PDA's Post Approval Change activities

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Companies

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

CTD

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

ICH
harmonisation for better health

Q12 Product Quality Lifecycle

Resolution 67.20 on regulatory systems strengthening

World Health Organization

…& other organizations & documents as well

So where does PDA fit in?

PDA®
Parenteral Drug Association
Connecting People, Science and Regulation®

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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  - *Comments submitted to FDA re Draft guidance*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

Imagine……

Specified change =

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

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