PDA’s Post Approval Change activities

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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
CTD

Time of submission $= 1$ dossier

PAC time $>> 1$ dossier

Product Lifecycle Years

Time on market $>>$ time in development
Solution?

Incentive?

SUSTAINABLE Drug Product AVAILABILITY
with timely improvement of quality, safety, efficiency

ICH harmonisation for better health

Q12 Product Quality Lifecycle

Resolution 67.20 on regulatory systems strengthening

...& other organizations & documents as well

So where does PDA fit in?
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  - Comments submitted to FDA re Draft guidance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

Imagine……

1 Specified change = 1 Global Change Protocol (gCP)

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