
Meeting USP Good Storage and Distribution Practices in a Complex Supply Chain
VAISALA
Pharmaceutical Technology
LIVE WEBCAST: Thursday, April 3, 2014
9:00 am PDT / 12:00 pm EDT

Webcast Notes

- Interact with speaker by typing your questions in the “Q&A” box, which can be found by clicking on the red “Q&A” widget at the bottom of the screen
- You can enlarge the slide window at any time by clicking on the small green icon in the upper right hand corner of the slides window– the slides will advance automatically throughout the event
- If you are experiencing technical problems with viewing or hearing the event, please click on the “Help” widget in the dock at the bottom of your presentation window

Today's Speakers

Moderator:

Jennifer Markarian
Manufacturing Editor
Pharmaceutical Technology

Speakers:

Paul Daniel
Senior Regulatory Compliance Expert
Vaisala

Mary G. Foster, PharmD,
Chair, USP Expert Committee, Packaging, Storage and Distribution
USP Governance Committee and Council of Experts Executive Committee

What's New?

USP 36 <1079> Update

VAISALA

Paul Daniel
Senior Regulatory Compliance Expert
Vaisala, Inc

Recent History

- Health Canada
  - GUI-0069 – Guidelines for Temperature Control of Drug Products during Storage and Transportation

- ISPE
  - Good Practice Guide: Cold Chain Management

Recent History

- PDA
  - Technical Report 58 – Risk Management for Temperature Controlled Distribution

- CDSCO (India)
  - Guidelines on Good Distribution Practice for Biological Products

Recent History

- CFDA (China)
  - Good Supply Practices for Pharmaceutical Products

- EMA (Europe)
  - (2013/C 68/01) Good Distribution Practice of Medicinal Products for Human Use

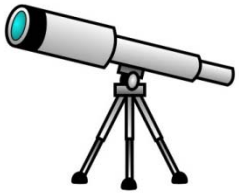
- USP 36
  - Chapter <1079> Good Storage and Distribution Practices for Drug Products

Goals

- What's new in USP 36 <1079>?
- What do the changes mean?
- What might be next?

Themes

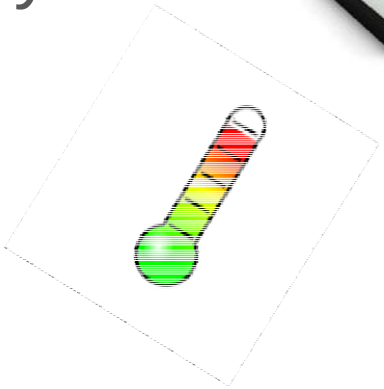
- Scope and Responsibility



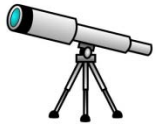
- Risk-Based Flexibility

- Quality Management System

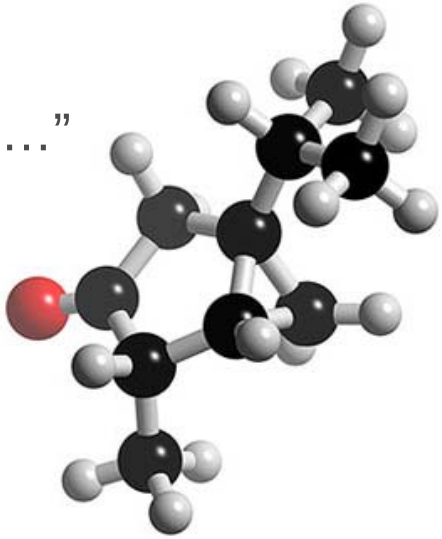
- Temperature Tool Kit



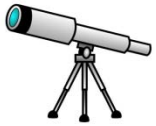
Scope - Focus



- Title Change:
  - From “Shipping” to “Distribution”
  - Added: “..for Drug Products
- Purpose Change:
  - “…provide general guidance…”
  - “…describe good storage and distribution practices…”
- Definitions:
  - Old: vague “Pharmacopeial preparations”
  - New: tightly defined “drug products”



Scope - Breadth



- Breadth
  - Dropped the diagram.

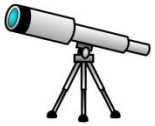
Figure 1. Drug product distribution.

  - offer a simple statement.

    "… distribution processes may involve a complex movement of product around the world, differences is documentation and handling requirements, and communication among various entities…"

  - Message: Each case is unique. All guidance can do is generalize.

Scope - Responsibility



- General Responsibility
  - "…All organizations along the supply chain bear responsibility."
  - GDP applies to "…all organizations and individuals involved in any aspect of storage and distribution…"

- Specific Responsibility :
  - Application Holder, Manufacturer, and Repackager
  - Note: EU says: "Wholesale Distributor"

Risk-Based Flexibility

- Old School Quality – 21 CFR 211
  - "Suitable and Appropriate" Solutions
- New School Approach
  - Smart and agile. Recognition of the cost and effort here.
- Examples
  - Label Storage Specs
    - Old: Standard Definitions (e.g. CRT)
    - New: "clearly defined" and not "subject to interpretation"
  - Transfer times
    - Old: 2 hours
    - New: Consistent with product and exposure.

Flexibility Quote

“It is recognized that conceivably there are special cases and many alternative means of fulfilling the intent of this chapter and that these means should be scientifically justified.”

USP U.S. Pharmacopeial Convention™

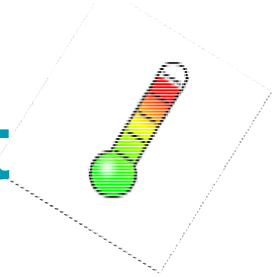
Quality Management System

- Necessary support for a lean risk-based approach.
- Sensitive feedback loop for continuous improvement.
- This is totally new to US GDP.
  - Reference ICH Q9 and Q10.

QMS for GDP

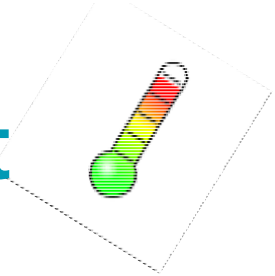
- Storage Management System
- Distribution Management System
- Environmental Management System
- Risk Management System

Temperature Tool Kit



- Proactive Tools
  - Mapping
    - They say HOW to map!
  - Monitoring –
    - Monitor as default unless other process in place.
  - Qualification
    - Add other processes, with a deeper dive.

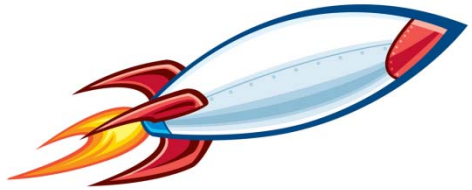
Temperature Tool Kit



- Reactive Tools
  - Deviation Management
    - Stability Data
    - Mean Kinetic Temperature (MKT)

Note: You can only use these tools if you have detailed data about your products and how they have been stored.

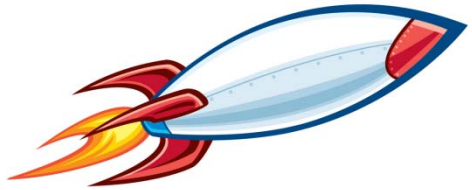
Future Quote



“It is equally important to stay current and be ready to change as new solutions evolve. These new technologies should be considered in developing strategies for good distribution practices, controls, and procedures.”

USP U.S. Pharmacopeial Convention™

What's next?



- They say stay current. I think that means stay tuned.
  - Technology is changing fast.
  - PIC/S is due to weigh in on GDP.
- 1000 series? Recommendations only.
  - Will it become enforceable?
- USP Publication on counterfeit drugs?

Summary

- What's new in USP 36 <1079>?
- What do the changes mean?
- What might be next?

Thanks for Attending!

Paul Daniel
Senior Regulatory Compliance Expert
Vaisala, Inc.

Email: paul.daniel@vaisala.com

Global Expertise
Trusted Standards
Improved Health

U.S. Pharmacopeial Convention

United States Pharmacopeia
Packaging, Storage & Distribution Expert Committee
USP PSD EC

USP General Chapter <1083> Good Distribution Practices

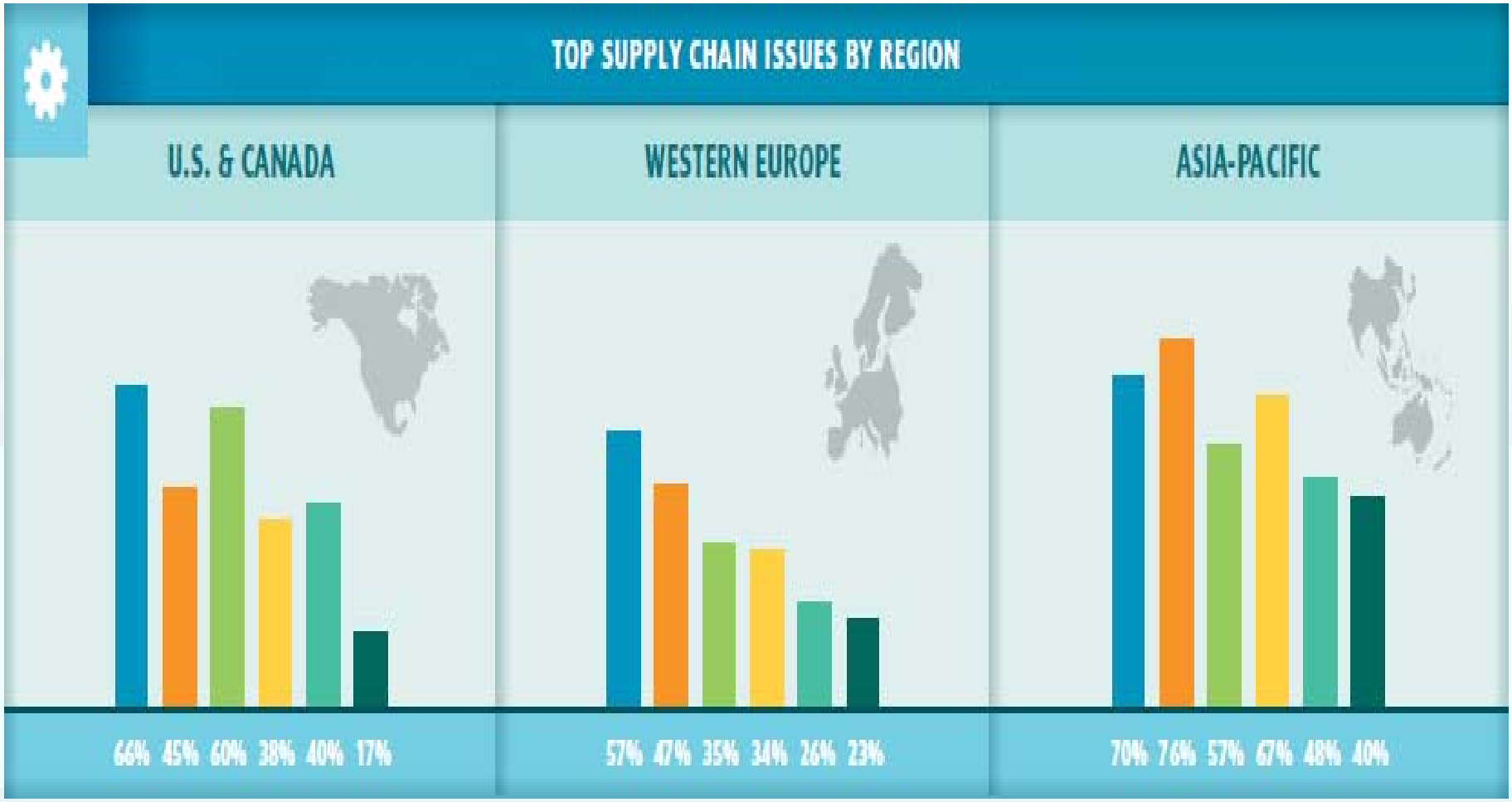
Mary G. Foster, PharmD
Chair, USP PSD EC
April 3, 2014

Pharmaceutical Technology
Webinar

Agenda

- United States Pharmacopeia, General Chapter, <1083> *Good Distribution Practices* [USP GC GDP]
  - Global Supply Chain Landscape, UPS Shared Data
  - Next Step: 2014 Expert Panel Formation
- 2015 - 2020 USP Cycle

Global Supply Chain Landscape

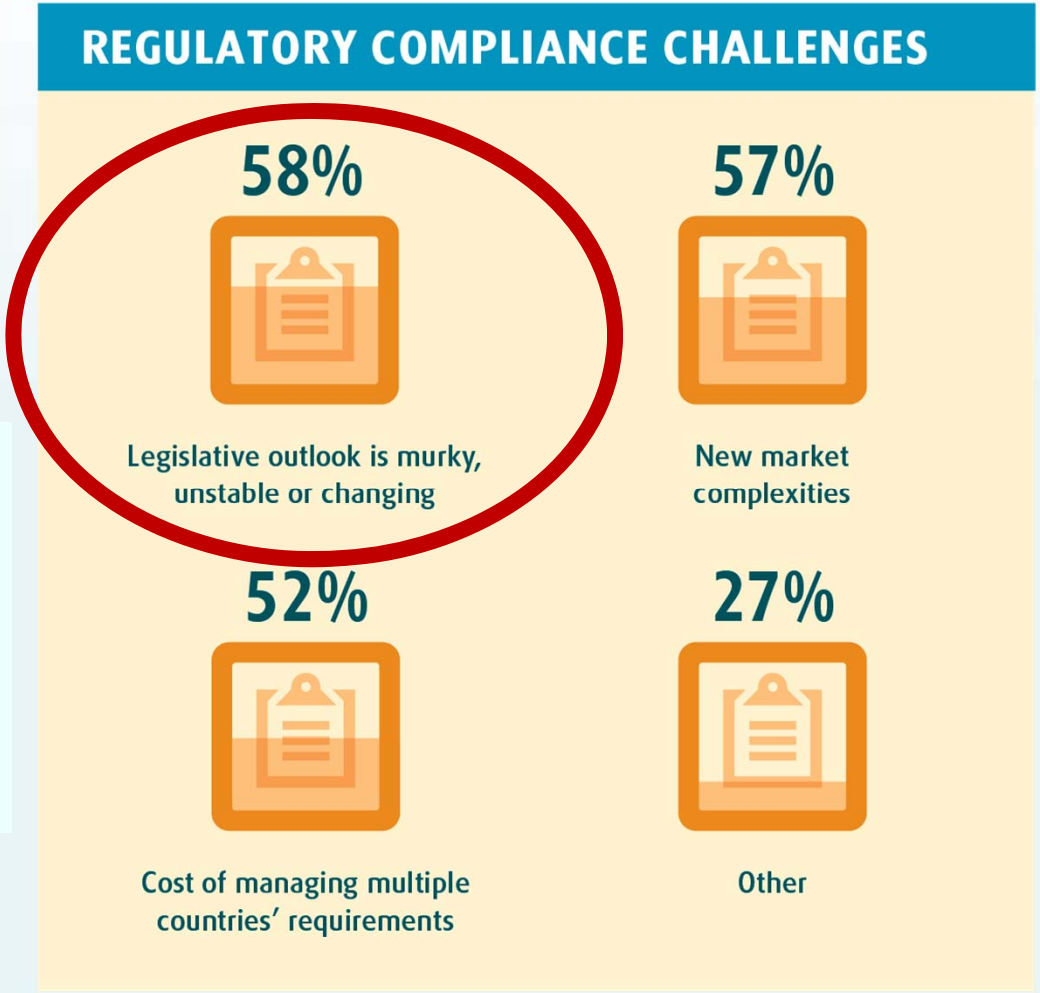


Global Supply Chain Landscape

TOP SUPPLY CHAIN CONCERN | REGULATORY COMPLIANCE

Strategies for **success**

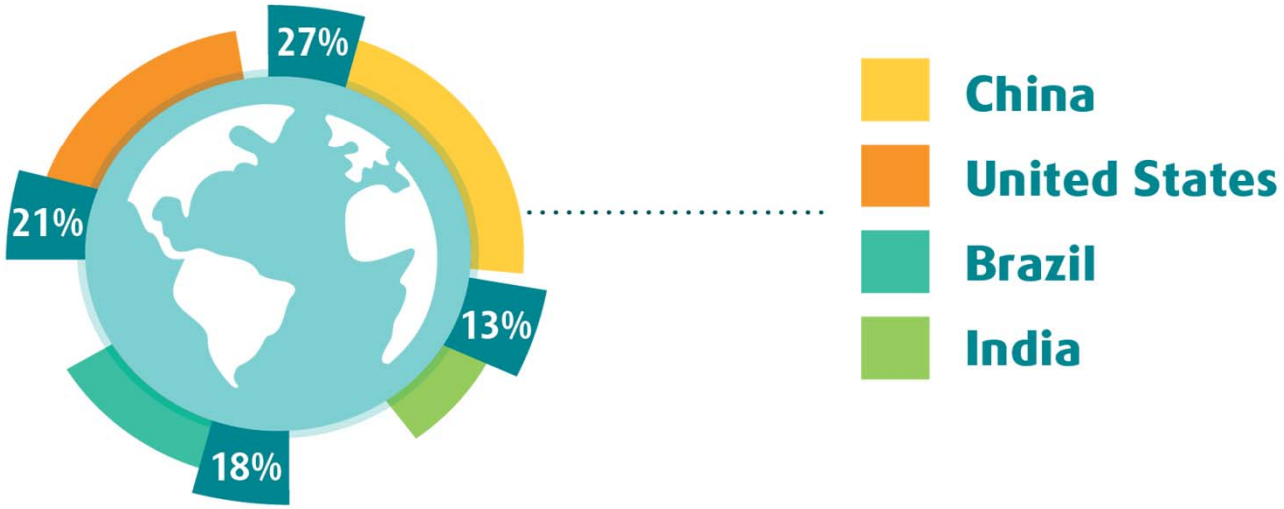
- **49%** IT investment: bar coding, serialization, e-pedigree
- **42%** Increasing regulatory expertise
- **41%** Hiring regulatory consultants
- **38%** Partnering: Local distribution firms
- **32%** Partnering: Large multi-national distribution firms



Global Supply Chain Landscape

COMPANIES EXPANDING DESPITE REGULATORY HURDLES

Top target markets for expanding companies



Supply Chain Conclave: Regulator * Aug 2013

Exporting to US

>150 Countries

>130,000 importers

>300,000 foreign facilities

FDA supply chain process

- 12 posts
- 10 countries
- 4 continents

Global Supply Chain Landscape

TOP SUPPLY CHAIN CONCERN | PRODUCT SECURITY

Strategies for **success**

- **61%** Investing in shipment insurance
- **56%** Investing in serialization or "e-pedigree" tech & other IT solutions
- **47%** Focused on in-transit monitoring & intervention

TOP SUPPLY CHAIN ISSUES OF 2013

53%	Product security
43%	Product damage or spoilage

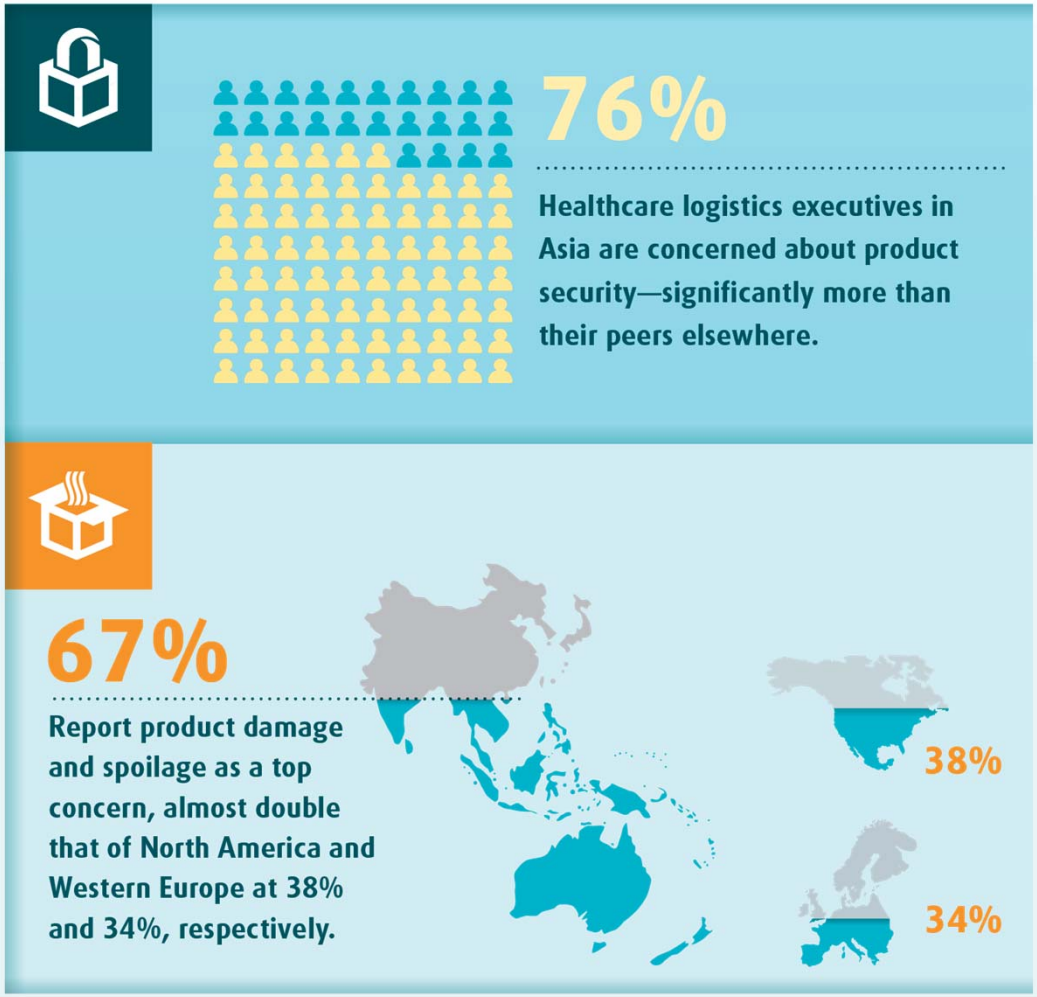
PRODUCT SECURITY CHALLENGES

Counterfeiter sophistication is growing faster than our countermeasures	48%
Poor supply chain visibility and too many supply chain hand-offs	40%
Inadequate law enforcement response	37%
Gray market or parallel trade	33%
Under-regulated wholesalers and repackagers	30%
IT and bar coding solutions have not solved the counterfeiting issue	28%
Proliferation of illegal online pharmacies creating a retail demand fulfillment channel	9%

ASIA-PACIFIC CLOSE-UP| PRODUCT PROTECTION

Product protection & solutions

- **67%** cite product damage & spoilage as a top concern
- **76%** say product security is an issue
- **71%** plan to invest in serialization technologies
- **68%** plan to invest in security-specific technologies
- **61%** will invest in temperature-sensitive technologies



USP Good Distribution Practices (GDP)

- Completed new GDP revision: Introduction & 4 Sub-Chapters proposed*: Pharmacopeia Forum* 40 (2) Mar-Apr 2014
- 90 day comment period

Good Distribution Practices Sub-Chapters
1. <1083.1> General Good Distribution Practices
2. <1083.2> Environmental Control Management
3. <1083.3> Importation/Exportation
4. <1083.4> Supply Chain Integrity

- Mar/Apr 2014 forming new Sub-Chapter Expert Panels

Good Distribution Practices Next Sub-Chapters Series
1. <1083.5> Finished Drug Products (Basics in <1079> & <1197>)
2. <1083.6> Excipients (replacing <1197>)
3. <1083.7> Active Pharmaceutical Ingredients
4. <1083.8> Packaging Components
5. <1083.9> Clinical Trial Materials

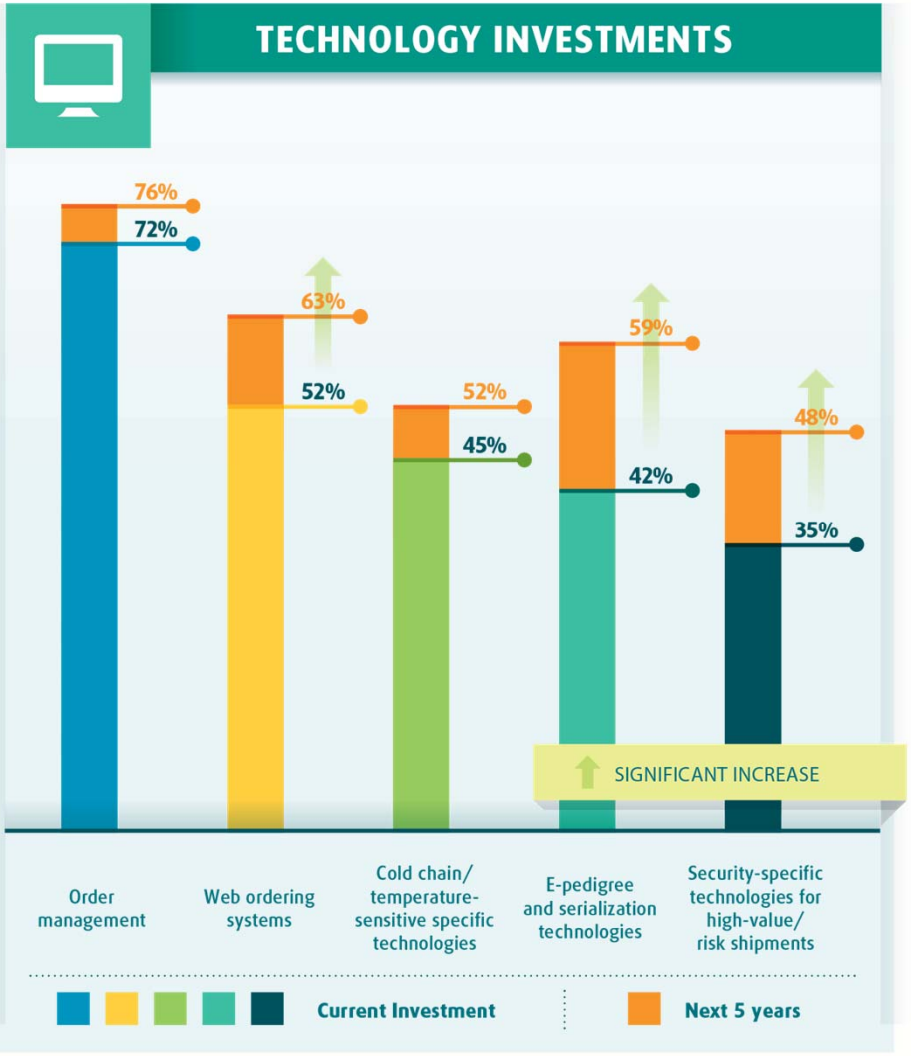
FUTURE STRATEGIES | Pharma Distribution Practices

Next 3-5 years

marked by

Technologies Investments:

1) *E-pedigree & Serialization*
2) *Security Specific (high value/risk)*



Closing

- Regulatory Compliance: No one regulatory authority/ organization can secure the supply chain
  - Prevention through strengthened regulatory capacity and tight supply chains (partnerships)
  - Entity-to-Entity visibility & collaboration
  - A collective response when substandard & counterfeit products are found
- Product Protection: Security & Damage
  - Early and rapid detection of suspicious products
  - Solutions for security and damage
- USP 1-Hour Webinar May 6, 2014 Noon–1pm EDT

What Can You Do?

- Submit an application to serve as an USP expert volunteer
  - New, account-based online application
- Promote the Call for Candidates to your colleagues
- Apply for current cycle's Expert Panels
- Questions?
  - Visit the USP web site at www.usp.org
  - Contact USP at USPVolunteers@usp.org or 301-816-8151

Thank You

Questions?

Thank you!