



## MEMBER OF THE QUARTER



Michael's efforts are contributing to continuous improvement in supplier quality processes. Michael and McKesson: Rx-360 is proud to protect patient safety, along with you.



### Michael Forkan

Senior Director  
Supplier and Vendor Quality

**MCKESSON**

Congratulations and thanks to Michael Forkan!

Michael has been an active member of Rx-360 since joining in 2024. He has led McKesson's utilization of The Joint Audit Program and has become an engaged member of the Supplier Quality Working Group, making meaningful contributions to our collective efforts to protect patient safety. His involvement and engagement in fostering collaboration amongst members on topics, such as best practices and regulatory standards, drives continuous improvement in supplier quality processes.

## Welcome New Members



## Welcome New Rx-360 Staff

Sierra Caponegro, Staff Accountant  
Lou Dube, Audit Scheduling & Execution  
Coordinator  
Tommy Giordano, Finance Intern  
Sufi Noor, Head of Marketing Operations

## Special Events

**APEC Drug Supply Chain Security Toolkit Virtual Workshop led by Ryan Kelly, Senior Director of Supply Chain Security and Brand Protection | Free to all**

When: May 19-20

Register: [apec.rx-360.org](https://apec.rx-360.org)

**Patient Safety Conference at Le Méridien in Washington, DC, following the PDA Regulatory Conference**

When: September 11-12

Register: [rx-360.org](https://rx-360.org)

**APEC Drug Supply Chain Security Toolkit Workshop led by Ryan Kelly, Senior Director of Supply Chain Security and Brand Protection | Free to all**

When: September 11

Register: [apec.rx-360.org](https://apec.rx-360.org)

## Conference Appearances

April 15-16

**HDA PCSC Educational Seminar | Whippany, NJ**

Rx-360 Staff: Katie Battista, Ryan Kelly, and Kendall Feshuk

April 30-May 1

**International Serum Industry Association | Budapest**

Rx-360 Staff: Jim Fries (presenting and moderating)

May 4-7

**World Conference on Quality Improvement | Denver**

Rx-360 Staff: Ben Mills

May 7-8

**CDMO Live | Rotterdam**

Rx-360 Staff: Ryan Kelly

May 12-13

**Excipient World Congress | Washington, DC**

Rx-360 Staff: Simone Lanchin

May 13-17

**American Society of Gene and Cell Therapy | New Orleans**

Rx-360 Staff: Alanna Benamy, Meredith Cavanaugh, Kendall Feshuk (exhibiting)

May 13-16

**National Association of Boards of Pharmacy | Fort Lauderdale**

Rx-360 Staff: Katie Battista, Renee Lee

May 20-22

**CPHI North America | Philadelphia**

Rx-360 Staff: All (exhibiting)

# Working Group Updates

Rx-360 Member Newsletter

## Get Involved with Rx-360 Working Groups

### Supply Chain Security Steering Committee of

Meetings: Third Wednesday of the month at 11 a.m. EST

Goal: Identify common security gaps and pain points in the supply chain; collaborate to improve on and provide industry solutions

Contact: Ryan Kelly (rkelly@rx-360.org)

### Logistics Security

Meetings: Every other Thursday at 11 a.m. EST

Goal: Have educational discussions among industry leaders on logistics risks, incidents, investigations, and trends, and mitigation tactics; benchmark with other members

Co-Chair: Scott Smith (Beigene-BeOne Medicines)

Contact: Ryan Kelly (rkelly@rx-360.org)

### Audit Operations

Meetings: Third Friday of the month at 10 AM EST

Goal: Drive direct impact on the Joint Audit Program; benchmark and discuss pharmaceutical auditing; provide a forum for members who want to present or lead discussions on certain topics

Recent Discussion Topic: AI in Pharma

Co-Leaders: Imelda Myer-Wilmes (Merck KGaA)

Contact: Ben Mills (bmills@rx-360.org)

### Data Integrity

Meetings: Every other Tuesday of the month at 10 a.m. EST

Goal: Develop processes, tools, and training to incorporate data integrity best practices

Current Project: Developing a guide to Spreadsheet validation based off data from 483 Warning Letters

Co-Chairs: Jim Henderson (Eli Lilly), Jerry Chapman (Redica Systems)

Contact: Alanna Benamy (abenamy@rx-360.org)

### Latin America Working Group

Meetings: Every other Friday at 10 AM EST

Goal: Identify issues impacting LATAM; produce projects to provide valuable resources regarding quality, brand protection, and distribution in both English and Spanish

Current Project: Developing guidance on temperature mapping

Chair: This group is chaired by Norma Amilpa (Eli Lilly)

Contact: Alanna Benamy (abenamy@rx-360.org)

### Specialty Therapies Working Group

Meetings: Third Tuesday of the month at 1 PM EST

Goal: Examine operations and best practices for high-cost medications distributed & dispensed in smaller quantities, including cell and gene therapies, personalized medicine, clinical products, orphan drugs, and specialty medications

Current Project: [Benchmarking Survey - High Value Medical Products Transported in Small Quantities via Parcel Shipping](#)

Contact: Ryan Kelly (rkelly@rx-360.org)

### Combination Products Working Group

Meetings: Presently polling interested members on best meeting date and time

Goal: To launch with a focus on alignment of supplier quality systems with the stringent requirements of both drug and device regulations; develop best practices for conducting supplier audits that address the full spectrum of regulatory expectations, identify and mitigate risks early, and ensure consistent quality across all components; improve the integration of quality agreements and change management processes and establishing standardized procedures

Chair: Subhi Saadeh (Gilead)

Contact: Alanna Benamy (abenamy@rx-360.org)

### Supplier Quality

Meetings: Third Thursday of the month at 10:30 AM EST

Goal: Bring pharmaceutical manufacturing and supplier sectors together; collaborate and create resources to meet the needs of both regulators and suppliers

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

Contact: Alanna Benamy (abenamy@rx-360.org)

### Supplier Assessment Questionnaire Subteam (SAQ)

Meetings: Every other Monday at 9 AM EST

Goal: To update and digitize the SAQ, a comprehensive guide to streamline the supplier qualification process - alleviating the time and resource burden on both manufacturers and suppliers

Chair: Christoph Hartmann (Merck KGaA)

Contact: Alanna Benamy (abenamy@rx-360.org)