# INNOVATION & CONTINUOUS IMPROVEMENT IN A SEEMINGLY ACCELERATED REGULATORY ENVIRONMENT

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Biopharmaceutical innovation can improve quality assurance, manufacturing capacity & process efficiency. However global regulatory trends are a barrier to continuous improvement and acceleration only exacerbates product development.

While several recent draft guidelines & initiatives[1-3] portend to enable innovation, in practice, regulatory expectations reflect increasingly punitive rather than incentive-based opportunities:

- Redundant downstream justification for upstream changes, i.e., stability
- Submission of GMP/supply chain information for review
- Misaligned regulatory review & inspection
- Global regulatory divergence – RSMs, viral clearance, PACs

This presentation describes manufacturing innovations in the context of increasing regulatory demands & under accelerated development timelines.

[1]*Assay Development & Validation for Immunogenicity Testing of Therapeutic Protein Products,* Draft Guidance for Industry, FDA/CDER, CBER & CDRH, April 2016.

[2]*Advancement of Emerging Technology Applications to Modernize the Pharmaceutical Manufacturing Base,* Draft Guidance for Industry, FDA/CDER, December 2015.

[3]*Established Conditions: Reportable CMC Changes for Drug and Biologic Products,* Draft Guidance for Industry, FDA/CDER & CBER, May 2015.