exl pharma

LIFE SCIENCE PRODUCT COMPLAINTS CONGRESS

Ensure Regulatory Compliance for Effective Processing, Investigating and Trending for PHARMACEUTICAL, BIOTECHNOLOGY and MEDICAL DEVICE Complaints

MAY 19-20, 2014 / PRINCETON MARRIOTT AT FORRESTAL / PRINCETON, NJ

PHARMACEUTICAL/ BIOTECHNOLOGY

DAWN LUNDIN,
GLOBAL CLINICAL & PHARMACOVIGILANCE COMPLIANCE,
MERCK & CO.

JP CLEMENT,
VP Drug Safety and Pharmacovigilance,
ONYX PHARMACEUTICALS

GREGORY ELLIS,
Sr. Manager, Product Monitoring, QA,
PURDUE PHARMA

MEDICAL DEVICE

ROBERT WALSH,
Medical Director, Global Product Safety,
WALSH MEDICAL CONSULTING, CONSULTANT TO ABBVIE

LAWRENCE PERRUZZA, M.SC, RAC,
Head, Case Investigation & Resolution,,
ROCHE MOLECULAR DIAGNOSTICS

MICHAEL VAN RYN,
Manager High Risk Complaints,
WELCH ALLYN

FEATURED TOPIC SESSIONS INCLUDE:

- **Handle complaints involving third parties**
- **Effective management of complaints on social media**
- **Compliant complaint reporting for combination products**
- **Develop SOPs for distinguishing and reporting adverse events and product complaints**
- **Drive efficient and effective recalls and clinical stock recoveries**
- **Effective trending and metrics for product improvement**

Dear Colleague,

Life Science companies receive thousands of product complaints each year and it is critical that they are resolved compliantly and in a timely manner. Knowledge of how to effectively process, investigate, resolve and trend product complaints can lead to increased process efficiency and improvement.

ExL Pharma's **Life Science Product Complaints Congress** provides a forum for Pharmaceutical, Biotechnology and Medical Device professionals to learn best practices on handling product complaints. Join a robust speaking faculty to hear take home examples, case studies and numerous strategies to ensure efficient, effective and compliant complaint handling.

By attending this conference you will hear **20+** sessions and case studies including:

- Root cause analysis and managing CAPAs
- Complaint handling: regulatory expectations and challenges
- Effective management of complaints on social media
- Adhering to global regulatory complaint handling guidelines
- Best practices for complaints involving third parties
- Reporting combination products
- SOPs for reporting adverse events and issues with drug quality
- Risk based approach in complaint management
- Strategies to build and implement effective pharmacogivilance platforms for post market surveillance
- Trending and metrics for medical devices

Learn to strategically ensure effective complaint handling pursuant to FDA regulations from the industry's most experienced product complaint professionals through case studies and informative sessions while benchmarking and networking with peers.

I look forward to welcoming you to Princeton, NJ in May!

Sincerely,

Nicole deVoe

Conference Production Director
ExL Pharma

VENUE

PRINCETON MARRIOTT AT FORRESTAL

100 College Road East. | Princeton, NJ 08540

ROOM RESERVATION INFORMATION

To make reservations guests can call 1-800-228-9290 or 609-452-7800 and request the negotiated rate for **ExL's May Meetings**. You may use the following weblink to make online reservations: http://gurl.im/a9e65lA **The group rate is available until April 28, 2014**. Please book your room early as rooms available at this rate are limited.

WHO SHOULD ATTEND

Professionals from Pharmaceutical, Biotechnology and Medical Device companies with the following responsibilities:

- **Product Complaints**
- **Product Quality**
- **QA/QC**
- **Product Safety**
- **Pharmacovigilance**
- **Compliance**
- **Regulatory Affairs**
- **Quality System and Engineering**
- **Patient Safety**
- **Medical Affairs**
- **Consumer Affairs**
- **Call Centers/Customer Service**
- **Clinical Affairs**

Service Providers

- **Complaint Tracking Software System Providers**
- **Inbound Call Centers**
- **Consulting Firms**
- **Law Firms**
- **Outsourced Medical/Regulatory Affairs Teams**

SPONSOR AND EXHIBIT OPPORTUNITIES

Do you want to spread the word about your organization's solutions and services to potential clients who will be 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 Pharma will work closely with you to customize a package that will suit all of your needs.

DAY 1 // MONDAY, MAY 19, 2014

WORKSHOP

8:15 REGISTRATION AND CONTINENTAL BREAKFAST FOR WORKSHOP ATTENDEES

9:00 **ROOT CAUSE ANALYSIS AND MANAGING CAPAS IN A REGULATORY ENVIRONMENT**

Recently FDA warning letters have identified insufficient CAPA programs as a source of significant quality system weakness. It is crucial that your organization is effectively implementing a CAPA system to ensure quality. This workshop provides strategies and best practices to implement, sustain and ensure effectiveness of a CAPA program.

- Understand the importance of CAPAs and Root Cause Analysis
- Discover how to monitor the effectiveness of your CAPA program
- Identify effective root cause analysis tools and learn how to utilize them properly
- Explore common challenges and pitfalls with CAPAs and Root Cause Analysis and understand how to avoid them
- Learn best practices in deploying an end to end CAPA program

Debara Reese, *VP Quality and Compliance,* **MAETRICS**

12:00 LUNCHEON FOR WORKSHOP ATTENDEES ONLY AND MAIN CONFERENCE REGISTRATION BEGINS

PLENARY SESSIONS

1:00 **CONFERENCE CO-CHAIRPERSON'S WELCOME AND OPENING REMARKS**

JP Clement, M.D., *VP Drug Safety and Regulatory Affairs,* **ONYX PHARMACEUTICALS**
Pearley Bhambri, *Director RA; Global High Risk Complaints & CAPA,* **WELCH ALLYN**

1:15 **REGULATORY EXPECTATIONS AND CHALLENGES OF COMPLAINT HANDLING**

- Regulatory considerations for reporting adverse events and issues with drug quality
- Strategies to screen and report adverse events and issues effectively and in a timely manner
- Enhance analysis strategies to effectively determine when a product complaint becomes an adverse event
- Strategies to support adverse event investigations
- Determine which returned samples associated with adverse events should be tested

Jaafar Zerhouni, *VP, Quality & CMC,* **ENDOCEUTICS INC.**

2:00 **RISK BASED APPROACH FOR GLOBAL COMPLAINT HANDLING IN ALL REGULATORY ENVIRONMENTS**

- Leverage risk to identify the categories of complaints
- Identify what is considered reportable to global regulators such as FDA, Health Canada, Competent Authorities and TGA
- How to assess complaints for reportability

Pearley Bhambri, *Director RA; Global High Risk Complaints & CAPA,* **WELCH ALLYN**

2:45 NETWORKING AND REFRESHMENT BREAK

3:15 **RISK BASED APPROACH TO SERIOUS INJURY/ADVERSE EVENT COMPLAINT INVESTIGATION, MEDICAL RECORD REVIEW, PRIORITIZATION AND DOCUMENTATION**

- Strategies to prioritize complaints involving reported serious injury and adverse events
- Understand the importance of timely documentation to be included in the complaint file as objective evidence
- Best practices in handling large volumes of medical records that are received for clinical investigations se challenges

Tanya Taft, RN, *Senior Manager Post Market Clinical Surveillance,* **FRESENIUS MEDICAL CARE**

4:00 **UNLEASH COMPLAINT HANDLING AS A COMPETITIVE ADVANTAGE**

- Understand the importance of putting the patient first
- Best practices to build global reach and local focus
- Navigate the global regulatory maze
- Achieve a quality mindset
- Implement a single quality system

Terry Meisner, RN *Director, Business Process- Complaints,* **JOHNSON & JOHNSON**

4:45 **PANEL DISCUSSION: EFFECTIVE MANAGEMENT OF COMPLAINTS ON SOCIAL MEDIA PLATFORMS**

- Best practices for monitoring product complaints posted on social media outlets
- Effectively control the negative impacts of complaints made on various media channels
- Compliantly handle and report product complaints and adverse reactions

Lawrence Perruzza, M.Sc., RAC, *Head, Case Investigation & Resolution,* **ROCHE MOLECULAR DIAGNOSTICS**
Dipa Ramolia, *Sr. Manager, Quality,* **LEO PHARMA**

5:30 **CONFERENCE CO-CHAIRPERSON'S CLOSING REMARKS**

JP Clement, M.D., *VP Drug Safety and Regulatory Affairs,* **ONYX PHARMACEUTICALS**

Pearley Bhambri, *Director RA; Global High Risk Complaints & CAPA,* **WELCH ALLYN**

5:45 DAY ONE CONCLUDES

DAY 2 // TUESDAY, MAY 20, 2014

8:00 CONTINENTAL BREAKFAST

PHARMACEUTICAL/BIOTECHNOLOGY

8:45 **CHAIRPERSON'S RECAP OF DAY ONE**
JP Clement, M.D., *VP Drug Safety and Regulatory Affairs,* **ONYX PHARMACEUTICALS**

9:00 **BEST PRACTICES FOR COMPLAINTS INVOLVING A THIRD PARTY**

- Understand that issues may arise when a vendor party is involved
- Interpret CFR part 21, section 211.198 complaint files
- Discuss investigations and review processes and investigation time frames
- Compile data for final responses to communicate effectively with reporters
- Ensure record retention throughout the complaint process

Dipa Ramolia, *Sr. Manager, Quality,* **LEO PHARMA**

MEDICAL DEVICE

CHAIRPERSON'S RECAP OF DAY ONE
Pearley Bhambri, *Director RA; Global High Risk Complaints & CAPA,* **WELCH ALLYN**

EXPLORE THE CHANGING LANDSCAPE FOR REPORTING COMBINATION PRODUCTS

- Explore basics of reporting for combination products the involve multiple organizations
- Implement new combination reporting process into SOPs
- Understand the effect of the new FDA requirements of the complaint handling process
- Implementing risk management in complaint handling

Robert Walsh, *Medical Director, Global Product Safety,* **WALSH MEDICAL CONSULTING, CONSULTANT TO ABBVIE**

	PHARMACEUTICAL/BIOTECHNOLOGY	MEDICAL DEVICE
9:45	**DEVELOP SOPs FOR REPORTING ADVERSE EVENTS AND ISSUES WITH DRUG QUALITY** ▶ Analyze when a product complaint becomes and adverse events ▶ Strategies to support adverse event investigations ▶ Determine which returned samples should associated with adverse events should be tested **Jaafar Zerhouni,** *VP, Quality & CMC*, **ENDOCEUTICS INC.**	**CASE STUDY: LESSONS LEARNED FROM CREATING A COMPLAINT HANDLING SYSTEM FOR MEDICAL DEVICES** ▶ Understand key aspects upfront when creating a complaint handling system ▶ Integrate the call center, investigations, failure analysis and MedWatch reporting to ensure effective complaint handling ▶ Ensure quality reporting effectiveness **Chuck Hagerman,** *Senior Regulatory Compliance Analyst,* **ROCHE DIAGNOSTIC CORPORATION**
10:30	**NETWORKING AND REFRESHMENT BREAK**	
11:00	**DATA INTEGRITY AND FRAUD PREVENTION** ▶ Employ best practices for identifying fraud ▶ Understand processes in handling counterfeit products	**APPLY A RISK BASED APPROACH IN COMPLAINT MANAGEMENT TO IMPROVE COMPLAINT HANDLING EFFECTIVENESS** ▶ Risk based approaches towards investigation ▶ Implementing a risk based complaint system ▶ Linking risk management and complaint management for more efficient complaint handling **Lawrence Perruzza, M.Sc., RAC,** *Head, Case Investigation & Resolution,* **ROCHE MOLECULAR DIAGNOSTICS**
12:00	**LUNCHEON**	
1:00	**DRIVE EFFICIENT AND EFFECTIVE RECALLS AND CLINICAL STOCK RECOVERIES** ▶ Understand the recall process for products in market and marketed products in clinical trials ▶ Determine the most effective recall strategy for your product ▶ Ensure compliance with FDA guidelines during a recall **Dawn Lundin,** *Global Clinical & Pharmacovigilance Compliance,* **MERCK & CO., INC.**	**COMPOSE COMPLIANT MEDICAL DEVICE REPORTS (MDRS)** ▶ Identify a reportable MDR event ▶ Understand the MDR timetable for reporting ▶ Best practices in composing compliant medical device reports **Michael Van Ryn,** *Manager High Risk Complaints,* **WELCH ALLYN**
1:45	**QUALITY RISK MANAGEMENT IN HANDLING PHARMACEUTICAL PRODUCT COMPLAINTS** ▶ Utilize data as a complaint handling tool ▶ Determine what, when and how to measure your Key Quality Indicators (KQIs) ▶ Explore next steps after a trend has been identified ▶ Understand what industry and regulators can do to improve processes **Gregory Ellis,** *Sr. Manager Product Monitoring, QA,* **PURDUE PHARMA**	**ASSESS ADVERSE EVENT COMPLAINTS ASSOCIATED WITH MEDICAL DEVICE AND COMBINATION DRUG/DEVICE PRODUCTS** ▶ Understand FDA requirements ▶ Assess causality to the device or combination product ▶ Manage data from multiple sources/databases ▶ Trending and signal detection ▶ Root cause analysis for adverse events ▶ Risk assessment for combination products **Daniel Wozinski,** *Senior Manager of Medical Device Safety,* **SANOFI-AVENTIS**
2:30	**NETWORKING AND REFRESHMENT BREAK**	
3:00	**DEVELOP STRATEGIES TO BUILD AND IMPLEMENT EFFECTIVE PHARMACOVIGILANCE PLATFORMS FOR POST MARKET SURVEILLANCE** ▶ Identify the objectives of post market surveillance • Full compliance with worldwide reporting obligations • Ability to feed a signal detection system with adequate information ▶ Ensure comprehensive, effective and efficient pharmacovigilance platforms ▶ Understand the importance of key factors such as, quality performance, safety culture and patient centric focus in your pharmacovigilance platform **JP Clement, MD,** *VP Drug Safety and Regulatory Affairs,* **ONYX PHARMACEUTICALS**	**COMPLAINT HANDLING OF SERVICEABLE DEVICES** ▶ Documenting failures, returned failures, and investigating those failures before servicing ▶ Proper root cause analysis of reported failures ▶ How deep is a deep enough evaluation of the product ▶ Complaint handling coding for proper failure trending. **Saad Attiyah,** *Sr. Regulatory Affairs Manager,* **LIFECELL CORPORATION**
3:45	**TREND MANAGEMENT OF COMPLAINTS FOR PROCESS IMPROVEMENT STRATEGIES** ▶ Trend Analysis • Why should we analyze trends • FDA regulations and citations • Tools and techniques and trending • Data handling for effective trending ▶ Process Improvement • Role of trending in process improvement • FDA regulations and citations • Tools and techniques for process improvement • Plan for successful implementation • CAPA system and effective monitoring • Lessons learned from other industries	**TRENDING AND METRICS FOR MEDICAL DEVICE COMPLAINTS** ▶ Implement effective trending system platforms • Trend the correct data • Trend at the correct frequency • Identify decisions that will be made from the data ▶ Establish a cross functional uses for trending data ▶ Use data to investigate and correct potential issues **Gregory Ellis,** *Sr. Manager Product Monitoring, QA,* **PURDUE PHARMA**
4:30	**CONFERENCE CHAIRPERSON CLOSING REMARKS** **JP Clement, M.D.,** *VP Drug Safety and Regulatory Affairs,* **ONYX PHARMACEUTICALS**	**CONFERENCE CHAIRPERSON CLOSING REMARKS** **Pearley Bhambri,** *Director RA; Global High Risk Complaints & CAPA,* **WELCH ALLYN**
4:45	**CONGRESS CONCLUDES**	

REGISTRATION INFORMATION

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PM360 — THE FULL SPECTRUM OF PRODUCT MANAGEMENT
www.PharmCast.com – Pharmaceutical Internet –
Medical News TODAY
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