



# Regulatory Strategies for Reliance



**28<sup>th</sup> to 30<sup>th</sup> October 2025**

# Regulatory Reliance & Collaboration

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- ❑ Regulatory Reliance (RR) is the act whereby the regulatory authority in **one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution**, or to any other authoritative information, in reaching its own decision \*
- ❑ The **relying authority remains independent, responsible and accountable regarding the decisions taken**, even when it relies on the decisions and information of others \*



## Patients & HC Providers

Timely access to safe, effective and quality medical products



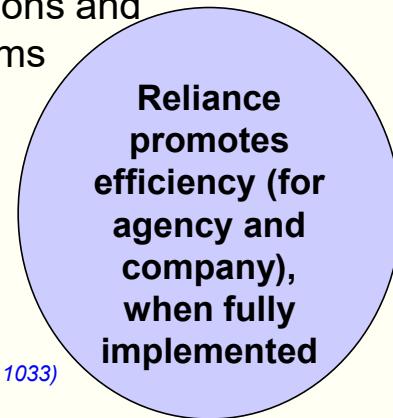
## Manufacturers

Streamlined management of regulatory submissions and global supply systems



## NRA's

Efficient utilization of resources by avoiding duplication of work, strengthening the regulatory system, maintaining sovereignty over decision-making



\* *Good Reliance Practices*, Annex 10 of the Fifty-fifth report of WHO Expert Committee on Specifications for Pharmaceutical Preparations: (TRS 1033)  
Confidential & Proprietary Information

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- Harmonized Regulatory Pathways**
- Collaborative Registration Procedure (CRP) - WHO PQ or SRA**
  - Awareness of vaccine CRP with more no's of local NRAs and vaccine manufacturers (trainings at regional level).
  - Success story of CRP for Pharma (medicines) to be replicated for PQ'ed vaccines
  - Reliance on the functional (semi-stringent) NRA may expedite review and registration of new vaccines & approval of PAC (Post Approval Changes)
  - Lifting the functional NRAs to stringent NRA
- Reliance for GMP Inspections** on NRA's designated as ML-3 and PIC/S countries and their Inspection Reports as well as GMP status
- Recognition of National Control Testing Laboratories**
- Reliance for “PQ Consistency” Testing

## Proposed Solution for Regulatory Convergence & Reliance

- Common harmonized Initial Registration Dossier as well as the Post-approval Variation package (fit for purpose) across the globe
- Policy and advocacy for Regulatory Convergence on outstanding Country-specific requirements, e.g., *common labelling requirements (similar to the EU countries)*
- Considering the quality risk, the post-approval changes can follow different approaches ranging from implementation of change under company QMS for changes with minor impact to Prior approval:

Types of Post-Approval Changes	Approach as per the Variation's Current Guideline (V.7.July 2015)	Proposed Approach based on Regulatory Convergence
Minor Changes (Type N)	<b>To be notified</b> within one month after approval by the NRA (File, wait for 30 days and implement)	No change
Moderate Changes (Type R)	<b>Annual reporting</b> (Implement and file)	No change
Major Changes (Type A)	<b>Prior-approval</b> (File, wait for approval and implement)	<b>Prior-approval</b> (File, wait for 75 days and implement)

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# THANK YOU