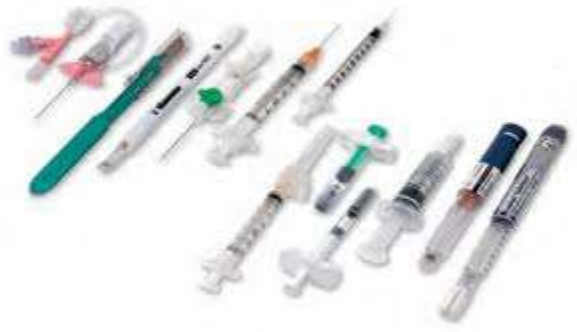
Overview of APEC Roadmap, Supply Chain Security Toolkit and Centers of Excellence

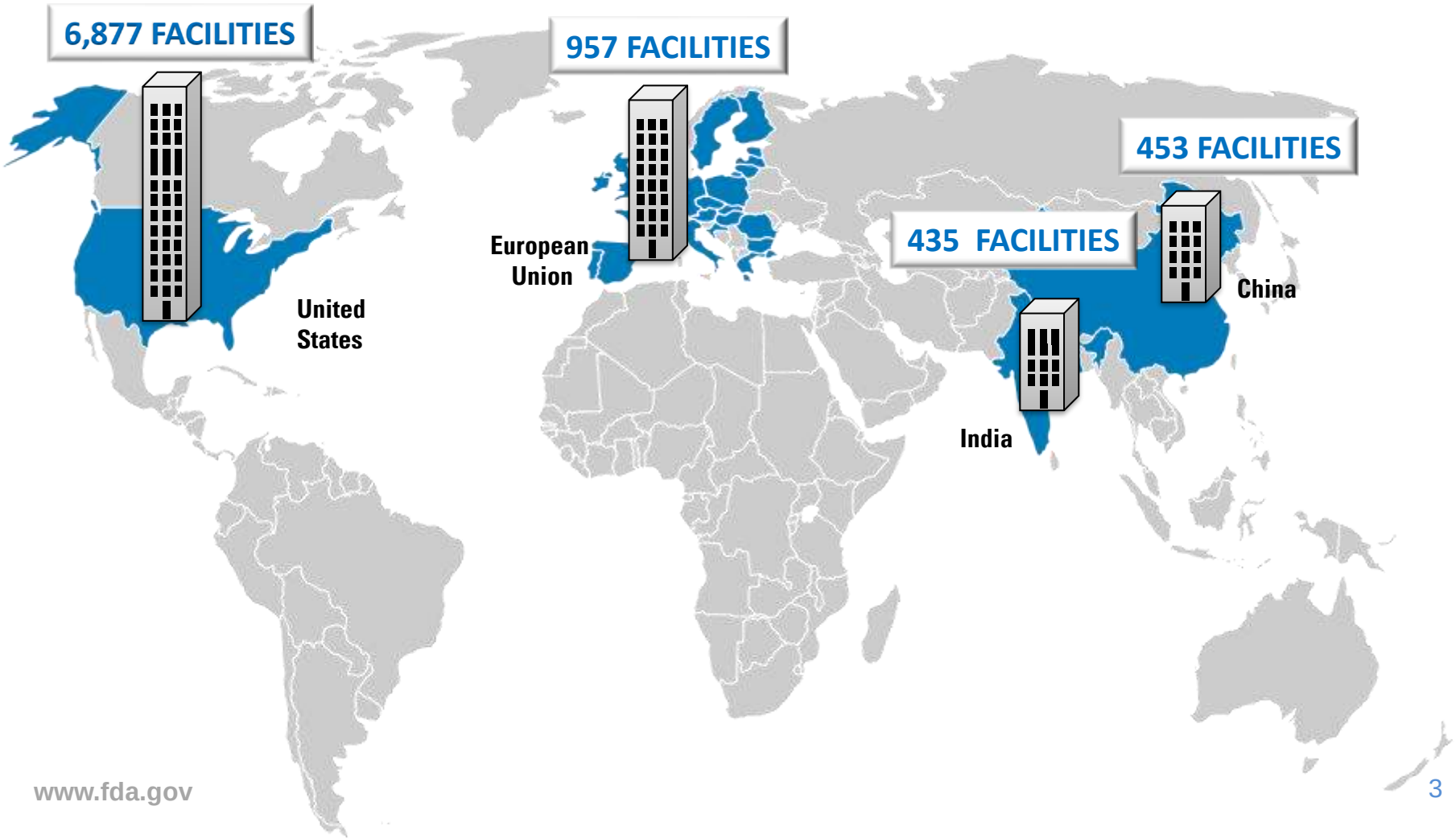


Lane Christensen, Ph.D.
U.S. Food and Drug Administration
Presented at:
2019 APEC CoE Pilot on Supply Chain Security
Taylor's University, Malaysia
September 25-27, 2019

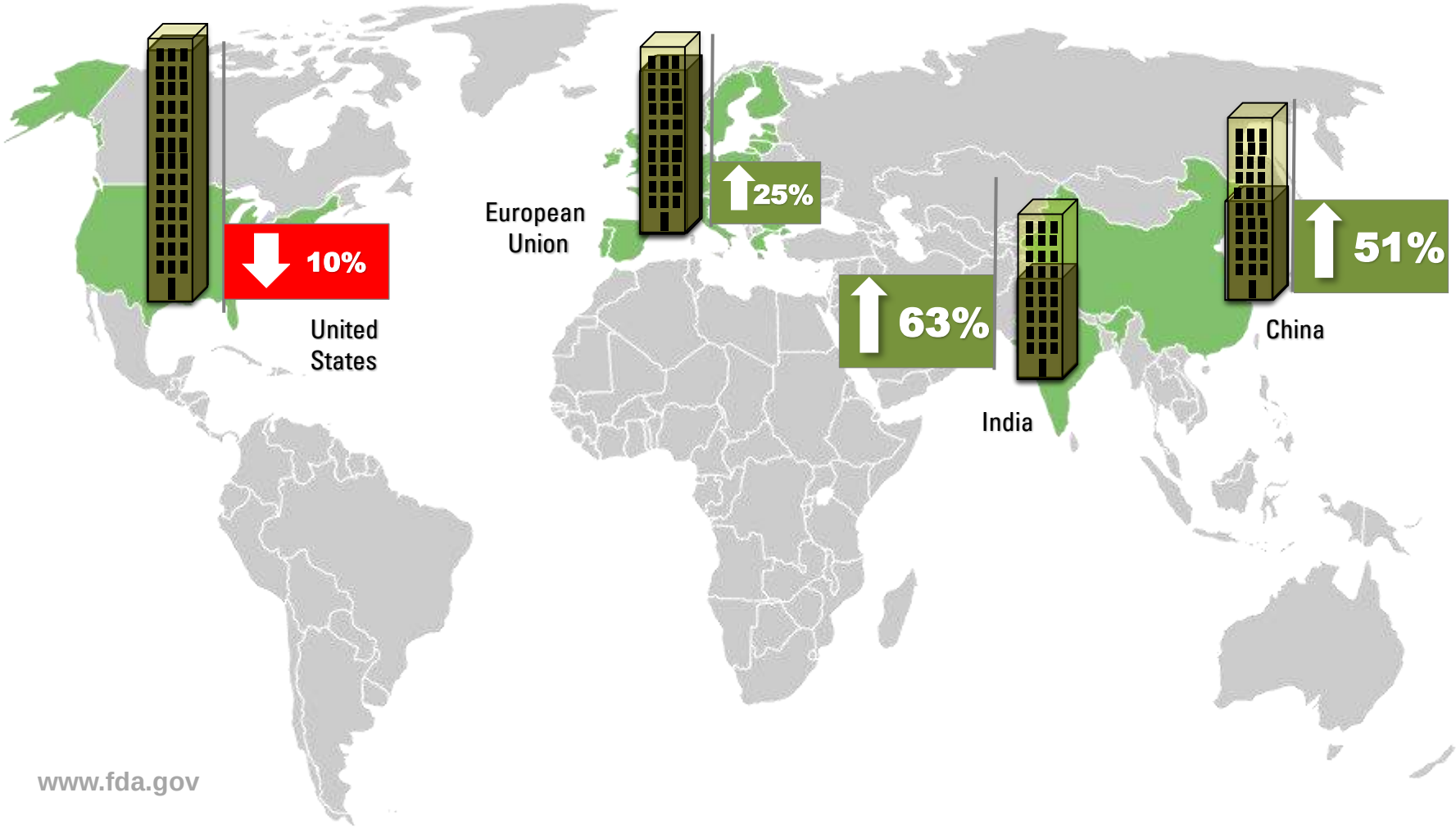
Presentation Overview

- Addressing the Problem
  - The Problem
  - Collaboration
- APEC Roadmap Project
  - Deliverables
  - Supply Chain Security Toolkit
  - Centers of Excellence

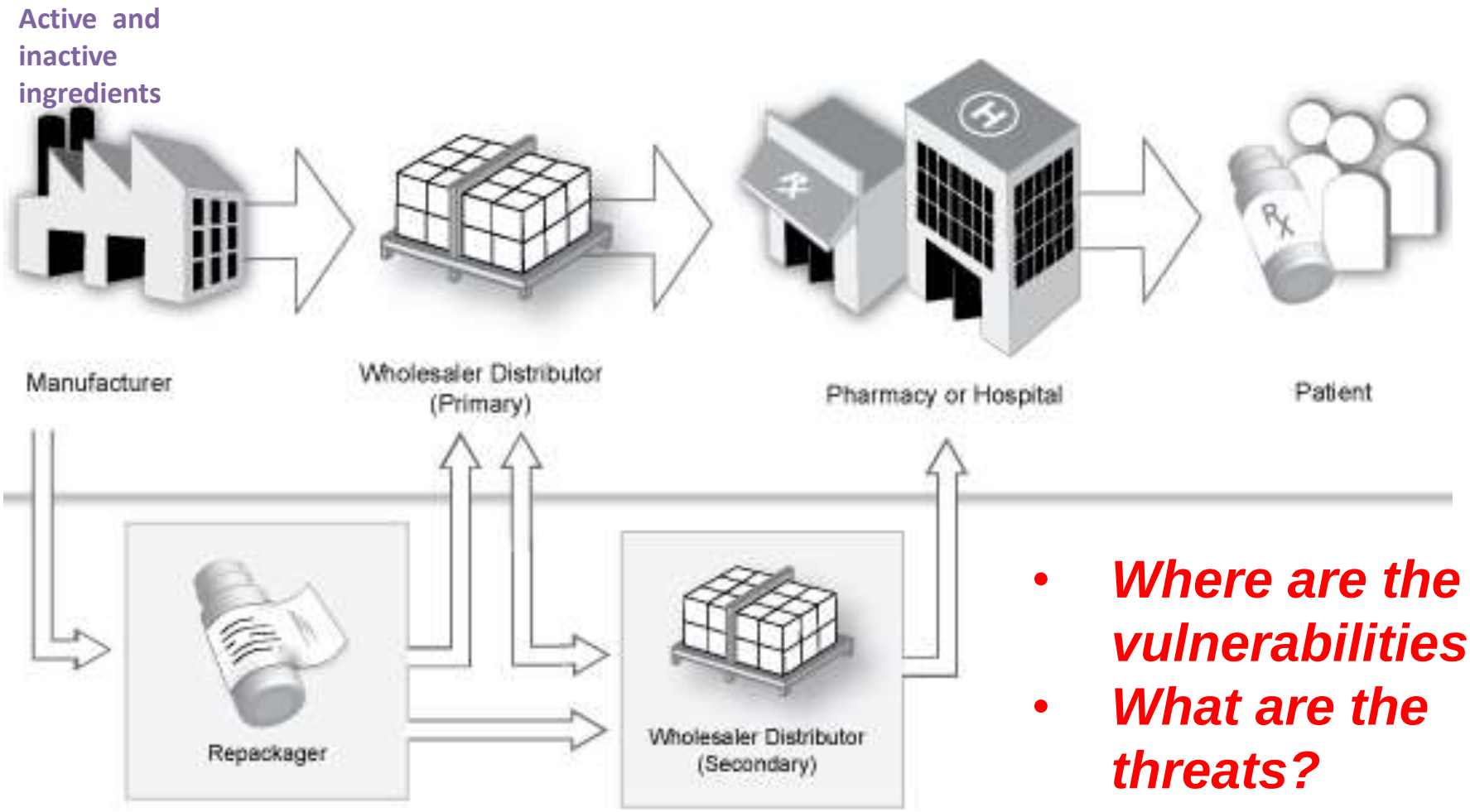
US FDA Registered Drug Facilities 2011



FDA Registered Drug Facilities
2018



Pharmaceutical Supply Chain

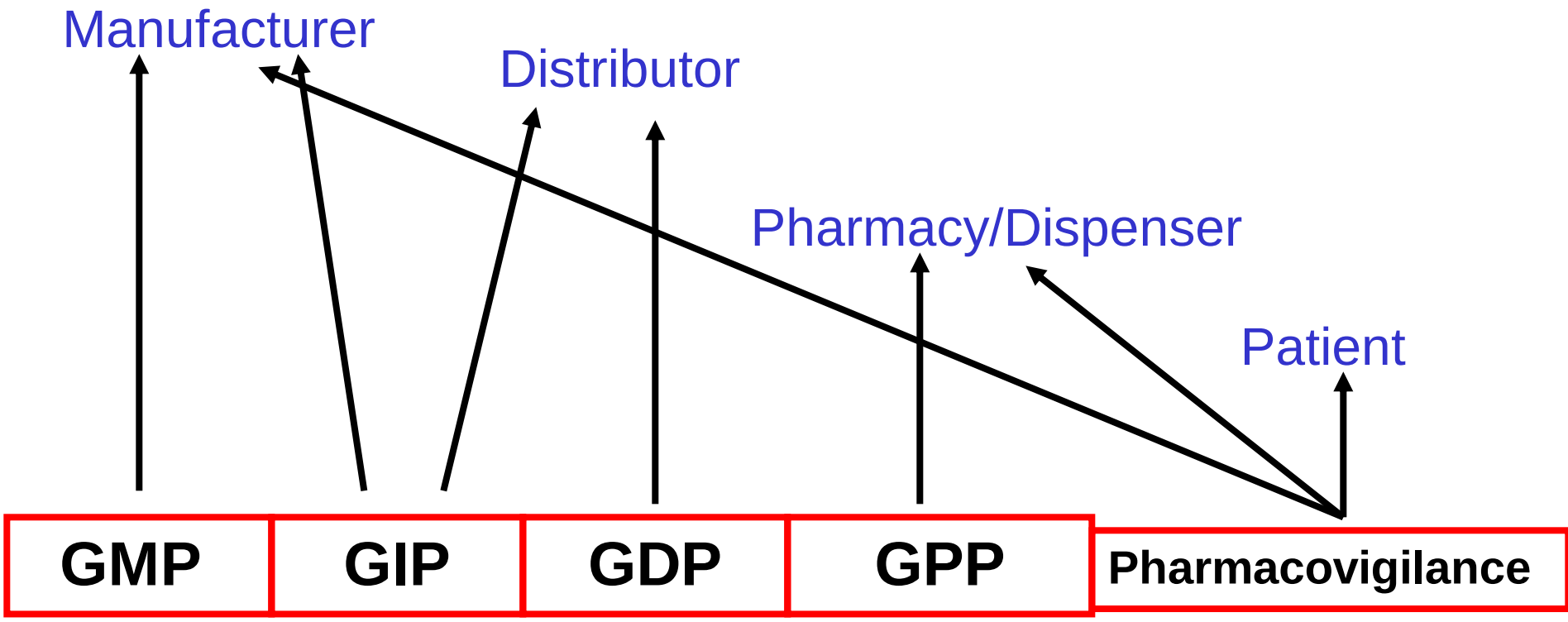


- ***Where are the vulnerabilities?***
- ***What are the threats?***

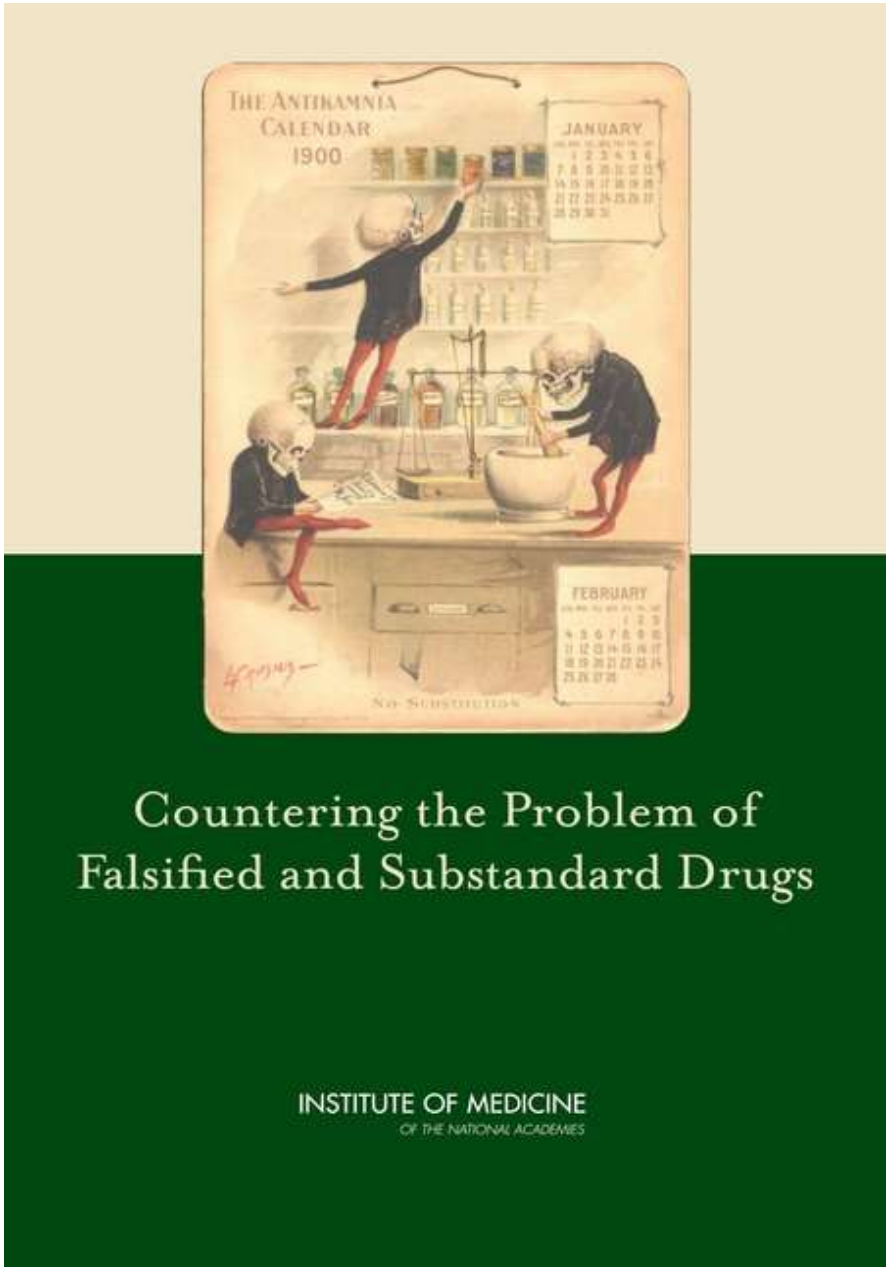
Protect the product → **Protect the patient**

Building on GxPs & pharmacovigilance

"Filling in the supply chain holes"

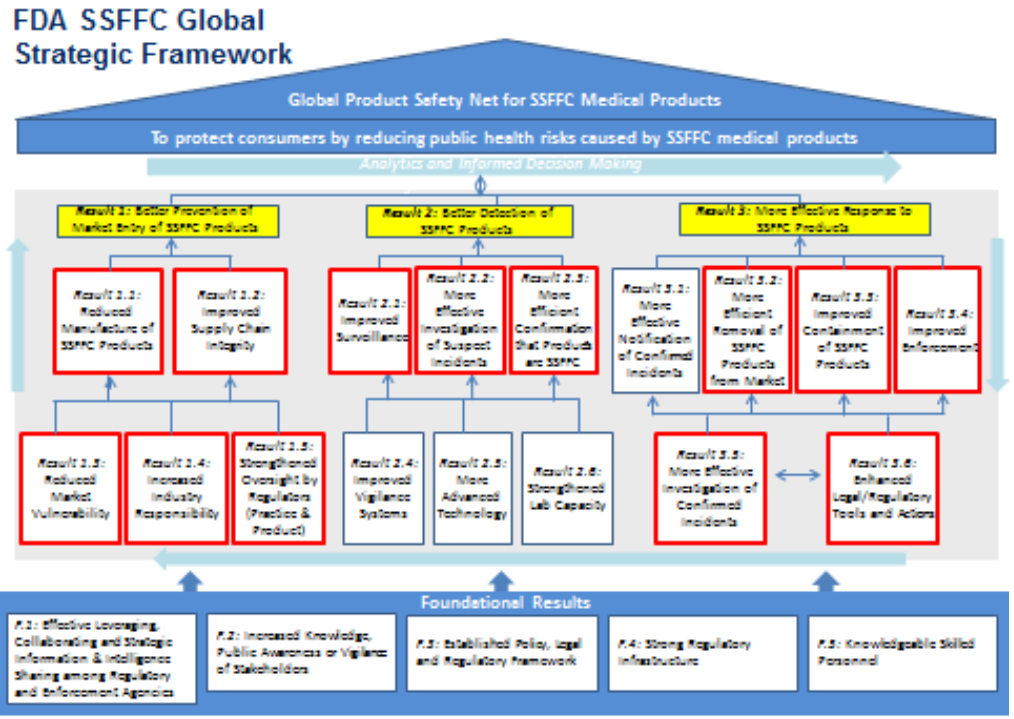


GMP=Good Manufacturing Practice, GIP=Good Importer Practices, GDP=Good Distribution Practice, GPP=Good Pharmacy Practice



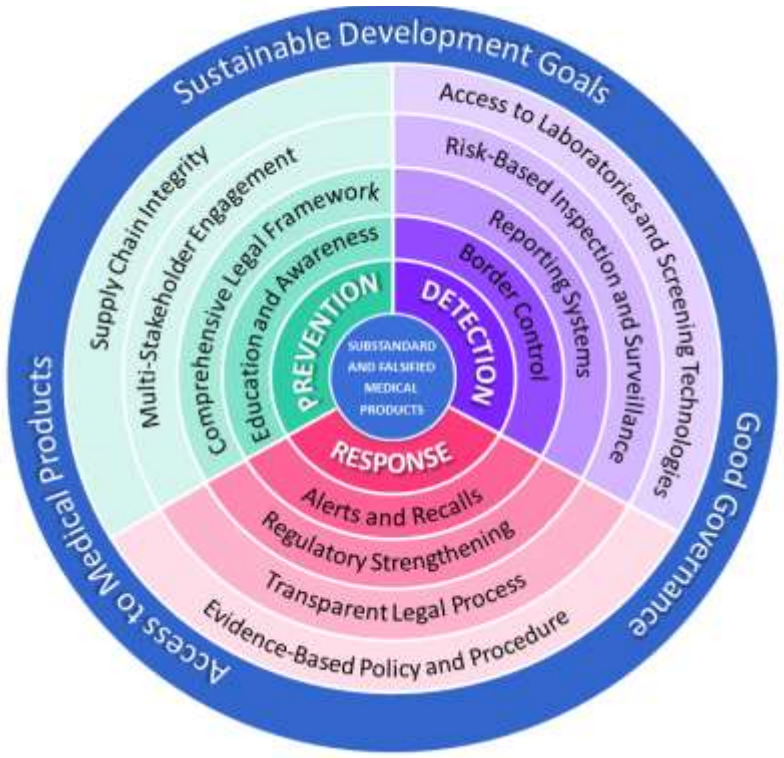
Institute of Medicine (IOM) Report – Published in February 2013

The FDA asked the IOM to assess the global public health implications of falsified, substandard, and counterfeit pharmaceuticals to help jumpstart international discourse about this problem.



Strategies and activities to combat substandard and falsified medicines

World Health Organization



Pan American Health Organization

INTERPOL

APEC
Asia-Pacific Economic Cooperation

WORLD TRADE ORGANIZATION

We must collaborate!!

- Why?

  It's a global problem, that needs global solutions

- How?
  - Share information
  - Work regionally, multilaterally
    - APEC, WHO, PAHO, others….

Asia-Pacific Economic Cooperation

FDA

- APEC is an international organization with the primary goal of facilitating sustainable economic growth and prosperity in the Asia Pacific Region.
- APEC provides funding for about 100 projects a year, which are open to participation for all 21 APEC member economies.
- The *Roadmap for Global Medical Product Quality and Supply Chain Security* was endorsed by the Life Science and Innovation Forum's Regulatory Harmonization Steering Committee (RHSC) in 2013.

Project Overview

- WHAT is the objective of the Roadmap?
  - Our *Roadmap for Global Medical Product Quality and Supply Chain Security* covers the entire supply chain and life cycle of medical products, from beginning to end (raw materials to patients).

- WHO is involved?
  - Regulators, industry members, academics, and other stakeholders from across the APEC economies, and EU, Africa, and other parts of South America.
  - US FDA is the Roadmap champion.

Work Groups

- Track and Trace Systems
- Good Distribution Practices
- Good Manufacturing Practices
- Good Import/Export Practices
- Clinical and Retail Pharmacy Practices
- Product Security
- Detection Technologies
- Single Points of Contact
- Internet Sales
- Surveillance and Monitoring Systems

Work Products

- "Final Report: APEC Roadmap to Promote Global Medical Product Quality and Supply Chain Security"
- Supply Chain Security Toolkit
  - Contains training materials intended to educate regulators, industry members, and others on a particular part of the supply chain, including items such as best practices, guidance documents,
  - Internet site:
    - Interactive PDF that pulls together the work from across the various work groups/toolkits into one place on the internet.
    - instructional videos, etc

INTERACTIVE SUPPLY CHAIN TOOLKIT

http://www.nifds.go.kr/apec/SupplyChain/APEC_SupplyChainToolkit_170317.pdf

Roadmap for Supply Chain Security

Member economies of the Asia Pacific Economic Cooperation (APEC) and non-APEC economies alike are adversely impacted by the international movement of substandard and falsified (S&F) medical products. As the medical products industry has become more globalized and specialized, economies must increasingly rely on the global marketplace to provide the medical products needed to keep citizens healthy and ensure that access to legitimate products is not disrupted. In an effort to address this modern issue, regulators, industry stakeholders, representatives from non-governmental organizations, international organizations, and academics from across the globe have come together as members of the "Roadmap to Promote Global Medical Product Quality and Supply Chain Security" ("Roadmap for Supply Chain Security") project, a collaborative multi-year project commissioned by APEC with oversight by its Life Science and Innovation Forum (LSIF) and the Regulatory Harmonization Steering Committee (RHSC). This work culminated in the development of this Supply Chain Security Toolkit. The Supply Chain Security Toolkit is intended to cover the entire supply chain and life cycle of medical products (i.e. raw materials to use by patients) and focuses on developing— and implementing through training programs— processes, procedures, and tools directed at enhancing global medical product quality and supply chain security. The Supply Chain Security Toolkit contains recommended best practices and tools to prevents and detect S&F medical products before they reach the consumer and to efficiently respond to incidents involving S&F medical products.

Comprehensive product quality and supply chain security requires a multilayer approach that includes prevention, detection, and response strategies and actions. The Supply Chain Security Toolkit is a comprehensive resource that addresses areas of vulnerability in the medical product supply chain. It contains recommended best practices and tools to prevent and detect S&F medical products before they reach the consumer and to efficiently and effectively respond to incidents involving S&F medical products. This section highlights the utility of the toolkit in in the prevention, detection, and response of S&F medical products.

In addition, the Supply Chain Security Toolkit can be used in conjunction with the World Health Organization's (WHO) guidance on developing a national plan for preventing, detecting, and responding to actions, activities, and behaviors that result in S&F medical products. This guidance is linked below.

Note: the APEC Supply Chain Security Toolkit was developed prior to the endorsement of the WHO S&F definitions and should be viewed as in alignment with the S&F definitions agreed upon by WHO Member States.

FINAL REPORT: APEC Roadmap to Promote Global Medical Product Quality and Supply Chain Security: Supply Chain Security Toolkit

Prevention....Detection....Response

World Health Organization: Guidance on Developing a National Plan for Preventing, Detecting, and Responding to Actions, Activities, and Behaviours that Result in Substandard and Falsified Medical Products

PREVENTION

Preventing Substandard and Falsified (S&F) products from entering the supply chain requires, among other things:

- Improving transparency, accountability, and integrity of the supply chain by ensuring compliance with robust current good manufacturing, distribution, and pharmacy practices.
- Implementing track and trace systems and end-to-end product security and supply chain solutions to help ensure medical products are legitimate and enhance detection of illegitimate drugs.
- Ensuring robust import and export regulations to protect the legitimate medical product supply chain from entry of S&F products.
- Strengthening oversight of the sale of medical products on the Internet, including who may sell and what may be sold, in order to prevent the entry of S&F medical products into the supply chain.

DETECTION

Detecting *Preventing Substandard and Falsified (S&F) products in the supply chain requires, among other things:*

- Incorporating detection technologies in order to improve surveillance and monitoring and identify products that are S&F.
- Improving surveillance, investigation, and actions against suspect S&F medical products.

RESPONSE

Responding *to incidents of Preventing Substandard and Falsified (S&F) products in the supply chain requires, among other things:*

- Establishing a single point of contact (SPOC) program among the national medical regulatory agency, law enforcement, and others in order to facilitate coordination, communication, and information-sharing regarding incidents with medical products.
- Improving communication about incidents by reporting to the global surveillance and monitoring system for S&F medical products.

WHO Guidance on Developing a National Plan for Substandard and Falsified Medical Products

Appendix 1

GUIDANCE ON DEVELOPING A NATIONAL PLAN FOR PREVENTING, DETECTING AND RESPONDING TO ACTIONS, ACTIVITIES AND BEHAVIOURS THAT RESULT IN SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/FALSIFIED/COUNTERFEIT (SSFFC) MEDICAL PRODUCTS

INTRODUCTION

1. Actions, activities and behaviours that result in SSFFC medical products are a local and global health problem related to the integrity of the manufacturing and supply chain that must be prevented, detected and effectively responded to, while maintaining a public health perspective.

2. The problem is potentially more severe in countries with weak or nonexistent health regulatory systems and health surveillance infrastructures. These characteristics increase the risk that medical products that are not in compliance with national and regional health regulations will be manufactured and/or distributed – a scenario that puts patients at risk.

3. High prices, inadequate access to affordable medicines, and drugs in shortage are incentives for actions, activities and behaviours that result in SSFFC medical products. These problems must be tackled from the public health perspective.

4. Attention should also be given to the supply of SSFFC medical products through the Internet,


Single Points of Contact
Good Manufacturing Practices
Surveillance and Monitoring
Good Distribution Practices
10
1
9
2
SUPPLY CHAIN
SECURITY
TOOLKIT
for Medical Products
Track and Trace System
8
3
Good Import/ Export Practices
7
4
6
5
Internet Sales
Clinical and Retail Pharmacy Practices
Detection Technology
Product Security

Good Manufacturing Practices (GMP)

Appropriate manufacturing is essential for global medical product quality and supply chain security. The materials below identify best practices related to medical product supply chain security, providing current good manufacturing practices (CGMP) recommendations for stakeholders. These recommendations for best practices are intended to minimize divergent practices and opportunities for the introduction of substandard and falsified (S&F) medical products into the global supply chain.

The information and materials below are intended for industry stakeholders and National Medical Regulatory Authorities (NMRAs)-

1. Industry may use this information to adopt best practices;
2. NMRAs may use this information to strengthen laws and regulations; and
3. Industry and government may use for training purposes.

GMP Tools

★ Introduction	Good Regulator Practices	Supply Chain Verification	Outsourcing
Show and Shadow Factories	Incoming Material Checking	Yield and Reconciliation	Repackaging
Product Release Procedure	Rejected and Returned Material	★ GMP GAP Assessment	

Conclusions and Recommendations

- The manufacturing practices work group has reviewed a wide range of global GMP standards and distilled out the best practices in terms of implementation by industry as well as supervision by regulatory authorities.
- The work group's recommendations are
  - Relevant regulators in APEC economies consider whether GMP legally applicable to manufacturers on their territories is compatible with these best practices or whether they need to take action to update applicable requirements or at least to promote these best practices as the appropriate interpretation of existing GMP requirements.
  - Similarly regulators should assess their own systems for supervision of manufacturers on their territories against the regulatory best practices identified in this document and consider whether improvements need to be made.
- Manufacturers located in the APEC economies should also look at the best practices identified in this report and seek to implement them in their day to day operations regardless as to the local regulatory framework in which they operate
- The working group has develop this training materials to help with the above

Centers of Excellence (CoE)

- The RHSC endorsed two programs for supply chain security:
  - United States Pharmacopeial Convention (USP)
    - Training--- March 2017
  - University of Tennessee Health Science Center (UTHSC)
    - Training---June 2017
- The RHSC endorsed an additional pilot program for supply chain security:
  - Taylor's University, Malaysia
    - September 2019

Thank You!!!!

Lane Christensen, Ph.D.
U.S. Food and Drug Administration

Lane.Christensen@fda.hhs.gov