11th ARC – Draft Conference Program
28 July 2022

Day 1 – Regulatory Agilities

Regulatory agilities and further accelerating patient access to safe and effective medicines and vaccines
Objective(s): review ongoing activities around use and implementation of regulatory agilities including the potential impact on patients.
Proposed Agenda/Topics:
• Special Session: Achieving ML4 Status & Embedding Use of Reliance
• Welcome & Introduction to the 11th ARC
• Regulatory Agilities & PQ KMS: What does it mean for Asia?
• Fireside Chat: Why are innovative and agile regulatory systems important for patients?
• Regulatory Agilities Project & Recommendations
• Perspectives on/Use of Regulatory Agilities in Asia
• Panel Session and Audience Q&A
• Closing & Wrap up of Day 1

Day 2 – Post Approval Changes

Reliance, Convergence/Harmonization and Risk Based Approaches to PACS
Objective(s): **Part I:** Convergence/Harmonization Presenting the perspectives of regulators, industry and regional experts, this session will explore how convergence/harmonization can support PACs **Part II:** Reliance is an important mechanism that supports regulatory acceleration and capacity building of regulatory systems. This session will explore how progress can be made in implementing reliance process to PACS. **Part III:** Risk based approach, ICH Q9,10 and 12 set out principles of risk-based approaches, understanding how these principles are being implemented and applied more broadly.
Proposed Agenda/Topics:

• Harmonization and convergence of PACS
• Trust building to realize objectives of the ICMRA collaborative assessment pilot
• Lessons learned in context of COVID-19
• Good reliance practice and the link with post approval changes (PAC)
• Illustration of a reliance pilot of a PAC
• PAC training e-Course
• Sharing experience of an existing mechanism of reliance / collaborative work
• What are PIC/S' recommendations to demonstrate what an effective PQS is for PACs
• How to enable a smooth implementation of PACs without running any risk to Quality, Safety and Efficacy
• How ICH has developed risk-based approaches for expediting the implementation of PACs
• Panel Discussion

Day 3 - Quality

Delivering products with the same quality standards to patients everywhere
Objective(s): **PART I:** Explain how companies create and maintain complex global supply chains, which ensure global quality standards and efficient product delivery • Highlight the importance of reliance and work-sharing through initiatives like PIC/S, and the added value of digital tools (e.g., virtual inspection) in global efforts towards more efficient regulatory frameworks • Debunk myths related to product sameness • Outline challenges with in-country testing and explain why it is redundant **PART II:** Advocate for an aligned approach to risk management based on experiences to date with substances of concern
Proposed Agenda/Topics:
• Supply chain complexity

• Reliance on GMPs
• Virtual inspections
• Product sameness
• In-country testing
• Q&A
• Impurities
• Q&A

Day 4 - ICH

ICH – The Foundations of Success
Objective(s): **PART I:** Set the scene and focus on developing outputs for sharing with the ICH Management Committee, including efficiency of the organization, ways of working and training. Followed/enriched by polls to screen audience's opinion on/experience with topics discussed. **PART II:** Delve deeper into clinical topics E6, E8 and E17 as a good example of ICH-piloted harmonization in Asian countries.
Proposed Agenda/Topics:
• Keynote - Setting the scene focused on training
• The road to ICH membership
• The role of industry in working with NRA to implement ICH/Experience of experts
• Panel discussion and transition to Q&A
• Harvard MRCT video – clinical (E6/E8/E17) training
• E17 case studies – industry perspective
• How do clinical guidelines link together & what are the challenges (lens on E6/E8/(E9)/E17)

• Panel discussion

Day 5 – Biotherapeutics & Advanced Therapies

Changing regulatory landscape of Biotherapeutics and Cell & Gene Therapies
Objective(s): **PART I:** Biotherapeutics Landscape • Overview of biotherapeutic regulatory landscape including the revision of WHO GLs for Biosimilars and mAbs and their implementation. • Panel Discussion: Changing landscape of biosimilar regulations including traceability and interchangeability. **PART II:** Cell & Gene Therapy Regulatory Convergence & Reliance • Discussion on the WHO GLs for ATMP regulatory convergence and their implementation • Panel Discussion: Promoting reliance approaches across the lifecycle of ATMPs (incl key topics such as classification, GMOs)
Proposed Agenda/Topics:
• Keynote: WHO Guideline Updates & Future Plans
• Overview of Biosimilar regulatory landscape (Interchangeability, Noncomparable biologics)
• Panel discussion on relianceand advanced therapies