



USP-APEC Center of Excellence Minimizing Quality Risks in the Upstream and Downstream

Supply Chain | *Regulators Dialogue & Training*

Tuesday, June 11th, 2019 – Thursday June 13th, 2019

WE ANTICIPATE SIMULTANEOUS TRANSLATION [ENGLISH-SPANISH]

DAY 1, Plenary & Ingredient (Excipient) Quality

*Draft/notional agenda: Agenda items and speakers may change

Day 1 JUNE 11th

8:00am – 9:00am	Arrival/Sign-In
Plenary Session 9:00am – 9:30am	Welcome and Opening Remarks <ul style="list-style-type: none"> University of Chile Representative USP-APEC CoE Representative ASOP Global Representative US-FDA Representative Chile-ISP Representative
Key Note Sessions 9:30am – 9:40am	Overview of APEC Road Map to Promote Global Medicine Product Quality and Supply Chain Security; <i>Katharine Neckers (US Food and Drug Administration (US-FDA))</i>
9:40am – 9:50am	Context and Goals for the CoE Program (2.5 days) <i>Phillip Nguyen; USP-APEC CoE Director</i> <ul style="list-style-type: none"> The Current Global State of Substandard/Falsified Medicines Securing quality in the Upstream and downstream supply chain: From Ingredients (Excipient) Quality, to Internet Sales
Panel Session 9:50am – 10:50am	GMP and Quality – Sharing perspectives from APEC and Latin America Moderator: John Giannone (<i>SMPO-Excipients, USP</i>) <i>Regulators share their existing regulatory agencies efforts on GMP and Quality, helping attendants understand key components of systems, collaborations, and general observations:</i> <ul style="list-style-type: none"> USA [~5 MIN] Chile [~5 MIN] Mexico [~5 MIN] Peru [~5 MIN] Philippines [~5 MIN] CARPHA [~5-7 MIN] Brazil [~5 MIN] Other economies maybe present [~10 mins] <i>Questions and Answers</i>
10:50 am – 11:05 am	BREAK
Keynote Session 11:05am – 12:30 pm	Good Manufacturing Practices (GMP) Supply Chain Tool Kit and Ingredient (Excipient) Quality; <i>Karen Takahashi (US-FDA) & Catherine Sheehan (Science-Excipients, USP)</i> The toolkit: Perspectives on GMP elements & supply chain integrity [US FDA]

Securing Medical Product Quality Through the Supply Chain



Regulatory Harmonization Steering Committee



Life Sciences Innovation Forum

	Ingredient (excipient) quality and applying the APEC GMP tool kit [USP] <ul style="list-style-type: none"> • Incoming material checking • Supplier Qualification/Verification • Quality Assurance/Quality Control and Product Release • Other tools and considerations
12:30pm – 2:00 pm	LUNCH
Breakout Session 2:00pm – 3:00pm	Case Study: Exploring GMP from an Ingredient Quality Perspective: Glycerin <i>John Giannone (Senior Director, SMPO-Excipients, USP) and Facilitators</i> <ul style="list-style-type: none"> • Introduce case [~10 min] • Breaking into small groups, participants will discuss approaches to a Glycerin historical case of substandard product quality using a discussion guide [~40 min]
Discussion Reflections 3:00 pm – 3:30 pm	Readout summaries from small groups (5-7 minutes per group) <i>Facilitators, all participants</i>
3:30pm – 3:50 pm	BREAK & Photo session
4:00pm – 4:40pm	Ingredients and Upstream Quality – Roundtables’ Reflections for Regulatory Practice: ‘Who to tell, What to look out for, What to bring back, What More to Understand’ <i>Moderator: Phillip Nguyen & Damian Cairatti (USP)</i> Reflecting on group readouts, participants will discuss how they plan to incorporate approaches, tools, and practices discussed to secure ingredient, answering the 4 questions posed above.
4:40pm – 4:50pm	Summary from Day 1: Organizers
4:50pm – 5:00pm	Housekeeping Announcements DAY 1 CLOSE

DAY 2, E-Commerce/ Internet Sales

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Day 2 JUNE 12th

8.30 am – 9.00 am	Arrival/Sign-In
Plenary Session 9:00am – 9:15am	Introductory Comments Representative, <i>Chile ISP</i> Overview of Day 2 Goals-ASOP Organizers
9:15am – 9:30am	Recap of Day 1 Discussion and Outputs [flip] Damian Cairatti (<i>USP</i>)
9:30am – 10:00am	Safe Online Pharmaceutical Sales – A Priority Issue [flip] Chile-ISP Representative
Keynote Session 10:00am – 10:30am	Summary of Implementation: APEC Internet Sales Toolkit and RHSC Supply Chain Medical Product Integrity Roadmap Katharine Neckers (<i>US-FDA</i>)
10:30am – 10:45am	BREAK
Keynote Session 10:45am – 11:30am	Global Internet Pharmacy Best Practices – Lessons Learned from Building Relationships Libby Baney (<i>The Alliance for Safe Online Pharmacies (ASOP Global)</i>)

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11:30am – 12:15pm	Existing Industry Initiatives to Promote Safe Medicines Kevin Currier (<i>Pharmaceutical Security Institute-Americas (PSI)</i>)
12:15pm – 1:30pm	LUNCH
International Session 1:30pm – 2:20pm	Models for Cooperation: from Operation PANGEA to the Medicrime Convention Oscar Alarcon Jiménez (<i>Council of Europe</i>) A European economy perspective Lynda Scammell (<i>United Kingdom-MHRA</i>) A Civil Society Perspective Mike Isles (<i>ASOP-Europe</i>)
Participant Breakouts 2:20pm – 3:45pm	Breakout Session #1: Sharing of Best Practices and Development of Consensus Standards for Economy Activity to Address Online Sales -ASOP & the above <ul style="list-style-type: none"> Leverage APEC Internet Sales Toolkit Discuss new regulatory approaches, tactics, and market developments
3:45pm – 4:00pm	BREAK
Breakout Recaps 4:00pm – 4:45pm	Readout Summaries from Breakout Sessions (5-7 minutes per group) <i>Facilitators, All Participants</i>
4:45pm – 5:00pm	Housekeeping Announcements DAY 2 CLOSE

Day 3, E-Commerce/Internet Sales, & Wrap Up

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Day 3 JUNE 13th

8.30 am – 9.00 am	Arrival/Sign-In
Plenary Session 9:00am – 9:15am	Recap of Day 2 Discussion and Outputs Matthew Rubin (<i>ASOP Global</i>)
Keynote Session 9:15am – 9:45am	Lessons from the European Context: Cooperation of Authorities and Information Exchange Oscar Alarcon Jiménez (<i>Council of Europe</i>)
Breakout Session 9:45am – 10:15am	Breakout Session #2: Promoting Inter-Economy Collaboration to Protect Patient Safety and Public Health Online <ul style="list-style-type: none"> Identification of specific opportunities for cross-border harmonization and enforcement.
Stakeholder Input 10:15am – 11:15pm	Opportunities for Collaboration and Implementation of Best Practices (report back, identify good ideas post-it?) <i>Facilitated by: Libby Baney (ASOP Global)</i> <ul style="list-style-type: none"> Participation by all present economies.
Stakeholder Input 11:15pm – 11:45 pm	Next Steps within Latin America: USP & Upstream Supply Chain <i>Facilitated by: USP-Brazil, USP organizers</i> <ul style="list-style-type: none"> How to disseminate and reach other stakeholders in individual economies: soliciting input
Wrap Up, Photos, & Certificates 11:45pm – 12:30pm	Concluding Remarks <i>Representative, Chile ISP, speakers, organizers</i> DAY 3 CLOSE