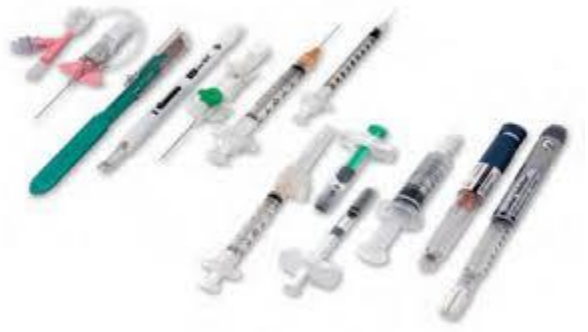
Roadmap to Promote Global Medical Product Quality & Supply Chain Security



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Agenda

- Background/history/scope of the Priority Work Area (PWA) – Global Supply Chain Security
- PWA Roadmap, updates and plans for 2021
- Role, structure & recent highlights from PWA Steering Committee
- List of Centers of Excellence (CoEs)/Pilot CoEs and programs
- Toolkit
- Supply chain – importance of global and multidimensional toolkits

Background/history/scope of PWA

- *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)

- Regulators, industry members, academics, and other stakeholders from across the APEC economies, European Union, Africa, and parts of South America

- US FDA is the Roadmap champion

PWA Recent Updates & Plans

- PWA participated in APEC SCCP SOM I in 2021 organized by New Zealand's Ministry of Health in February

- High interest in PWA efforts in the supply chain including the information contained in the Toolkit especially due to COVID-19 pandemic and its need for vaccines globally

- Consider updates and additions to the current Toolkit where new information from pandemic experiences could be valuable for our stakeholders

Supply Chain Security Steering Committee

- Purpose: Provide strategic direction, coordination, and oversight for training and other initiatives undertaken by the Centers of Excellence (CoEs)
- Frequency: Meetings are held quarterly
- Role of CoEs: Agent for feedback loop & follow through among participants including the users of training materials
- Core Curriculum & Performance Indicators: Workshops
- Toolkit Updates: Process for identification, coordination & prioritization
- Membership & Participants: USP, Taylor's University joined in 2020, Roche, Merck, WHO, AHC, APEC RHSC Co-Chair

Centers of Excellence (CoEs)/Pilot CoEs

Organization Names	CoE Pilot programs (sponsored by AHC)	CoE programs (workshops)
United States Pharmacopeia (USP) - Rockville, Maryland, USA	February 2018, Singapore: Regulators Roundtable on Upstream Ingredient Quality	June 2019 at University of Chile, School of Pharmacy: Regulator Dialogue and Securing Quality in Upstream & Downstream Supply Chain (focused on GMP, Internet Sales, SPoC)
University of Tennessee Health Sciences Center (UTHSC) - Memphis, Tennessee, USA	June 2017, USA: Protecting Patient Safety in the Global Marketplace Through GDPs and Product Security Measures	
Taylor's University - Malaysia	3-day training in September 2019 in Malaysia, hosted by Taylor's and AHC: GDP, Track and Trace, Internet Sales	Virtual 2-day workshop in March 2021, to be hosted by Taylor's and USP: Track and Trace, and GDP

New CoE: Completed in 2021

- Taylor's University along with USP are holding their 1st training workshop (virtual) now
  - http://taylorscoe.org/future-training

- Taylor's University along with USP have been delivering 3 webinars since late 2020
  - http://taylorscoe.org/webinars

What the toolkit contains

- Toolkit was updated in the spring, 2020
  - Maintained by the APEC Harmonization Center (AHC) at the following link: http://www.nifds.go.kr/apec/SupplyChain/APEC_SupplyChainToolkit_170317.pdf

- Supply Chain Security Toolkit
  - Contains training materials intended to educate regulators, industry members, and others on a particular part of the supply chain, including its best practices, guidance documents, etc.
  - On internet site, interactive PDF pulls together the work from across the various work groups into one place called the toolkit.

- "Final Report: APEC Roadmap to Promote Global Medical Product Quality and Supply Chain Security"


Asia-Pacific Economic Cooperation
HOME
ROADMAP FOR SUPPLY CHAIN SECURITY
CENTERS OF EXCELLENCE
CONTACT
Single Points of Contact
Good Manufacturing Practices
Surveillance and Monitoring
Good Distribution Practices
Track and Trace System
Good Import/ Export Practices
SUPPLY CHAIN SECURITY TOOLKIT
for Medical Products
Internet Sales
Clinical and Retail Pharmacy Practices
Detection Technology
Product Security
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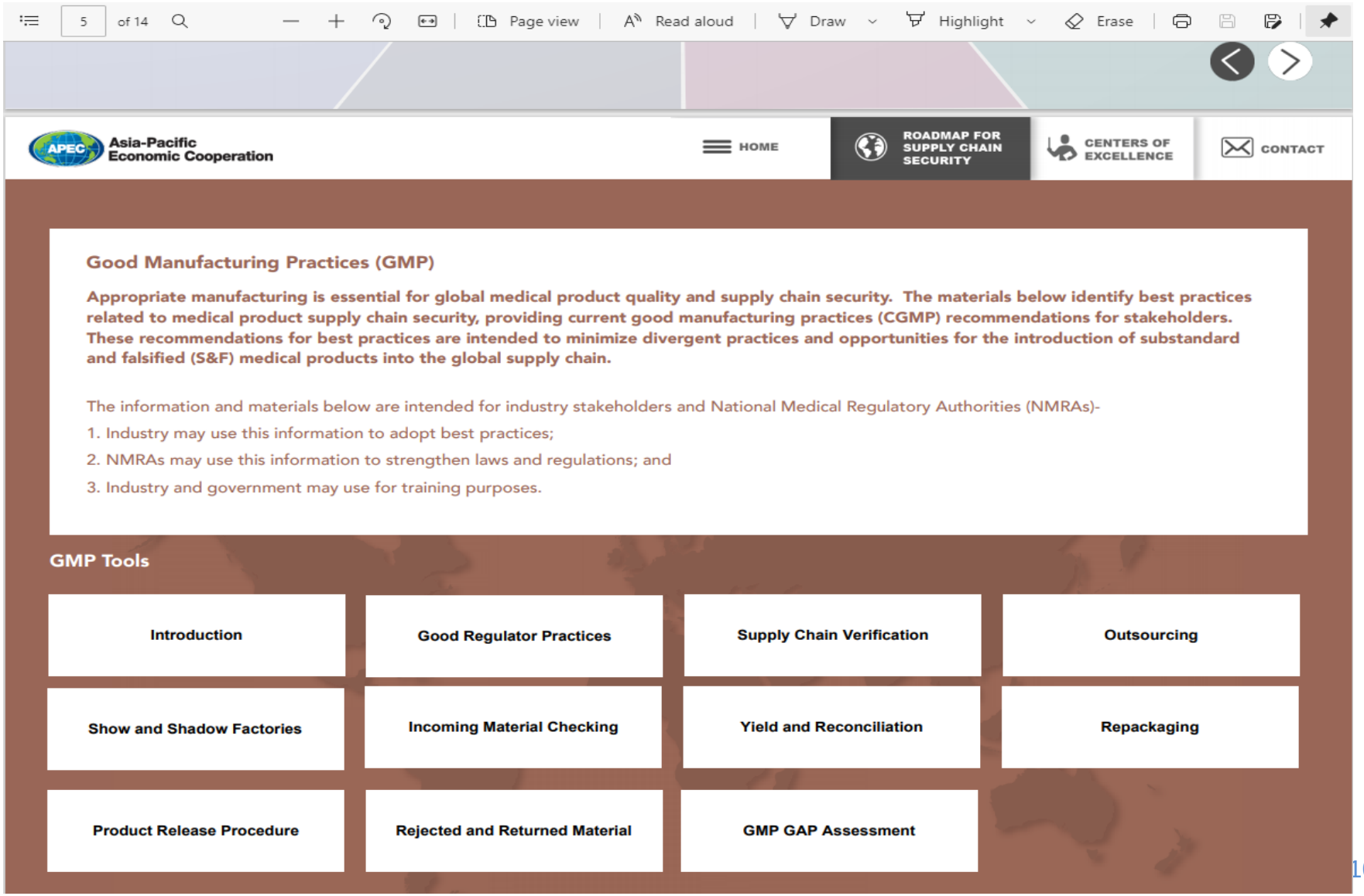
Toolkit: GMP workstream



Supply Chain Security Toolkit

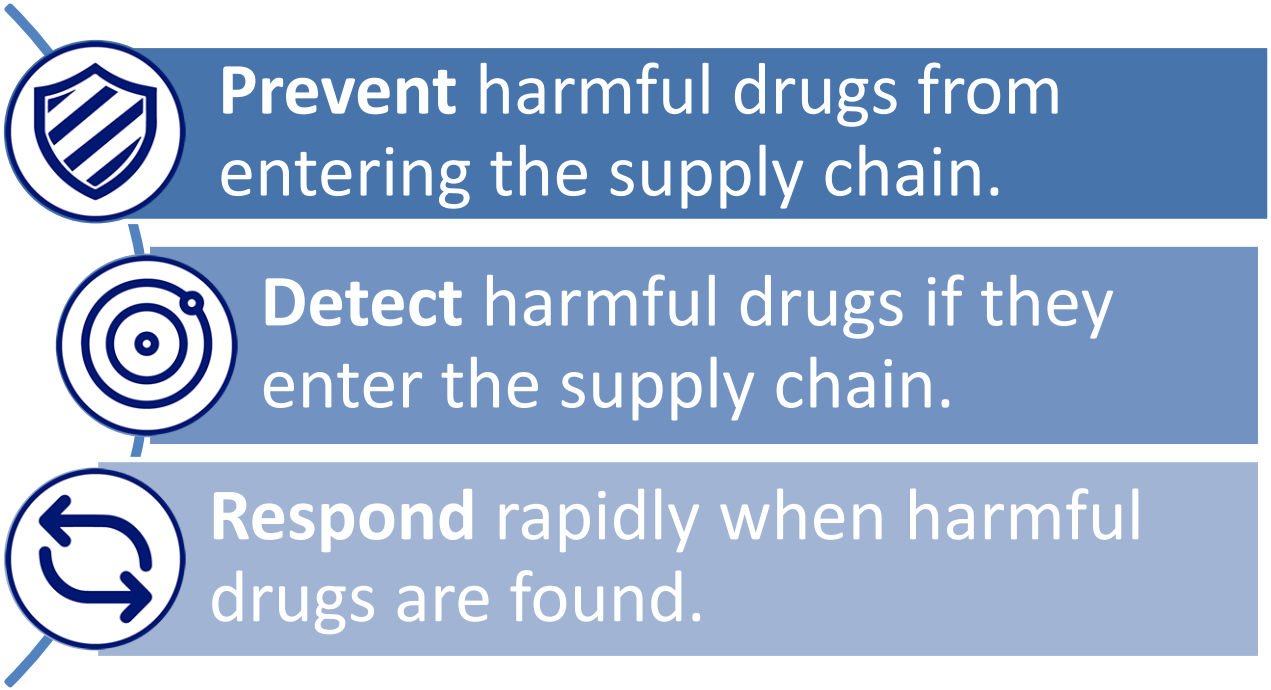
- Updates
  - Steering Committee established process for prioritizing, reviewing and accepting proposed updates
    - Updated Surveillance and Monitoring toolkit in 2019
    - Updated Product Security toolkit in 2020
  - Steering Committee facilitates/implements updates with the APEC Harmonization Center
  - Established feedback loop with CoEs to help determine which toolkits need revision

Supply Chain Security Toolkit

- Currently…
  - Industry experts are discussing potential updates to the Internet Sales toolkit
  - Steering Committee is looking to leverage ability of CoEs to partner across non-APEC economies to maximize return on investment for training

Life Cycle of medical product in the supply chain

Be vigilant and diligent!!



THANK YOU!!

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