Lifecycle Management of Drug Products: FDA’s Perspective

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Disclaimer

This speech reflects the views of the author and should not be construed to represent the U.S. Food and Drug Administration’s views or policies.
Lifecycle Management – Our Quality Journey

- Vision
- Strategies
- Infrastructure
- Support System
Started with the Birth of OPQ
– January 11, 2015

Advances CDER’s Quality Initiative to the next level

Vision:
“A maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high quality drugs without extensive regulatory oversight.”
• A single unit in CDER dedicated to product quality
  – All drug products (new drugs, generic drugs, OTC drugs)
  – All sites (domestic and foreign)

• Creates ‘one quality voice’ streamlining quality oversight throughout the lifecycle of a drug product
  – Aligns review, inspection, and research functional areas
  – Spans pre- and post-approval for brand and generic drugs
  – Strengthens surveillance and inspections of facilities globally
Strategy – OPQ

• Encourages use of modern, more efficient manufacturing technologies
• Establishes consistent quality standards and clear expectations for industry
• Balances potential quality risks with the risk of a patient not getting a drug
• Anticipates quality problems before they develop to help prevent drug shortages
ONDP & OLDP: Lifecycle Partners

**ONDP**
- NDA
- DMF
- Biopharm
- Knowledge
- Expertise

**OLDP**
- sNDA
- ANDA
- sANDA
- Lifecycle
Resource and Functions

- Division of New Drug API
- Division of New Drug Products 1
- Division of New Drug Products 2
- Division of Biopharmaceutics
- Division of Lifecycle API
- Post-Marketing Activities I (sNDAs)
- Immediate Release Products I
- Immediate Release Products II
- Modified Release Products
- Liquid-based Drug Products
- ANDA Pre-Marketing Divisions
- Post-Marketing Activities II (ANDAs)
Integrated Knowledge Base

**Phase 1 - IND→NDA→sNDA**
- Knowledge base of quality issues and potential risks established

**Phase 2 - sNDA**
- Knowledge base accumulated during NDA post-marketing phase

**Phase 3 – ANDA**
- Knowledge base guides ANDA pre-marketing quality assessment

**Phase 4 – sANDA**
- Knowledge base accumulates during ANDA post-marketing phase

Hand-off: NCE - 3 yrs; 505(b)(2) - 1 yr
Lifecycle Management of Drug Product Quality

Knowledge Management System

Work in a continuum rather than in silos
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Questions?

Please complete the session survey:

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Thank You!