S56-6 New drug evaluation and blood products

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New drug that's to be actually used in clinical practice requires evaluations by the developers (for verification of the efficacy and safety by conducting the quality test, nonclinical and clinical studies) and by regulatory authority (for approval review). These evaluations are conducted by the pharmaceutical Regulatory Science-based decisions. The clinical assessment of new drug is based upon findings of clinical trials; however, it is necessary to predict the efficacy and safety of new drug when that is used in many patients in the post-marketing stage because the number of cases is limited in the stage of clinical trials. Regulatory science differs significantly in this light from general experimental science.

With regard to the evaluation for blood products, basically, it is not greatly different from other chemical drugs though, with the quality evaluation, there are details that are different in some items, and they are evaluated as so-called Biologics. Previously, blood products have been prepared from human blood. These days, they have become to be produced by genetic engineering (recombinant product). It is very important for blood products derived from human blood to asses the viral contamination (icl. the presence of unrecognized viruses), whereas it is essential for recombinant blood products to assess impurities that are derived from the manufacturing process and in producing cells.