S36-1 Consideration points for manufacturing process research of drug substance

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After discovery of a new compound having medicinal properties in research of pharmaceutical agents, the manufacturing process research (Process Chemistry) of the developing compound (drug substance) is started toward to non-clinical studies, clinical studies, and then commercial production. In development of pharmaceutical agents, it is important to manufacture rapidly the developing compound (drug substance) from laboratory-scale to large-scale. It is also important for us to understand substantially the regulation for its application and to develop steadily under the manufacturing process control. These observations lead up to the success of short-term application/approval. Therefore, we have to develop the new practical synthesis method, which is fitting more in large-scale than in laboratory-scale, with its quality assurance in consideration for the production efficiency, patentability, and safety.

In this symposium, first we will present some differences between laboratory-scale synthesis (Medicinal Chemistry) and large-scale production (Process Chemistry) and then some consideration points to scale up production from laboratory- to large-scale. Finally we will take up and introduce Pazufloxacin mesilate （PZFX・CH_3SO_3H）, which has been developed as an antibacterial injectable quinolone by us, as an example of the scale up production.