ANSI Homeland Security Standards Panel
Global Supply Chain Security Standards and Annual Plenary Meeting

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September 13, 2012 * ANSI-HSSP Workshop
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

Increased supply chain complexity and risk

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

#### 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?

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**Guidance through USP General Chapter Good Distribution Practices**
Supply Chain Management Overview

**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
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
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
Questions