



USP-APEC RHSC

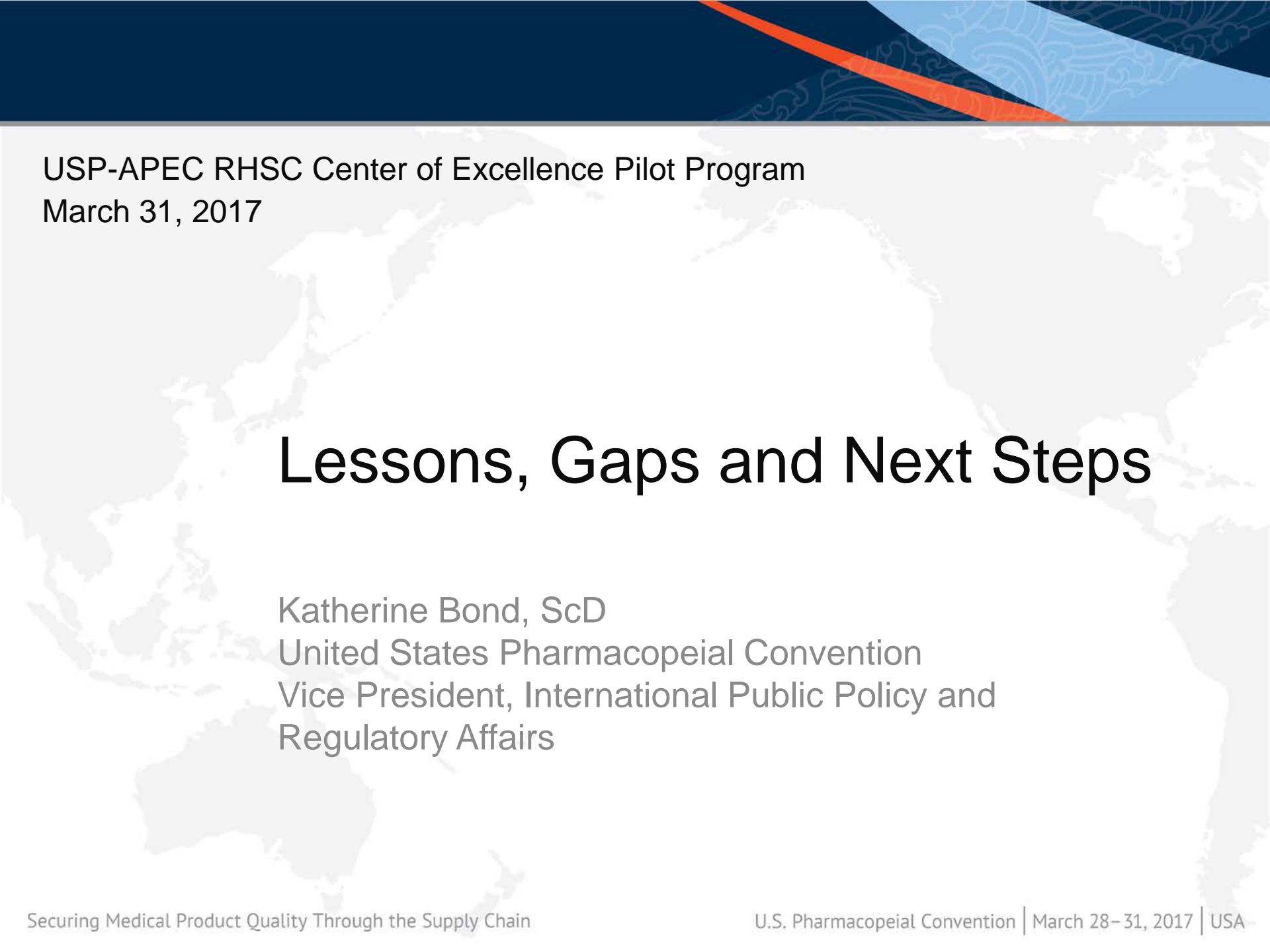
Center of Excellence (CoE) for Product
Quality & Supply Chain Pilot Program:

Securing Medical Product Quality Through the Supply Chain

U.S. Pharmacopeial Convention (USP) | March 28–31, 2017 | USA



Welcome



USP-APEC RHSC Center of Excellence Pilot Program

March 31, 2017

Lessons, Gaps and Next Steps

Katherine Bond, ScD

United States Pharmacopeial Convention

Vice President, International Public Policy and

Regulatory Affairs

Content Overview Day 4

- **Group Discussion**
 - Reflections
 - Next steps
 - Topics for proposals for future CoE programs
- **Closing and Presentation of Certificates of Participation**

Securing Medicines Quality in the Supply Chain

Goals

- Enhance the implementation and sustainability of the RHSC's Supply Chain Integrity Roadmap best practices with focus on "Securing Medical Product Quality through the Supply Chain"
- Convene diverse group of APEC economy regulators, thought-leaders, academics and industry representatives
- Serve as platform to refine and continually develop the RHSC Supply Chain Tool Kits and identify and address gaps in standards development

Principles

- Holistic approach to the continuum of the pharmaceutical supply chain
- Focus on risk
- Communities of practice, knowledge sharing
- Thought leadership platform

Securing Medicines Quality in the Supply Chain

Focus

- Highlight the role of public standards and best practices in addressing quality and supply chain integrity issues
- Target specific aspects of the APEC Supply Chain Roadmap where best practices can have great impact on medicines quality:
 - Good Manufacturing Practices
 - Good Distribution Practices
 - Good Pharmacy Practices
 - Internet Sales
 - Screening and Detection Technologies

Methods

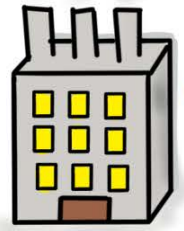
- Keynote talks
- Panel sessions
- Presentations
- Case studies
- Hands-on demonstrations

What is Quality?

- ▶ The USP Quality Institute defines medicine quality as a balanced, risk-based set of characteristics, systems and requirements that consistently ensure a medicine's delivery of stated and implied clinical outcomes for patients.
- ▶ This definition is meant to encompass aspects of a medicine's entire life cycle, including design, manufacturing, supply chain, storage and distribution, as well as falsification. It does not consider the quality of treatment guidelines and practices.



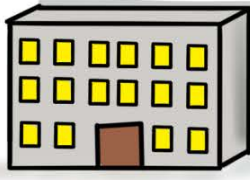
MEDICINE SUPPLY CHAIN



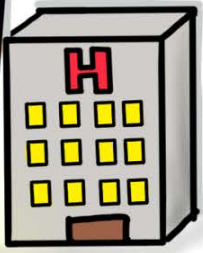
• MANUFACTURERS



• CULTURE OF QUALITY



• WHOLESALERS & DISTRIBUTORS

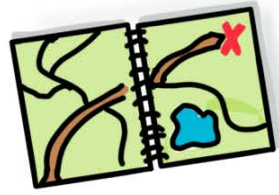


• HOSPITALS & PHARMACIES



• PATIENTS

- ✓ PREVENTION,
- ✓ DETECTION, and
- ✓ RESPONSE



• ROAD MAP for ENTIRE SUPPLY CHAIN

• Problems with quality can occur at manufacturer and/or along the supply chain



• FINAL REPORT

• SC Security & TOOL KIT



✓ ENDORSED!



PROTECT the INTEGRITY of the SUPPLY CHAIN

EFFECTS of POOR QUALITY MEDICINES...

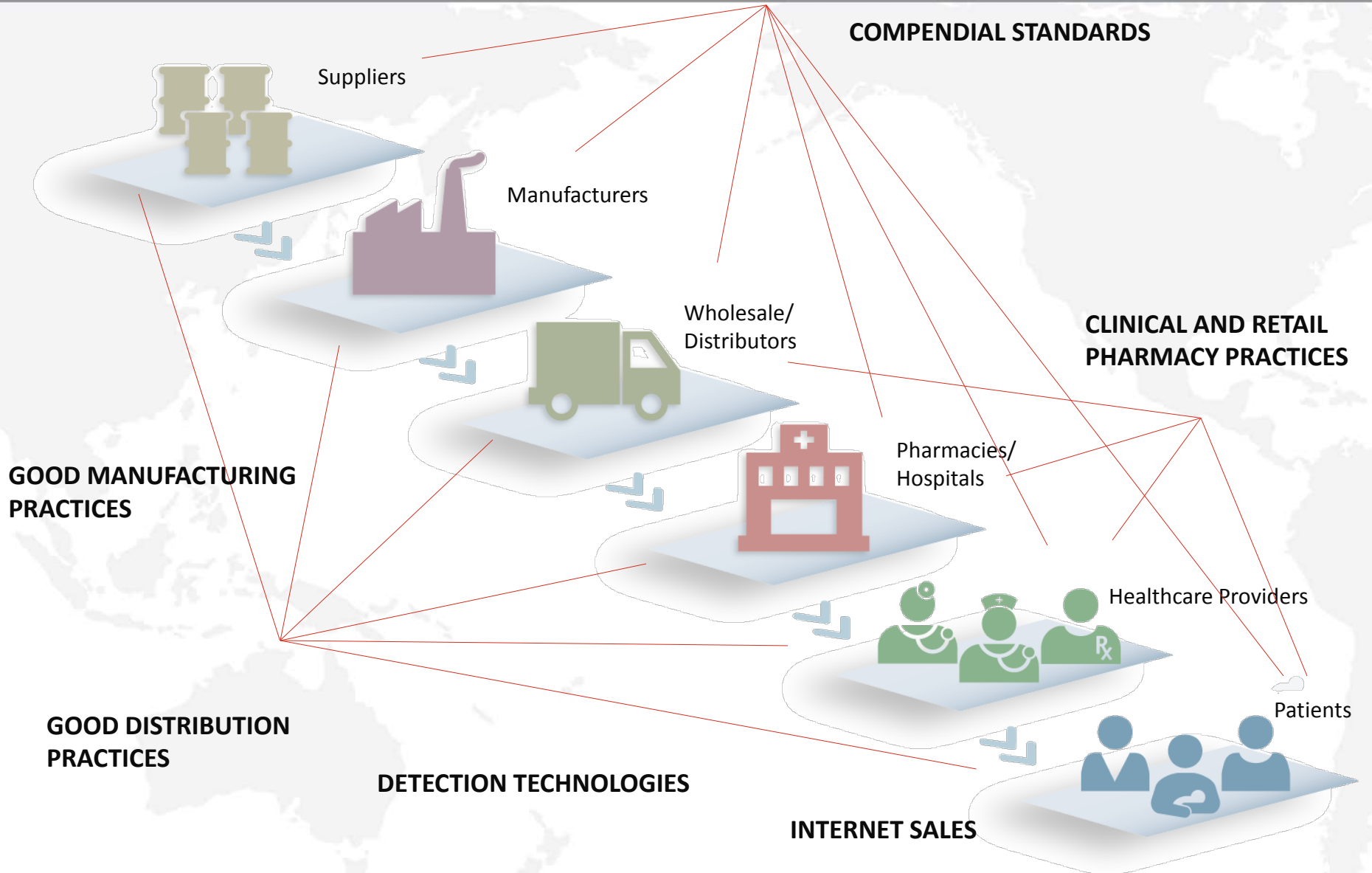
- Adverse events
- Inadequate Tx
- Therapeutic failure
- Drug resistance
- Reduced Pt trust
- Increased costs

Ilisa Bernstein, FDA
 Ron Piervincenzi, USP
 • DAY 1 KEY NOTES •

• USP-APEC RHSC •



Roadmap Toolkits



Questions for Reflection

Choose two modules.

For each, please answer the following questions on the matching color sticky pad...

What were
you key
lessons
learned?

What more do
you need?

What actions
will you take
when you get
home?



Questions



Thank You
