BioTherapeutic Case Studies
George Klein & Andrew Lennard, Amgen

Background/Challenges: Ideally, ICH guidelines would define expectations for development of globally harmonized specifications for pharmaceutical products. However, the goal of a globally harmonized specification has not been realized for most biotechnology products due to conflicting criteria in existing guidance and regulatory practice that are considered in establishing acceptance limits.

Approach Being Taken: This presentation will provide case studies where inconsistency between major regulatory regions in the acceptance of patient centric specifications has resulted in regional specification variants, and the impact having regional differences has had, including shorter shelf-life and rejection of batches that met quality expectations in other regions. While still a challenging area, there have been successes in developing a globally harmonized specification and the session will also provide examples of such successes and how they were achieved.

Conclusions: Revision to ICH Q6A/B to account for QbD development approaches would provide a harmonized framework for establishment of science and risk-based specifications.