The Regulatory Hurdles and Challenges for Post Approval Changes of Legacy (Existing) Products

PDA Australian Chapter

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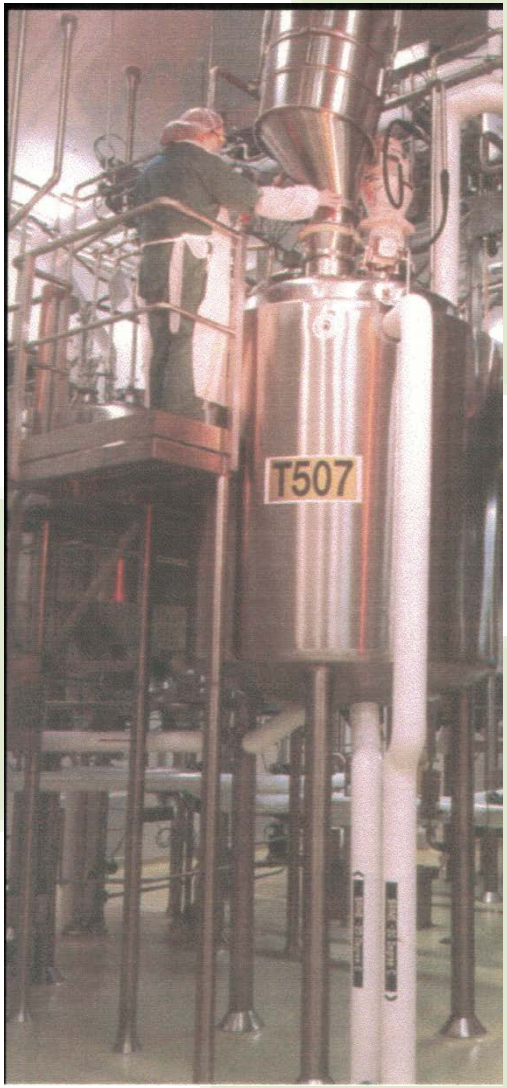

About Me

- 22 years experience in Pharmaceuticals and Medical Devices
- 15 years in Regulatory Affairs
- Manufacturing, planning, quality and management
- TGA Prescription Medicines IWG
- PDA AUS committee member 2004-2008
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Overview

- What are Legacy Products?
- Causes for Change – Quality
- Hurdles and Challenges
- Regulatory – Keys to Success
- Regulator Plan
- Opportunity and Benefits

What are Legacy Products?

- Originally developed in the past (as early as 1930's).
- Dossier were developed when there was a lack of framework and regulation.
- Old Registered Products > 15 years
- Minimal Documentation regarding the Pharmaceutical Development or Validation

What are Legacy Products?

- Legacy Products are refer to "grandfathered“ products.
- Grandfathered products are products that were in the market before the commencement of the current legislation.
  - Australia: *Therapeutic Goods Act 1989* (i.e. in 1991)
  - New Zealand: *The Medicines Act 1981* and Medicines Regulations 1984

Causes for Change- Quality

Manufacturing Site Transfers	• Drug Product • Drug Substance • Testing sites
Change to Manufacturing Process	• Equipment • Use of new technology • Method of manufacture • Increase in batch size
Formulation	• Reformulation • Excipient • Stability • Container closure
New Products	• New fill • Pack sizes • Extension of existing products into new markets

Hurdles and Challenges

- Lack of Baseline Information
  - Regulatory dossier
  - Site documentation
- Project Scope
  - Poorly defined
  - Project creep
- Communication
  - Project management
  - Cross functional team

Hurdles and Challenges

- Regulator engagement
  - Pre-submission Scientific/Strategy meeting
  - Audit
- Changes are based on Good Science not just cost or this is how we always did it.
- Non Quality consequential changes
- Hidden Markets
- Supply Strategy
- Cost

Regulatory- Key to Success

- Involve RA during the scoping of your changes
- Project Plan
- Management commitment to the project
- Communicate changes of scope, regulation and delays
- Regulator engagement
- Realistic timeframes
- Good Data Package
- Document a Regulatory Plan/ Strategy and keep it updated.

Regulatory Strategy

- Regulatory Strategy Plan documents the regulatory strategy for the implementation of a post approval change event or series of events.
- Initiated at any point of the post approval change cycle and is a living document intended to be updated as the project changes.
- Used to communicate to “in country” sales and marketing
- Not a change control but can be added as an addendum to a change control
- Dynamic – Electronic Document
- Version controlled - not a formal controlled document.

Regulatory Strategy

Opportunities and Benefits

- Harmonising process and products
- Regulatory compliance
- Regulator confidence
- Robust, reliable, product and processes
- Opportunities to extend products into new markets.
- Safer and consistent products
- Better Patient outcomes

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