

PDA's Post Approval Change activities

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Regulatory agencies

Globalization vs Nationalization

Why is this a problem ?

One change often takes years to get approved worldwide

SUSTAINABLE Drug Product **AVAILABILITY** is challenged

Deincentivizes **CONTINUAL IMPROVEMENT** & **INNOVATION** that has the objective to

- Improve quality & safety (any new knowledge)
- Improve process control and reduce variability
- Improve efficiency



<u>CTD</u>

Time of submission = 1 dossier

PAC time >> 1 dossier

Product Lifecycle Years



Solution? Incentive?

SUSTAINABLE Drug Product AVAILABILITY

with timely improvement of quality, safety, efficiency



Resolution 67.20 on regulatory systems strengthening



...& other organizations & documents as well

So where does PDA fit in?



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Achieve practical implementation of concepts by Involving PDA subject matter expert members



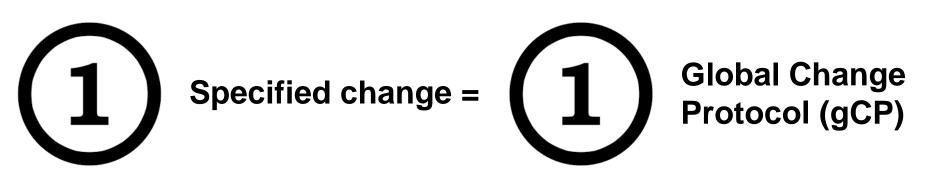
Where is PDA Playing an Active Role for ICH Q12

- Drug Shortages caused by manufacturing quality issues
 - Technical Report TR68 (includes PAC section for expedited approvals), risk-based triage model, tools & templates, training, website
- Established Conditions influence emerging guidance
 - Comments submitted to FDA re Draft guidance
- Lifecycle Management Plan (LCMP)
 - Template and practical examples
 - How can the LCMP be leveraged effectively for PACs
- **Survey** getting industry feedback
 - Where have companies had success with PAC effort relief
- PQS reduced reporting
 - How can a robust PQS be effectively leveraged to manage PACs
- Global Change protocols (gCPs)
 - Facilitate alignment on common technical improvements & innovation that can benefit from gCPs
 - Template



Our Science is global





Agile PAC management: Science and risk driven harmonization globally to enable technical innovation & drug product availability

Let's be ambitious in shaping the future of PACs together...

- Lifecycle Management Plan
- Survey
- PQS
- Global Change protocols



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