

AGENDA



The University of Tennessee Health Science Center (UTHSC) and APEC Center of Excellence Pilot Program for Global Medical Product Quality and Supply Chain Security:

Protecting Patient Safety in the Global Marketplace Through GDPs and Product Security Measures

- Hot breakfast provided daily at The Peabody.
- Light refreshments provided on campus.
- Lunch provided daily on campus (College of Pharmacy Building.)
- Transportation provided from The Peabody Hotel to and from all sessions.

MONDAY, JUNE 26, 2017

6:00 – 8:00 pm

Introduction and Networking

The Peabody Hotel

149 Union Avenue, Memphis, TN 38103

Evening introduction and networking opportunity.

TUESDAY, JUNE 27, 2017

8:00 – 8:30 am

Registration

UTHSC College of Pharmacy

881 Madison Avenue, Memphis, TN 38163

Morning Session

Moderator: Mr. Brian S. Johnson, Program Co-Chair

Educate attendees on the problem global economies are facing relative to falsified medicines, how APEC and RHSC are responding via the Roadmap, and the tools available to them going forward via the Roadmap strategy/UTHSC Center of Excellence.

8:30 – 9:00 am

Introductions and Welcome

9:00 – 9:15 am

AHC Welcome/Opening Remarks via video

Dr. Yeowon Sohn

Director, AHC

UTHSC Welcome

Dr. Kennard Brown

Executive Vice Chancellor and Chief Operations Officer, UTHSC

9:15 – 9:45 am

The APEC Supply Chain Security Roadmap and Center of Excellence

Dr. Ilisa Bernstein

Deputy Director, Office of Compliance Center for Drug Evaluation and Research, FDA

Introduce and educate attendees on the overall “Roadmap” and APEC Center of Excellence. Goal is to put this workshop into perspective relative to the overall “Roadmap” strategy.

9:45 – 11:00 am

Falsified Medicines Case Studies (Regulator Perspective)

Mr. Mick Deats

Group Lead, Substandard and Falsified Medical Products, WHO (Switzerland)

Mr. Charles Grinstead

Assistant Special Agent in Charge, Kansas City Field Office, FDA

Dr. Rocio Delgado

The General Directorate of Medicines, Supplies and Drugs (DIGEMID) – Health Ministry, Peru

Provide real-life examples (blinded) from APEC economies on vulnerabilities in our supply chains. Goal is for attendees to understand supply chain weaknesses, criminal schemes, how detected, start thinking about solutions, and understand patient safety impact.

AGENDA (continued)

11:00 – 11:10 am

Break

11:10 am – 12:15 pm

**Falsified Medicines Case Studies
(Industry Perspective)**

Dr. Tony Zook

Executive Director-Product Integrity, Merck & Co., Inc.

Mr. Rich Kaeser

Vice President, Global Brand Protection, J&J

12:15 – 12:30 pm

Question and Answer Session

Morning Speakers

12:30 – 1:30 pm

Lunch

Afternoon Session

Moderator: Ms. Katie Neckers, Program Co-Chair

Educate attendees on holistic approaches to supply chain security from both an industry and regulatory perspective starting with strategy development. Expose attendees to actual examples of deployed strategies and key program elements. Assist attendees in identifying important supply chain issues affecting their markets/companies.

1:30 – 2:30 pm

**Supply Chain Security Strategies
(Regulatory Perspective)**

Dr. Ilisa Bernstein

Deputy Director, Office of Compliance Center for Drug Evaluation and Research, FDA

Mr. Mick Deats

Group Lead, Substandard and Falsified Medical Products, WHO, Switzerland (TBD)

2:30 – 3:30 pm

**Supply Chain Security Strategies
(Industry Perspective)**

Mr. Brian Johnson

Senior Director Supply Chain Security, Pfizer

Mr. Rich Kaeser

Vice President, Global Brand Protection, J&J

Dr. Tony Zook

Executive Director-Product Integrity, Merck & Co., Inc.

3:30 – 3:45 pm

Break

3:45 – 5:00 pm

**Supply Chain Security Strategies
Case Study**

All Speakers

WEDNESDAY, JUNE 28, 2017

Morning Session

Moderator: Mr. Mark Paxton

Educate attendees on select product security tools that can be used by regulators and industry stakeholders to mitigate supply chain security vulnerabilities. The first session of workshops will focus on product protection during transit, which will serve as preparation for our visit to a local wholesaler/logistics supplier.

8:30 – 9:00 am

**Keynote: “Improving Performance in
Pharmaceutical Supply Chains”**

Dr. Ernie Nichols

Associate Professor of Supply Chain Management,
University of Memphis

9:00 – 10:05 am

Rotating Sessions:

**Industry and Regulator Notification
Systems**

Dr. Tia Harper-Velasquez

Captain, United States Public Health Service Branch Chief,
Supply Chain Strategy & Policy Branch, Division of Supply
Chain Integrity, FDA

Mr. Brian Johnson

Senior Director, Supply Chain Security, Pfizer

Educate industry and regulators on systems and requirements companies and regulators need for notification of falsified medicines.

AGENDA (continued)

Preventing Product Diversion

Mr. Michael Cummins

Senior Operations Manager Special Agent Office of Criminal Investigations, FDA

Dr. Tony Zook

Executive Director-Product Integrity, Merck & Co., Inc.

Mr. Rich Kaeser

Vice President, Global Brand Protection, J&J

Risk factors and best practices to prevent product diversion and regulatory systems to support prevention, detection and response.

Intersection of GDP's and Product Security

Mr. Dave Ulrich

QA Director, Supply Chain Compliance, Abbvie

Mr. Tony Orme

Senior GDP Inspector, MHRA

A comparison of global GDP's, the convergence of key GDP attributes, auditing LSP's, and tools available for regulators and companies.

Supply Chain Academy/Rx-360 Training Programs

Mr. Claudio Mendes

Operations Executive, Pharmed Pharmaceuticals

An overview of Supply Chain Academy and Rx-360 training programs that can be deployed in your markets.

10:05 – 10:25 am

Break

10:25 am – 12:30 pm

Rotating Sessions (continued)

12:30 – 1:30 pm

Lunch

Afternoon Session

Moderator: Mr. Dave Ulrich

2:00 – 4:00 pm

Hands on Visit to McKesson

Mr. Harvey Thomas

Expose attendees to “GDPs in action” through a site visit to a large distribution center. Operational reviews will be given on product receipt, storage, picking, disposition controls, returns, destruction, re-packing, and transportation.

6:00 – 8:00 pm

Evening Social – Dinner and Tour

National Civil Rights Museum

450 Mulberry Street, Memphis, TN 38103

An informal gathering for drinks and dinner. Included in the price of your registration fee. Dress casual.

THURSDAY, JUNE 29, 2017

Morning Session

Moderator: Mr. Michael Cummins, FDA

Educate attendees on select product security tools from the “Roadmap” that can be used by regulators and industry stakeholders to mitigate supply chain security vulnerabilities. The second session of roundtable workshops will focus on product security and monitoring the marketplace.

8:30 – 9:00 am

Keynote: “An Overview of Quality Compliant Rd2Rx Track & Trace Approach for Drug Supply Chain Security Management”

Dr. Harry Kochat

Director of the Plough Center for Sterile Drug Delivery Systems, UTHSC

9:00 – 10:05 am

Rotating Sessions:

Regulatory Monitoring and Surveillance Programs

Mr. Mick Deats

Group Lead, Substandard and Falsified Medical Products, WHO, Switzerland (TBD)

Dr. Ilisa Bernstein

Deputy Director, Office of Compliance Center for Drug Evaluation and Research, FDA

AGENDA (continued)

Marketplace Surveillance and Criminal Investigation Programs

Dr. Tony Zook

Executive Director-Product Integrity, Merck & Co., Inc.

Mr. Michael Cummins

Senior Operations Manager Special Agent Office of Criminal Investigations, FDA

Educate attendees on systems and processes that companies can use to help detect falsified medicines in the marketplace and on industry and regulator collaborations and systems around criminal investigations and enforcement.

Mitigating Supply Chain Theft

Mr. Lee Spach

Director, Global Brand Protection & Supply Chain Security, Biogen

Dr. Tia Harper-Velasquez

Captain, United States Public Health Service Branch Chief, Supply Chain Strategy & Policy Branch Division of Supply Chain Integrity, FDA

Training session on preventing cargo theft/industry best practices for conveyance security and regulatory systems for reporting and responding to cargo thefts.

10:05 – 10:25 am

Break

10:25 am – 12:30 pm

Rotating Sessions (continued)

12:30 – 1:30 pm

Lunch

Afternoon Session

Moderators: Mr. Mick Deats and Dr. Ilisa Bernstein

Hands-on interactive workshop for industry stakeholders and regulators to apply prevention/detection/response framework to case studies and identify what can be applied to their markets or companies. Ideally, each attendee will leave with a plan for what they can take back to their companies or countries for further consideration.

1:30 – 3:30 pm

Workshop

3:30 – 3:50 pm

Break

3:50 – 4:45 pm

Session Discussion and Conclusions

4:45 – 5:00 pm

Closing Plenary Session

Dr. Kennard Brown

Executive Vice Chancellor and Chief Operations Officer, UTHSC