Panel: Securing the Supply Chain via Effective Risk Management Practices

Moderator: Rob Welsh, Vice President of Bioprocessing Segment Solutions – the Americas | VWR International

Panelists:
- TJ Christl, Director, Office of Drug Security, Integrity, & Response | U.S. Food & Drug Administration (FDA)
- Mark Paxton, CEO | Rx-360
- Pete Scilla, Vice President of Supply Chain Innovation | RAAD360 LLC

Supply chain vulnerabilities have consistently been cited as top business risk factors in SEC filings of the Top 100 Life Science companies in recent years. This session will focus on practices meant to operationalize effective risk management controls to prevent, detect, and respond to issues encompassing the End-to-End Supply Chain from:

- **Sourcing of materials** involving risk management, supplier oversight including assessments and audits, material qualification, inspecting and testing, security of inbound logistics, and change notification
- **Manufacture processes** including GMPs, security incident reporting, incorporation of anti-counterfeiting measures, and product recall management
- **Product Authentication** such as implementation of local serialization solutions and compliance with local security features requirements
- **Warehouse & Cargo Security** including cGDP auditing, logistical service provider management, CTPAT, security, inventory control, cGDP practices, issues such as carrier assessment, shipment tracking, LSP Assessment, and security measures
- **Market Surveillance** including reporting of counterfeit signals, education and adoption of controls by distributors

**Discussion will include reference to:**

- The Drug Quality and Security Act (DQSA), which was signed into law by President Obama on November 27, 2013. [Title II of DQSA, the Drug Supply Chain Security Act](https://www.gpo.gov/fdsys/pkg/Pl90366-pg597/html/Pl90366-pg597.html), outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.
- An output of multi-year project commissioned by Asia Pacific Economic Cooperation (APEC) with oversight by its Life Science and Innovation Forum (LSIF) and the Regulatory Harmonization Steering Committee (RHSC) whose work culminated in the development of “The APEC Supply Chain Security Toolkit for Medical Products” led by FDA’s CDER Office of Compliance.
Rob Welsh (Moderator)
Vice President, Bioprocessing Segment Solutions – the Americas
VWR International

As Vice President, Bioprocessing Segment Solutions, Rob is responsible for leading a cross-functional effort to enhance VWR's Bioprocessing Operational, Product, and Service solutions in response to evolving customer and market needs. His efforts are largely focused in the areas of risk mitigation, supply chain security, and assurance of supply. This involves leveraging VWR's investments in people, processes, and the global distribution network to offer reliable and transparent supply chain solutions.

Rob serves as VWR’s representative on the Board of Rx-360, an International Pharmaceutical Supply Chain Consortium with the mission to "Protect patient safety by sharing information and developing processes related to the integrity of the healthcare supply chain and the quality of materials within the supply chain." He is also Co-Chair of the Rx-360 Supply Chain Security Steering Committee and the Upstream Work Group.

Rob’s career with VWR spans more than 27 years in various category management, operational, and business development roles primarily focused on serving customer requirements in the Pharmaceutical, Biotech, Life Science, Medical Device, Semiconductor and Industrial markets segments. Rob is a graduate of Pennsylvania State University’s Smeal College of Business.

Commander Thomas J. (“TJ”) Christl (Panelist)
Director, Office of Drug Security, Integrity, & Response
U.S. Food & Drug Administration (FDA)

Commander (CDR) TJ Christl is the Director for the Center for Drug Evaluation and Research’s (CDER) Office of Drug Security, Integrity, & Response (ODSIR). ODSIR’s mission is to protect the security and integrity of the global pharmaceutical supply chain, including imports, exports, recalls, and counterfeit drugs. In 2014, CDR Christl spent two months working at the Monrovia Medical Unit Ebola Treatment Unit outside of Monrovia, Liberia.
Prior to joining ODSIR, CDR Christl was with CDER’s Office of Counter-Terrorism and Emergency Coordination, where he was a project manager for the development of medical countermeasures to weapons of mass destruction, and played a central role in developing CDER’s crisis coordination capabilities.

---

**Mark S. Paxton (Panelist)**  
CEO  
Rx-360

Mark Paxton serves as CEO of Rx-360, an international medical product supply chain consortium dedicated to patient safety by promoting practices to protect supply chains and distribution channels. Rx-360 is based in Washington, D.C.

Prior to joining Rx-360, Mark served as a Regulatory Counsel in the CDER Office of Compliance, where he was responsible for developing supply chain security policies, both domestically and internationally, including serving as the overseer of a major global initiative under the auspices of Asia-Pacific Economic Cooperation (APEC) to establish best practices for ensuring product quality moving in international commerce.

Before joining the FDA, Mark served as Associate Vice-President, International Regulatory Affairs at the Pharmaceutical Research and Manufacturers of America (PhRMA). In that capacity, Mark established a number of ongoing dialogues and work programs with drug regulatory authorities throughout Japan, China, East Asia, India, Europe, and Latin America. These efforts were designed to assist regulators and constituent companies operating in these markets to better understand complex regulatory issues arising from the globalization of the pharmaceutical industry.

Mark is a regulatory attorney by education, experience, and training, and prior to joining PhRMA, was in private practice in Lexington, Kentucky, where he focused his practice on food and drug law. Mark received his Bachelors (1991) and Masters (1993) degrees in Economics from the University of Kentucky, and his J.D. from the University of Dayton School of Law in 1998.
Pete Scilla *(Panelist)*  
Vice President, Supply Chain Innovation  
RAAD360 LLC

Pete has a passion for helping fulfill the mission of uninterrupted, secure delivery of goods by successfully navigating the increasing risks in complex Global Supply Chains.

He has been on multiple speaker panels addressing S&OP, Demand Management, Supplier Management, and Supply Chain Risk Management sponsored by organizations including Logi-Pharma, APICS, IMS and DCMC.

Pete has 40 years of experience establishing and leading supply chains and IT functions, including 20 years with Johnson & Johnson Pharma companies, and six years as Vice President of Global Supply Chain at newly-formed and start-up pharmaceutical companies prior to joining RAAD360.

He has been guiding the development of RAAD360 LLC’s cutting edge integrated Supply Chain Risk Management (SCRM) Platform, RAAD™.