U.S. PHARMACOPEIA
The Standard of Quality℠



ANSI Homeland Security Standards Panel

Global Supply Chain Security Standards and Annual Plenary Meeting

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The FHI 360 Conference Center * Washington, DC

Understanding the SC Risks

Raw Materials, Excipients, API's, Clinical Trials , Medical Devices
Manufacturing, Packaging, Storage, Distribution & Sales

Industry Trends

- Rise of emerging markets
- Healthcare spending
- Regulation or lack thereof
- Supply chain breaches
- No common ground

Business Models

- Increased global outsourcing
- Increased partnerships
- Virtual companies

What should the USP role be in providing guidance?

Standards for Drug Product Integrity
Pharma Supply Chain & Anti-Counterfeiting

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

Understanding the threats

- What are the supply chain security threats?
- How big is each threat?
- What strategy should be put in place?
- What countries around the world are involved?
- Focus on risk mitigation & management

Current vs. Future State Mapping

- What business departments are involved?
- What are the key processes?
- Define the action plan from a holistic approach
- What are the effectiveness evaluation actions needed?

Developing the Strategy

- What is the future state vision?
- What is the continuous improvement plan?
- How do our processes need to change?
- How do we ensure the end user receives drug product that meets its identity, strength, quality, purity & safety?

Guidance through USP General Chapter Good Distribution Practices

Supply Chain Management Overview

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

Trends

Medicines changing

- Digital care
- New processes
- Lifecycle changes

Expertise driven

- Outsourcing >35 different contractors used

Exportation driven

- 2002-2009 13% increase drug importation FDA regulated products; 150 countries; 300,000 sites outside

Changes

Industry success factors

- New technologies to stay competitive

Stricter regulations? No single set of rules

- Multiple standards: GMP, GIP (importer), GDP, GPP (pharmacy practice)
- Greater pharmacovigilance

Expect collaboration & transparency

- All along supply chain path
- With regulators

Future

Accelerated importation

- India forecast 12% increase FDA regulated products 2010-2020

Highly sensitive production processes

New geographies

- Increase in spectra of harm to end user
- Threats: counterfeiting, *thefts & diversion, economically motivated adulteration;

*Cargo theft is on the rise globally, with a 350% increase from 2007 to 2009 in the US alone *(CBS News)*

Good Distribution Practices
* General GDPs * SC Temp Management * Good Import/Export Practices * SC Integrity

USP GC <1079>
Good Storage & Shipping Practices
*Official 2005
*Revision Dec1, 2012

- Provides recommendations to ensure GDP
- Drug Products: Human, Vet, Clinical
- General GDP Concepts
- Distribution is transportation
- No practices on combating counterfeiting or technologies

USP GC <1083>
GDP – SC Integrity
*PF Mar/Apr 2012; Industry input under review - Expert Panel

- Describes recommended practices on SC integrity
- API's, Excipients, Drug Products, Medical Devices
- Basic information
- Discusses practices to combat counterfeiting and packaging technologies

USP GC <1197>
GDP for Bulk Pharma Excipients
*Official USP 36

- Provides recommendations GDPs
- Excipients only
- General GCP concepts
- Traceability discussed
- Risks: adulteration & contamination – not specific
- Importation – not specific
- Pharmacy compounding

USP GC <xxxx> GDP

- <xxxx.1> Basic Guidance
- <xxxx.2> Pedigree
- <xxxx.3> Track & Trace
- <xxxx.4> Serialization
- <xxxx.5> Anti-Counterfeiting
- <xxxx.6> Natural Disasters

Pharma Good Distribution Practices (GDP)

Looking Beyond the Obvious: GDP – *Leading to USP Guidance Chapter(s)*

Understanding the SC Risks – *Drug/Medical Device/Clinical Trial Finished Product , Active Pharma Ingredients (API), Excipients & Raw Materials;* *** PLUS *** Packaging, Storage, Distribution

Creating a Common-Sensed Mindset: *PSD EC Workshop SC Integrity Outcomes*

Navigating to the Future: *Strategic Plans for GDP GC; Ideas – Spectral Library*

What Are We Missing?

GDP = Good Distribution Practices
USP = United States Pharmacopeia
SC = Supply Chain
PSD EC = Packaging, Storage & Distribution Expert Committee
GC = General Chapter

Global Forces Reshaping Pharma SCM

Preparing for what's next

- Collaboration - people management internal and external resources
  - Partnerships where multi-companies act as one
  - understand competencies needed, establish program elements, train and continuously develop
- Global operating model – Industry Standards
  - Information-rich
  - Corporate strategic priority
  - Global scale but local scope
- Transparency

Look to other industries

- Innovation
- Holistic approach
- Effectiveness evaluation

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Questions