

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

# New CoE: Completed in 2021

- Taylor’s University along with USP are holding their 1<sup>st</sup> 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>



Regulatory Harmonization Steering Committee (APEC), Life Sciences Innovation Forum (LSIF), TAYLOR'S UNIVERSITY (Widely • Integrity • Excellence), usp, MINISTRY OF HEALTH MALAYSIA

## THE TECHNOLOGY FOR IMPLEMENTATION OF TRACK AND TRACE

THIRD IN A SERIES OF MONTHLY WEBINARS HELD CONSECUTIVELY OVER 3 MONTHS LEADING TO A 2-DAY VIRTUAL TRAINING IN MARCH 2021

**24<sup>TH</sup> FEBRUARY 2021 | 9:00am – 10:30am**  
(Malaysia/Singapore Time) (+8 hours GMT)



**'THE EVOLUTION JOURNEY FROM BATCH CODING TO TRACEABILITY BY USING GLOBAL STANDARDS'**  
**Volker Ditscher**  
 Director of Global Sales Track & Trace, WIPOTEC-OCS  
 Bio LinkedIn: <https://www.linkedin.com/in/volkerditscher/>

**'IMPLEMENTATION OF TRACK AND TRACE AND COST CONSIDERATIONS IN TECHNOLOGY-LIMITED COUNTRIES'**  
**Daniel Laverick**  
 Head of SAP & IT Solutions, Zuellig Pharma  
 Bio LinkedIn: <https://www.linkedin.com/in/daniel-laverick-6580101a>

**OBJECTIVES**

- This webinar will discuss the current trends in implementation of track and trace in the pharmaceutical supply chain, including:
  - ✓ To have an overview of the technology available/in use for Track and Trace.
  - ✓ To understand approaches such as serialization for Track and Trace.
  - ✓ To gain an awareness of the challenges in the implementation of Track and Trace.

**WHO SHOULD ATTEND**

- Regulators, Pharmaceutical industry personnel, healthcare workers, enforcement officers and those involved in the supply chain and logistics of medical products.

**REGISTER NOW!** via <https://forms.gle/G9HE4LU69NlunWZM6> or Scan QR Code here

 The 2-day Virtual Training will be held from 11<sup>th</sup> – 12<sup>th</sup> March 2021, with the theme "Good Distribution Practice and Track and Trace"

For enquiries, please email: [Taylors.APECCOE@taylors.edu.my](mailto:Taylors.APECCOE@taylors.edu.my) or go to [taylorscoe.org](http://taylorscoe.org)

Jointly organised by:  
 APEC-LSIF Taylor's University Centre of Excellence for Global Supply Chain Integrity  
 APEC-LSIF USP Center of Excellence for Global Supply Chain Integrity  
 Ministry of Health Malaysia

# 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](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”





# Toolkit: GMP workstream

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APEC Asia-Pacific Economic Cooperation | HOME | ROADMAP FOR SUPPLY CHAIN SECURITY | CENTERS OF EXCELLENCE | CONTACT

### 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	

# 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



## Global Drug Manufacturing Supply Chain



Illustration of drug manufacturing supply chain: A U.S. finished drug may be produced using an active pharmaceutical ingredient (API) made in China and ingredients made in Europe, Japan, or the U.S. These components may be shipped to India where the finished drug is manufactured and then imported into the U.S. for distribution.

## Be vigilant and diligent!!



**Prevent** harmful drugs from entering the supply chain.



**Detect** harmful drugs if they enter the supply chain.



**Respond** rapidly when harmful drugs are found.

# THANK YOU!!

## **Disclaimer**

This presentation is intended only to provide a general overview. It is not intended to be comprehensive nor does it constitute legal advice. Please refer to the appropriate guidances, regulations, or law for specific information.