action to hand on the acquired knowledge, skills, and attitude and behaviors to the next generation.

# 1 Learning Methods

- 1. To focus on current issues in healthcare, welfare, and medication, social trend, and scientific advances, finding out new methods of problems solving.
- 2. To clarify the important matters and problems on the contents of lectures, textbooks/papers domestic and international, and retrieved information.
- 3. To assess the reliability and validity of information collected.
- 4. To integrate information collected logically and combine it with previous knowledge as well as with your own thinking and experience.
- 5. To use the Internet as a tool to expand sources of knowledge available, while maintaining information security and privacy.

#### (2) Outline of Pharmaceutical Education

- 1. To describe the "10 Professional Competencies for Pharmacists" with concrete examples.
- 2. To recognize pharmaceutical science as an integrated science and to link the role of pharmacists with its learning content.

#### (3) Life-long Learning

- 1. To describe the importance of life-long learning and to describe its significance.
- 2. To collect information necessary for the continuous life-long learning.

#### (4) Cultivation of Next Generation Human Resources

- 1. To contribute to the development of the next generation of pharmacists and to act as a role model.
- 2. To provide necessary training to less experienced students/pharmacists.

#### **B. Pharmaceutical Sciences in Society**

GIO: To understand systems, economic issues, and legal norms governing healthcare and welfare, together with the roles of the community pharmacies and pharmacists and to act in full compliance with laws and guidelines in order to contribute to the public good as a pharmacist.

#### (1) Pharmacists Serving the Public

# GIO: To understand human psychology and behavior, social structure, and how pharmacists interact with individuals and society.

- 1. To describe factors influencing human behavior.
- 2. To discuss various attitudes toward and beliefs about pharmaceuticals held by individual and society.
- 3. To discuss the purposes of the various systems and regulations and guiding pharmacists' activities from the perspectives of individuals and society.
- 4. To discuss the importance of the pharmacist's adhering to ethical and legal norms.
- 5. To comply with ethical and legal norms governing professional activity and behavior.

### (2) Laws and Regulations Governing Pharmacists and Pharmaceuticals

GIO: To understand the laws and regulations and their significance for the work of pharmacists, pharmaceutical affairs, and public health, particularly those governing the preparation and dispensing of pharmaceuticals and related products (quasi-drugs, cosmetics, medical devices, and regenerative medicine products).

# (1) Laws and Regulations Governing Pharmacists' Social Position and Responsibility

- 1. To describe the regulations and their structure governing the work of pharmacists.
- 2. To describe the provisions of the Pharmacists' Act with regard to the profession of pharmacists.
- 3. To describe the provisions of the Pharmacists' Act with regard to the profession of pharmacists.
- 4. To summarize the provisions of the regulations governing other medical professions.
- 5. To describe the provisions and significance of the Medical Care Act with regard to medical ideals and the responsibilities of medical care professionals.
- 6. To describe the provisions and significance of the Medical Service Act with regard to the medical care delivery system.
- 7. To summarize the management of personal information.
- 8. To describe pharmacists' responsibilities and potential legal liabilities under the Penal Code and/or Civil Code (including product liability).

# (2) Laws and Regulations Ensuring the Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices.

 To describe the purpose of Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices and the definition of related products (such as pharmaceuticals, quasi-drugs, cosmetics, medical devices, and biologics /tissue- engineered products).

- 2. To describe the processes from the development to approval of pharmaceuticals and regulations governing those processes.
- 3. To describe the purpose, systems for conducting, and significance of the results of clinical trials.
- 4. To describe the laws and regulations governing the marketing and the manufacturing of pharmaceuticals and related products.
- 5. To describe post-marketing surveillance and post-marketing safety measures.
- 6. To describe the laws and regulations governing pharmacies and the sale of drugs and medical devices.
- 7. To describe the provisions of the Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices governing the handling of pharmaceuticals.
- 8. To describe the significance and structure of the Japanese Pharmacopoeia.
- 9. To describe the laws and regulations governing the management of biological products and the supply of blood products.
- 10. To describe the relief system for adverse health effects.
- 11. To describe the need for and significance of the regulatory sciences.

# (3) Laws and Regulations Governing Supervised Pharmaceuticals and Substances

- 1. To describe the regulations governing narcotics, psychotropics, and stimulants' raw materials.
- 2. To adhere to the preventive regulations governing stimulants, cannabis, opium, designated substances, etc.
- 3. To adhere to the regulations governing poisonous and harmful substances.

#### (3) Japanese Social Security System and Health Economics

# GIO: To understand the current situation and issues related to the provision of medical care and welfare under the social security system and the roles of the pharmacists.

#### (1) Systems of Medical, Welfare, and Long-Term Care Services

- 1. To describe the mechanisms and features of the Social Security System of Japan.
- 2. To describe the Japanese health insurance system.
- To describe the Rules for Health Insurance-Covered Medical Institution or Health Insurance-Covered Pharmacy and Health Insurance-Covered Physician or Health Insurance-Covered Pharmacist.
- 4. To describe the publicly funded medical care system.
- 5. To describe Long-Term Care Insurance System.
- 6. To stay abreast of changes in the drug pricing system.
- 7. To describe the mechanisms of dispensing, medical service, and long-term care fees.

#### (2) Pharmacoeconomics and Health Economics

- 1. To describe the features of the pharmaceutical market and mechanisms of the distribution system.
- 2. To stay abreast of trends in national medical care expenditure.
- 3. To describe generic drugs and their roles in medical care.
- 4. To describe methods for the economic evaluation of pharmacotherapy.

# (4) Roles of Community Pharmacies and Pharmacists

GIO: To understand the current situation and issues concerning local health, medical care and welfare and how pharmacies and pharmacists can contribute to improving them.

# (1) Roles of Pharmacies in the Community

- 1. To describe the functions and duties of pharmacies in the community.
- 2. To describe the significance of pharmaceutical management by pharmacies and pharmacists.
- 3. To describe the role of pharmacies in self-medication.
- 4. To describe the role of pharmacies in times of disaster.
- 5. To describe the role of the pharmacies in ensuring appropriate medical expenditure.

# (2) Collaboration among Healthcare, Medical Care, and Welfare Providers at the Community Level and the Role of Pharmacists

- 1. To describe the concept of community-based integrated care.
- 2. To describe the roles of pharmacies and pharmacists in supporting home medical and in-home care services.
- 3. To describe the role of school pharmacists.
- 4. To describe the social resources available for community health, medical care, and welfare.
- 5. To discuss community expectations of collaboration among medical institutions, social welfare facilities, and regional administrative bodies.

#### C. Fundamentals of Pharmaceutical Sciences

#### C1. Physical Properties of Substances

GIO: To acquire knowledge of basic atomic/molecular structure, thermodynamics, and reaction kinetics to understand the physicochemical properties of substances.

#### (1) Structures of Substances

# GIO: To acquire the fundamentals of atomic/molecular structures and the formation of chemical bonds.

#### (1) Chemical Bonds

- 1. To describe the modes of chemical bonding.
- 2. To describe the fundamental concepts of molecular orbitals and orbital hybridization.
- 3. To describe the concepts of conjugation and resonance.

#### (2) Intermolecular Interactions

- 1. To describe van der Waals force.
- 2. To describe electrostatic interactions and to give specific examples.
- 3. To describe dipole-dipole interactions and to give specific examples.
- 4. To describe dispersion forces and to give specific examples.
- 5. To describe hydrogen bond formation and to give specific examples.
- 6. To describe charge-transfer interactions and to give specific examples.
- 7. To describe hydrophobic interactions and to give specific examples.

#### (3) Behavior of Atoms and Molecules

- 1. To describe the properties of electromagnetic waves and their interaction with substances.
- 2. To describe molecular vibration, rotation, and electronic transition.
- 3. To describe electronic and nuclear spins and their magnetic resonance.
- 4. To describe refraction, polarization, and optical rotation of light.
- 5. To describe light scattering and interference.
- 6. To describe the basics of crystal structures and diffraction phenomena.

#### (4) Radiation and Radioactivity

- 1. To describe the structures of atoms and radioactive disintegration.
- 2. To list the types of ionizing radiation and describe their properties and interactions with substances.
- 3. To describe the physical properties of typical radionuclides.
- 4. To describe nuclear reactions and radioactive equilibrium.
- 5. To describe the basic principles and use of radiation measurements.

#### (2) Energy of Substances and Equilibrium States

#### GIO: To acquire the fundamentals of thermodynamics to understand substance states.

#### (1) Gas-Phase Microstates and Macrostates

- 1. To describe the Van der Waals equation of state.
- 2. To describe the relationship between molecular movement and the energy of gases.

3. To describe energy quantization and the Boltzmann distribution.

# (2) Energy

- 1. To describe systems, surroundings, and boundaries in thermodynamics.
- 2. To describe the first law of thermodynamics.
- 3. To describe the difference between state function and path function.
- 4. To describe isobaric, isovolumetric, isothermal, and adiabatic processes.
- 5. To describe heat capacities at constant volume and pressure.
- 6. To describe enthalpy.
- 7. To describe enthalpy changes in chemical reactions.

# **3** Spontaneous Change

- 1. To describe entropy.
- 2. To describe the second law of thermodynamics.
- 3. To describe the third law of thermodynamics.
- 4. To describe Gibbs energy.
- 5. To predict the direction and degree of spontaneous change using thermodynamic functions.

#### **4**) Principles of Chemical Equilibrium

- 1. To describe the relationship between Gibbs energy and chemical potential.
- 2. To describe the relationship between Gibbs energy and equilibrium constants.
- 3. To describe the effects of pressure and temperature on equilibrium constants.
- 4. To describe the principles of coupled reactions.

#### (5) Phase Equilibrium

- 1. To describe heat transfer associated with phase changes.
- 2. To describe phase equilibrium and the phase rule.
- 3. To describe phase diagrams.

#### (6) Solution Properties

- 1. To describe the colligative properties of dilute solutions.
- 2. To describe activity and activity coefficients.
- 3. To describe the concentration-dependent changes in the electric conductivity and molar conductivity of electrolyte solutions.
- 4. To describe ionic strength.

### **7** Electrochemistry

- 1. To describe the relationship between electromotive force and Gibbs energy.
- 2. To describe electrode potential (oxidation-reduction potential).

#### (3) Kinetic Properties of Chemical Reactions

# GIO: To acquire the fundamentals of reaction kinetics to understand the conversion processes of substances.

### (1) Reaction Rates

- 1. To describe reaction orders and rate constants.
- 2. To convert differential rate equations to integral rate equations.
- 3. To describe the typical methods determining reaction order.
- 4. To measure the reaction rates of typical (pseudo-)first-order reactions and calculate the rate constants.
- 5. To describe the characteristics of typical compound complex reactions (reversible, parallel, and consecutive reactions, etc.).
- 6. To describe the relationship between reaction rate and temperature.
- 7. To describe typical catalytic reactions (acid/base catalytic reactions, enzymatic reactions, etc.).

#### C2. Analysis of Chemical Substances

GIO: To acquire the fundamentals of qualitative and quantitative analyses to analyze chemical substances (including drugs) accurately.

#### (1) Fundamentals of Analytical Methodology

GIO: To acquire the fundamentals of the use of analytical instruments and the use of analytical data.

# (1) Fundamentals of Analysis

- 1. To use analytical instruments appropriately.
- 2. To treat analytical data appropriately.
- 3. To describe method validation procedures.

# (2) Chemical Equilibria in Solutions

GIO: To acquire the fundamentals of various types of chemical equilibria in solutions.

#### (1) Acid-Base Equilibrium

- 1. To describe the theory of acid-base equilibrium.
- 2. To describe pH and dissociation constants.
- 3. To measure the pH of solutions.
- 4. To describe buffer actions and specific buffers.

# (2) Other Types of Chemical Equilibria

- 1. To describe complex/chelate formation equilibrium.
- 2. To describe precipitation equilibrium.
- 3. To describe oxidation-reduction equilibrium.
- 4. To describe partition equilibrium.

#### (3) Qualitative and Quantitative Analyses of Chemical Substances

# GIO: To acquire the fundamentals of qualitative and quantitative analyses of chemical substances.

# (1) Qualitative Analysis

- 1. To describe the qualitative reactions of typical inorganic ions.
- 2. To list and describe the identification tests of the typical drugs listed in the Japanese Pharmacopoeia.

# 2 Quantitative Analysis (Volumetric and Gravimetric Analyses)

- 1. To describe the principles, procedures, and applications of neutralization titration (including nonaqueous titration).
- 2. To describe the principles, operating procedures, and applications of chelatometric titration.
- 3. To describe the principles, operating procedures, and applications of precipitation titration.
- 4. To describe the principles, operating procedures, and applications of oxidation-reduction titration.
- 5. To perform volumetric analysis of typical drugs listed in the Japanese Pharmacopoeia.
- 6. To list and describe the purity tests included in the Japanese Pharmacopoeia.
- 7. To describe the principles and procedures of gravimetric analyses included in the Japanese Pharmacopoeia.

#### (4) Instrumental Analysis

#### GIO: To acquire the fundamentals of the principles and applications of instrumental analysis.

#### (1) Spectroscopic Analysis

- 1. To describe the principles and applications of ultraviolet-visible absorption spectrophotometry.
- 2. To describe the principles and applications of fluorometry.
- 3. To describe the principles and applications of infrared (IR) absorption spectrophotometry.
- 4. To describe the principles and applications of atomic absorption spectrophotometry, inductivity coupled plasma (ICP) emission spectrometry, and ICP mass spectrometry.
- 5. To describe the principles and applications of polarimetry (including optical rotatory dispersion).
- 6. To analyze typical drugs included in the Japanese Pharmacopoeia using spectroscopic methods.

#### (2) Nuclear Magnetic Resonance Spectroscopy

1. To describe the principles and applications of nuclear magnetic resonance (NMR) spectroscopy.

#### (3) Mass Spectrometry

1. To describe the principles and applications of mass spectrometry.

#### (4) X-ray Analysis

- 1. To describe the principles and applications of X-ray crystallography.
- 2. To describe the principles and uses of the X-ray powder diffraction method.

#### (5) Thermal Analysis

- 1. To describe the principles of thermogravimetry.
- 2. To describe differential thermal analysis and differential scanning calorimetry.

# (5) Separation Analysis

# GIO: To acquire the fundamentals of separation analysis.

### 1 Chromatography

- 1. To describe separation mechanisms in chromatography.
- 2. To describe the characteristics and typical detection methods of thin-layer chromatography.
- 3. To describe the characteristics and typical detection methods of liquid chromatography.
- 4. To describe the characteristics and typical detection methods of gas chromatography.
- 5. To identify and determine samples using chromatography.

# 2 Electrophoresis

1. To describe the principles and applications of electrophoresis.

# (6) Techniques for Biomedical Analysis

GIO: To acquire the fundamentals of typical analytical techniques used in clinical practice.

# 1 Preparation for Analysis

- 1. To describe pretreatment methods appropriate for the biomedical analysis.
- 2. To describe the significance of quality control and standard reference materials in biomedical analysis.

#### (2) Analytical Techniques

- 1. To list typical analytical methods used in biomedical analysis.
- 2. To describe the principles of immunochemical assays.
- 3. To describe the principles of typical analytical methods using enzymes.
- 4. To describe typical dry chemistry methods.
- 5. To describe typical diagnostic imaging techniques (X-ray examination, magnetic resonance imaging (MRI), ultrasound, endoscopy, nuclear medicine examination, etc.).

# C3. Properties and Reactions of Chemical Substances

GIO: To acquire the fundamentals of the structures, properties, reactions, separation methods, and structural determination methods of typical organic compounds as well as the structures and properties of typical inorganic compounds to understand chemical substances.

#### (1) Fundamental Properties of Chemical Substances

GIO: To acquire the fundamentals of the nomenclature, electronic configurations, types and processes of reactions, and stereostructures of basic organic compounds.

#### (1) Fundamentals

- 1. To name typical compounds according to the IUPAC rules.
- 2. To describe typical compounds used in pharmacy using their common names.
- 3. To draw basic compounds using Lewis structures.
- 4. To describe the relationship between the properties and resonance of organic compounds.
- 5. To define Lewis acids and bases as well as Brønsted acids and bases.

- 6. To understand the characteristics of basic organic reactions (substitution, addition, and elimination) and to classify them.
- 7. To describe the structures and properties of reaction intermediates containing carbon atoms (carbocations, carbanions, and radicals).
- 8. To describe the processes of reactions using energy diagrams.
- 9. To describe basic organic reaction mechanisms using curved arrows indicating the motion of electrons.

# (2) Three-Dimensional Structures of Organic Compounds

- 1. To describe the difference between structural isomers and stereoisomers.
- 2. To describe the relationship between chirality and optical activity.
- 3. To describe enantiomers and diastereomers.
- 4. To describe racemic and meso compounds.
- 5. To describe the notations for absolute configurations and to draw the structures of chiral compounds.
- 6. To describe the stereoisomerism of carbon-carbon double bonds (*cis-trans* and *E-Z* isomerism).
- 7. To draw the structures of organic compounds using Fischer and Newman projections.
- 8. To describe the conformations of ethane and butane and their stability.

# (2) Structures and Reactions of Basic Organic Compounds

# GIO: To acquire the fundamentals of the structures, properties, and reactivity of aliphatic and aromatic compounds.

# (1) Alkanes

- 1. To describe the basic properties of alkanes.
- 2. To illustrate the structural isomers of alkanes.
- 3. To describe the factors determining ring strain in cycloalkanes.
- 4. To illustrate the carbon-hydrogen bond directions (axial and equatorial) in the chair conformations of cyclohexanes.
- 5. To describe the factors determining the stable conformations of substituted cyclohexanes.

#### (2) Alkenes and Alkynes

- 1. To list the typical addition reactions to alkenes and describe their characteristics.
- 2. To list the typical oxidation and reduction reactions of alkenes and describe their characteristics.
- 3. To list the typical reactions of alkynes and describe their characteristics.

#### (3) Aromatic Compounds

- 1. To describe the properties and reactivity of typical aromatic hydrocarbon compounds.
- 2. To describe the concept of aromaticity.
- 3. To describe the effects of substituents on the reactivity and orientation in the electrophilic substitution reactions of aromatic hydrocarbons.
- 4. To describe the properties of typical aromatic heterocycles in relation to aromaticity.
- 5. To describe the effects of substituents on the reactivity and orientation in the electrophilic substitution reactions of typical aromatic heterocycles.

### (3) Properties and Reactions of Functional Groups

# GIO: To acquire the fundamentals of the properties and reactivity of organic compounds containing functional groups.

# (1) Overview

- 1. To list typical functional groups and describe their properties.
- 2. To conduct isolation and purification procedures based on the properties of functional groups.

#### (2) Organohalogen Compounds

- 1. To list and describe the basic properties and reactions of organohalogen compounds.
- 2. To describe the characteristics of nucleophilic substitution reactions.
- 3. To describe the characteristics of elimination reactions.

#### (3) Alcohols, Phenols, and Ethers

- 1. To list and describe the basic properties and reactions of alcohols and phenols.
- 2. To list and describe the basic properties and reactions of ethers.

# 4 Aldehydes, Ketones, Carboxylic Acids, and Carboxylic Acid Derivatives

- 1. To list and describe the basic properties and reactions of aldehydes and ketones.
- 2. To list and describe the basic properties and reactions of carboxylic acids.
- 3. To list and describe the basic properties and reactions of carboxylic acid derivatives (acid halides, acid anhydrides, esters, and amides).

#### (5) Amines

1. To list and describe the basic properties and reactions of amines.

#### **(6)** Electronic Effects

1. To describe the electronic effects of functional groups.

#### (7) Acidity and Basicity

- 1. To compare and describe the acidity of alcohols, phenols, carboxylic acids, and carbon acids.
- 2. To compare and describe the basicity of nitrogen-containing compounds.

#### (4) Structural Determination of Chemical Substances

GIO: To acquire the fundamentals of structural determination methods using typical instrumental analyses including nuclear magnetic resonance (NMR), infrared absorption (IR), and mass spectrometry (MS).

### 1 Nuclear Magnetic Resonance

- 1. To describe briefly the information obtained from 1H and 13C NMR spectra.
- 2. To identify the approximate chemical shifts of typical protons in organic compounds.
- 3. To describe the meaning of the integration of 1H NMR spectra.
- 4. To describe the basic modes of splitting where 1H NMR signals are split by adjacent protons (coupling).
- 5. To determine the substructures of typical compounds based on 1H NMR spectra.

# (2) Infrared Absorption

- 1. To describe briefly the information obtained from IR spectra.
- 2. To describe the characteristic IR spectral absorptions of basic functional groups and assign them.

#### (3) Mass Spectrometry

- 1. To describe briefly the information obtained from mass spectra.
- 2. To choose appropriate ionization methods based on the properties of compounds.
- 3. To describe the types of peaks (base peaks, molecular ion peaks, isotopic peak, and fragment peaks) obtained in IR spectra.
- 4. To analyze the mass spectra of typical compounds.

# **4** Comprehensive Practice

1. To determine the structures of typical compounds using common instrumental analytical methods.

#### (5) Structures and Properties of Inorganic Compounds and Complexes

GIO: To acquire the fundamentals of the structures and characteristics of typical inorganic compounds and complexes (including drugs).

# (1) Inorganic Compounds and Complexes

- 1. To list main group elements and transition elements.
- 2. To list the names, structures, and properties of typical inorganic oxides and oxo compounds.
- 3. To list the names, structures, and properties of reactive oxygen species and nitrogen oxides.
- 4. To describe the names, structures, and basic properties of typical complexes.
- 5. To list typical inorganic compounds and complexes used as drugs.

#### C4. Chemistry of Biomolecules and Drugs

GIO: To acquire the fundamentals of the structures and characteristics of drug targets and drugs, and the chemistry of biological reactions to understand the biological effects of drugs from the viewpoint of chemistry.

#### (1) Structures and Chemical Properties of Target Molecules

GIO: To acquire the fundamentals of the basic structures and chemical properties of target molecules.

# (1) Chemical Structures of Target Molecules

- 1. To describe the chemical properties of molecules (amino acids, sugars, lipids, nucleotides, etc.) constituting typical biopolymers based on their structures.
- 2. To describe the three-dimensional structures of biopolymers (proteins, nucleic acids, etc.) and the chemical bonds and interactions that determine them.

#### (2) Small Organic Compounds in the Human Body

1. To describe the structures and characteristics of typical endogenous ligands for cell membrane receptors and intracellular (nuclear) receptors.

- 2. To describe the roles of typical coenzymes in enzymatic reactions from the aspects of organic reaction mechanisms.
- 3. To describe the biological reactions using reactive oxygen spices and nitric oxide from the viewpoint of structural chemistry.
- 4. To describe the chemical roles of typical metal ions and complexes present in the human body from the viewpoint of chemistry.

#### (2) Chemistry of Biological Reactions

#### GIO: To acquire the fundamentals of biological reactions determining the activities of drugs.

# 1 Phosphorus and Sulfur Compounds in the Human Body

- 1. To describe the structures and chemical properties of phosphorus compounds (phosphorus acid and its derivatives, etc.), and sulfur compounds (thiols, disulfides, thioesters, etc.).
- 2. To describe the biological functions of phosphorus compounds (phosphorus acid and its derivatives, etc.) and sulfur compounds (thiols, disulfides, thioesters, etc.) based on their chemical properties.

#### (2) Enzyme Inhibitors and Their Modes of Action

- 1. To describe the actions of irreversible enzyme inhibitors based on the reaction mechanisms of enzymes.
- 2. To describe how substrate analogues act as competitive inhibitors based on the reaction mechanisms of enzymes.
- 3. To describe how transition state analogues act as competitive inhibitors based on the reaction mechanisms of enzymes.

### (3) Receptor Agonists and Antagonists

- 1. To describe the differences between typical receptor agonists and antagonists by comparing their structures with those of endogenous ligands.
- 2. To explain why low-molecular endogenous ligand derivatives are often used as drugs.

#### (4) Organic Reactions in the Human Body

- 1. To describe the metabolic reactions of typical biological molecules (fatty acids and cholesterols, etc.) from the viewpoint of organic chemistry.
- 2. To describe xenobiotic metabolic reactions (e.g., metabolic activation of carcinogens) from the viewpoint of organic chemistry.

# (3) Structures, Properties, and Actions of Drugs

# GIO: To acquire the fundamentals that relate typical structures and properties of drugs affecting their actions.

#### (1) Interactions Between Drugs and Biomolecules

1. To describe the interactions between drugs and biomolecules from the viewpoint of chemistry (binding affinity and free-energy change, electronic effects, steric effects, etc.).

# (2) Properties of Drugs Based on Their Chemical Structures

- 1. To describe the physicochemical properties (acidity, basicity, hydrophobicity, hydrophilicity, etc.) of drugs based on their structures.
- 2. To describe the chemical structures of drugs, such as prodrugs, based on pharmacokinetics.

#### (3) Components of Drugs

- 1. To describe the pharmacophores of typical drugs.
- 2. To describe bioisosteres giving typical examples.
- 3. To classify typical heterocycles in drugs based on their structures and to describe their properties as drug components.

#### (4) Structures and Properties of Drugs Acting on Enzymes

- 1. To list typical drugs with nucleoside and nucleobase analogues and to describe their properties based on their chemical structures.
- 2. To list typical drugs with phenylacetate or phenylpropionate structures and to describe their properties based on their chemical structures.
- 3. To list typical drugs with sulfonamide structures and to describe their properties based on their chemical structures.
- 4. To list typical drugs with quinolone skeletons and to describe their properties based on their chemical structures.
- 5. To list typical drugs with beta-lactam structures and to describe their properties based on their chemical structures.
- 6. To list typical peptide analogue drugs and to describe their properties based on their chemical structures.

#### (5) Structures and Properties of Drugs Interacting with Receptors

- 1. To list typical drugs with catecholamine skeletons and to describe their properties based on their chemical structures.
- 2. To list typical acetylcholine analogue drugs and to describe their properties based on their chemical structures.
- 3. To list typical steroid analog drugs and to describe their properties based on their chemical structures.
- 4. To list typical drugs that have benzodiazepine and barbital skeletons and to describe their properties based on their chemical structures.
- 5. To list typical opioid analogue drugs and to describe their properties based on their chemical structures.

#### (6) Structures and Properties of Drugs Acting on DNA

- 1. To list DNA binding drugs (alkylating agents and cisplatins) and to describe their chemical structures and reaction mechanisms.
- 2. To list DNA intercalating drugs and to describe their structural characteristics.
- 3. To list DNA-strands breaking drugs and to describe their structural characteristics.

# (7) Structures and Properties of Drugs Interacting with Ion Channels

1. To describe the properties of typical structures of basic drugs interacting with ion channels (e.g., dihydropyridines).

#### C5. Pharmacognosy (Naturally Derived Drugs)

GIO: To acquire the fundamentals of the sources, properties, and clinical applications of typical crude drugs, and the isolation, structures, physical properties, and actions of natural bioactive substances to used natural substances as drugs.

### (1) Plant, Animal, and Mineral Sources of Drugs

GIO: To acquire the fundamentals of sources, description, constituents, and quality evaluation of plant-, animal-, and mineral-derived drugs.

### (1) Medicinal Plants

- 1. To list the scientific names, medicinal parts, and medicinal effects of typical medicinal plants.
- 2. To describe and identify typical medicinal plants based on their external morphologies.
- 3. To describe the major internal morphologies of medicinal plants.
- 4. To describe the characteristics of plants for which handling is legally regulated (cannabises and poppies).

#### 2 Sources of Crude Drugs

1. To list typical crude drugs (derived from plants, animals, algae, and fungi) included in the Japanese Pharmacopoeia and to describe their sources and medicinal parts.

### (3) Uses of Crude Drugs

- 1. To describe the medicinal effects, constituents, and uses of typical crude drugs (derived from plants, animals, algae, fungi, and minerals) included in the Japanese Pharmacopoeia.
- 2. To list and describe typical crude drugs that may cause side effects and require caution when used.

#### (4) Identification and Quality Evaluation of Crude Drugs

- 1. To describe the methods of identification and quality evaluation of crude drugs.
- 2. To describe the general rules for and testing of crude drugs in the Japanese Pharmacopoeia.
- 3. To discriminate typical crude drugs.
- 4. To describe the identification tests for typical crude drugs.
- 5. To describe the purity tests for typical crude drugs.

#### (2) Natural Products and Their Derivatives as Drug Sources

GIO: To classify and organize natural bioactive substances as drug sources based on their structures and to acquire the fundamentals of their uses.

#### (1) Structures and Activities of Bioactive Substances Derived from Crude Drugs

1. To classify typical bioactive substances derived from crude drugs based on their chemical structures and to describe briefly their biosynthetic pathways.

- To list typical bioactive substances derived from crude drugs which are classified as lipids or carbohydrates and describe their activities.
- 3. To list typical bioactive substances derived from crude drugs which are classified as aromatic compounds and describe their activities.
- 4. To list typical bioactive substances derived from crude drugs which are classified as terpenoids or steroids and describe their activities.
- 5. To list typical bioactive substances derived from crude drugs which are classified as alkaloids and describe their activities.

#### (2) Structures and Activities of Bioactive Substances Derived from Microorganisms

- 1. To classify bioactive substances derived from microorganisms based on their chemical structures.
- 2. To list typical bioactive substances derived from microorganisms and describe their activities.

#### (3) Handling of Natural Bioactive Substances

1. To describe and perform typical methods of extraction and isolation/purification of natural bioactive substances.

# (4) Uses of Natural Bioactive Substances

- 1. To list common natural bioactive substances used as drugs and describe their uses.
- To list common drugs developed through chemical modification of natural bioactive substances and describe their uses and lead compounds.
- 3. To list common natural bioactive substances used as pesticides or cosmetics and describe their uses.

# C6. Fundamentals of Biochemistry

GIO: To acquire the fundamentals of the structures of cells and biomolecules to ensure understanding of organisms biochemically at the cellular and molecular levels.

#### (1) Structures and Functions of Cells

GIO: To acquire the fundamentals of the structures and functions of cell membranes, organelles, and cytoskeletons.

#### (1) Cell Membranes

- 1. To list common biological materials that constitute cell membranes and describe their functions at the molecular level.
- 2. To describe endocytosis and exocytosis.

#### (2) Organelles

1. To describe the structures and functions of organelles (nuclei, mitochondria, endoplasmic reticula, lysosomes, Golgi apparatus, peroxisomes, etc.) and ribosomes.

#### (3) Cytoskeletons

1. To describe the structures and functions of cytoskeletons.

#### (2) Fundamentals of Biomolecules

#### GIO: To acquire the fundamentals of the structures, characteristics, and roles of biomolecules.

# 1 Lipids

1. To describe the types, structures, characteristics, and roles of common lipids.

#### (2) Carbohydrates

- 1. To describe the types, structures, characteristics, and roles of common monosaccharides and disaccharides.
- 2. To describe the types, structures, characteristics, and roles of common polysaccharides.

#### (3) Amino Acids

1. To list amino acids and to describe their characteristics based on their structures.

#### (4) Proteins

1. To describe the structures (primary, secondary, tertiary, and quaternary structures) and characteristics of proteins.

#### (5) Nucleotides and Nucleic Acids

1. To describe the types, structures, and characteristics of nucleotides and nucleic acids (DNA and RNA).

#### (6) Vitamins

1. To describe the types, structures, characteristics, and roles of common vitamins.

#### (7) Trace Elements

1. To describe the types and roles of common essential trace elements.

#### (8) Identification and Quantification of Biomolecules

 To conduct qualitative and quantitative tests of lipids, carbohydrates, amino acids, proteins, and nucleic acids.

#### (3) Proteins Responsible for Biological Functions

# GIO: To acquire the fundamentals of the structures, characteristics, functions and metabolisms of proteins responsible for biological functions.

#### (1) Structures and Functions of Proteins

1. To describe the various functions of proteins (enzymes, receptors, signaling molecules, membrane transporters, carrier/transporter proteins, reserve proteins, structural proteins, adhesion proteins, defensive proteins, and regulatory proteins.)

#### (2) Maturation and Degradation of Proteins

- 1. To describe the maturation process of proteins after translation (transport between organelles and post-translational modification).
- 2. To describe the intracellular degradation of proteins.

#### (3) Enzymes

- 1. To describe the characteristics and kinetics of enzymatic reactions.
- 2. To describe the roles of coenzymes and trace metals in enzymatic reactions.
- 3. To describe typical regulatory mechanisms of enzyme activity.

4. To determine and analyze enzyme kinetics.

#### **4** Nonenzyme Proteins

- 1. To describe the types, structures, and functions of membrane transporters.
- 2. To describe the types, structures, and functions of plasma lipoproteins.

#### (4) Fundamentals of Genetics

#### GIO: To acquire the fundamentals of the replication and expression of genes and their regulation.

#### (1) Overview

- 1. To describe the mechanisms of the storage and expression of genetic information.
- 2. To describe the definitions of DNA, genes, chromosomes, and genomes.

#### (2) Molecules of the Substance for Genetic Information

- 1. To describe the structures of chromosomes (nucleosomes, chromatins, centromeres, telomeres, etc.).
- 2. To describe the structures of genes (promotors, enhancers, exons, introns, etc.).
- 3. To describe the different types of RNA (hnRNA, mRNA, rRNA, tRNA, etc.) and their functions.

# **3** Genome Replication

1. To describe the process of DNA replication.

#### (4) Process and Regulation of Transcription and Translation

- 1. To describe the process of transcription from DNA to RNA.
- 2. To describe epigenetic regulations of the transcriptional.
- 3. To describe transcriptional regulation by transcription factors.
- 4. To describe RNA processing (cap structures, splicing, snRNP, poly-A chains, etc.).
- 5. To describe the process of translation of RNA to proteins.

#### (5) Genome Mutation and Repair

1. To describe DNA mutation and repair.

#### (6) Recombination of DNA

- 1. To describe genetic engineering techniques (gene cloning, cDNA cloning, PCR, recombinant protein expression, etc.).
- 2. To describe genetically modified organisms (transgenic or knockout animals, cloned animals, and genetically modified plants).

#### (5) Fundamentals of Metabolism

GIO: To acquire the fundamentals of the production, storage, and use of bioenergy, and the metabolism of carbohydrates, lipids, proteins, and nucleic acids that are responsible for those functions.

# 1 Overview

1. To describe the general process of energy metabolism.

#### (2) ATP Production and Carbohydrate Metabolism

- 1. To describe the glycolytic pathway and lactic acid production.
- 2. To describe the citric acid cycle (tricarboxylic acid cycle [TCA] cycle).

- 3. To describe the electron transport chain (oxidative phosphorylation) and ATP synthase.
- 4. To describe glycogen metabolism.
- 5. To describe gluconeogenesis.

#### (3) Lipid Metabolism

- 1. To describe the biosynthesis and beta-oxidation of fatty acids.
- 2. To describe the biosynthesis and metabolism of cholesterols.

#### 4 Starvation and Repletion

- 1. To describe energy metabolism in the starvation state, e.g. the use of ketone bodies.
- 2. To describe the mechanisms of surplus energy storage.

# **(5) Other Metabolic Pathways**

- 1. To describe the metabolism of carbon and nitrogen in amino acid molecules (e.g., the urea cycle).
- 2. To describe the biosynthesis and degradation of nucleotides.
- 3. To describe the pentose phosphate cycle.

#### (6) Intercellular Communication and Intracellular Signal Transduction

# GIO: To acquire the fundamentals of the modes and roles of intercellular communication and intracellular signaling.

#### (1) Overview

1. To describe the modes of signaling in intercellular communication.

#### (2) Intracellular Signal Transduction

- 1. To describe intracellular signaling via receptors containing cell membrane channels.
- 2. To describe intracellular signaling from cell membrane receptors via the G protein system.
- 3. To describe intracellular signaling via phosphorylation of cell membrane receptor proteins.
- 4. To describe the role of second messengers in intracellular signaling.
- 5. To describe intracellular signaling via intracellular (nuclear) receptors.

#### (3) Intercellular Communication

- 1. To describe intercellular adhesion structures and the types and characteristics of major cell adhesion molecules.
- 2. To describe the types and characteristics of major extracellular matrix proteins.

#### (7) Cell Cycle

#### GIO: To acquire the fundamentals of the cell cycle, cell division, and cell death.

# 1 Cell Division

- 1. To describe the cell cycle and its regulatory mechanisms.
- 2. To describe the division of somatic and germ cells.

#### (2) Cell Death

1. To describe cell death (apoptosis and necrosis).

# (3) Cancer Cells

- 1. To describe the difference between normal cells and cancer cells.
- 2. To describe the roles of oncogenes and tumor suppressor genes.

#### C7. Anatomy and Human Physiology

GIO: To acquire the fundamentals of the structure, functions, and regulation of the human body for an understanding of anatomy at the overall physical, organ, and cellular levels.

#### (1) Fundamentals of Human Anatomy

GIO: To acquire the fundamentals of genetics, ontogeny, and the structures and functions of organs.

#### (1) Genetics

- 1. To describe genes and the mechanisms of heredity.
- 2. To describe genetic polymorphisms.
- 3. To describe common genetic disorders.

# (2) Ontogeny

- 1. To describe ontogenesis.
- 2. To describe the roles of stem cells and precursor cells in cellular differentiation.

# **3** Overview of Organ Systems

- 1. To list the names, morphologies, locations, and functions of the organs and organ systems constituting in the human body.
- 2. To identify the names and locations of various organs, using laboratory animals, anatomical models of the human body, or simulators.
- 3. To observe tissues and cells of typical organs under the microscope.

#### (4) Nervous System

- 1. To describe the roles and functions of the central nervous system.
- 2. To describe the roles and functions of the peripheral nervous system (autonomic and somatic nervous systems).

#### (5) Skeletal and Muscular Systems

- 1. To list major bones and muscles.
- 2. To list the names of typical skeletal muscles and joints and identify their locations.

### (6) Skin

1. To describe the roles and functions of the skin.

#### (7) Circulatory System

- 1. To describe the roles and functions of the cardiac system.
- 2. To describe the roles and functions of the vascular system.
- 3. To describe the roles and functions of the lymphatic system.

#### (8) Respiratory System

1. To describe the roles and functions of the lungs and bronchi.

# (9) Digestive System

- 1. To describe the roles and functions of the digestive tracts (stomach, small intestine, and large intestine).
- 2. To describe the roles and functions of the liver, pancreas, and gallbladder.

#### (10) Urinary System

1. To describe the roles and functions of the urinary tract system.

#### (11) Reproductive System

1. To describe the roles and functions of the reproductive system.

# (12) Endocrine System

1. To describe the roles and functions of the endocrine system.

# (13) Sensory Organs

1. To describe the roles and functions of the sensory organs.

### (4) Blood and Hematopoietic System

1. To describe the roles and functions of the blood and the hematopoietic system.

#### (2) Fundamentals of Human Physiology

GIO: To acquire the fundamentals of the types and mechanisms of action of common transmitters responsible for the information networks involved in homeostasis.

# 1 Regulatory Mechanisms Controlled by the Nervous System

- 1. To describe the regulatory mechanisms for the excitation and conduction of nerve cells and synaptic transmission.
- 2. To list common neurotransmitters and to describe briefly their bioactivities and mechanisms of action.
- 3. To describe common examples of the regulatory mechanisms for homeostasis via the nervous and sensory systems.
- 4. To describe the regulatory mechanisms for muscle contraction by nerves.

#### (2) Regulatory Mechanisms Controlled by Hormones and the Endocrine System

1. To list typical hormones and to describe briefly their production organs, bioactivities, and mechanisms of action.

#### (3) Regulatory Mechanisms Controlled by Autacoids

1. To list common autacoids and to describe briefly their bioactivities and mechanisms of action.

#### (4) Regulatory Mechanisms Controlled by Cytokines and Growth Factors

1. To list common cytokines and growth factors and to describe briefly their bioactivities and mechanisms of action.

#### (5) Regulatory Mechanisms of Blood Pressure

1. To describe the mechanisms regulating blood pressure.

#### (6) Regulatory Mechanisms of Blood Glucose

1. To describe the mechanisms regulating blood glucose levels.

# (7) Body Fluid Regulation

- 1. To describe the mechanisms regulating body fluids.
- 2. To describe the mechanisms regulating urine production and urine volume.

#### (8) Body Temperature Regulation

1. To describe the mechanisms regulating body temperature.

# (9) Blood Coagulation and Fibrinolytic System

1. To describe the mechanisms regulating blood coagulation and the fibrinolytic system.

#### 10 Menstrual Cycle Regulation

1. To describe the mechanisms regulating the menstrual cycle.

### C8. Biological Defense Mechanisms and Microorganisms

GIO: To acquire the fundamentals of biological defense mechanisms through immune reactions, their failure, and common pathogenic microorganisms to understand the changes that occur when homeostasis is disrupted.

# (1) Fundamentals of Immunology

# GIO: To acquire the fundamentals of immune responses as the primary biological defense system in the human body.

#### 1 Biological Defense

- 1. To describe roles of physical, physiological, and chemical barriers and complements against pathogen invasion.
- 2. To describe the features of immune reactions (self/non-recognition, specificity, diversity, clonality, memory, and tolerance).
- 3. To describe natural immunity, acquired immunity, and their relationship.
- 4. To describe humoral and cell-mediated immunity.

#### (2) Immunocompetent Tissues and Cells

- 1. To list the tissues involved in immunity and describe their roles.
- 2. To describe the types and roles of immunocompetent cells.
- 3. To describe the major intercellular networks in immune reactions.

#### (3) Molecular Mechanisms of Immunity

- To compare and describe the recognition of invasive pathogens in innate immunity and adaptive immunity.
- 2. To describe the structures and functions of major histocompatibility complex (MHC) antigens and their roles in antigen presentation.
- 3. To describe the diversity of antigen recognition (gene rearrangement) by T and B cells and their activation.
- 4. To describe the basic structures, types, and roles of antibody molecules.
- 5. To list major cytokines involved in the immune system and to briefly describe their activities.

### (2) Fundamentals of the Human Immune Response

# GIO: To acquire the fundamentals of the regulation and failure of immune responses and clinical applications of immune reactions.

# (1) Regulation and Failure of Immune Responses

- 1. To describe the common symptoms of, cells responsible for, and reaction mechanisms of inflammation.
- 2. To classify allergies and to describe the cell responsible and reaction mechanisms.
- 3. To describe autoimmune diseases and immunodeficiency syndromes.
- 4. To describe the relationship between organ transplantation and immune reactions (rejection, immunosuppressants, etc.).
- 5. To describe the relationship between infections and immune responses.
- 6. To describe the immune reactions involved in tumor elimination and suppression.

### 2 Application of Immune Reactions

- 1. To describe the principles and types of vaccines (live vaccines, inactivated vaccines, toxoids, combination vaccines, etc.).
- 2. To describe monoclonal and polyclonal antibodies.
- 3. To describe serotherapy and antibody drugs.
- 4. To perform tests based on antigen-antibody reactions (ELISA, Western blotting, etc.).

### (3) Fundamentals of Microbiology

# GIO: To acquire the fundamentals of the classification, structures, and life cycles of microorganisms.

#### (1) Overview

1. To describe the characteristics of prokaryotes, eukaryotes, and viruses.

#### (2) Bacteria

- 1. To describe the classification and characteristics of bacteria (phylogenetic classification, Gram-positive vs. Gram-negative bacteria, aerobic vs. anaerobic bacteria, etc...).
- 2. To describe the structures and proliferation mechanisms of bacteria.
- 3. To describe catabolism (respiration and fermentation) and anabolism in bacteria.
- 4. To describe gene transmission (conjugation, transduction, and transformation) in bacteria.
- 5. To describe drug-resistant bacteria and resistance acquisition mechanisms.
- 6. To describe common bacterial toxins.

#### (3) Viruses

1. To describe the structures, classifications, and proliferation mechanisms of viruses.

#### (4) Fungi, Protozoans, and Helminths

- 1. To describe the characteristics of fungi.
- 2. To describe the characteristics of protozoans and helminths.

#### (5) Disinfection and Sterilization

1. To describe the concepts of sterilization, disinfection and sanitization, and bacteriostasis.

2. To describe typical sterilization and disinfection methods.

# (6) Detection Methods

- 1. To perform Gram staining.
- 2. To perform aseptic manipulation.
- 3. To perform the isolation and pure culture of common bacteria or fungi.

## (4) Human Pathogenic Microorganisms

# GIO: To acquire the fundamentals of human-microorganism relationships and pathogenic microorganisms.

# (1) Establishment of Infection and Symbiosis

- 1. To describe the routes of infection (sources, pathways, portals of entry, etc.) and symbiosis, e.g., intestinal bacteria.
- 2. To describe opportunistic infection and hospital-acquired infections.

# (2) Typical Pathogens

- 1. To describe DNA viruses (human herpes viruses, adenoviruses, papillomaviruses, hepatitis B viruses, etc.).
- 2. To describe RNA viruses (noroviruses, rotaviruses, polioviruses, coxsackieviruses, echoviruses, rhinoviruses, hepatitis A viruses, hepatitis C viruses, influenza viruses, measles viruses, rubella viruses, Japanese encephalitis viruses, rabies viruses, mumps viruses, HIV, HTLV, etc.).
- 3. To describe Gram-positive cocci (*Staphylococcus* spp., *Streptococcus* spp., etc.) and Gram-positive bacilli (*Clostridium tetani*, *Clostridium perfringens*, *Clostridium botulinum*, *Corynebacterium diphtheriae*, *Bacillus anthracis*, *Bacillus cereus*, *Clostridium difficile*, etc.).
- 4. To describe Gram-negative cocci (Neisseria gonorrhoeae, Neisseria meningitidis, etc.) and Gram-negative bacilli (Escherichia coli, Shigella spp., Salmonella spp., Salmonella enterica serovar Typhi, Yersinia spp., Klebsiella spp., Vibrio cholerae, Bordetella pertussis, Vibrio parahaemolyticus, Pseudomonas aeruginosa, Legionella spp., Haemophilus influenzae, etc.).
- 5. To describe Gram-negative spirilla (*Helicobacter pylori*, *Campylobacter jejuni/coli*, etc.) and Spirochaeta.
- 6. To describe acid-fast bacilli (*Mycobacterium tuberculosis*, *Mycobacterium leprae*, etc.).
- 7. To describe Mycoplasma, Rickettsia, and Chlamydia.
- 8. To describe fungi (*Aspergillus* spp., *Cryptococcus* spp., *Candida* spp., *Mucor* spp., *Trichophyton* spp., etc.).
- 9. To describe protozoans (*Plasmodium* spp., *Toxoplasma gondii*, *Trichomonas vaginalis*, *Cryptosporidium* spp., *Entamoeba histolytica*, etc.) and helminths (*Ascaris* spp., *Trichuris* spp., *Anisakis* spp., *Echinococcus* spp., etc.).

### D. Health and Environmental Sciences

#### **D1. Health Sciences**

GIO: To acquire the basic knowledge, skills, and behavior about prevention of diseases and nutrition in contemporary society and to contribute to the people's health promotion and improvement of public health.

### (1) Public Health

GIO: To acquire basic knowledge and skills on health statistics and epidemiology to learn current status and influential factors of public health.

## (1) Definition of Health and Disease

1. To describe histories of the concepts of health and disease.

## (2) Health Statistics

- 1. To describe the significance of population statistics in the current situation of public health.
- 2. To describe the technical terms in population and disease statistics.
- 3. To describe chronological changes in the demographic statistics (cause-specific mortality, etc.).

# (3) Epidemiology

- 1. To describe the role of epidemiology in disease prevention.
- 2. To describe the three major factors of epidemiology (agent, environment, host, etc.).
- 3. To describe the types of epidemiology (descriptive epidemiology, analytic epidemiology, etc.) and their methodologies.
- 4. To describe and calculate odds ratio, relative risk, attributable risk, and confidence interval for risk evaluation.

#### (2) Disease Prevention

GIO: To acquire the basic knowledge, skills, and behavior in the current situation and prevention of infectious disease, life-style related diseases, and occupational diseases, etc.

# 1 Disease Prevention in Japan

- 1. To describe disease prevention in terms of three clinical stages such as health care, early diagnosis, and rehabilitation.
- 2. To describe Japanese health promotion policies (Health Japan 21, etc.).

## (2) Infectious Diseases and Their Prevention

- 1. To describe contemporary infectious diseases (opportunistic infectious, hospital-acquired infectious, emerging infectious, and reemerging infectious diseases).
- 2. To describe infectious diseases and their classification in Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases in Japan.
- 3. To describe the major sexually transmitted diseases and their prevention.
- 4. To describe the importance and methods of vaccination.

# (3) Life-style Related Diseases and Their Prevention

- 1. To describe the types and trends of life-style related diseases.
- 2. To describe the major risk factors of life-style related diseases and their preventive methods.
- 3. To discuss the relationship between life-style related diseases and habits such as diet, smoking, etc.

# (4) Health of Pregnant Women and Children

- 1. To describe the importance of neonatal mass-screening and to list major inspection items.
- 2. To describe the major diseases transmitted from a mother to children and the prevention methods of their mother-to-child transmission.

# (5) Occupational Health

- 1. To describe the major occupational hazards and diseases.
- 2. To describe the occupational health management.

## (3) Nutrition and Food Safety

# GIO: To acquire the basic knowledge and skills about nutrition, functions of food, and food hygiene to understand the significance of diet in human health.

# (1) Nutrition

- 1. To describe the roles of nutrients such as carbohydrates, fats, proteins, vitamins, and minerals.
- 2. To describe the processes of digestion, absorption, metabolism, and catabolism of each nutrient.
- 3. To describe the nutritional significance of carbohydrate, fats, and proteins in food.
- 4. To describe the functions of food ingredients other than the five nutrients mentioned above (dietary fiber, anti-oxidant, etc.).
- 5. To describe the meanings of basal metabolic rate, respiratory quotient, and estimated energy requirement for catabolism of nutrients.
- 6. To describe Dietary Reference Intakes for Japanese.
- 7. To describe the major diseases caused by excess or deficiency of nutrients.
- 8. To describe the significance of nutrients for disease treatments.

### (2) Putrefaction and Deterioration of Nutrients, Food Additives, and Foods with Health Claims

- 1. To describe mechanisms for putrefaction of carbohydrates and proteins.
- 2. To describe mechanisms of deterioration of oil and fat and to perform a deterioration tests of oil and fat.
- 3. To describe methods to avoid putrefaction and deterioration of food (methods for preservation, etc.).
- 4. To describe mechanisms for carcinogenesis of food ingredients.
- 5. To describe the function of food additives according to their usage.
- 6. To describe the special-use food and health-promoting foods.
- 7. To describe the legal regulations for food safety.

## (3) Food Poisoning and Food Contamination

1. To describe the major bacterial and viral food poisonings in Japan, and to describe their pathogens, clinical symptoms, poisoned foods, and prevention methods.

- 2. To describe naturally occurring poisons that cause food poisonings, and their causal substances, the mechanisms for poisonous action, and the clinical symptoms of food poisoning.
- 3. To describe food contaminations by chemical substances (heavy metals, pesticide residue, etc.), and their effects on human health.

#### **D2.** Environmental Sciences

GIO: To acquire the basic knowledge, skills, and behavior on chemical substances for their effects on human and environmental health, their appropriate use, and their effects on the global ecosystem and our daylife and to contribute to the maintenance of better environment and the improvement and promotion of public health.

#### (1) Effects of Chemical Substances and Radiation on Health

GIO: To acquire the basics knowledge and behavior about the toxicity of chemical substances to appropriately use chemical substances without their harmful effects on the human and environmental health.

# (1) Toxicology of Chemical Substances

- 1. To describe the basic processes of absorption, distribution, metabolism, and excretion of major toxic substances.
- 2. To enumerate major chemical substances that have organ-specific toxicities on liver, kidneys, nerves system, etc.
- 3. To describe the acute and chronic toxicity of pesticides and toxic substances such as heavy metals, PCBs, dioxins, etc.
- 4. To describe biofactors to prevent harmful effects caused by heavy metals and reactive oxygen species.
- 5. To describe and discuss effects of drug abuse on the human and public health.
- 6. To describe methods of treatment on the toxicosis caused by major chemical substances.
- 7. To describe methods to treat chemical substances including substance abuse.

## (2) Risk Assessment and Appropriate Use of Chemical Substances

- 1. To discuss risk communication and appropriate use of chemical substances.
- 2. To list and describe methods to treat toxic chemical substances.
- 3. To describe the dose-response relationship, threshold, no-observed-adverse-effect level (NOAEL), etc. to evaluate the toxicity of chemical substances.
- 4. To describe safe intake levels of chemical substances (acceptable daily intake, etc.).
- 5. To describe legal regulations (Chemical Substances Control Law, Chemical Substances Managing Law, etc.) for preventing the adverse effects of toxic chemical substances on human and environmental health.

# (3) Chemical Carcinogenesis

- 1. To describe mechanisms of metabolic activation of substances such as carcinogens.
- 2. To describe the principles of genotoxicity tests (Ames-test, etc.).
- 3. To describe processes of carcinogenesis (initiation, promotion, etc.).

## (4) Effects of Radiation

- 1. To describe ionizing radiations and their effects on humans.
- 2. To describe the interactions between major radioactive nuclides (i.e., naturally occurring and artificial) and the human body.
- 3. To describe methods to protect from ionizing radiation.
- 4. To describe non-ionizing radiations (ultraviolet, infrared radiation, etc.) and their effects on the human body.

## (2) Regulatory Sciences in Environmental Health

GIO: To acquire basic knowledge, skills, and behavior about the origin, testing methods, health effects, prevention measure, and removal of environmental pollutants to contribute to maintain the sustainable global ecology and environment.

# (1) Global Environment and Ecosystems

- 1. To describe the global environmental problems and their effects on human health.
- 2. To describe the members of the ecosystem, and their function and characteristics, and relationships among them in the ecosystem.
- 3. To describe the dynamics of chemical substances in the environment such as bioaccumulation.
- 4. To describe protocols for sustainable global environment.
- 5. To discuss ecological problems as a responsible member of the ecosystem.

# (2) Environmental Conservation and Regulatory Sciences

- 1. To describe the seven typical pollution (air pollution, water contamination, soil contamination, noise, vibration, land subsidence, and offensive odor), and their present situations as well as the four major pollutions in Japan (Minamata disease, Niigata-Minamata disease, Yokkaichi asthma, and Itai-itai disease).
- 2. To describe the principles of Environment Basic Law in Japan.
- 3. To describe the legal regulations to prevent the pollutions in Japan.

# (3) Water Management

- 1. To describe sources of tap water.
- 2. To describe functions of water supply facility and chlorination of tap water.
- 3. To describe the water quality standards for tap water in Japan and to perform the quality control tests.
- 4. To describe methods of sewage processing and drainage processing in Japan.
- 5. To describe and perform methods to measure indices of water contamination.
- 6. To describe causes and problems of eutrophication and to suggest solution against eutrophication.

# **4** Air Pollution

- 1. To describe chronological changes, origin, and health effects of major air pollutants.
- 2. To measure major air pollutants.
- 3. To describe meteorological factors affecting air pollution (an inversion layer, etc.).

# (5) Indoor Environment

- 1. To describe and measure major indices to evaluate indoor environment.
- 2. To describe the relationship between indoor environment and human health.

# (6) Waste Treatments and Their Regulations

- 1. To describe categories of waste in Japan and their treatment methods.
- 2. To describe problems in waste treatment and the countermeasures.
- 3. To describe the manifest system for waste control in Japan.

## E. Therapeutics: Clinical Pharmacology, Pharmacotherapy, and Pharmacokinetics

# E1. Pharmacology, Pathophysiology, and Clinical Laboratory Tests

GIO: To understand the process of drug actions based on the knowledge of general diseases and pharmacology.

## (1) Pharmacology

# GIO: To acquire basic knowledge of pharmacodynamics/kinetics to understand the appropriate use of pharmaceuticals.

# (1) Pharmacology

- 1. To describe dose-response relationships.
- 2. To describe agonists (stimulants) and antagonists (blockers, inhibitors) and their mechanisms of action.
- 3. To describe the mechanism of action of drugs by listing receptors, enzymes, ion-channels, and transporters.
- 4. To list major receptors and describe physiological reactions when they are stimulated or blocked.
- 5. To list major intracellular signaling systems related to the onset of the action of drugs and describe physiological reactions when activated or inhibited.
- 6. To describe the relationships between pharmacokinetics (absorption, distribution, metabolism, excretion) and the onset of pharmacological effects.
- 7. To describe, in a detailed manner, the factors (age, disease state, pregnancy, etc.) affecting the selection and adjustment of drugs, dosages, or administration methods.
- 8. To list major drug interactions derived from pharmacological effects and describe their mechanisms.
- 9. To describe drug dependency and tolerances with examples.

## (2) Animal Experimentation

- 1. To practice animal experiments in an ethical manner.
- 2. To handle experimental animals appropriately.
- 3. To perform representative drug administrations during animal experiments.

## 3 Japanese Pharmacopoeia

1. To describe the characteristics of biological assays listed in the Japanese Pharmacopoeia.

## (2) Pathophysiology and Clinical Laboratory Tests

# GIO: To acquire fundamental knowledges of patients' symptoms, conditions, and clinical laboratory tests to diagnose disease.

# 1 Symptoms and Conditions

1. To describe the major diseases causing the following symptoms and conditions, and to give a preliminary patient diagnosis:

shock, high blood pressure, low blood pressure, fever, convulsions, unconsciousness and fainting, cyanosis, dehydration, general malaise, overweight, underweight, jaundice, rash, anemia, bleeding tendencies, lymph node swelling, edema, rapid heartbeat, palpitations, pleural effusion, chest pain,

breathing difficulties, cough and phlegm, hemoptysis, dizziness, headaches, paralysis and involuntary movements, muscle weakness, abdominal pain, nausea and vomiting, swallowing difficulties, anorexia, diarrhea, constipation, hematemesis and melena, abdominal distension (including ascitic fluid retention), proteinuria, hematuria, urine and abnormal urination, menstrual abnormalities, joint swelling and joint pain, back pain, memory impairment, sensory abnormalities including numbness, nerve pain, visual impairment, and hearing impairment.

# (2) Disease Status and Laboratory Tests

- 1. To list the items examined in urinalysis and stool analysis, to describe the objectives, and to recognize abnormal values in the results.
- 2. To list the items examined in blood, blood coagulation, and cerebrospinal fluid tests, to describe the objectives, and to recognize abnormal values in the results.
- 3. To list the items examined in blood and serum chemical tests, to describe the objectives, and to recognize abnormal values in the test results.
- 4. To list the items examined in immunological tests, to describe the objectives, and to recognize abnormal values in the results.
- 5. To list the items examined in arterial blood gas, to describe the objectives, and to recognize abnormal values in the results.
- 6. To list the laboratory tests commonly ordered for major physiological function (heart, kidney, liver, respiratory system, etc.), histopathological, and imaging examinations, and to describe their objectives, and to recognize abnormal values in the results.
- 7. To list the laboratory tests commonly ordered for microbial examinations, to describe the objectives, and to recognize abnormal values in the results.
- 8. To list the laboratory tests commonly ordered for physical assessment examinations, to describe the objectives, and to recognize abnormal values in the results.

### (3) Common Disease States and an Overview on Making Clinical Decisions

# GIO: To acquire the basic knowledge of medical treatment and pharmacotherapy for major diseases to work as part of an interprofessional team.

- 1. To describe the roles of drug, diet, and non-drug therapies (surgery, etc.) in treating major diseases.
- 2. To discuss the significance of drug therapy in major diseases based on disease state, pharmacology, and pharmacokinetics.

### (4) Medication Safety and Quality Improvement

# GIO: To acquire the basic knowledge of adverse events (side effects, interactions), drug-induced injury/damage, and drug abuse to avoid the risks associated with pharmacotherapy.

- 1. To describe the effects, side effects, and toxicity of drugs and their relationships.
- 2. To describe the differences between side effects and adverse events.

- 3. To describe the drugs, physical tests, laboratory tests, and methods to treat major side effects and disease states such as:
  - blood disorders, electrolyte abnormalities, liver failure, renal failure, digestive disorders, circulatory disorders, mental disorders, skin disorders, respiratory problems, drug allergies (including anaphylactic shock), metabolic disorders, and muscle disorders.
- 4. To discuss major drug-induced damage/injury and drug abuse issues from the viewpoint of health risk management.

# E2. Pharmacology, Pathophysiology, and Pharmacotherapy

GIO: To acquire fundamental knowledge of pharmacology, pathophysiology, and pharmacotherapy to participate in appropriate treatment through the selection of appropriate pharmaceuticals, dosages, and routes of administration while following drug information and safety guidelines.

## (1) Drugs Used for the Treatment of Nervous System Disorders

GIO: To acquire fundamental knowledge of pharmacology, pathophysiology, and pharmacotherapy of drugs for the treatment of nervous system disorders and to learn the basics of collecting and analyzing information for the appropriate use of pharmaceuticals.

# (1) Drugs Affecting the Autonomic Nervous System

- 1. To list the major drugs that affect the sympathetic nervous system by altering the functions of the governing organs and to describe their pharmacology, mechanisms of action, and major side effects.
- 2. To list the major drugs that affect the parasympathetic nervous system by altering the function of the governing organs and describe their pharmacology, mechanisms of action, and major side effects.
- 3. To list the major drugs that affect the ganglia and describe their pharmacology, mechanisms of action, and major side effects.
- 4. To evaluate the efficacy of major drugs that affect the autonomic nervous system in animal experiments.

# (2) Drugs Affecting the Somatic Nervous System and Drugs Used for the Treatment of Muscle Disorders

- 1. To list the major drugs that affect the sensory nerves and to describe their pharmacological effects, mechanisms of action, and major side effects.
- 2. To list the major drugs that affect the motor nervous system and to describe their pharmacological effects, mechanisms of action, and major side effects.
- 3. To evaluate the efficacy of major drugs that affect the sensory and motor nerves in animal experiments.
- 4. To describe the following diseases: progressive muscular dystrophy, Guillain-Barre syndrome, and myasthenia gravis.

### (3) Drugs Used for Treatment of Central Nervous System Disorders

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of general anesthetics and hypnotic drugs.

- To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications (including the WHO three-step analgesic ladder) of narcotic analgesics and non-narcotic analgesics.
- 3. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of the central nervous system stimulants.
- 4. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of the drugs used to treat schizophrenia as well as disease state (pathophysiology, symptoms, etc.).
- 5. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat major depression, mania, and depressive (bipolar) disorders as well as disease state (pathophysiology, symptoms, etc.).
- 6. To describe pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat anxiety disorders (panic, general anxiety disorders), psychosomatic disorders, and insomnia as well as disease state (pathophysiology, symptoms, etc.).
- 7. To describe the pharmacology (pharmacological effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat epilepsy as well as disease state (pathophysiology, symptoms, etc.).
- 8. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat cerebrovascular diseases (intracerebral hemorrhage, cerebral infarction including thrombosis, embolism, transient cerebral ischemia, and subarachnoid hemorrhage) as well as disease state (pathophysiology, symptoms, etc.).
- 9. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat Parkinson's disease as well as disease state (pathophysiology, symptoms, etc.).
- 10. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat dementia (Alzheimer's disease, cerebrovascular dementia) as well as disease state (pathophysiology, symptoms, etc.).
- 11. To describe pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat migraine as well as disease state (pathophysiology, symptoms, etc.).
- 12. To evaluate the efficacy of drugs that affect the central nervous system in animal experiments.
- 13. To discuss central nervous system disorders that may affect social life and the significance of pharmacotherapy.
- 14. To discuss the following diseases: encephalitis, meningitis, multiple sclerosis, amyotrophic lateral sclerosis, narcolepsy, drug addiction, and alcoholism.

#### (4) Chemical Structure and Drug Effect

1. To describe briefly the basic chemical structures and effects (pharmacology, pharmacokinetics) of major drugs that affect the nervous system.

- (2) Immunosupressants, Antiinflammatory Agents, Drugs Used for the Treatment of Allergies, and Bone/Joint Disorders
- GIO: To acquire fundamental knowledge of the pharmacology, pathophysiology, and pharmacotherapy of drugs for immunosupressants, antiinflammatory agents, drugs for the treatment of allergies and bone/joint disorders and to collect and analyze information for the appropriate use of pharmaceuticals.

# (1) Antiinflammatory Agents

- 1. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of antiinflammatory agents (steroidal, non-steroidal) and anti-pyretic analgesic agents.
- 2. To describe inflammation based on the mechanism of action of antiinflammatory drugs.
- 3.To describe the process of wound healing.

# (2) Immunosupressants, Antiinflammatory Agents, Drugs Used for the Treatment of Allergies

- 1. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of drugs used to treat allergies (antihistamines, antiallergic agents, etc.).
- 2. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of immunosuppressants.
- 3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following allergic diseases as well as disease state (pathophysiology, symptoms, etc.): atopic dermatitis, urticaria, contact dermatitis, allergic rhinitis, allergic conjunctivitis, pollen allergies, digestive allergies, and asthma.
- 4. To describe the drugs used to treat the following drug-induced allergies as well as disease state (pathophysiology, symptoms, etc.):
  Stevens-Johnson syndrome, toxic epidermal necrosis, drug-induced hypersensitivity syndrome, and drug eruption.
- 5. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat anaphylactic shock as well as disease state (pathophysiology, symptoms, etc.).
- 6. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) for the following diseases:

  psoriasis vulgaris, bullous dermatosis, photodermatosis, and Behçet's disease
- 7. To describe the pharmacology (pharmacological effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following organ-specific autoimmune diseases as well as disease state (pathophysiology, symptoms, etc.):

  Grave's disease, Hashimoto's thyroiditis, pernicious anemia, Addison's disease, type 1 diabetes mellitus, myasthenia gravis, multiple sclerosis, idiopathic thrombocytopenic purpura, autoimmune hemolytic anemia, and Sjogren's syndrome.

- 8. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following systemic autoimmune diseases as well as disease state (pathophysiology, symptoms, etc.): systemic lupus erythematosus, scleroderma, polymyositis/dermatomyositis, and rheumatoid arthritis.
- 9. To describe the disease state (pathophysiology, symptoms, etc.), pharmacotherapy (drug selection, etc.) of rejection and graft-versus-host disease (GVHD) associated with kidney, liver, and bone marrow transplantation and with umbilical cord blood, and blood transfusion.

# (3) Drugs Used for the Treatment of Bone/Joint and Calcium Metabolism Disorders

- 1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat rheumatoid arthtritis as well as disease state (pathophysiology, symptoms, etc.).
- 2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs to treat osteoporosis as well as disease state (pathophysiology, symptoms, etc.).
- 3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs to treat osteoporosis as well as disease state (pathophysiology, symptoms, etc.).
- 4. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following calcium metabolism disorders as well as disease state (pathophysiology, symptoms, etc.): hyper/hypoparathyroidism, osteomalacia (including rickets), and hypercalcemia associated with malignant tumors.

# (4) Chemical Structure and Drug Effects

1. To describe briefly the basic structures and effects (pharmacology, pharmacokinetics) of major drugs such as immunosupressants, antiinflammatory agents, and drugs for the treatment of allergies.

# (3) Drugs Used for the Treatment of Cardiovascular, Hematological, Renal/Urinary Tract, and Reproductive Disorders

GIO: To acquire fundamental knowledge of the pharmacology, pathophysiology, and pharmacotherapy of drugs used to treat cardiovascular, hematological, renal/urinary tract, and reproductive disorders and to collect and analyze information for the appropriate use of pharmaceuticals.

# 1 Drugs Used for the Treatment of Cardiovascular Disease

1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following types of cardiac arrhythmia and related conditions as well as disease state (pathophysiology, symptoms, etc.): supraventricular premature contraction (PAC), premature ventricular contraction (PVC), atrial fibrillation (AF), paroxysmal supraventricular tachycardia (PSVT), WPW syndrome, ventricular tachycardia (VT), ventricular fibrillation (VF), atrioventricular block, and long QT syndrome.

- 2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat acute and chronic heart failure as well as disease state (pathophysiology, symptoms, etc.).
- 3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat ischemic heart disease (angina pectoris, myocardial infarction) as well as disease state (pathophysiology, symptoms, etc.).
- 4. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following forms of hypertension as well as disease state (pathophysiology, symptoms, etc.): essential hypertension and secondary hypertension (including renal vascular hypertension and renal hypertension).
- 5. To describe arteriosclerosis obliterans (ASO), cardiogenic shock, valvular disease, and congenital heart disease.
- 6. To evaluate the efficacy of drugs to treat circulatory disorders in animal experiments.

# 2 Drugs Used for the Treatment of Blood and the Hematopoietic System Disorders

- 1. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of hemostatic drugs.
- 2. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of anti-thrombotic drugs, anti-coagulants, and thrombolytic agents.
- 3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following types of anemia as well as disease state (pathophysiology, symptoms, etc.): iron deficiency anemia, megaloblastic anemia (pernicious anemia, etc.), aplastic anemia, autoimmune hemolytic anemia (AIHA), renal anemia, and sideroblastic anemia.
- 4. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat disseminated intravascular coagulation (DIC) as well as disease state (pathophysiology, symptoms, etc.).
- 5. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection etc.) of drugs used to treat the following blood and hematopoietic system disorders as well as disease state (pathophysiology, symptoms, etc.): hemophilia, thrombotic thrombocytopenic purpura (TTP), leukopenia, thromboembolism, leukemia, and malignant lymphoma.

## (3) Drugs Used for the Treatment of Urinary Tract and Reproductive System Disorders

- 1. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of diuretic agents.
- 2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat acute and chronic renal failure as well as disease state (pathophysiology, symptoms, etc.).

- 3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat nephrotic syndrome as well as disease state (pathophysiology, symptoms, etc.).
- 4. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat overactive/underactive bladder as well as disease state (pathophysiology, symptoms, etc.).
- 5. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following urinary tract disorders as well as disease state (pathophysiology, symptoms, etc.): chronic kidney disease (CKD), glomerulonephritis, diabetic nephropathy, drug-induced nephropathy, pyelonephritis, cystitis, urinary tract infection and urinary stones.
- 6. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat prostatic hypertrophy, endometriosis, and uterine fibroids as well as disease state (pathophysiology, symptoms, etc.).
- 7. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs related to conception, pregnancy, and birth as well as the physical conditions associated with them.
- 8. To describe the processes of the reproductive system in cases of infertility and during abnormal pregnancy and abnormal delivery.

## (4) Chemical Structures and Drug Effects

1. To describe the basic structures and effects (pharmacology, pharmacokinetics) of major drugs used to treat cardiovascular, urinary, and reproductive system disorders.

# (4) Drugs Used for the Treatment of Respiratory and Digestive Tract Disorders

GIO: To acquire fundamental knowledge of the pathophysiology of respiratory and digestive tract disorders as well as the pharmacology and pharmacotherapy of drugs used to treat them and to collect and analyze information for the appropriate use of pharmaceuticals.

#### (1) Drugs Used for the Treatment of Respiratory Tract Disorders

- 1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat bronchial asthma as well as disease state (pathophysiology, symptoms, etc.).
- 2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat chronic obstructive pulmonary disease (COPD) and tobacco-related diseases (including nicotine dependence) as well as disease state (pathophysiology, symptoms, etc.).
- 3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat interstitial pneumonia as well as disease state (pathophysiology, symptoms, etc.).

4. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of antitussive, expectorant, and respiratory stimulants.

## (2) Drugs Used for the Treatment of Digestive Tract Disorders

- 1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat gastroesophageal reflux (including reflux esophagitis), peptic ulcer, and gastritis as well as disease state (pathophysiology, symptoms, etc.).
- 2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat inflammatory bowel disease (ulcerative colitis, Chrohn's disease, etc.) as well as disease state (pathophysiology, symptoms, etc.).
- 3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat liver disease (hepatitis, liver cirrhosis including viral cirrhosis, and drug-induced liver damage as well as disease state (pathophysiology, symptoms, etc.).
- 4. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat pancreatitis as well as disease state (pathophysiology, symptoms, etc.).
- 5. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat biliary tract disease (cholelithiasis, cholangitis) as well as disease state (pathophysiology, symptoms, etc.).
- 6. To describe t the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat gastrointestinal function disorders, including irritable bowel syndrome, as well as disease state (pathophysiology, symptoms, etc.).
- 7. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat constipation and diarrhea as well as disease state (pathophysiology, symptoms, etc.).
- 8. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat nausea and vomiting as well as disease state (pathophysiology, symptoms, etc.).
- 9. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat hemorrhoids as well as disease state (pathophysiology, symptoms, etc.).

#### (3) Chemical Structures, Properties, and Activities of Drugs

1. To describe briefly the basic structures and effects (pharmacology, pharmacokinetics) of drugs used to treat respiratory and digestive disorders.

## (5) Drugs Used for the Treatment of Metabolic and Endocrine Disorders

GIO: To acquire fundamental knowledge of the pharmacology, pathophysiology, and pharmacotherapy of drugs for the treatment of endocrine and metabolic disorders and to collect and analyze information for the appropriate use of pharmaceuticals.

# 1 Drugs Used for the Treatment of Metabolic Disorders

- 1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat diabetes mellitus and its complications as well as disease state (pathophysiology, symptoms, etc.).
- 2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat dyslipidemia as well as disease state (pathophysiology, symptoms, etc.).
- 3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat hyperuricemia and gout as well as disease state (pathophysiology, symptoms, etc.).

## (2) Drugs Used for the Treatment of Endocrine Disorders

- 1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of sex hormone-related drugs used to treat endocrine system disorders as well as disease state (pathophysiology, symptoms, etc.).
- 2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat Basedow's (Grave's) disease as well as disease state (pathophysiology, symptoms, etc.).
- 3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat thyroiditis (chronic Hashimoto's thyroiditis and subacute thyroiditis) as well as disease state (pathophysiology, symptoms, etc.).
- 4. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat diabetes insipidus as well as disease state (pathophysiology, symptoms, etc.).
- 5. To describe the following diseases:
  acromegaly, hyperprolactinemia, hypopituitarism, ADH syndrome of inappropriate secretion
  (SIADH), hyperparathyroidism, hypothyroidism, Cushing's syndrome, aldosteronism,
  pheochromocytoma, adrenal insufficiency (acute, chronic), endometriosis and Addison's disease.

### (3) Chemical Structure and Drug Efficacy

1. To describe briefly the basic structures and effects (pharmacology, pharmacokinetics) of drugs used for the treatment of metabolic and endocrine system disorders.

# (6) Drugs Used for the Treatment of Ophthalmological, Ear/Nose/Throat, and Dermatological Conditions

GIO: To acquire fundamental knowledge of the pathophysiology, pharmacology, mechanisms of action, and side effects of drugs used for the treatment of ophthalmological, ears/nose/throat, and dermatological conditions and to collect and analyze information for the appropriate use of pharmaceuticals.

# (1) Drugs Used for the Treatment of Ophthalmological Conditions

- 1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat glaucoma as well as disease state (pathophysiology, symptoms, etc.).
- 2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat cataract as well as disease state (pathophysiology, symptoms, etc.).
- 3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat age-related macular degeneration as well as disease state (pathophysiology, symptoms, etc.).
- 4. To describe conjunctivitis, retinopathy, uveitis, and retinitis pigmentosa.

## (2) Drugs Used for the Treatment of Ears/Nose/Throat Conditions

- 1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat dizziness, motion, sickness, Meniere's disease, etc. as well as disease state (pathophysiology, symptoms, etc.).
- 2. To describe the following diseases: allergic rhinitis, hay fever, sinusitis, otitis media, pharyngitis, tonsillitis, and epiglottitis.

# (3) Drugs Used for the Treatment of Dermatological Conditions

- 1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat atopic dermatitis as well as disease state (pathophysiology, symptoms, etc.).
- 2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat fungal diseases of the skin as well as disease state (pathophysiology, symptoms, etc.).
- 3. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat decubitus as well as disease state (pathophysiology, symptoms, etc.).
- 4. To describe the following diseases: urticaria, drug eruption, bullous dermatosis, psoriasis, contact dermatitis, and photodermatosis

## (4) Chemical Structure and Drug Effect

1. To describe briefly the basic structures and effects (pharmacology, pharmacokinetics) of drugs used for the treatment of ophthalmological, ears/nose/throat, and dermatological conditions.

## (7) Drugs Used for the Treatment of Infectious Diseases and Cancer

GIO: To acquire fundamental knowledge of the pharmacology, pathophysiology, and pharmacotherapy of drugs used for the treatment of infectious diseases and cancers and to collect and analyze information for the appropriate use of pharmaceuticals.

# 1 Antibacterial Agents

- 1. To describe the pharmacology (effects, mechanisms of action, antibacterial spectrum, major side effects, interactions, tissue absorption) and clinical applications of drugs used for the treatment of infectious diseases, including  $\beta$  lactams, tetracyclines, macrolides, aminoglycosides, new quinolones, glycopeptide-based, anti-tuberculosis drugs, sulfa drugs (including the ST case agent), and other antibacterial agents.
- 2. To list the major biological agents (vaccines, etc.) related to bacterial infection and describe their mechanisms of action.

## (2) Antibacterial Drug Resistance

1. To describe the mechanism of resistance acquisition of resistance to major anti-bacterial agents and how to treat patients with drug-resistant bacterial infections.

## (3) Drugs Used for the Treatment of Bacterial Infections

- 1. To describe the disease states (pathophysiology, symptoms, etc.), infection route, preventive methods, and pharmacotherapy (drug selections, etc.) in the treatment of the following respiratory tract infections:
  - upper respiratory infection (common cold syndrome), bronchitis, tonsillitis, bacterial pneumonia, pulmonary tuberculosis, Legionella infection, pertussis, and mycoplasma pneumonia.
- 2. To describe the disease states (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) in the treatment of the following gastrointestinal tract infections: acute appendicitis, cholecystitis, cholangitis, pathogenic *E. coli* infection, food poisoning, *Helicobacter pylori* infection, dysentery, cholera, typhoid, paratyphoid, and pseudomembranous colitis.
- 3. To describe the disease states (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) in the treatment of the following sensory organ infections: sinusitis, otitis media, and conjunctivitis.
- 4. To describe the disease states (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) in the treatment of the following urinary tract infections: pyelonephritis, cystitis, and urethritis.
- 5. To describe the disease states (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) in the treatment of the following sexually transmitted diseases: syphilis, gonorrhea, and chlamydia.
- 6. To describe the disease states (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) in the treatment of encephalitis and meningitis.

- 7. To describe the disease states (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) in the treatment of the following bacterial skin infections: contagious impetigo, erysipelas, carbuncle, folliculitis, and leprosy.
- 8. To describe the disease states (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) in the treatment of infective endocarditis and pleurisy.
- 9. To describe the route of transmission, preventive measures, disease states (pathophysiology, symptoms, etc.), and pharmacotherapy (drug selections, etc.) in the treatment of hospital-acquired infections caused by the following drug-resistant bacteria: methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), *Serratia* spp., *Pseudomonas aeruginosa*, etc.
- 10. To describe the disease state (pathophysiology, symptoms, etc.), route of transmission, preventive measures, and pharmacotherapy (drug selections, etc.) in the treatment of the following systemic bacterial infections: diphtheria, fulminant group A  $\beta$ -hemolytic streptococcus infection, neonatal group B streptococcal infection, tetanus, and sepsis.

## (4) Drugs Used for the Treatment of Viral Infections and Prion Diseases

- 1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat herpesvirus infections (herpes simplex, varicella zoster) as well as disease state (pathophysiology, symptoms, etc.).
- 2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat cytomegalovirus infections as well as disease state (pathophysiology, symptoms, etc.).
- 3. To describe t the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat influenza as well as disease state (pathophysiology, symptoms, etc.).
- 4. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drugselection, etc.) of the drugs used to treat viral hepatitis A, B, and C (HVA, HVB, and HCV) infection, acute hepatitis, chronic hepatitis, cirrhosis, and liver cell carcinoma as well as routes of transmission, preventive measures, and disease state (pathophysiology and symptoms, etc.).
- 5. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of the drugs used to treat acquired immunodeficiency syndrome (AIDS) as well as the routes of transmission, preventive measures, and disease states (pathophysiology, symptoms, etc.).
- 6. To describe the routes of transmission, preventive measures, disease states (pathophysiology, symptoms, etc.), and pharmacotherapy (drug selections, etc.) to treat the following viral infections (including prion diseases): infectious erythema, hand-foot-and-mouth disease, mononucleosis, exanthema subitum, pharyngoconjunctival fever, viral diarrhea, measles, rubella, mumps, common cold syndrome, and Creutzfeldt-Jakob disease.

# (5) Drugs Used for the Treatment of Fungal Infections

- 1. To describe the pharmacology (effects, mechanisms of action, major side effects) and clinical applications of antifungal drugs.
- 2. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) for the treatment of the following fungal infections: skin mycosis, candidiasis, pneumocystis pneumonia, pulmonary aspergillosis, and cryptococcosis.

## (6) Drugs Used for the Treatment of Protozoal and Parasitic Infections

- 1. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following protozoal infections as well as disease state (pathophysiology, symptoms, etc.): malaria, toxoplasmosis, trichomoniasis, and amoebic dysentery.
- 2. To describe the pharmacology (effects, mechanisms of action, major side effects) and pharmacotherapy (drug selection, etc.) of drugs used to treat the following parasitic infections as well as disease state (pathophysiology, symptoms, etc.): ascariasis, pinworm disease, and anisakiasis.

# (7) Malignant Tumors

- 1. To describe the definition of tumors (the differences between benign and malignant tumors).
- 2. To describe the following aspects related to malignant (cancerous) tumors: histological type classifications, stages, tumor examinations (cytodiagnosis, tissue diagnosis, diagnostic imaging, tumor markers (including mutant genes and gene products), epidemiology (trends in morbidity and mortality), risks for development, and preventive measures.
- 3. To describe the significance of pharmacotherapy in the treatment of cancers.

### (8) Drugs Used for the Treatment of Malignant Tumors

- 1. To describe the pharmacology (effects, mechanisms of action, major side effects, interactions, and tissue migration) of the following anticancer agents and their clinical applications: alkylating agents, antimetabolites, antitumor antibiotics, mitotic inhibitors, topoisomerase inhibitors, hormonal agents, platinum agents, molecular-targeted therapy, etc.
- 2. To escribe the mechanism of acquired resistance to anti-cancer agents.
- 3. To describe treatments to reduce the following major side effects of anti-cancer agents: diarrhea, nausea, vomiting, leukopenia, and skin disorders including hand-foot syndrome and thrombocytopenia.
- 4. To describe major chemotherapy regimens (FOLFOX, etc.) including the agents involved, their roles and side effects, and target diseases.
- 5. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat the following types of leukemia: acute (chronic) myelogenous leukemia, acute (chronic) lymphocytic leukemia, and adult T-cell leukemia (ATL).
- 6. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat malignant lymphoma and multiple myeloma.

- 7. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat osteosarcoma.
- 8. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat the following digestive tract cancers: stomach, esophageal, liver, colon, gallbladder, bile duct, and pancreatic.
- 9. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat lung cancer.
- 10. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat malignancies of the following head/neck and sensory organs: brain, retinoblastoma, larynx, pharynx, nasal cavity, paranasal sinuses, and oral cavity.
- 11. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat the following genital cancers: prostate, uterine, and ovarian.
- 12. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat kidney and bladder cancers.
- 13. To describe the disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used to treat breast cancer.

## (9) Terminal and Palliative Care

- 1. To describe disease state (pathophysiology, symptoms, etc.) and treatments for the terminal stages of cancer.
- 2. To describe disease state (pathophysiology, symptoms, etc.) and pharmacotherapy (drug selections, etc.) used for the treatments of cancer-related pain.

### (10) Chemical Structure and Drug Activities

1. To describe the basic structures and activities (pharmacology, pharmacokinetics) of drugs used to treat pathogenic microorganism infections and malignant neoplasms.

# (8) Biologics, Cell Therapy, and Genomics

GIO: To acquire fundamental knowledge of treatments utilizing proteins, genomics, and cellular agents for appropriate use with ethical considerations as well as an understanding of basic genomics.

# (1) Recombinant Pharmaceutical Products

- 1. To describe the characteristics and significance of recombinant pharmaceuticals.
- 2. To list major recombinant pharmaceuticals.
- 3. To describe the safety risks of recombinant pharmaceuticals.

### (2) Gene Therapy

1. To describe the mechanisms, methods, and procedures of gene therapies and to describe the current status of associated ethical issues.

# (3) Transplantation Therapy Utilizing Cells and Tissues

- 1. To describe the mechanisms, methods, and procedures of transplantation therapies, and to describe the current status of ethical issues associated with the utilization of genomic information.
- 2. To describe transplantation therapies utilizing isolated or cultured tissues.
- 3. To describe transplantation therapies utilizing blood stem cells derived from umbilical cord blood, peripheral blood, and bone marrow.
- 4. To describe cell transplantation therapies utilizing embryonic stem cells (ES cells) and induced pluripotent stem cells (iPS cells).

# (9) Over-the-Counter and Behind-the-Counter Drugs and Self-Medication

- GIO: To acquire fundamental knowledge of behind-the-counter, over-the-counter drugs, and self-medication to contribute to the community health and medical care by offering the appropriate drug therapy and to collect appropriate information for providing drug therapy.
  - 1. To describe the role of pharmacists in caring for the health of the community, health promotion, and self-medication.
  - 2. To describe both over-the-counter and behind-the-counter drugs and to list the major ones by risk category (class-1, -2, and -3).
  - 3. Based on major symptoms, to list the diseases that appear to be strongly related and diseases that should not to be overlooked.
  - 4. To collect specific patient information to determine whether over-the-counter or behind-the-counter drugs should be used or whether patients should be advised to consult a physician.
  - 5. To list over-the-counter and behind-the-counter drugs for self-medication that can be used to treat the following conditions and symptoms: fever, pain, itching, digestive and respiratory symptoms, allergies, bacterial/fungal infections or lifestyle-related diseases.
  - 6. To describe health improvement methods (including exercise, diet, supplements, and health-promoting food) and to describe their significance in maintaining/ promoting people's health.
  - 7. To describe major interactions among over-the-counter and behind-the-counter drugs, prescription drugs, supplements, and health-promoting food.
  - 8. To collect and evaluate information on therapeutic outcomes and side effects of over-the-counter and behind-the-counter drugs.

#### (10) Kampo Medicine

GIO: To acquire basic knowledge of Kampo medicines, including disease concepts, indications, side effects and precautions.

## (1) Fundamentals of Kampo Medicine

- 1. To describe the characteristics of Kampo medicine.
- To describe the following basic words of Kampo medicine:
   Yin/Yang , Deficiency/Excess Cold/Heat, Exterior/Interior, Qi/Blood/Fluid, and Patterns.

- To describe the systematic classification of Kampo medicines based on the components of crude drugs.
- 4. To describe the differences between Kampo medicines and modern pharmaceuticals, folk medicines, supplements, and health-promoting food.

# (2) Application of Kampo Medicines

- 1. To describe the diagnostic methods, patient approach such as, conditions and disease states, and treatments used in Kampo medicine.
- 2. To describe with examples the patterns, symptoms, and diseases related to the Kampo medicines listed in the Japanese Pharmacopoeia.
- 3. To describe the significance of Kampo medicines in modern pharmacotherapy.

# (3) Precautions Related to the Use of Kampo Medicines

1. To describe with examples possible side effects and precautions for the use of Kampo medicines.

# (11) Therapeutics Optimization

GIO: To acquire fundamental knowledge of collecting and analyzing information for treatments and appropriate use of pharmaceuticals in order to contribute to the optimal drug therapy.

# (1) Comprehensive Exercises

- 1. To discuss optimal drug therapies based on patient and drug information.
- 2. To discuss treatments for overdose toxicity (including antidotes).
- 3. To list complications associated with long-term care and discuss their drug therapy.

# E3. Essential Information for Pharmacotherapy

GIO: As part of interprofessional teamwork, to acquire fundamental knowledge of and skills in providing and applying drug information and patient information into clinical problems, in order to provide necessary information on pharmacotherapy, to develop pharmaceutical care plans, and to solve clinical problems.

## (1) Drug Information

GIO: To acquire fundamental knowledge of and skills in applying drug information, evidence-based medicine (EBM), biostatistics, and clinical research designs and analytics.

## (1) Fundamentals of Drug Information

- 1. To identify essential drug information for pharmaceutical administration and handling.
- 2. To describe which professionals (governmental, clinical, and pharmaceutical) provide different types of drug information and the roles those professionals play.
- 3. To describe examinations and clinical trials in new drug development including generic drugs, and drug information data to those trials.
- 4. To describe outline of post-marketing surveillance and studies and drug information obtained from them.

5. To describe major regulations such as Good Clinical Practice (GCP), Good Pharmacovigilance Practice (GVP), Good Postmarketing Study Practice (GPSP), risk management plans (RMP), etc. and regulatory science.

# (2) Drug Information Resources

- 1. To describe primary, secondary, and tertiary drug information resources.
- 2. To list major secondary and tertiary resources and to describe the characteristics of each each.
- 3. To describe the types of drug information provided by the Ministry of Health, Labor and Welfare, Pharmaceutical and Medical Devices Agency (PMDA), and Pharmaceutical companies.
- 4. To describe the legal roles of package inserts.
- 5. To list the items (boxed warnings and precautions, contraindications, indications and usage, dosage and administration, cautions, etc.) in package inserts and to explain each item.
- 6. To describe the difference between the roles of drug interview forms and package inserts.

# (3) Clinical Applications of Drug Information (Collection, Evaluation, Processing, Provision, Management)

- 1. To select the appropriate source for each purpose (usage, adverse reactions, interactions, identification, pregnancy and nursing, toxicity, etc.) and to retrieve and collect drug information effectively from each source.
- 2. To understand the importance of key words and thesauruses in literature retrieval and to search secondary databases of medical and pharmaceutical publications (e.g., MEDLINE) appropriately.
- 3. To identify the items for evaluating the reliability and scientific validity of drug information.
- 4. To evaluate the quality of original articles on clinical trials and in the tertiary literature.
- 5. To describe handling methods and ethical issues (intellectual property and privacy policy) in applying drug information.

## (4) Evidence-based Medicine

- 1. To summarize the meaning of "evidence-based medicine" and to explain the 5 steps of the evidence-based medicine process.
- 2. To explain the advantages and disadvantages of different study designs (randomized controlled trial, cohort study, case-control study, etc.), and describe the evidence level of each study design.
- 3. To describe critical literature evaluation and identify internal validity (accuracy and reproducibility) and external validity (generalizability).
- 4. To understand the concept of meta-analyses and to explain the results.

## (5) Biostatistics

- 1. To describe and distinguish the basic statistics used in clinical trials (mean, median, standard deviation, standard error, confidence interval, etc.)
- 2. To explain the null hypothesis and define tests of significance and estimations.
- 3. To describe basic statistical distributions (normal, t-, binomial, Poisson, chi-squared, and F-).
- 4. To list major parametric tests and non-parametric tests and describe their usage.
- 5. To analyze significance differences between patient/treatment/placebo groups in clinical trials (t-test, chi-squared test, etc.).

- 6. To describe the major methods for conducting regression analyses (linear regression, logistic regression, etc.), and tests to determine correlation coefficients.
- 7. To describe knowledge of methods used to analyze survival time (Kaplan-Meier curve, etc.)

# (6) Clinical Study Design and Analysis

- 1. To describe the main clinical study designs (interventional study, observational study) and to explain the characteristics of each.
- 2. To describe bias and confounding in clinical trial design.
- 3. To describe the main epidemiological study designs for observational studies (case report, case series, case-controlled study, nested case-control study, case-cohort study, etc.).
- 4. To describe the algorithms used to determine causality in analyzing adverse drug reactions.
- 5. To describe the difference between superiority and noninferiority trials.
- 6. To describe the techniques applied in interventional studies (sample size, randomization, blinding, etc.).
- 7. To describe factors involve in statistical analysis.
- 8. To describe different endpoints used in interventional studies (true and surrogate endpoints, primary and secondary endpoints) by giving examples.
- 9. To describe and calculate the major outcomes (efficacy and safety) in clinical trials (relative risks, relative risk reduction, absolute risks, absolute risk reduction, number needed to treat, odds ratios, incidence rates, and incidence proportions).

## (7) Drug Evaluation

- 1. To describe how formularies are produced in hospital and community pharmacies.
- 2. To compare and evaluate efficacy and safety in major allogeneic same effect pharmaceuticals with the same activities using drug information.
- 3. To compare and evaluate quality, safety, and economy in branded and generic drugs using drug information.

### (2) Patient Information

GIO: To acquire basic knowledge of how to obtain and assess patient information.

## (1) Fundamentals of Patient Information

- 1. To list the basic patient information necessary to determine the most appropriate pharmacotherapy.
- 2. To list the resources for obtaining patient information and to explain the differences among them.

### (2) Clinical Assessment

- 1. To describe the problem-oriented system (POS)
- 2. To describe SOAP and how to record patient information.
- 3. To describe the types of patient information necessary to evaluate drug efficacy and adverse drug reactions.
- 4. To describe the importance of privacy policies when managing patient information.

## (3) Personalized Medicine

## GIO: To acquire the fundamental issues about personalized pharmacotherapy.

## (1) Genetic factors

- 1. To give examples and describe the major genetic factors influencing drug main drug effects and side effects.
- 2. To give examples and describe the major genetic factors (gene mutations in drug-metabolizing and transporter groups, etc.) affecting pharmacokinetics.
- 3. To give examples and describe pharmacotherapy taking genetic factors into consideration.

# (2) Age-Related Factors

- 1. To describe the cautions in pediatric pharmacotherapy and pharmacokinetics in low-birth weight infants, newborns, and infancy.
- 2. To describe the cautions in geriatric pharmacotherapy and pharmacokinetics in the elderly.

# (3) Special Populations (Liver Dysfunction, Renal Dysfunction, Heart Diseases, etc.)

- 1. To describe the cautions of pharmacotherapy as well as pharmacokinetics and how to develop pharmaceutical care plans for patients with kidney disease and renal dysfunction.
- 2. To describe the cautions of pharmacotherapy as well as pharmacokinetics and how to develop pharmaceutical care plans for patients with liver disease and liver dysfunction.
- 3. To describe the cautions of pharmacotherapy as well as pharmacokinetics and how to develop pharmaceutical care plans for patients with heart diseases.

# **4** Other Special Populations (Pregnant and Lactating Women, Obese or Emaciated Patients, Menopausal Women, et al.)

- 1. To identify the physiological factors affecting drug effects: gender, menopausal status, circadian rhythm, etc.
- 2. To describe the cautions of pharmacotherapy and pharmacokinetics as related to reproductive status, pregnancy, lactation, etc.
- 3. To describe the cautions of pharmacotherapy as well as pharmacokinetics and to develop pharmaceutical care plans based on nutrition status such as obesity, hypoalbuminemia, presence of ascites, etc.

## (5) Personalized Therapeutics Plans

- 1. To develop pharmaceutical care plans based on individual patient background (genetics, age, organ function, etc.) and drug information.
- 2. To give examples and explain pharmacotherapy based on companion diagnostics.

# **E4. Drug Disposition**

GIO: In order to understand drug disposition and to provide dosage regimens for individual patients, to acquire fundamental knowledge of pharmacokinetics and skills in their applications.

## (1) Drug Disposition

GIO: To acquire the fundamental issues of the processes of drug absorption, distribution, metabolism, excretion (ADME) and pharmacokinetic interaction.

# (1) Permeation through Biomembranes

- 1. To describe simple diffusion, facilitated diffusion, and active transport in the permeation of drugs across the cell membranes.
- 2. To list the transporters involved in drug permeation across the cell membranes and to describe their characteristics as well as their roles in pharmacokinetics.

# 2 Absorption

- 1. To describe drug absorption after oral administration.
- 2. To describe drug absorption after non-oral administration.
- 3. To list and describe the factors (drug properties, physiological factors, etc.) affecting drug absorption.
- 4. To list and describe drug interactions in the process of drug absorption.
- 5. To describe the first-pass effect.

### (3) Distribution

- 1. To list major plasma-binding proteins and identify drugs with high proteins-binding rates.
- 2. To describe the quantitative relationship between tissue distribution (distribution volume) and plasma/ tissue binding of drugs.
- 3. To describe the how to measure and analyze drug protein binding and binding inhibition.
- 4. To describe the structure and function of the blood–tissue barrier, and drug distribution into the brain or fetus.
- 5. To describe distribution of drugs into the lymphatic system and breast milk.
- 6. To list and describe drug interactions in the process of drug distribution.

## (4) Metabolism

- 1. To list major drug-metabolizing enzymes and to describe the sites of drug metabolism (tissue and subcellular organelles) and mode of reaction.
- 2. To give examples of and explain phase I reactions (oxidation, reduction, and hydrolysis) and phase II reactions (conjugation) in drug metabolism.
- 3. To list drugs metabolized by major drug-metabolizing enzymes.
- 4. To list and explain prodrugs and active metabolites.
- 5. To list and describe the mechanisms of inhibition and induction of drug-metabolizing enzymes, and related drug interactions.

# (5) Excretion

- 1. To describe the mechanisms of renal drug excretion.
- 2. To describe the quantitative relationships between renal clearance and glomerular filtration, tubular secretion, and tubular reabsorption.
- 3. To list major drugs excreted mainly by the kidneys.
- 4. To describe the biliary excretion and enterohepatic circulation of drugs.
- 5. To list and describe drug interactions in the process of drug excretion.

## (2) Pharmacokinetic Analysis

## GIO: To acquire the fundamental issues of pharmacokinetic analysis and drug dosage regimens.

# (1) Pharmacokinetics

- 1. To describe the concept of the linear compartment model and the associated pharmacokinetics parameters (total body clearance, distribution volume, elimination half-life, bioavailability, etc.).
- 2. To analyze pharmacokinetics based on a linear 1-compartment model (bolus injection, oral administration [single and repeated dosage], constant infusion).
- 3. To list drugs with nonlinear pharmacokinetics and analyze them based on a nonlinear model.
- 4. To describe the moment analysis and how to calculate the associated parameters.
- 5. To describe hepatic clearance, renal clearance, and intrinsic clearance and to describe their relationships using equations.
- 6. To describe pharmacokinetics-pharmacodynamics (PK-PD) analysis.

#### (2) Therapeutic Drug Monitoring and Dosage Regimens

- 1. To describe the significance of therapeutic drug monitoring (TDM) and to list the drugs requiring TDM.
- 2. To describe sampling timing, sample handling, and drug assays in for TDM.
- 3. To apply pharmacokinetic parameters to individual dosage regimens.
- 4. To describe the concept of population pharmacokinetics and its applications.

## **E5. Science for Drug Formulation**

GIO: To acquire the fundamentals of the physical properties of drugs and other formulation ingredients, formulation designs, and drug delivery systems to understand the significance and the features of drug formulations.

## (1) Properties of Formulations (Dosage Forms)

GIO: To acquire the fundamentals of the physical properties of drugs and other formulation ingredients.

# 1 Solid Ingredients

- 1. To describe the properties of powders.
- 2. To describe the properties of crystals (stable and meta-stable forms), amorphous forms, anhydrates, and hydrates.

- 3. To describe the dissolution phenomena of solid ingredients (including the solubility and the dissolution equilibrium) as well as the diffusion of dissolved materials and dissolution rates.
- 4. To describe the factors (including pH and temperature) affecting the dissolution of solid ingredients.
- 5. To list and explain typical pharmaceutical technologies that increase the solubility and dissolution rates of solid ingredients.

# 2 Semisolid and Liquid Ingredients

- 1. To describe flow and transformation (rheology).
- 2. To describe the structures of polymers and characteristics of polymer solutions (including viscosity).

# (3) Dispersion System

- 1. To describe the properties of interfaces (including interfacial tension, distribution equilibrium, and adsorption), and the typical surfactants and their properties.
- 2. To list and explain typical dispersion systems and their properties, including self-assembly, colloids, emulsions, and suspensions.
- 3. To explain stability and separation phenomena (including precipitation) of dispersed particles.
- 4. To explain typical pharmaceutical technologies that increasing dispersion stability.

# (4) Physical Properties of Drugs and Other Formulation Ingredients

- 1. To understand the structures of polymers which are commonly used in drug formulation and to describe the physical properties of the polymers.
- 2. To describe drug stability, including reaction rates and complex composite reactions as well as factors (including pH and temperature) affecting drug stability.
- 3. To describe typical pharmaceutical technologies improving drug stability.

### (2) Design of Formulations

# GIO: To learn the types, production processes, and qualities of formulations.

### (1) Typical Formulations

- 1. To describe the general information and significance of drug formulations.
- 2. To describe various formulations for oral applications and their features.
- 3. To describe various formulations for mucous-membrane applications (including ophthalmic formulations and agents) and their features.
- 4. To describe various formulations for injections and their features.
- 5. To describe various formulations for cutaneous applications and their features.
- To describe other drug formulations (including those for natural medicines and dialysis) and to describe their features.

## (2) Methods for Formulation and for Formulation Testing

- 1. To list typical pharmaceutical excipients and to describe their usages and properties.
- 2. To explain individual formulation processes, commonly used formulation devices, and formulation processes.
- 3. To explain commonly used containers and packaging and their features.
- 4. To list and explain formulation-related tests.

# (3) Bioequivalence

1. To describe bioequivalence as related to formulation features including drug application sites and the release of active ingredients.

## (3) Drug Delivery Systems

GIO: To Acquire basic knowledge of drug delivery systems (DDS) in related to the optimization of administration routes and pharmacokinetics.

# (1) Use of DDS

- 1. To describe the concept and usefulness of DDS.
- 2. To list and describe typical DDS technologies.

# (2) Controlled Release

- 1. To describe the concept and significance of controlled-release drugs.
- 2. To list and describe typical controlled-release technologies for each drug application site and their features.
- 3. To list typical drugs using controlled-release technologies.

# (3) Targeting

- 1. To describe the concept and significance of drug targeting.
- 2. To list the typical targeting technologies for each drug application site and to describe their features.
- 3. To list typical drugs using targeting technologies.

# **4** Absorption Enhancement

- 1. To describe the concept and significance of absorption enhancement.
- 2. To list and describe the typical absorption enhancement technologies for each drug application site and their features.
- 3. To list typical drugs using absorption enhancement technologies.

## F. Pharmacy Practice Experiences

- GIO: To acquire the essential skills necessary to be actively involved in pharmacotherapy, inter-professional collaborative work, and community healthcare by maintaining a patient-/consumer-centered perspectives.
  - \*F: The minimum medical conditions covered in this section include cancer, hypertension, diabetes mellitus, heart diseases, cerebrovascular diseases, neuropsychiatric diseases, immunologic and allergic diseases, and infectious diseases. Students should gain practical experience in healthcare facilities and community pharmacies on an ongoing basis through clinical training that provides actual contact with patients with these conditions.

\*Pre: Basic Requirements for Students Prior to Pharmacy Practice Experiences

# (1) Fundamentals of Pharmacy Practice

GIO: To understand the appropriate attitude and basic workflow in pharmacy practice settings to play a participatory role in a professional and appropriate manner.

# (1) Introductory Pharmacy Experience

\*Prerequisite Course Work Prior to Completion of the Second Year

- 1. To observe and discuss the role of the pharmacists and interact with them in various pharmacy practice settings to gain an understanding of the patient/consumer perspective.
- 2. To observe and discuss the role of the pharmacists and interact with them in community healthcare, medical care, and welfare settings, and to gain an understanding of important relevant issues in those settings.
- 3. To describe basic lifesaving procedures (cardiopulmonary resuscitation, trauma life support, etc.) and to perform them using simulators.

# (2) Laws and Ethics in Pharmacy Practice

- 1. \*Pre: To discuss the ethical principles and legal regulations for healthcare professionals.
- 2. \*Pre: To keep personal information confidential while ensuring respect for the right to patient/consumer self-determination.
- 3. \*Pre: To discuss the importance of the pharmacists' contributions to patient/consumer recovery, health maintenance, and quality of life.
- 4. To follow ethical principles and behave appropriately as a healthcare professional.
- 5.To maintain respect for the fundamental rights and self-determination of a patients/consumers.
- 6. To obtain informed consent prior to providing a drug therapy plans.
- 7. To comply with confidentiality obligations with respect to information obtained in the course of pharmacists' duties.

### (3) Basics of Pharmacy Practice

- 1. \*Pre: To describe the basic workflow in pharmacy practice settings.
- 2. \*Pre: To describe the importance of drug therapy plans in pharmacy practice settings.
- 3. \*Pre: To describe the structure, functions, and professional relationships within a hospital pharmacy practice setting.

- 4. \*Pre: To describe the job titles, roles, and responsibilities of various hospital personnel.
- 5. \*Pre: To describe the universal healthcare system (medical care, welfare, home visit care) involving pharmacists.
- 6. To describe the operation and management of hospital pharmacy systems and their coordinating functions with other departments.
- 7. To describe appropriate drug therapy managements for major diseases in inpatient settings.
- 8. To participate in treatment form admission to discharge.
- 9. To describe drug therapy managements in acute care (emergency medicine, intensive care, trauma care, etc.) and care before, during, and after surgery.
- 10. To describe appropriate drug therapy plans in perinatal care and pediatric care.
- 11. To describe appropriate drug therapy plans in terminal care and palliative care.
- 12. To describe appropriate drug therapy plans in outpatient chemotherapy.
- 13. To describe national health insurance system requirements pertaining to pharmacists.
- 14. To describe the workflow of the pharmacists in a community pharmacy setting.
- 15. To perform the processing and dispensing of prescriptions and to counsel patients on drug therapy under a preceptor's supervision.

## (2) Prescription Processing, Medication Preparation, and Dispensing

GIO: To acquire the essential basic skills in the provision and management of pharmaceutical products for safe, and appropriate prescription processing, medication preparation, and dispensing.

## (1) Compliance with Pharmacy Laws and Regulations

- 1. \*Pre: To adhere to pharmacy laws and regulations in prescription processing, medication preparation, and dispensing (prescriptions, dispensing records, inquiries, etc.).
- 2. To maintain complete and accurate legal documents (prescriptions, dispensing records, etc.).
- 3. To participate in the process of ensuring pharmacy compliance with legal and regulatory requirements.
- 4. To describe the regulatory requirements governing facilities, equipment, and supplies for community pharmacies.

### (2) Medication Order Review and Medication Therapy Management

- \*Pre: To identify indications and usage, dosages and routes of administration, warnings, contraindications, adverse reactions, and interactions of drugs used for the treatment of major common conditions and diseases.
- 2. \*Pre: To describe the prescription ordering system and electronic medical record system.
- 3. \*Pre: To describe the legal requirements for the format and contents of a prescriptions.
- 4. \*Pre: To describe the significance and precautions of medication verification by the pharmacists.
- 5. \*Pre: To verify prescriptions and identify potentially inappropriate prescribing.
- 6. \*Pre: To contact prescribers for clarification of prescriptions.

- 7. To demonstrate the ability to review and assess the appropriateness of prescriptions (for drug names, dosages, and directions for use, etc.).
- 8. To demonstrate the ability to review and assess the appropriateness of injection medication orders (for drug names, dosages, rates, and route of administration, etc.).
- 9. To give examples of appropriate prescription form requirements.
- 10. To determine whether prescriptions are appropriate for the patients' treatment by utilizing information from the medication history, medical records, and type of condition or disease.
- 11. To demonstrate the ability to communicate with prescribers utilizing information from patients' medication history, medical records, and type of condition or disease.

# (3) Medication Preparation and Dispensing

- 1. \*Pre: To label prescriptions correctly, meeting the requirements for content and format.
- 2. \*Pre: To identify trade and generic names, dosage forms, strengths, etc. of major medications.
- 3. \*Pre: To perform necessary pharmaceutical calculations accurately to fill or dispense prescriptions.
- 4. \*Pre: To describe strategies for generic drug substitutions.
- 5. \*Pre: To explain the mechanisms and the characteristic evidence for incompatibility of representative injectables, powders, liquid drug forms, etc.
- 6. \*Pre: To demonstrate basic aseptic techniques and describe processes and facilities needed to provide sterile compounded parenteral solutions.
- 7. \*Pre: To demonstrate appropriate and safe techniques for the handling of hazardous drugs such as chemotherapy products.
- 8. \*Pre: To demonstrate the procedures utilized in verification/checking of the selection, preparation, and/or organization of a drug products.
- 9. To participate in the selection/compounding of the appropriate medications, dosage forms, and amounts in order to fill prescription orders.
- 10. To perform appropriate selection processes in generic drug substitutions.
- 11. To accurately perform any necessary pharmaceutical calculations to fill or dispense prescriptions accurately.
- 12. To identify whether tablet crushing or capsule opening is appropriate and to participate in the preparations for dispensing.
- 13. To identify whether one-dose packaging is clinically necessary for patients and to participate in the preparations for dispensing.
- 14. To participate in the preparation of injectable medications.
- 15. To determine the methods for preventing incompatibility of injectable, powder, and liquid medications, etc.
- 16. To demonstrate aseptic techniques and describe processes and facilities needed to provide sterile compounded parenteral solutions including total parenteral nutrition, etc.
- 17. To demonstrate appropriate, safe techniques for handling hazardous drugs such as chemotherapy products.

- 18. To demonstrate appropriate techniques for the dispensing and handling of pharmaceutical products that requiring special attention (powerful, poisonous, psychotropic, or chemotherapy drugs, etc.).
- 19. To demonstrate the procedures utilized in verification/checking of the selection, preparation, and/or organization of an injectable drug products.

# (4) Professional Attitudes and Behaviors of Practice, Patient Education, and Counseling

- 1. \*Pre: To exhibit behaviors and values consistent with the trust placed in the profession by patients or consumers.
- 2. \*Pre: To identify the special needs of individual patients for serving or counseling, including pregnant or lactating women, children, the elderly, et al.
- 3. \*Pre: To collect important background information on patients or consumers (symptoms, psychological states, medical history, lifestyle habits, allergies, medication history, history of adverse reactions, etc.).
- 4. \*Pre: To counsel patients or consumers clearly on major medications including efficacy and effects, dosages and routes of administration, warnings, contraindications, adverse reactions, interactions, storage, etc.
- 5. \*Pre: To identify lifestyle modifications that should be made in order to help manage major disease
- 6. \*Pre: To demonstrate to the patients how to use various dosage forms (eye ointments, suppositories, inhalers, self-injectables, etc.).
- 7. \*Pre: To describe the significance and importance of a medication history and medical record contents.
- 8. \*Pre: To document medication education properly for patients with major conditions and disease.
- 9. To exhibit the behaviors and values consistent with the trust placed in the profession by patients or consumers.
- 10. To obtain important background information on patients or consumers (symptoms, psychological states, past medical history, lifestyle habits, allergies, medication history/reconciliation, history of adverse reactions, etc.).
- 11. To counsel patients on medications utilizing effective education techniques in accordance with the prescribers' objectives.
- 12. To counsel/educate patients/consumers on how to take medications safely and effectively based on their medical conditions and backgrounds.
- 13. To exhibit behaviors and values that are consistent with the trust placed in the profession by patients or consumers who have special needs for serving or counseling, including pregnant or lactating women, children, the elderly, et al.
- 14. To counsel patients on medications utilizing effective patient educational materials such as patients' medical record handbooks, health notebooks, and medication instruction leaflets.
- 15. To document appropriately patient information collected from medication history and/or medical records.

# (5) Pharmacy Procurement, Inventory Management, and Controlled Substance Management

- 1. \*Pre: To describe the significance and importance of pharmaceutical product management.
- 2. \*Pre: To describe the workflow of pharmaceutical product management.
- 3. \*Pre: To describe the conditions and procedures for the handling of powerful, poisonous, and psychotropic drugs, as well as the raw materials of stimulants, etc.
- 4. \*Pre: To describe the management and handling of specified bio-derived products.
- 5. \*Pre: To describe the classes and applications of representative radiopharmaceuticals and their appropriate storage conditions.
- 6. \*Pre: To describe the significance, preparation processes, and quality assurance for hospital pharmacy compounding products.
- 7. \*Pre: To describe briefly pharmacy compounding products and Kampo medicines.
- 8. \*Pre: To describe the factors affecting the quality of pharmaceutical products and their storage conditions.
- 9. To supply, storage, and dispose of pharmaceutical products appropriately.
- 10. To perform appropriate inventory management of pharmaceutical products.
- 11. To describe the workflow processes of the inventory management of pharmaceutical products.
- 12. To manage and handle powerful, poisonous, and psychotropic drugs appropriately as well as the raw materials of stimulants.
- 13. To manage and handle specified bio-derived products appropriately.

# (6) Medication Safety and Quality Improvement

- 1. \*Pre: To identify the most common types of medication errors in prescribing, dispensing, storing, preparing, and administering medications.
- 2. \*Pre: To identify the characteristics of medication errors associated with high-risk medications (chemotherapy products, medications for diabetes mellitus, controlled substances, etc.) and measures to reduce those errors.
- 3. \*Pre: To understand and discuss representative medication error incidents including near-misses and accident reports to identify the characteristics, concrete measures, coping strategies, and opportunities to enhance patient safety.
- 4. \*Pre: To describe the fundamental principles of infection prevention and control.
- 5. \*Pre: To demonstrate aseptic techniques for sterile hand washing and standard infection control precautions.
- 6. \*Pre: To describe the preparation, applications, and optimal concentrations of representative disinfectants.
- 7. \*Pre: To describe briefly the risk management strategies for medication usage.
- 8. To participate in the procedures for monitoring the safety of high-risk medications (chemotherapy products, medications for diabetes mellitus, controlled substances, etc.).
- 9. To describe various policies, procedures, and protocols in place for the prevention of dispensing errors.

- 10. To create concrete proposals and coping strategies to enhance patient safety based on past medication error incidents including near-misses and accident reports.
- 11. To review and comply with the safety guidelines for the clinical sites.
- 12. To demonstrate aseptic techniques for sterile hand washing and standard infection control standard precautions.
- 13. To handle clinical specimens and infectious waste appropriately.
- 14. To create concrete proposals for infection control (infection and transmission prevention, etc.) for hospital sites.

# (3) Practical Application of Pharmacotherapy

GIO: In order to provide safe and optimized pharmacotherapy to patients, to acquire skills in collecting patient information, assessing patients' conditions, and developing drug therapy plans.

# (1) Collection of Patient Information

- 1. \*Pre: To describe basic medical terminology and abbreviations.
- 2. \*Pre: To obtain appropriate patient information from various information resources such as medical records, medication histories, pharmacists' notes, nursing records, patients' medical record handbooks, and patients' own medications.
- 3. \*Pre: To describe the purposes of a physical assessments and the applications of the physical findings to a drug therapy plans.
- 4. \*Pre: To perform basic physical assessments and evaluate the physical findings.
- 5. To use basic medical terminology and abbreviations.
- 6. To obtain information from patients, pharmacy consumers, and various information resources such as medical records, medication histories, pharmacists' notes, nursing records, patients' medical record handbooks, and patients' own medications.
- 7. To incorporate physical findings in pharmaceutical care plans.

### (2) Management of Drug Information

- 1. \*Pre: To obtain, categorize, and synthesize drug information for pharmacotherapy.
- 2. To understand and utilize the medical information resources of a facilities.
- 3. To document drug information (DI) requests for pharmacotherapy and the evidence-based resources used for the responses.
- 4. To understand the drug information needs of healthcare professionals and patients and to provide them.
- 5. To evaluate and synthesize drug information to provide safe and effective pharmacotherapy.
- 6. To manage emergency information such as Dear Healthcare Professional Letters of Emergent Safety Communications (Yellow Letter), Dear Healthcare Professional Letters of Rapid Safety Communications (Blue Letter), drug products for recall and discontinued products in healthcare facilities.

# (3) Application of Pharmaceutical Care Plans and Pharmacotherapy (Pharmaceutical Care Plans and Recommendations)

- 1. \*Pre: To develop drug therapy plans for different stages of major conditions and diseases based on clinical evidence.
- 2. \*Pre: To select appropriate medications and explain their usage and administration in terms of effects on organ (kidney, liver, etc.) function and physiological specificity such as for pregnant or lactating women, children, and the elderly.
- 3. \*Pre: To describe methods for evaluating medication adherence, common reasons for non-adherence, and management methods.
- 4. \*Pre: To describe the basic injection techniques for various routes of administration such as subcutaneous, intramuscular, intravenous injections, continuous infusion, etc.
- 5. \*Pre: To describe typical infusion solutions and their usage.
- 6. \*Pre: To evaluate patients' nutrition and fluid intake status and excess/deficiency of electrolytes.
- 7. To determine pharmacotherapy strategies in major diseases by assessing diagnosis, clinical state, and scientific evidence.
- 8. To propose a drug therapy plans based on evidenced-based information such as treatment guidelines.
- 9. To provide an appropriate drug therapy plans by evaluating patient status (disease states and severity, comorbidities, liver and kidney function, general condition, individual genetic differences, etc.), patients' psychological status and preferences, and characteristics of medications (mechanisms of action, pharmaceutical characteristics, etc.).
- 10. To incorporate drug administration protocols and clinical pathways when developing a drug therapy plans.
- 11. To evaluate patients' home medications and provide appropriate recommendations such as which medications should be continued, discontinued, or switched to alternatives.
- 12. To recommend changes in prescribed regimens, usage, or administration methods to improve medication adherence.
- 13. To select appropriate generic medications for reasons including efficacy, safety, and cost-effectiveness, when developing a pharmaceutical care plans or drug therapy plans.
- 14. To communicate the elements of a pharmaceutical care plans or drug therapy plans (reasons for selection, usage, administration, duration, etc.) to other healthcare professionals.

# **(4)** Application of Pharmaceutical Care Plans and Pharmacotherapy (Evaluation of Effectiveness and Safety)

- 1. \*Pre: To describe monitoring parameters such as clinical symptoms and laboratory findings to evaluate the effects and adverse effects of medicines used for treating major diseases.
- Pre: To obtain necessary patient information to evaluate pharmacotherapy for the treatment of major diseases.
- 3. \*Pre: To identify and evaluate drug-related problems of in major diseases, to develop drug therapy plans, and to document pharmacist interventions in simple object access protocol (SOAP) notes, etc.

- 4. To understand laboratory parameters to monitor the effects and adverse effects of medicines, and to recommend the ordering of relevant laboratory tests.
- 5. To recommend ordering therapeutic drug monitoring (TDM) for patients prescribed medications requiring it.
- 6. To predict the effects and adverse effects of medicines by analyzing the results of TDM.
- 7. To describe drug-related abnormal values of the laboratory data values.
- 8. To evaluate the effects of pharmacotherapy by assessing patients' clinical symptoms and laboratory findings.
- 9. To evaluate the adverse effects of pharmacotherapy by assessing patients' clinical symptoms and laboratory findings.
- 10. To advise physicians on adjusting drug therapy plans (type of medications, dose and route of administration, duration of therapy, etc.), based on drug effects and adverse reactions to current therapy, and results of TDM.
- 11. To document accurately patient information using the "who, what, where, when, why, and how" (5W1H) approach.
- 12. To identify and evaluate drug-related problems, to develop pharmaceutical care plans, and to document pharmacist interventions in simple object access protocol (SOAP) notes, etc.
- 13. To document the necessary information on adverse incident report forms for the Pharmaceuticals and Medical Devices Agency (Japan).

## (4) Participation on Interprofessional Collaborative Work

GIO: In order to participate in interprofessional collaborative work at healthcare facilities or in the community, to understand the role and meaning of interprofessional collaborative work, and to share obtained information with other healthcare professionals to provide better medical treatment.

# 1 Interprofessional Collaborative Work in a Healthcare Facilities

- 1. \*Pre: To describe the role of pharmacists in interprofessional collaborative work.
- 2. \*Pre: To describe the purpose of interprofessional collaborative work and the role of each team member.
- 3. \*Pre: To describe the importance of collaborative interactions between hospitals and the community, and to describe examples such as: collaborative clinical pathways, discharge counseling, collaborations among hospitals, community pharmacies, and other healthcare facilities, etc.
- 4. To collaborate with pharmacists and other healthcare professionals to solve drug-related problems.
- 5. To share information relevant to patients' conditions (e.g., disease state, laboratory findings, allergy history, life environment) and changes in them (e.g., outcomes, adverse reactions, psychological states, and quality of life) after initiation of therapy with other healthcare professionals.

- 6. As a member of interprofessional collaborative work, to discuss patients' therapy goals and courses of treatment with other healthcare professionals during an interprofessional team conferences or team rounds.
- 7. To develop optimal drug therapy plans for patients by collaborating with other healthcare professionals.
- 8. To evaluate discharge care plans by collaborating with other healthcare professionals.
- 9. To participate in various interprofessional collaborations such as infection control teams, nutrition support teams, pain control teams, or pressure ulcer care teams in healthcare facilities.

# (2) Collaborative Practice in the Community

- 1. \*Pre: To describe the types of professions relevant to community healthcare, medical care, and welfare and to describe the meaning of collaborative practice in the community.
- \*Pre: To understand and discuss the importance of collaborative practice between healthcare facilities and community pharmacists.
- 3. To experience collaborative practice between healthcare facilities and community pharmacists.
- 4. To share information on community residents with healthcare professionals in the community healthcare setting.

# (5) Participation in Community Healthcare, Medical Care, and Welfare

GIO: In order to contribute to community healthcare, medical care, and welfare, to understand the systems and meanings of home visit care, community healthcare, welfare, primary care, and self-medication, and to be involved in recovering/maintaining/improving the health of the community residents by participating through those activities.

### (1) Pharmacist Involvement in Home Visit Care

- 1. \*Pre: To describe the purpose, system, and support of home visit care.
- 2. \*Pre: To describe the characteristics and backgrounds of the patients who receive home visit care.
- 3. \*Pre: To describe the role of the pharmacists in home visit care.
- 4. To perform drug therapy management in home visit care.
- 5. To perform home visit care service in the community, and to collaborate with care managers.
- 6. To collect relevant home visit care patient information on their conditions (disease, clinical symptoms, disease state, severity, nutrition status, etc.), progress, and living environment and to write reports.

### (2) Advancing Pharmacy Health Literacy in the Community

- 1. \*Pre: To describe the role of pharmacists in community health care and major activities such as prevention of drug abuse and suicide, infection control, and antidoping activities.
- 2. \*Pre: To describe infection control methods in terms of public health.
- 3. To understand and undertake the tasks of school pharmacists.
- 4. To undertake pharmacists' activities in community health management such as antisepsis, food poisoning prevention, and prevention of accidental ingestion of chemical substances in household items.

# (3) Role of Pharmacists in Primary Care and Self-Medication

- 1. \*Pre: To understand and discuss the importance of primary care and self-medication in the current health care system.
- 2. \*Pre: For patients with typical clinical symptoms such as headaches, abdominal pain, and fever, to evaluate patients from obtained information and to provide appropriate relief.
- 3. \*Pre: To describe common pharmacy compounding products including Kampo medicines, medications requiring a pharmacists' counseling and over-the-counter drugs and to handle those products appropriately.
- 4. \*Pre: To advise patients on typical lifestyle modifications.
- 5. To manage pharmacy compounding products including Kampo medicines, medications requiring a pharmacists' counseling, and over-the-counter drugs depending on the risks.
- 6. To assess the consumers' clinical conditions (disease, severity of the illness, etc.) and physical conditions based on consumer information and physical findings.
- 7. Depending on the clinical symptoms, to provide appropriate advice to consumer such as referrals to physicians; offer first aid; recommend medications requiring pharmacists' counseling, over-the-counter drugs, or test products; and suggest lifestyle modifications.
- 8. To advice consumers clearly on how to use pharmacy compounding products including Kampo medicines, medications requiring a pharmacists' counseling, over-the-counter drugs, health foods, dietary supplements, and medical devices.
- 9. To perform to advise patients on disease prevention and health management.

## (4) Role of Pharmacists in Disaster Medicine

- 1. \*Pre: To describe the fundamentals of disaster medicine.
- To describe disaster management plans including systems for managing medical supplies and medical aid in the community.
- 3. To understand and discuss the role of hospitals, community pharmacies, and pharmacists during disasters.

### G. Research

GIO: To acquire the ability to undertake research and identify and solve problems to contribute to advances and improvements in the pharmaceutical and healthcare sciences.

## (1) Research in Pharmaceutical Sciences

- GIO: To understand the roles of research in the pharmaceutical sciences and to develop a research-oriented mind-set and contribute to healthcare throughout the career as a pharmacist.
  - 1. To describe the objectives and roles of research ranging from basic to clinical.
  - 2. To recognize that research requires autonomy and originality.
  - 3. To observe phenomena objectively and think logically.
  - 4. To develop a creative mindset to tackle new challenges.

# (2) Legal Regulations and Ethical Principles Governing Research

- GIO: To understand the legal regulations and guidelines governing research and to follow them at all times.
  - 1. To describe the legal regulations and guidelines affecting one's own research.
  - 2. To describe the regulatory and ethical considerations in conducting research and handling patient information.
  - 3. To conduct research with respect for its justice, social significance, and integrity, while adhering to legal regulations.

## (3) Conducting Research

# GIO: To develop the ability to use knowledge and skills comprehensively and to solve problems through research processes.

- 1. To search for, interpret, and evaluate domestic and international research findings related to one's own research projects.
- 2. To identify problems to be solved for the completion of projects and to develop research programs.
- 3. To actively conduct research, according to research plans.
- 4. To record each process and step in research appropriately and to discuss the results.
- 5. To make effective presentations of research findings and answer questions about them appropriately.
- 6. To compile research findings into reports and papers.

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\* Preface

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