CASSS CONFERENCE
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Unblocking Regulatory Barriers to CMC & Quality Innovation for Biotechnology Products - Escaping Inertia, Embracing Change

Enabling Global Pharmaceutical Innovation

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ABSTRACT

The pharmaceutical industry faces significant barriers to innovation, driven primarily by global regulatory divergence and high costs associated with development of novel technical approaches. Enhanced product quality and improved patient access to medicines and vaccines can, and should be, drivers to encourage innovations, establish expeditious and harmonized review processes and ostensibly cultivate alignment among regulatory authorities. While ICH has provided alignment on "what" harmonized standards are, limited progress demonstrating "how" global harmonization improves regulatory alignment has severely curtailed investments in technical innovations.

Recent collaborative efforts to advance opportunities for reliance have underscored that it is not simply the "what", but the "how" that ultimately reduces barriers to innovation. The adoption of reliance pathways and workshare initiatives directly enable global acceptability of innovative technologies by encouraging regulatory authorities to leverage authoritative assessments from one another. The pervasive pace and obduracy of digital technologies will inevitably reinforce the need for mutual reliance. The emergence of regulatory leadership to coordinate effective collaboration between regulatory authorities will also serve as an enduring framework to eliminate barriers to implementation of innovations globally and may meaningfully reduce the time to achieve global approvals for innovative technologies.

CONTENT

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  - Barriers to Innovation
  - ICH: Harmonization of the “What, not the “How”
- OPPORTUNITIES
  - ICMRA & PIC/S
  - ANVISA
- DRIVER FOR CHANGE
  - Digital Transformation

ISPE HARMONIZATION INITIATIVE: BARRIERS TO INNOVATION SURVEY RESULTS

PURPOSE

To catalyze consistent & harmonized interpretation & implementation of ICH guidelines to improve global patient access to innovative medicines & technology.

APPROACH

Identify sources of regulatory & industry challenges that are barriers or create limitations in applicability across multiple therapeutic modalities

RESULTS

- RoI is a critical factor in decisions to develop & implement innovative technologies.
- Global regulatory divergence is a key concern, w/associated cost, in evaluating innovations
- Case studies confirm & amplify results from published ISPE reports, that regulatory reliance & alignment among regulatory authorities would effectively offset investment risk.*

**A Report on the Barriers to Innovation Survey at* https://ispe.org/sites/default/files/regulatory/2024/Report%20EnabPrmaInnov.pdf

ISPE HARMONIZATION INITIATIVE: ACTIONS TO ADDRESS BARRIERS TO INNOVATION

- Identify long term incentives for developing, adopting & implementing innovative technologies
- Introduce opportunities for collaborations between regulatory authorities
  - Align w/**ICMRA**: "*One set of queries & one agreed/ harmonized outcome*."
  - Improve engagement with ETT/CATT & QIG, etc.
- Establish innovation as a fundamental opportunity in partnerships among pharmaceutical manufacturers & CDMO/CROs

ICH: HARMONIZATION OF THE "WHAT, NOT THE "HOW"

ICH Guidelines are intended to:

- Describe convergence of regulatory requirements, guidelines & expectations
- Provide regulatory clarity
- Reduce proliferation of multiple competing regulatory standards
- Adopt holistic regulatory alignment across guidelines
- Serve as definitive & complete standards

THE WHAT

ASPIRATIONS FOR INNOVATIONS IN PHARMACEUTICAL MANUFACTURING

Pharmaceutical Industry

- Improve productivity & reduce costs
- Reduce quality issues
- Improve quality assurance
- Global regulatory convergence, i.e., Mutual Reliance/ Recognition
- Increase flexibility to accelerate
- Improve regulatory collaboration & reduce punitive oversight
- Introduce incentives to innovate old & Gx products
- Automate

Regulatory Authorities

- Resolve quality issues
- Improve quality assurance
- Establish quality mfg. maturity
- Focus on product reliability & sustainability
- Create agile & flexible mfg.
- Provide regional adaptable technology
- Integrate mfg. redundancy
- Leverage ICH

Patients

- Provide consistent product quality
- Reduce costs
- Improve quality assurance
- Increase access to medicines
- Improve convenience for administration compliance

CURRENT MECHANISMS

- Successful Models for joint scientific advice
  - FDA ETT & AMTD
  - EMA QIG
  - ACCESS Consortium (Australia, Canada, Singapore, Switzerland, UK)
  - Work sharing (Asia, Middle East, Africa)
- PIC/s

THE HOW

OPPORTUNITIES

- Expand mutual reliance/recognition
  - Acknowledged alignment or deference to application assessment from another regulatory authority
  - Shared or joint review of applications serve as the basis of approval by all
    - ✓Global database
    - ✓Regional governance
    - ✓Leverage International Pharmaceutical Regulatory Programme (IPRP)
- Establish an independent organization to evaluate innovative technologies for regulatory approval

THE HOW

OPPORTUNITIES: REGIONAL REGULATORY LEADERSHIP – ANVISA

- Willingness to serve as a regional leader in Latin America
- Continue establishing alignment w/other global regulatory authorities outside of LatAm
- Predicates:
  - ICH Training
  - Capacity to develop work sharing in LatAm

CHALLENGES

- Conflicting frame of reference & risk tolerance
- Innovative technology is unprecedented
  - Limited empirical experience
  - Need for training & socialization
- Local statutory framework may not be amenable
  - Reduced flexibility in guidelines
  - Implementation delays

DIGITAL TRANSFORMATION

- Digital data management
  - Knowledge management & data standardization
  - Access to information ⇨ Shared regulatory content
- Applications of Artificial Intelligence
  - Candidate Selection
  - Adaptive Controls
  - Author regulatory documents
  - Review regulatory applications

ASPIRATION: WHAT SUCCESS LOOKS LIKE

- Simultaneous global development & harmonized regulatory submissions
- Improve post-approval change implementation
  - Increase investment in continual improvement ⇨ Improve quality assurance
  - Harmonize global approval times ⇨ Reduce review time ⇨ Improve ROI
  - Reduce drug shortages
  - Increase patient access to medicines
- Reduce supply chain complexity ⇨ Improve global compliance
- Increase capacity at regulatory authorities
- Reduce costs for industry & BOHs

THANK YOU!