

2018 APEC Harmonization Center Global Supply Chain Integrity Training

August 28-30, 2018
Sheraton Seoul Palace Gangnam Hotel
Seoul, Republic of Korea

Dynasty Hall (B1F)
(Version updated on **June 25, 2018**)

Day 1: Tuesday, August 28 th , 2018		
Time	Topics	Speakers
09:00-09:30	Registration	
09:30-09:45	Welcome & Opening Remarks	Sun Hee Lee (AHC) KPBMA
09:45-09:55	Congratulatory Remarks	US FDA
09:55-10:05	Group Photo	
10:05-10:15	Break	
10:15-11:00	Introduction <ul style="list-style-type: none"> - Overview of APEC Roadmap, Toolkit, Center of Excellence - Objectives/Expectations for the 3 days 	Ilisa Bernstein (US FDA)
11:00-12:00	Prevention, Detection, Response <ul style="list-style-type: none"> - FDA's framework for Prevention, Detection, Response - WHO's Guidance for Developing a National Plan for Preventing, Detecting, and Responding to Actions, Activities, and Behaviours that Result in Substandard Falsified Medical Products" 	Ilisa Bernstein (US FDA) Diana Lee (WHO)
12:00-13:30	Lunch	
13:30-14:30	Prevention, Detection, Response (Continue) <ul style="list-style-type: none"> - Industry's strategies for Prevention, Detection, Response 	Anthony Zook (Merck)
14:30-15:00	Introducing Korea's Pharmaceutical Management System <ul style="list-style-type: none"> - Quality Management - Surveillance 	MFDS
15:00-15:15	Break	
15:15-15:45	Supply Chain Security Toolkit <ul style="list-style-type: none"> - High-level overview of the 9 Work Streams 	Ilisa Bernstein (US FDA)

Good Manufacturing Practice

15:45-16:45	<p><u>What's in the toolkit: Perspectives on GMP elements to secure supply chain integrity</u></p> <p>Regulatory Perspectives (30')</p> <ul style="list-style-type: none"> - Overview and goals of GMP that most impact supply chain integrity and the quality of medicines <p>Industry perspectives (20')</p> <ul style="list-style-type: none"> - Insight and Industry's view on GMP Principles as they apply to supply chain best practices <p><u>Discussion and Questions (10')</u></p>	<p>Alicia Mozzachio (US FDA - TBC)</p> <p>Jordi Vall-Llossera (Novartis)</p>
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Day 2: Wednesday, August 29th, 2018

Time		Topics	Speakers
09:00-09:30	30'	Registration	
09:30-09:45	15'	Introduction to Day's Objective	
Good Distribution Practice			
09:45-10:45	60'	<p><u>Introduction and Overview of Toolkit</u></p> <ul style="list-style-type: none"> - Why GDP is important and highlight of toolkit - Common inspection findings in GDP <p><u>Discussion and Questions:</u></p> <p>Audience sharing challenges and experiences in GDP implementation</p> <ul style="list-style-type: none"> - Examples of how to encourage best practice in implementing GDP 	<p>Tony Orme (MHRA);</p> <p>Chloe Lee (Roche)</p>
10:45-11:00	15'	Break	
Clinical and Retail Pharmacy Practice			
11:00-12:00	60'	<p><u>Key elements of Clinical and Retail Pharmacy Practices in the APEC Toolkit</u></p> <ul style="list-style-type: none"> - Overview of toolkit development, current tools and insights into adoption of best practices in diverse contexts - Engaging the provider: thinking through compounding practices in a supply chain context 	<p>Magaly Rodriguez de Bittner (University of Maryland - TBC)</p> <p>Damain Carattii (USPC - TBC)</p>
12:00-13:30	90'	Lunch	
Product Security			

13:30-14:30	60'	<u>Intro (15')</u> <ul style="list-style-type: none"> - Background and overview of product security section of the roadmap - Toolkit summary <u>Industry Application (15')</u> <ul style="list-style-type: none"> - Examples of how industry is using the toolkit <u>Regulatory Application (15')</u> <ul style="list-style-type: none"> - Examples of how regulatory body are using the toolkit <u>Discussion and Questions (15')</u>	Reggie Jackson (Pfizer) Anthony Zook (Merck) Eun Kyung Shin (MFDS)
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Detection Technology

14:30-15:30	60'	<u>Introduction (15')</u> <ul style="list-style-type: none"> - Introductory remarks, composition of the Detection Technology Working group, the process used for developing the detection technology toolkit and guidance document, past training programs and alignment with other RHSC working group <u>Detection Technology Toolkit and Overview & Guidance Document (30')</u> <ul style="list-style-type: none"> - Role of stakeholders, overview of what's included in the toolkit and guidance document, summary of toolkit and guidance document recommendations, and next steps and remaining tasks - Q & A and Discussion <u>Closing Remarks and Next Steps (10')</u>	Yin LiHui (NIFDC) Kevin Biggs (USPC)
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15:30-15:45	15'	Break	
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Internet Sales

15:45-16:45	60'	<u>Introduction</u> <ul style="list-style-type: none"> - Background - Internet Sales Work Group - Methodology <u>Overview of What's included in the Toolkit</u> <u>Next steps</u> <u>Discussion and Questions</u>	Katie Neckers (US FDA) Libby Baney (ASOP)
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Day 3: Thursday, August 30th, 2018

Time		Topics	Speakers
09:00-09:30	30'	Registration	

09:30-09:45	15'	Introduction to Day's Objective	
Track and Trace			
09:45-10:45	60'	<p><u>Goal of the Toolkit (5')</u></p> <ul style="list-style-type: none"> - Objective & Recommendations <p><u>Overview of What's included in the Toolkit ('45)</u></p> <ul style="list-style-type: none"> - Introductory: How to get started (20') <ul style="list-style-type: none"> • 1st Recommendation: Define Clear Objectives to be achieved • 2nd Recommendation: Collaborate with stakeholders - Intermediate: How to choose appropriate traceability model (10') <ul style="list-style-type: none"> • What is traceability • Traceability process approach • How to choose the appropriate traceability system? - Advanced: How to drive implementation of traceability requirements (15') <ul style="list-style-type: none"> • 3rd Recommendation: Recommend the use of GDS • Identify and Capture • Share <p><u>Discussion and Questions (10')</u></p>	Tania Snioch (GS1 Global Office)
10:45-11:00	15'	Break	
Surveillance and Monitoring System			
11:00-12:00	60'	<p><u>Introduction (15')</u></p> <ul style="list-style-type: none"> - Introductory Remarks and overview of WHO work on substandard and falsified medical products, including on the Global Surveillance and Monitoring System and Member State Mechanism <p><u>Overview of Toolkit (40')</u></p> <ul style="list-style-type: none"> - Overview of toolkit and prevention, detection and response approach - Practical application and use of toolkit (including the Global Focal Point Network) for participants - Next Steps <p><u>Questions and Discussion (10')</u></p>	Diana Lee (WHO)
12:00-13:30	90'	Lunch	
Single Point of Contact			
13:30-14:30	60'	<p><u>Intro ('10)</u></p> <ul style="list-style-type: none"> - Political initiative and operational concept for prevention and fight against trafficking of falsified medical products, global use of 	<p>Christian Tournie (OCLAESP)</p> <p>Lynda Scammell (MHRA)</p>

		<p>Medicrime</p> <p><u>Content ('15)</u></p> <ul style="list-style-type: none"> - Toolkit, multidisciplinary approach, CMED committee and SPOC principle (based on toolkit), interaction with other national and international initiatives <p><u>Sharing of practical experience (25')</u></p> <ul style="list-style-type: none"> - Outcome SPOC event (recommendations) and current projects - Example of a functional SPOC network, best practices and case example of SPOC cooperation <p><u>Discussion ('10)</u></p>	
14:30-14:40	10'	Break	
Hands-on Exercise			
14:40-16:05	85'	<p>Participant Exercise: Case Study</p> <ul style="list-style-type: none"> - Introduction (5') - Small Group Discussion (55') <p>Breaking into 5 small groups, participants will discuss utility of toolkits to mock scenario</p> <ul style="list-style-type: none"> - Reports out and Q&A (25') 	<p>Moderator:</p> <p>Ilisa Bernstein (US FDA)</p>
16:05-16:15	10'	Break	
Overview of Center of Excellence (CoE) – Panel Discussion			
16:15-17:00	45'	<p>Lessons learned from pilot CoEs</p> <ul style="list-style-type: none"> - United States Pharmacopeia (USP) - University of Tennessee Health Science Center (UTHSC) <p>Perspectives on APEC Center of Excellence</p> <ul style="list-style-type: none"> - Kanazawa University <p>Panel Discussion</p>	<p>Moderator:</p> <p>Ilisa Bernstein (US FDA)</p> <p>Panel:</p> <p>Phillip Nguyen (USPC)</p> <p>Kennard Brown (UTHSC)</p> <p>Kazuko Kimura (Kanazawa Univ.)</p>
17:00-17:10	10'	Closing	