

Working Groups at a Glance



SCHEDULE & DESCRIPTION

Supply Chain Security Steering Committee: Third Wednesday of the month at 11 a.m. EST

Focuses on the evolving regulatory landscape for tariffs, trade, geopolitical uncertainty, and the enforcement of the DSCSA
Examples of guest speakers and presentations: Eric Marshall (Partnership for DSCSA Governance), Shabbir Safdar (Partnership for Safe Medicines), Libby Baney, (Faegre Drinker and the Alliance for Safe Online Pharmacies), Justin Macy (National Association of Boards of Pharmacy)

Rx-360 Facilitator: Ryan Kelly, Senior Director of Supply Chain Security and Brand Protection

Logistics Security: Every other Thursday at 11 a.m. EST

Focuses on the increasing risk of cargo theft and transport disruptions

Examples of agenda topics: Iberian Peninsula Blackout Ad Hoc Meeting, FraudWatch Product Demo by Overhaul

Rx-360 Facilitator: Ryan Kelly, Senior Director of Supply Chain Security and Brand Protection

Audit Operations: Scheduled in advance once per quarter

Drives innovations within the Joint Audit Program; benchmarks and discusses pharmaceutical auditing; provides a forum for members who want to present or lead discussions on certain topics

Examples of agenda topics: AI in Pharma, Transportation, Supply Chain Security Auditing

Leader: Imelda Myer-Wilmes (Merck KGaA)

Rx-360 Facilitator: Ben Mills, Senior Director of Quality and Audit Operations

Data Integrity: Every fourth Friday of the month at 10 a.m. EST

Develops processes, tools, and trainings to incorporate data integrity best practices

Current Project: Guide to spreadsheet validation based off declassified CAPAs

Chair: Jim Henderson (Eli Lilly)

Rx-360 Facilitator: Ben Mills, Senior Director of Quality and Audit Operations

Latin America: Every other Friday at 10 AM EST

This multi-lingual team identifies issues impacting LATAM and produces projects to provide valuable resources regarding quality, brand protection, and distribution

Chair: Norma Amilpa (Eli Lilly)

Rx-360 Facilitator: Katie Battista, Senior Director of Membership and Marketing

Combination Products: Every other Thursday of the month at 11:30 am EST

Focuses on alignment of supplier quality systems with the requirements of both drug and device regulations; develops best practices for conducting supplier audits that address regulatory expectations and identify risks

Chair: Subhi Saadeh (Gilead)

Rx-360 Facilitator: Katie Battista, Senior Director of Membership and Marketing

Supplier Quality: Third Thursday of the month at 10:30 AM EST

Brings the pharmaceutical manufacturing and supplier sectors together to collaborate and create resources to meet the needs of both regulators and suppliers

Co-Chairs: Longo Gouveia (Merck), Stephan Peeters (Lonza)

Rx-360 Facilitator: Katie Battista, Senior Director of Membership and Marketing

Supplier Assessment Questionnaire: Every other Monday at 9 AM EST

Maintains and evolves the SAQ, a comprehensive guide to streamline the supplier qualification process

Chair: Christoph Hartmann (Merck KGaA)

Rx-360 Facilitator: Sufi Noor, Head of Marketing Operations

MISSION

Our mission is to protect patient safety by sharing information and developing processes related to the integrity of the healthcare supply chain and the quality of its materials.