## Industry perspective on ICH Q6 revision and expectations for setting specifications based on enhanced approach

Since the establishment of ICH Q6B in 1999, the biopharmaceutical industry has experienced significant advancements in manufacturing and analytical technologies. Especially, the rise of monoclonal antibody drugs has been remarkable. Since monoclonal antibodies have common molecular structures and characteristics, manufacturers can streamline production, ultimately accelerating the development and availability of high-quality therapeutic antibodies. Analytical advancements, such as mass spectrometry, also allow for detailed analysis of quality attributes, leading to better product and process understanding and control of the manufacturing process, ensuring high-quality products.

In addition to technology advances in the biological field, new modalities such as antibody-drug conjugates, and cell and gene therapies, are emerging. To implement these advancements and reflect science- and risk-based approaches introduced from ICH Q8-11 guidelines, the revision of the ICH Q6A and Q6B guidelines has been adopted as a topic, and discussions have begun by the expert working group.
This presentation will delve into these technological developments, perspective on ICH Q6 revision, and discuss the expectations for setting specifications based on enhanced approach.