# Evolving SUPAC for Today's Complex Products - Industry Position

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# SUPAC for Complex Generics

- For Complex products, Industry recognizes, there is a framework for a predictable, science driven pathway for filing and market, however, for Post-approval Lifecycle Management, the development of SUPAC Guidance's remains a challenge

- **ICH Q12**
  - ✓ Complements ICH Q8, Q9, Q10 and Q11
  - ✓ Provides flexible, science-driven and risk-based approach for Post-approval Lifecycle Management

# ICH Q12 Elements in ICH Q8, Q9, Q10 & Q11

| | |
|---|---|
| **ICH Q8** | • ICH Q12 operationalizes QbD by enabling flexible change management through Established Conditions (ECs) and Product Lifecycle Management (PLCM) |
| **ICH Q9** | • ICH Q12 utilizes risk-based approach and Post Approval Change Management Protocol (PACMP) to manage changes |
| **ICH Q10** | • ICH Q12 leverages PQS to manage certain changes without / lower category of regulatory submission, if justified by risk and science |
| **ICH Q11** | • ICH Q12 facilitates management of post-approval CMC changes related to drug substance manufacture through ECs and PLCM |

# ICH Q12 Elements & Industry Position

| EC | PACMP | PLCM | PQS |
| --- | --- | --- | --- |
| • ECs can be tailored to reflect CMAs, and CPPs which impact CQAs product performance per established specifications / control strategy | • Use PACMP to plan scale-up, site transfers, or equipment changes with regulatory pre-approval, reducing uncertainty and delays | • Annual product review can be tailored to reflect PLCM to maintain traceability of changes | • Change Management system to enable risk-based decision-making and continuous improvement |

# Change Type - SUPAC vs ICH Q12 Approach

| Change Type | SUPAC Approach | ICH Q12 Approach |
|---|---|---|
| **Formulation** | Classified by dosage form (IR, MR, SS); limited flexibility for complex generics; requires submission / CC based on level of change | Managed via ECs and PACMP; allows predefined pathways for changes with regulatory predictability |
| **Site** | Requires prior approval or supplements depending on impact | Handled through PACMP and PQS; enables planned site transfers with reduced regulatory burden |
| **Equipment** | Evaluated based on scale and impact; may require submission if affecting product quality | Assessed via risk-based PQS and ECs; changes within defined boundaries may not require regulatory submission / reduced regulatory burden. |
| **Process** | Limited guidance for complex processes; often requires prior approval supplements | Supported by ECs and PLCM document; encourages continuous improvement and QbD integration |

# SUPAC for Complex Products

- ✓ **ICH Q12 - <u>SUPAC Guidance for Complex Products,</u>** enables predictability and efficiency by leveraging the adopted framework from ICH Q8, Q9, Q10, and Q11

- ➢ Examples of ECs, will help the Industry reinforce the adopted framework to establish for Post-approval Lifecycle Management of Complex products

# Thank you

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