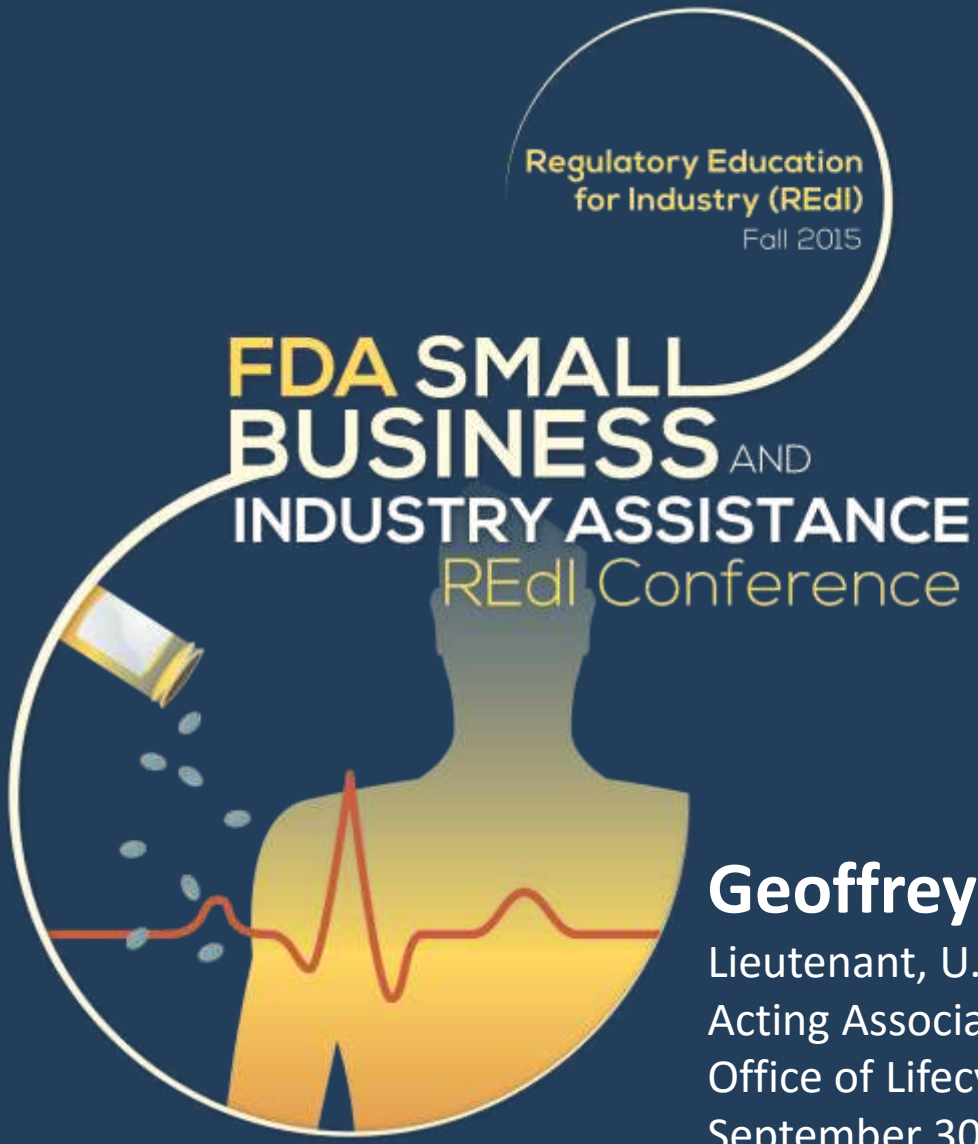

Lifecycle Management of Drug Products: FDA's Perspective

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Office of Lifecycle Drug Products, OPQ, CDER
September 30, 2015

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."

Strategy – OPQ

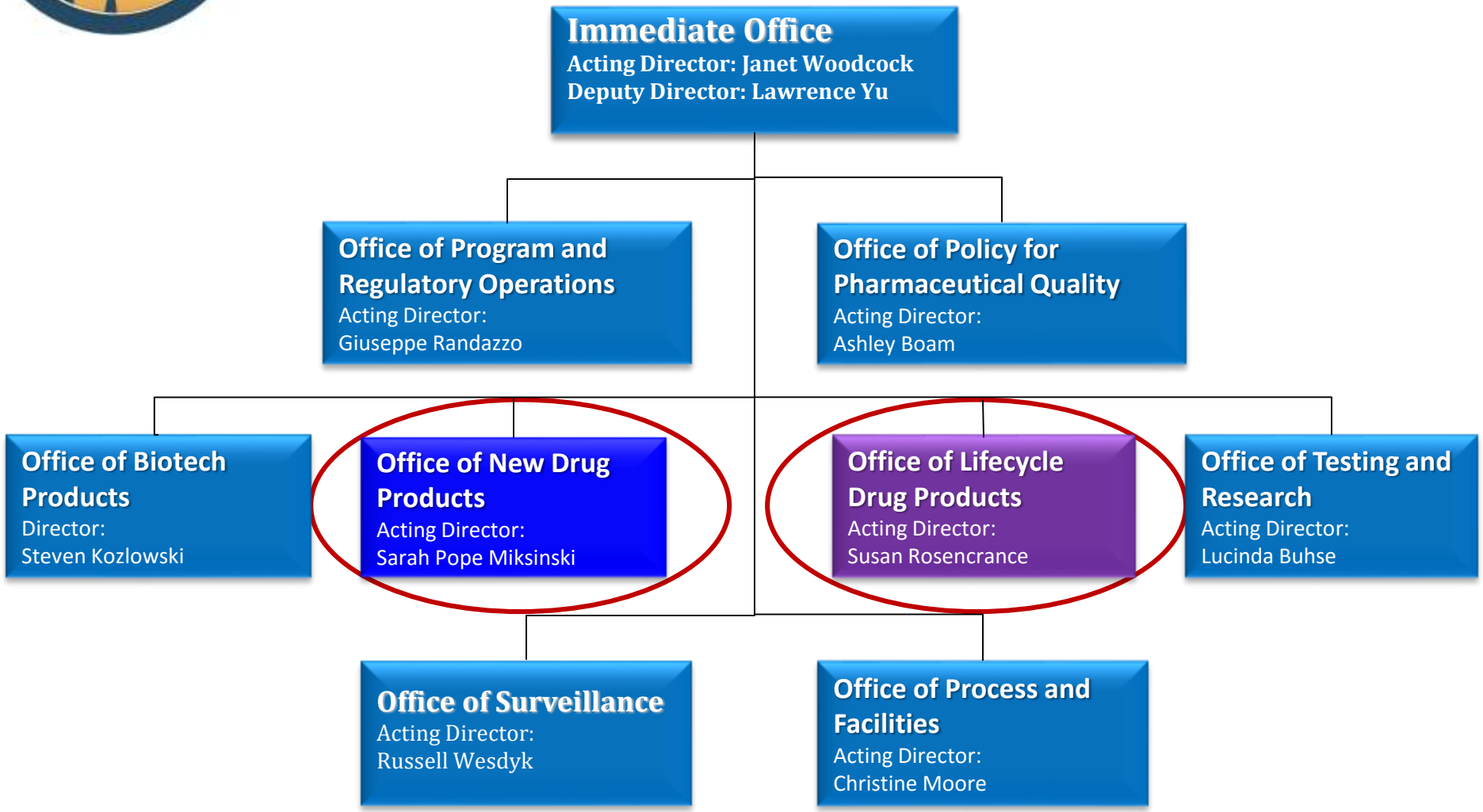
- A single unit in CDER dedicated to product quality
  - All drug products (new drugs, generic drugs, OTC drugs)
  - All sites (domestic and foreign)

- 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

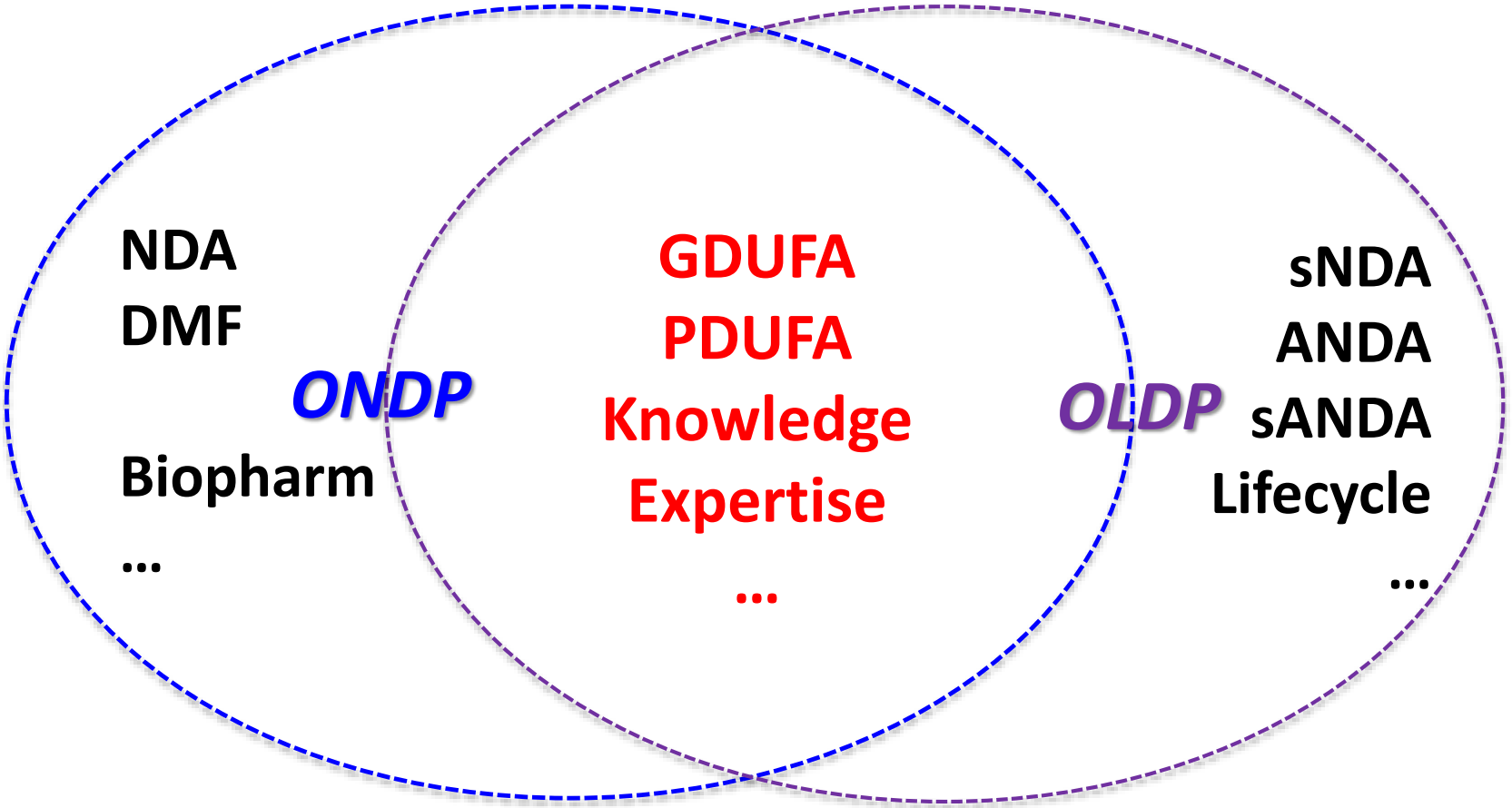
Strategy – OPQ

- 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

OPQ Structure



ONDP & OLDP: Lifecycle Partners



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

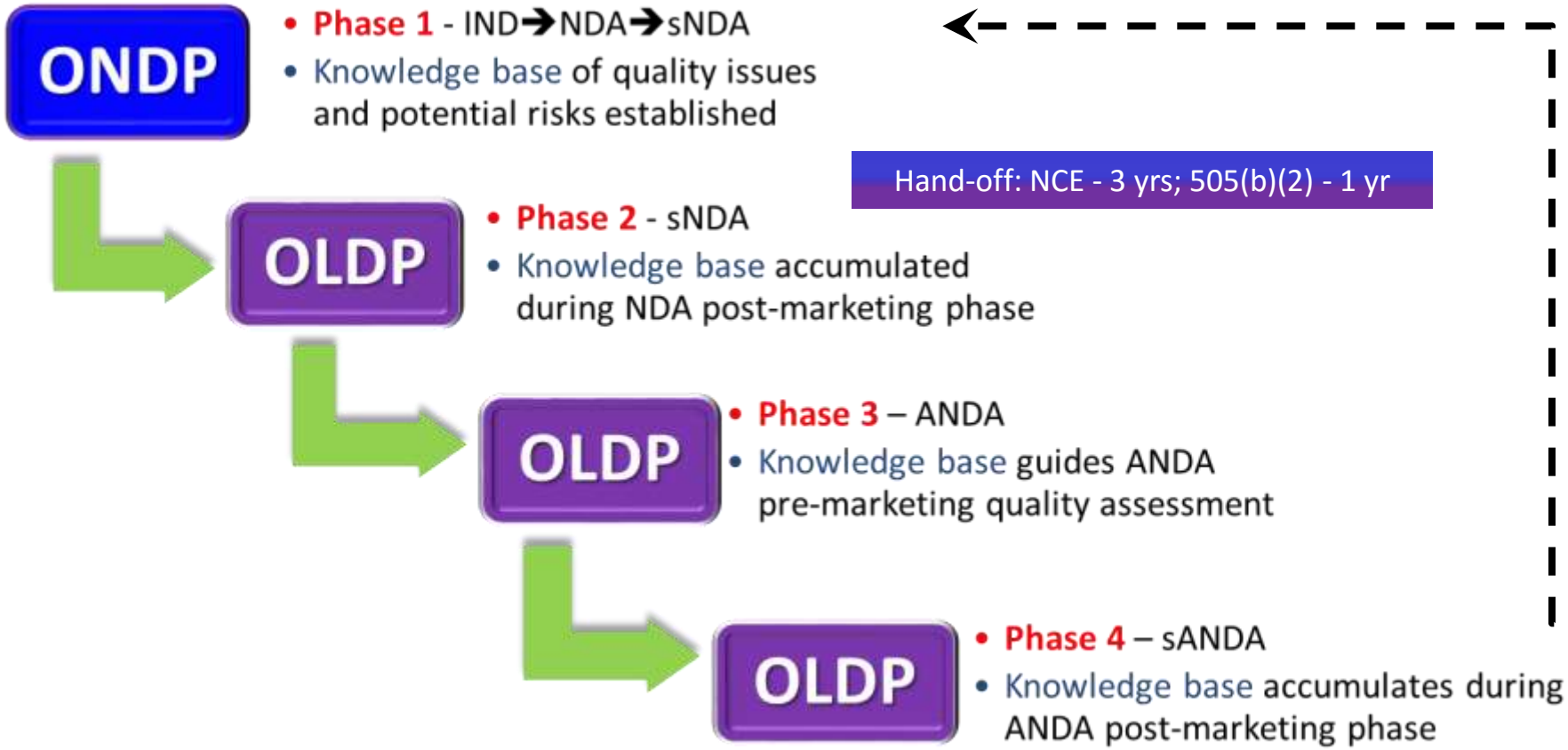
Modified Release Products

Liquid-based Drug Products

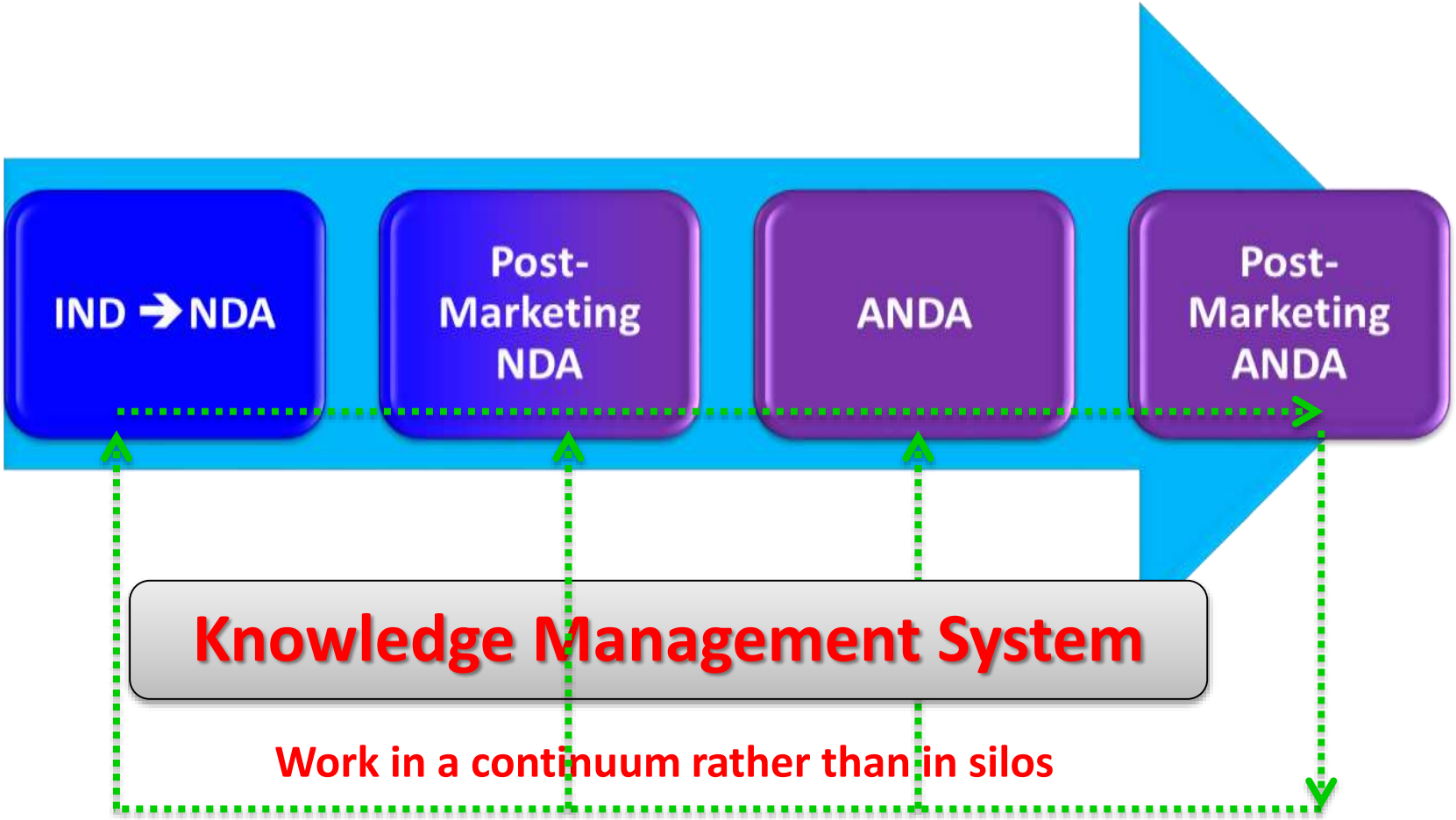
ANDA Pre-Marketing Divisions

Post-Marketing Activities II (ANDAs)

Integrated Knowledge Base



Lifecycle Management of Drug Product Quality



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Questions?

Please complete the session survey:

surveymonkey.com/r/DRG-D2S5

Thank You!