March 26-27, 2018

Sheraton Philadelphia University City Hotel | Philadelphia, PA

exl events

2ND

Product Complaints FORUM

Explore How to Manage the Complete Life Cycle of Product Complaints and Potential Recalls for Pharmaceutical and Medical Device Products

SPEAKERS

GREGORY ELLIS

Sr. Manager Product Monitoring, Quality Assurance,
ALEXION PHARMACEUTICALS, INC.

VAISHALI SHUKLA

Director, Due Diligence and Quality Integration,
SHIRE

RICHARD SHIELDS

Consumer Complaint Investigator, Consumer Health,
BAYER

JAYLAXMI NALAWADE

Senior Manager — Drug Safety and Risk Management,
LUPIN LIMITED

FEATURED SESSIONS

- Identify All Risks Throughout the Product's Life Cycle
- Audit Preparation: New Incoming Challenges With Product Complaints
- Regulatory Requirements for Safety Related Product Quality Complaints
- Creative Strategies on How to Manage Drug Recalls
- Using Statistically-Based Quality Metrics in Complaint Trending to Ensure FDA Compliance
- Combination Products and the Impact of FDA Rulings

JULII LINDQUIST

VP Quality and Regulatory,
WESTERN ENTERPRISES

SONNY NGUYEN

Director of Quality Assurance and Regulatory Affairs,
PERIGEN

SPONSOR

Sparta Systems

LAWRENCE PERRUZZA

Director/Head, Case Investigation and Resolution,
ROCHE

MICHAEL VAN RYN

Sr. Staff Regulatory Compliance Specialist,
STRYKER

Dear Colleague,

With pharmaceutical and medical device companies receiving thousands and thousands of product complaints and potential recalls each year, it's extremely important that they follow FDA requirements. By having an effective complaint management system, life science organizations have a better chance to ward off inspections by using the appropriate guidelines and regulations. Monitoring complaint trends over time and having a complaint program improves the customer's experience with your products.

The 2nd Product Complaints Forum will expand on last year's conference by providing current trends, best practices, and strategies to reduce product complaints and avoid inspections. Come network and learn from over 65 industry experts and choose between two tracks on Day Two that explore specific industry challenges for the pharmaceutical and medical device industries. By attending this two-day educational event, you will gain knowledge from 15+ sessions and panels, spanning a number of topics designed for biotech, pharmaceutical and medical device professionals, including:

- Metrics implementation per FDA guidance
- Experiences of vigilance/complaint inspections
- Complaint handling, and recall execution
- 'ISO 13485:2016, MDSAP, and EU MDR planning and implementation
- Combination products and the impact of FDA rulings
- How to avoid inspection findings

I look forward to welcoming you to Philadelphia this March!

Sincerely,

Kelly Osmulski

Kelly Osmulski
Conference Production Director

WHO SHOULD ATTEND

This event is designed for pharmaceutical, biotech, and medical device professionals with responsibilities in the following areas:

- Product Complaints
- QA/QC
- Product Safety/Recalls
- Quality Systems and Engineering
- Patient Safety
- Medical/Consumer/Regulatory/ Clinical Affairs
- Call Centers/Customer Service
- Compliance
- CMO Management
- Business Support Coordination
- Product Surveillance
- Clinical Operations
- Quality Compliance and Audits
- Postmarketing Surveillance
- Complaint Handling
- Quality Compliance
- QA and Supply Integration
- Global Device Coordination

This conference is also of interest to:

- Drug Safety and Complaint Software Companies
- Consulting Firms
- Law Firms
- Inbound Call Centers

VENUE INFORMATION

Sheraton Philadelphia University City
3549 Chestnut St, Philadelphia, PA 19104

To make reservations, please call 1-888-627-7071 and request the negotiated rate for **ExL's March Meeting**. You may also make reservations online using the following weblink: http://bit.ly/2fN5S1K. The group rate is available until **March 12, 2018**. Please book your room early, as rooms available at this rate are limited.

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SPONSORSHIP AND EXHIBITION OPPORTUNITIES

Do you want to spread the word about your organization's solutions and services to potential clients attending this event?

Take advantage of the opportunity to exhibit, underwrite an educational session, host a networking event or distribute promotional items to attendees. ExL Events will work closely with you to customize a package that will suit all of your needs.

Monday, March 26, 2018

8:00 Registration and Continental Breakfast

8:45 Chairperson's Opening Remarks

Vaishali Shukla, *Director, Due Diligence and Quality Integration,* **SHIRE**
Michael Van Ryn, *Sr. Staff Regulatory Compliance Specialist,* **STRYKER**

9:00 **Audit Preparation: New Incoming Challenges With Product Complaints**

- Review how to identify risk areas with complaint handling
- Collaborate new challenges and solutions to prepare for an inspection
- Explore recent trends and feedback
- Gather the roles and reasonability in preparation for audit
- Study adverse event reports and CAPA

Lawrence Perruzza, *Director/Head, Case Investigation and Resolution,* **ROCHE**

9:45 **Impact of Monitoring Trending and Metrics Impact on Product Complaints**

- Assess trending product complaints and using metrics to measure the system
- Understand the shift in data in product complaints and how to handle these dosages
- Implement how FDA uses data to identify issues that trigger inspections
- Discuss the complaint process, including escalation to management assessment and investigation review
- Establish strategies to reduce product complaints and product complaints trend analysis

Gregory Ellis, *Senior Manager Product Monitoring, Quality Assurance,* **ALEXION PHARMACEUTICALS**

10:30 Networking Break

11:00 **Identify All Risks Throughout the Product's Life Cycle**

- Explore medical device reporting for manufacturers — guidance for industry and FDA staff — final issued on November 8, 2016
- Examine MDR/MEDWATCH format standards and postmarket management
- Learn best practices to promote reporting efficiency

Sonny T. Nguyen, *Director of Quality Assurance and Regulatory Affairs,* **PERIGEN**

11:45 **Drug Safety and Risk Management Complaints**

- Discuss the implementation of pharmacovigilance activities in the U.S., Europe, and Australia
- Review safety reports activities and how to monitor your complaints
- Master best practices to promote reporting efficiency
- Understand how to create and approve the risk management plan

Jaylaxmi Nalawade, *Senior Manager — Drug Safety and Risk Management,* **LUPIN LIMITED**

12:30 Luncheon

1:30 **Explore How to Monitor Worldwide Inspections to Help Protect Your Brand**

- Ensure effective reporting and trending in emerging markets
- Discuss post-inspection correspondences
- Learn how to comply with all worldwide regulations and laws relating to reporting adverse events, other safety and product complaints
- Review and assess global requirements and how to maintain findings, them for multiple regions

Sophie Vaillot, *Regulatory Affairs Director and Leader of Global Postmarket,* **GE HEALTHCARE**

2:15 **Navigate the Fundamentals of Recalls**

- Demonstrate the classification and reporting process
- Gather regulations, guidelines and expectations of handling product recall
- Explore worldwide recall execution
- Define how to effectively report recalls

Joe Falvo, *Senior Manager: Postmarket Risk Management,* **ORTHO CLINICAL DIAGNOSTICS**

3:00 Networking Break

3:30 **Utilizing Social Media to Actively Engage With Customers and Encourage Product Feedback**

- Identify FDA social media guidelines and enforcement activities
- Understand how social media impacts compliance
- Discuss how to keep up with industry issues regarding social media
- Demonstrate how to use social media tools
- Create a social media policy

Sharon Perez, Ph.D., *Director, Global Medical Safety,* **NOVOCURE**

4:15 **CAPA System Within the Pharmaceutical Quality System**

- Explore CAPA system procedures and requirements
- Discuss how to monitor your CAPA program and risk category
- Implement how to be more efficient in performing trend analysis

Krishna Kotha, *Associate Director — External Manufacturing,* **DR. REDDY'S LABORATORIES**

5:00 **Prepare for an Inspection to Avoid Inspection Findings — Pharma/Medical Device Perspectives**

PANEL

- Uncover how to avoid inspections
- Collaborate your team's role in conducing an inspection
- Hear experiences and evaluate the complaint process and if it is reportable, how do you report it?
- Demonstrate a mock inspection and review all stages of properly preparing for an inspection

Michael Van Ryn, *Sr. Staff Regulatory Compliance Specialist,* **STRYKER**
Vaishali Shukla, *Director, Due Diligence and Quality Integration,* **SHIRE**

5:45 Day One Concludes

Tuesday, March 27, 2018

8:30 Registration Opens and Continental Breakfast

	Medical Device	Pharma/ Biotech
9:15	Chairperson's Recap of Day One **Michael Van Ryn,** *Sr. Staff Regulatory Compliance Specialist,* **STRYKER**	Chairperson's Recap of Day One **Vaishali Shukla,** *Director, Due Diligence and Quality Integration,* **SHIRE**
9:30	**Medical Device Reporting and Recall** ·Identify multiple MDR reportable events ·Deliver best practices and lessons learned for completing and submitting MDRs ·Review inspections and potential recalls for enforcements ·Implement how to reduce the risk of a complaint or recall **Michael Van Ryn,** *Sr. Staff Regulatory Compliance Specialist,* **STRYKER**	**Risk Management Metrics and Product Complaint Expectations** ·Master an and effective complaint handling process ·Manage the metrics implementation of FDA guidance ·Learn best practices in customer complaint trending ·Understand quality metrics guidances to monitor complaints **Krishna Kotha,** *Associate Director — External Manufacturing,* **DR. REDDY'S LABORATORIES**
10:30	**Implement How to Handle Medical Device Complaints** ·Clarify key actions and best practices for an effective complaint handling system ·Study risk management and complaint handling ·Establish how to maintain complaint files ·Create an effective complaint handling procedure **Sonny T. Nguyen,** *Director of Quality Assurance and Regulatory Affairs,* **PERIGEN**	**Regulatory Requirements for Safety-Related Product Quality Complaints Surpass Product Quality Issues and Drug Safety** ·Learn the regulatory landscape needed for integrated quality management ·Analyze early warning signals for product quality issues ·Navigate product assessment and trending **Linda Lum,** *Team Lead Pharmacovigilance Science, Global Pharmacovigilance and Epidemiology,* **BRISTOL-MYERS SQUIBB**
11:00	Networking Break	
11:30	**Use Statistically-Based Quality Metrics in Complaint Trending to Ensure FDA Compliance** ·Examine trending customer complaints based on risk ·Establish customer complaint triggers using statistically-based methods ·Understand how to be compliant with medical device complaint regulations and FDA complaint regulations ·Avoid customer complaint 483s using lessons learned ·Best practices for improving customer complaint compliance **Julii Lindquist,** *VP Quality and Regulatory,* **WESTERN ENTERPRISES**	**Quality Risk Management in Handling Pharmaceutical Product Complaints** ·Understand how to manage risk into product complaints ·Explore complaint process flow — risk associated with each step of the process ·Reduce compliance risk ·Glean input from complaints, for product improvement opportunity and risk reduction ·Study how to maintain complaint files, updates with CAPA processes, and all customer complaint investigations ·Walk through experiences with vigilance and complaint inspections ·Risk associated with global integration of product complaints **Vaishali Shukla,** *Director, Due Diligence and Quality Integration,* **SHIRE**
12:15	**EU Medical Device Regulation** PANEL ·Review ISO 13485:2003, medical devices, quality management systems ·Evaluate requirements for regulatory purposes ·Ensure product development processes including a postmarket surveillance plan and review	**Benchmarking What Should (and Shouldn't) go into a Consumer Complaint Investigation** PANEL ·Discuss how different sites in same country may vary in content investigated ·Clarify same company, but different countries, and the vary in content that is investigated ·Highlight on how contract manufacturers (CMO) investigations may vary in content, and possibly scope, as compared to your own internal investigations **Richard Shields,** *Consumer Complaint Investigator, Consumer Health,* **BAYER**
1:00	Luncheon	
2:00	**Combination Products and the Impact of FDA Rulings** ·Review challenges and preparation necessary for the implementation of the 2016 final rule, "Postmarketing Safety Reporting (PMSR) for Combination Products" ·Highlight drug/biologic considerations for validation testing ·Implement pre/postmarket change controls ·Comply with requirements associated with application types (January 2017) **Khaudeja Bano, M.D.,** *Senior Medical Director,* **ABBOTT**	**Creative Strategies on How to Manage Drug Recalls** ·Strategize how to lessen and reduce recalls ·Hear past experiences and lessons learned in dealing with recalls ·Implement on how to handle trend analysis with recalls **Sameer Thapar,** *Assistant Professor and Advisor, Drug Safety and Pharmacovigilance,* **RUTGERS UNIVERSITY**

Tuesday, March 27, 2018

2:45

Risk-Based Customer Complaint Handling for Medical Devices

- Minimize customer complaints by developing better communication through all of your investigations
- Incorporate the key elements of defining risk
- Understand "how to" handle issues with customer complaints and better manage them for future investigations
- Establish how to better manage customer expectations

Sophie Vaillot, *Regulatory Affairs Director and Leader of Global Postmarket,* **GE HEALTHCARE**

Consumer and Customer Complaint Trending

- Develop consistent data handling
- Discuss external factors across products, types, processes, areas, equipment, and shifts for identifying patterns
- Highlight successes and challenges
- Review SOPs for complaints, PV triage, field alert reports, investigation, and CAPA

Rupesh Patel, *Product Quality Complaint Lead, Associate Director,* **OTSUKA**

3:15 Conference Concludes

Registration

Registration Fees for Attending ExL's 2nd Product Complaints Forum

EARLY BIRD PRICING — *Register by February 9, 2018*	
Conference	$1,895
STANDARD PRICING — *Register After Friday, February 9, 2018*	
Conference	$2,095
ONSITE PRICING	
Conference	$2,195

Group Discount Program

Save 25% per person when registering four

For every three simultaneous registrations from your company, you will receive a fourth complimentary registration to the program (must register four at one time). This is a savings of 25% per person.

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