Track 10 | Regulatory CMC and Product Quality

The Regulatory CMC and Product Quality Track provides a comprehensive view of risk-based approaches across the product lifecycle. The track scope spans from the scientific understanding gained through product and process development to lifecycle expectations for global regulatory CMC submissions, CGMP (Current Good Manufacturing Practice), and Quality Systems. Sessions address the increasing regulatory complexity of development and manufacturing for worldwide markets, accelerated development timelines, new technologies, emerging regulations, and increased scrutiny of manufacturing operations and data.

This track is recommended for regulatory affairs, manufacturing, quality assurance, and quality control professionals involved in drug development and/or manufacturing for small molecule drugs, biologics, and vaccines.

Included Topic Areas

CMC expectations for dossiers, quality management system expectations, new technologies, patient-centered quality risk management of products, and ICH quality related guidelines (Q & M topics). Topics related to bioethical issues are also welcome and may be considered for a special track in the meeting.

Priority Topics

1. **International Convergence for Product Quality: ICMRA, PIC/S and IPRP**
2. **Trends in Product Quality: Nitrosamines and Titanium Dioxide**
3. **Patient-Centric Quality Standards: Specification Setting Based on Patient Needs**
4. **One Global Dossier for Regulatory CMC**
5. **Drug Shortage Avoidance Strategies: Innovation, Incentives and New Requirements**
6. **Building Trust Between Regulators: Reliance and Recognition for Product Quality**
7. **Regulatory CMC Challenges with Cell and Gene Therapy Products**