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Bridging Innovation and Access: Advancing Regulatory Capacity and AI-Driven Drug Development

aligning innovation with regulatory readiness

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Regulatory Challenge

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Accelerating pace of biopharmaceutical innovation

Increasing product complexity (e.g., cell/gene therapies, complex biologics)

Global regulatory systems under pressure to adapt quickly

Why Regulatory Capacity Matters

Regulatory confidence as a driver of access and equity

Gaps in resources, expertise, and infrastructure

The cost of delays and uncertainty in drug approval

PATIENTS

Regulatory Harmonization

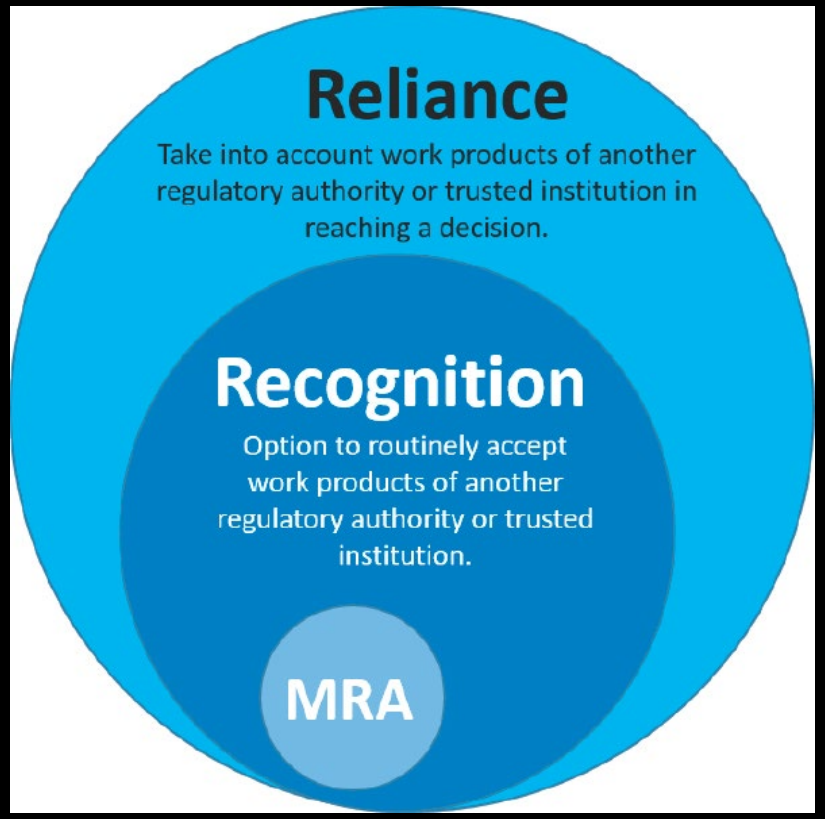
- the process by which technical guidelines are developed to be uniform across participating authorities.

Regulatory Convergence

- a process whereby the regulatory requirements across countries or regions become more similar or “aligned” over time as a result of the gradual adoption of **internationally recognized technical guidance documents**, standards and scientific principles, common or similar practices and procedures, or adoption of regulatory mechanisms that might be specific to a local legal context but that align with shared principles to achieve a common public health goal.
- It does not necessarily represent the harmonization of laws and regulations, which is not a prerequisite for allowing the alignment of technical requirements and greater regulatory cooperation.

Regulatory Reliance

The act whereby the national regulatory authority (NRA) in one jurisdiction may take into account and give significant weight to assessments performed by another national regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision.



Our Approach

- Dual Strategy:
  - Strengthening regulatory capacity (training and applied research)
  - Leveraging AI for drug development and regulatory science
- Academic institutions as trusted global partners

Core Values—Ubiquitous to our Regulatory System Strengthening

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- ***Experiential Learning***
  - Multiple pathways to get valuable experience
- ***Flexible offerings***
  - Multiple locations, multiple delivery formats, many courses and workshops to choose from
  - Online, on-ground, and hybrid courses are offered
- ***Industry-based faculty***
  - Understand the current demands in the field, and make sure you are prepared

Building Regulatory Capacity

- Train regulators on best practices and international guidelines based on approved curricula to promote regulatory convergence.
- A collaborative network to ensure long-term regulatory system strengthening.
- On-site, hybrid, and virtual training models
- Use-inspired research projects supporting regulators
- ***Sample topics:*** Drug Stability, Quality by Design, Good Regulatory Practices, Analytical Characterization and many more…

Global Partnerships

- APEC Regulatory Harmonization Steering Committee (RHSC)
  - Center of Regulatory Excellences in:
    - Biologics
    - Advanced Therapies
- World Health Organization (WHO)
  - Coalition of Interested Parties (Member)
- International Council for Harmonisation (ICH)
  - Training Associate (Quality)
- America Rise for Health
- Geographic reach: Africa, Latin America, Asia

Case Study: America Rise for Health

To promote regulatory convergence, reliance, and Good Regulatory Practices throughout the Western Hemisphere

Good Regulatory Practices

Adoption of 9th Summit of the Americas on Good Regulatory Practices as they related to medical products (e.g. public consultations, reasonable notice of planned regulatory actions)

Regulatory Convergence & Reliance

Adoption of harmonized international Guidance and standards, and internationally recognized scientific principles, practices, and procedures

- *Promote regulatory convergence through implementation of internationally recognized standards and guidance*
- *Promote the implementation of CTD/eCTD (Pharma) & IMDRF nIVD MA ToC/IVD MA ToC (Medical Devices)*
- *Promote the digitalization of regulatory practices*
- *Promote regulatory agility learned from COVID-19*
- *Promote simplified and accelerated pathways for approval and surveillance*
- *Analyze reliance practices*

RISE Regulatory Training

Proposal

Concept	**Host a hybrid 2 -day training for regulators** • Train regulators on curriculum developed through RISE process • Require a commitment from applicant regulators to implement their learnings • Offer 1:1 consultations for participating regulators to: 1) assess NRAs' status of regulatory reliance and 2) develop plan for implementation • Provide a follow up call in 4-6 week with regulators on progress/status of implementation plan
Draft Agenda	**Day 1** 9:00 - 3:00 | Training **Day 2** 9:00 – 12:00 | Training 12:00 – 5:00 | 1:1 Consultations based on RISE KPIs
Audience	**All regulatory authorities will be invited to hybrid training** • In Person: Regulators from host country + other NRAs if self funded • Virtual: Regulators from other NRAs
Location	• Mexico City, Brasilia, Argentina • Host at NRA's office
Timing	• Late Q4 2025

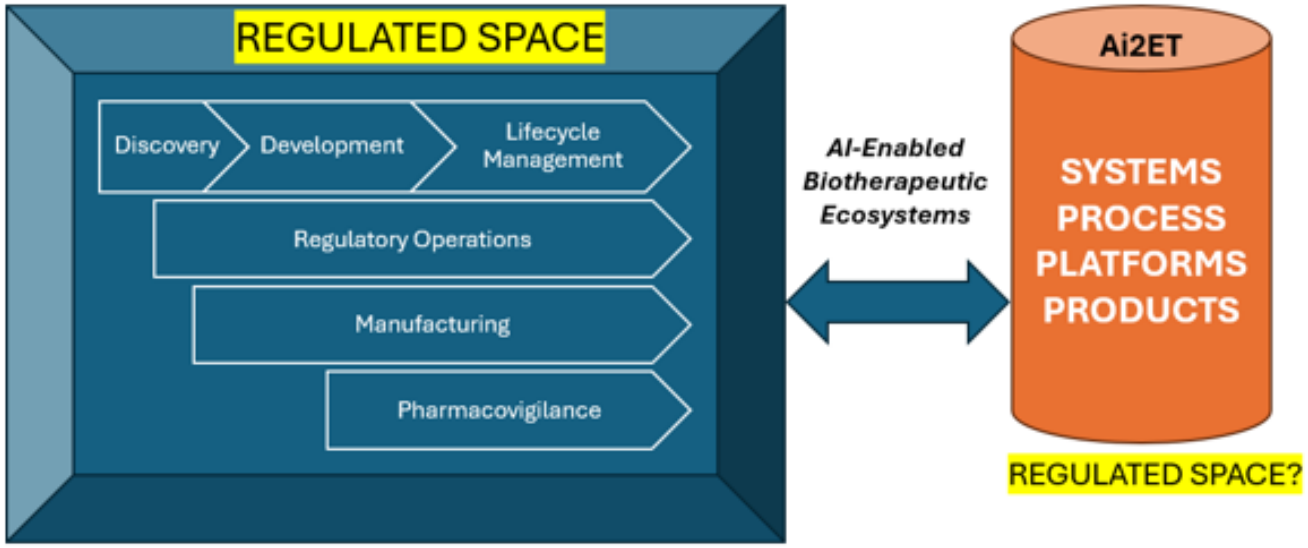
Emerging Needs

- Continued regulatory capacity building is needed due to emerging needs such as,
  - Advanced methodologies (multi-attribute method, MAM)
  - Lifecycle data integration and digital quality systems
  - Risk-based regulatory approaches
  - Artificial Intelligence (AI)

AI in Drug Development

- Turning complex datasets into actionable insights
- Role in analytical characterization and CMC
- Complementing-not replacing-human expertise
- Efficiency gains for development timelines

Figure 1. How *AI-enabled biotherapeutic ecosystem* AI2ET is related to the various stages of creating human medicines--Discovery to Lifecycle Management (and vice versa)

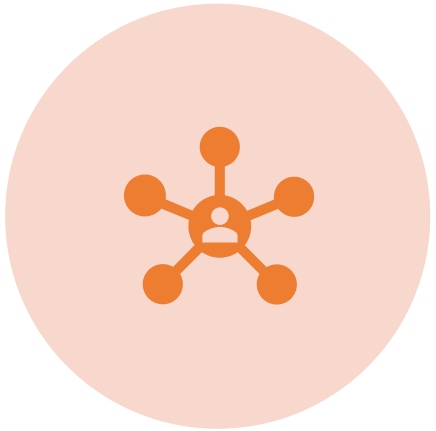


Benefits to Regulators

- Better decision-making through structured data
- Enhanced transparency and reproducibility
- Potential for harmonization across the globe
- AI research + training can lead to improved regulatory outcomes

Lessons Learned

IMPORTANCE OF CULTURAL/CONTEXTUAL ADAPTATION



BUILDING SUSTAINABLE NETWORKS, NOT ONE-OFF INTERVENTIONS

BRIDGING THE LANGUAGE GAP BETWEEN SCIENCE AND POLICY

The Role of Academia

NEUTRAL CONVENER BETWEEN INDUSTRY, REGULATORS, AND PUBLIC HEALTH

CAPACITY BUILDING AS A MORAL AND STRATEGIC IMPERATIVE

TRAINING THE NEXT GENERATION OF REGULATORY SCIENTISTS

SUBJECT MATTER EXPERTISE COMBINED WITH GOOD TEACHING PEDAGOY

Looking Ahead

- Continued capacity building as products become more complex and regulatory systems adapt
- Scaling AI-enabled regulatory science globally
- Integrating new modalities and digital health
- Aligning with global health equity goals

PATIENTS

Call to Action

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- Invest in regulatory science as innovation’s equal partner
- Strengthen global collaborations
- Ensure AI adoption is ethical, equitable, and evidence-based
- Continue to support regulatory capacity building across the globe

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VERITAS

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