5TH SIGNAL DETECTION, ROOT CAUSE ANALYSIS & CAPA SUMMIT

JANUARY 22-23, 2015
KEY BRIDGE MARRIOTT • ARLINGTON, VA

Prevent Non-Compliance and Achieve Successful Root Cause Analyses and CAPA Systems Implementation from Clinical to Post-Market

OUR ESTEEMED FACULTY INCLUDES:

CHAIRPERSON
KEVIN WILSON
Manager, Medicines Quality Organization, ELI LILLY AND COMPANY

FEDERICO FELDSTEIN
JD, Vice President, Medical Regulatory Compliance, PFIZER, INC.

DIOGO ARAUJO
Global CAPA Manager, BAYER HEALTHCARE

KARL VAHEY
Senior Director of Global Quality Compliance and Audit, COVIDIEN

REGI THOMAS
Principal Quality Specialist, ROCHE MOLECULAR SYSTEMS

TERI SAVAGE
Principal Quality Improvement Analyst, MEDTRONIC

What's new for the 2015 event?

2 TRACKS covering clinical and post-market CAPAs

CAPAs for medical device companies

INTERACTIVE SESSIONS on root cause analysis, signal detection and CAPAs development

10+ unique perspectives on CAPA systems implementation and management

4+ interactive panel sessions and group discussions

20 SESSIONS COVERING:

• Tools, Challenges and Considerations for the Verification and Validation of CAPAs
• Systemic vs. Non-systemic issues and the Execution of a CAPA
• Vendor and Technology Management in the CAPA Landscape
• Risk-Based Monitoring and the Impact on Clinical Sites
• Audits and Inspection Readiness in the CAPA Setting
• Root Cause Analysis and CAPA Implementation in Small vs. Big Companies
• Developing CAPAs in the Medical Devices Industry
• Investigator-Initiated Trials and CAPAs Development

Sponsors:

ClinAudits, LLC
PathWise

TO REGISTER call 866-207-6528 or visit www.exlevents.com/CAPA
Dear Colleague,

Whether you work in the clinical or post-market space, the ability to implement an effective CAPA system that can identify systemic and non-systemic issues and determine their root cause to prevent future non-conformities is always going to be an important part of your processes.

Even though establishing corrective AND preventive actions is critical, most companies place a majority of their emphasis on corrective, not preventative, actions. An increase in warning letters indicates the FDA has started to pay much more attention to this subject in the last few years, requiring the execution of CAPA, evidence of how it was completed and proof that adequate action was taken in an attempt to prevent future reoccurrences.

Because of this, numerous pharmaceutical and medical device companies have developed robust CAPA systems in their clinical and post-market operations. The 5th Signal Detection, Root Cause Analysis and CAPA summit addresses the main considerations for implementing a pre-market CAPA system that ensures quality in clinical operations and addresses post-market CAPAs that touch upon risk assessment and post-market surveillance in order to support product safety and compliance.

Please join me at this unique event designed to help all life science organizations gain insights on how to develop corrective action plans and tremendously improve proactive preventive plans.

I look forward to meeting you in January!

Sincerely,

Katerina Leon
Conference Production Director
kleon@exlpharma.com

Venue Information:
Key Bridge Marriott
1401 Lee Highway
Arlington, VA 22209
Phone: 703-524-6400

Room Reservations: If you require overnight accommodations please contact the hotel to book your room. ExL Events has reserved a block of rooms at a discounted rate for conference participants. We encourage conference participants to make reservations by January 12, 2015.

To make reservations guests can call 1 800-228-9291 and request the negotiated rate for “ExL’s January Meetings.” Please book your room early as rooms available at this rate are limited.

TO REGISTER call 866-207-6528 or visit www.exlevents.com/CAPA
<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00</td>
<td>Registration Opens &amp; Continental Breakfast</td>
</tr>
<tr>
<td>9:00</td>
<td><strong>CHAIRPERSON’S OPENING REMARKS</strong></td>
</tr>
<tr>
<td></td>
<td>Kevin Wilson, Manager, Medicines Quality Organization</td>
</tr>
<tr>
<td></td>
<td>ELI LILLY AND COMPANY</td>
</tr>
<tr>
<td>9:15</td>
<td><strong>SYSTEMIC VS. NON-SYSTEMIC ISSUES AND THE EXECUTION OF A CAPA</strong></td>
</tr>
<tr>
<td></td>
<td>Tools and considerations for accurately identifying systemic issues</td>
</tr>
<tr>
<td></td>
<td>Examine ways to respond to the identification and occurrence of systemic vs. non-systemic issues</td>
</tr>
<tr>
<td></td>
<td>Addressing systemic issues in multiple sites and how to execute a CAPA</td>
</tr>
<tr>
<td></td>
<td>Best practices to put in place a plan of action that will allow fast response</td>
</tr>
<tr>
<td></td>
<td>time when a CAPA is needed</td>
</tr>
<tr>
<td></td>
<td>Federico Feldstein, JD, Vice President, Medical Regulatory Compliance, PFIZER INC.</td>
</tr>
<tr>
<td>10:00</td>
<td><strong>THE IMPORTANCE OF TECHNOLOGY AND VENDOR MANAGEMENT IN THE CAPA LANDSCAPE</strong></td>
</tr>
<tr>
<td></td>
<td>Considerations for the selection of the appropriate vendors and technology</td>
</tr>
<tr>
<td></td>
<td>platforms for successful CAPAs implementation</td>
</tr>
<tr>
<td></td>
<td>Gap assessment and determining ownership of a CAPA when working with vendors</td>
</tr>
<tr>
<td></td>
<td>Ways to integrate technology into process</td>
</tr>
<tr>
<td></td>
<td>Venessa Galate, Director, Quality Processes Liaisons, JANSSEN RESEARCH &amp; DEVELOPMENT, J&amp;J</td>
</tr>
<tr>
<td>10:45</td>
<td>Networking &amp; Refreshment Break</td>
</tr>
<tr>
<td>11:15</td>
<td><strong>INSTITUTING A ROBUST QUALIFICATION PROGRAM TO SUPPORT THE CAPA SYSTEM</strong></td>
</tr>
<tr>
<td></td>
<td>Determining roles in the CAPA system</td>
</tr>
<tr>
<td></td>
<td>Defining qualification expectations</td>
</tr>
<tr>
<td></td>
<td>Comparing qualification options</td>
</tr>
<tr>
<td></td>
<td>Examining independent performance criteria</td>
</tr>
<tr>
<td></td>
<td>Establishing effective documentation expectations</td>
</tr>
<tr>
<td></td>
<td>Nathan Conover, President &amp; CEO, PATHWISE</td>
</tr>
<tr>
<td>12:00</td>
<td>Luncheon</td>
</tr>
<tr>
<td>1:15</td>
<td><strong>TOOLS, CHALLENGES AND CONSIDERATIONS FOR THE VERIFICATION AND VALIDATION OF CAPAS</strong></td>
</tr>
<tr>
<td></td>
<td>Performance metrics to validate and verify CAPA processes</td>
</tr>
<tr>
<td></td>
<td>Methodologies and tactics to prevent the reoccurrence of the initial problems that caused the incident</td>
</tr>
<tr>
<td></td>
<td>Considerations for acceptance criteria, involved parties, risk management and timelines for accurate CAPA closing</td>
</tr>
<tr>
<td></td>
<td>What to expect when a CAPA verification/validation is not done properly</td>
</tr>
<tr>
<td></td>
<td>PANELISTS:</td>
</tr>
<tr>
<td></td>
<td>Linda Sullivan, Chief Operating Officer, METRICS CHAMPION CONSORTIUM</td>
</tr>
<tr>
<td></td>
<td>Pam Strobel, Quality Risk Management Portfolio Lead, PFIZER, INC.</td>
</tr>
<tr>
<td></td>
<td>Venessa Galate, Director, Quality Processes Liaisons, JANSSEN RESEARCH &amp; DEVELOPMENT, J&amp;J</td>
</tr>
<tr>
<td></td>
<td>Federico Feldstein, JD, Vice President, Medical Regulatory Compliance, PFIZER INC.</td>
</tr>
<tr>
<td>2:00</td>
<td><strong>ROOT CAUSE ANALYSIS (RCA) AND EFFECTIVE CAPA SYSTEMS</strong></td>
</tr>
<tr>
<td></td>
<td>Determining which quality issues should have a root cause analysis conducted and which should not</td>
</tr>
<tr>
<td></td>
<td>Understanding of root cause analysis tools in order to perform accurate</td>
</tr>
<tr>
<td></td>
<td>statistical sampling and analysis</td>
</tr>
<tr>
<td></td>
<td>Signal detection integration and impact on CAPA processes and RCA</td>
</tr>
<tr>
<td></td>
<td>Considerations for linking a CAPA to a RCA and how to determine when a new cause is needed</td>
</tr>
<tr>
<td></td>
<td>Regi Thomas, Principal Quality Specialist, ROCHE MOLECULAR SYSTEMS</td>
</tr>
<tr>
<td>2:45</td>
<td>Networking &amp; Refreshment Break</td>
</tr>
<tr>
<td>3:15</td>
<td><strong>CAPA PROCESS IMPLEMENTATION AND CULTURE CHANGE FOR CONTINUAL IMPROVEMENT</strong></td>
</tr>
<tr>
<td></td>
<td>Essential activities of a robust CAPA process</td>
</tr>
<tr>
<td></td>
<td>Why does culture matter?</td>
</tr>
<tr>
<td></td>
<td>CAPA experts (they’re closer than you think)</td>
</tr>
<tr>
<td></td>
<td>Are your CAPAs contributing to continual improvement?</td>
</tr>
<tr>
<td></td>
<td>Paula Parsons, Compliance Manager, AMGEN INC.</td>
</tr>
<tr>
<td>4:00</td>
<td><strong>EVALUATION OF RISK MANAGEMENT STRATEGIES, ROOT CAUSE ANALYSES AND CAPA PROCESSES</strong></td>
</tr>
<tr>
<td></td>
<td>Discuss the different risk management strategies employed by companies of all sizes in order to achieve successful RCA and CAPA implementation</td>
</tr>
<tr>
<td></td>
<td>Ways to determine risk and criticality of CAPAs</td>
</tr>
<tr>
<td></td>
<td>Managing internal resources and communication within different stakeholders to efficiently manage risks and close CAPAs in a timely manner</td>
</tr>
<tr>
<td></td>
<td>PANELISTS:</td>
</tr>
<tr>
<td></td>
<td>Denise Nazario, Global CAPA Manager, STRYKER</td>
</tr>
<tr>
<td></td>
<td>Dwayne Brazelton, Director, Clinical Quality Assurance, MACROGENICS, INC.</td>
</tr>
<tr>
<td></td>
<td>Glenda Abbott, Director, Quality Assurance, ABBOTT DIAGNOSTICS</td>
</tr>
<tr>
<td>4:45</td>
<td>Closing Remarks and Day One Concludes</td>
</tr>
</tbody>
</table>

“I like that the topics in the forum continue to evolve as the industry’s approach to CAPA and RCA continues to evolve.”

– Janssen

“One of the best conferences I have attended in my career”

– Pfizer
## POST-MARKET TRACK
### DAY TWO AGENDA / FRIDAY, JANUARY 23, 2015

**8:00** Registration & Continental Breakfast

**8:45** CHAIRPERSON’S OPENING REMARKS  
Kevin Wilson, Manager, Medicines Quality Organization, ELI LILLY AND COMPANY

### CLINICAL TRACK

**9:00** AUDITS AND INSPECTION READINESS IN THE CAPA LANDSCAPE  
- Determining a course of action when dealing with inspection findings, non-compliance and protocol deviations  
- CAPA closure for audit findings  
- Preparing for audits by categorizing CAPAS in order to determine the existence of systemic issues  
- Considerations for developing joint processes between industry organizations and CROs to prepare for inspections  

**PANELISTS:**  
Pearl Boakye, Head, Compliance Management, BAYER HEALTHCARE  
Cheri Wilczek, President, CLINAUDITS, LLC.  
Pamela Spierer, Director, Corporate Audit, PFIZER, INC.

**9:45** UTILIZING THE CAPA SYSTEM TO MOVE FROM REACTIVE TO PROACTIVE QUALITY  
- Trending of signals to identify study risks  
- Using past corrective actions to build preventive actions  
- Using the skills from root cause analysis to implement failure modes effects analysis  
- Closing the loop to continuously improve the quality in the design of studies  

**Kevin Wilson, Manager, Medicines Quality Organization, ELI LILLY AND COMPANY**

### POST-MARKET TRACK

**9:00** INDUSTRY’S BEST PRACTICES TO ACHIEVE AN EFFECTIVE POST-MARKET AND GLOBAL CAPA MANAGEMENT SYSTEM  
- Discuss the different integral procedures companies use to assess CAPAs escalations/de-escalations and which SOPs have been developed and employed  
- Learn about employee training, well-documented SOPs, and the use of technology to support post-market operations and compliance  

**PANELISTS:**  
Karl Vahey, Senior Director of Global Quality Compliance and Audit, COVIDIEN  
Julii Lindquist, CAPA and Audit Manager, BAYER HEALTHCARE (MEDRAD)  
Denise Nazario, Global CAPA Manager, STRYKER

**11:00** AN EXPLORATORY STUDY OF CAPA SYSTEMS IN GCP  
- Hear the reasons behind conducting a GCP study on CAPA systems  
- Learn about the steps for developing and implementing study, including lessons learned and key results  
- Discuss the challenges and potential benefits of a common approach for an effective CAPA system in GCP  

**Diogo Araujo, Global CAPA Manager, BAYER HEALTHCARE**

**11:45** RISK BASED MONITORING AND THE UNKNOWN IMPACT ON CLINICAL SITES  
- Discuss ways to improve quality and efficiency of clinical trials through the use of technology & collaboration  
- Learn about the impact of risk based monitoring on the roles of CRAs and site relationship  
- Challenges and considerations for clinical operations in a risk-based monitoring environment for the research site  

**Christine Pierre, President of the Society for Clinical Research Sites (SCRS)**  
**Stephanie deRijke, Director, Clinical Trials Audit and Compliance, EMORY UNIVERSITY**  
**Dawn Niccum, Quality Manager, ENDOCYTE**

### Panel

**10:30** Networking & Refreshment Break

**12:30** Luncheon

**1:45** INVESTIGATOR INITIATED TRIALS AND CAPAS DEVELOPMENT  
- Describe small-scale RCA and CAPA processes for single sites  
- Explore ways to engage the PI and study team  
- Discuss implications of institutional review board (IRB) reports and institutional involvement  

**Stephanie deRijke, Director, Clinical Trials Audit and Compliance, EMORY UNIVERSITY**

**2:00** DEVELOPING CAPAs IN THE MEDICAL DEVICES INDUSTRY  
- Methodologies for developing compliant CAPAs in the medical devices space  
- Evaluation of adverse events that arise from the use of medical devices and the link to a CAPA  
- How to address recalls and medical performances in comparison to other marketed products  

**Teri Savage, Principal Quality Improvement Analyst, MEDTRONIC**

**2:45** CONDUCTING AN EFFECTIVE FAILURE INVESTIGATION WHILE ADDRESSING THE TRUE ROOT CAUSE AND NOT THE SYMPTOMS  
- Importance of a failure investigation to achieve process improvements and the elimination of recurring issues  
- Failure investigations steps, risk assessment, good investigation practices, tools and examples  
- Industry performance, corrective actions and lessons learned  

**Karl Vahey, Senior Director of Global Quality Compliance and Audit, COVIDIEN**

**4:15** A POST-MARKET CAPA INTEGRATED QUALITY SYSTEM TO ELIMINATE THE CAUSES OF POTENTIAL NON-CONFORMITIES  
- Understand a company’s use of documented quality systems to prevent reoccurrence of non-conformities and minimize device failures  
- Ways to identify and verify product and quality problems, including communicating and documenting CAPA activities by the responsible parties  
- Examine CAPAs in complaint handling, reports of corrections and removals, product recalls, safety surveillance, quality audits and device tracking  

**Denise Nazario, Global CAPA Manager, STRYKER**

---

**Panelists:**  
Pearl Boakye, Head, Compliance Management, BAYER HEALTHCARE  
Cheri Wilczek, President, CLINAUDITS, LLC.  
Pamela Spierer, Director, Corporate Audit, PFIZER, INC.  
Diogo Araujo, Global CAPA Manager, BAYER HEALTHCARE  
Stephanie deRijke, Director, Clinical Trials Audit and Compliance, EMORY UNIVERSITY  
Dawn Niccum, Quality Manager, ENDOCYTE  
Kevin Wilson, Manager, Medicines Quality Organization, ELI LILLY AND COMPANY  
Karl Vahey, Senior Director of Global Quality Compliance and Audit, COVIDIEN  
Julii Lindquist, CAPA and Audit Manager, BAYER HEALTHCARE (MEDRAD)  
Denise Nazario, Global CAPA Manager, STRYKER  
Glenda Abbott, Director, Quality Assurance, ABBOTT DIAGNOSTICS  
Teri Savage, Principal Quality Improvement Analyst, MEDTRONIC  
Karl Vahey, Senior Director of Global Quality Compliance and Audit, COVIDIEN  
Denise Nazario, Global CAPA Manager, STRYKER  
Glenda Abbott, Director, Quality Assurance, ABBOTT DIAGNOSTICS
2:30 PROACTIVE RISK MANAGEMENT TO PREVENT THE CAUSE OF NON-CONFORMITIES AND THE USE OF CAPAs

- Methodologies for understanding risks involved in a CAPA management process
- Best practices for preventing risks and ways to respond to non-compliance
- Tools for proactive risk management, documentation and follow-ups
- CAPAs implementation without the need for a warning letter — shifting from the corrective action to the preventative action mindset

Pam Strobel, Quality Risk Management Portfolio Lead, Pfizer Inc.

3:15 Closing Remarks & Summit Concludes

Registration Fees:

<table>
<thead>
<tr>
<th>DISCOUNT</th>
<th>PRICING</th>
<th>DATES</th>
</tr>
</thead>
<tbody>
<tr>
<td>EARLY BIRD</td>
<td>$1,895</td>
<td>Register before December 5, 2014</td>
</tr>
<tr>
<td>STANDARD</td>
<td>$2,095</td>
<td>Register after December 5, 2014</td>
</tr>
<tr>
<td>ONSITE</td>
<td>$2,195</td>
<td></td>
</tr>
</tbody>
</table>

Group Discount Programs

Offers cannot be combined, early-bird rates do not apply. To find out more on how you can take advantage of these group discounts, call 866-207-6528.

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.

SAVE 15% PER PERSON WHEN REGISTERING THREE
Can only send three? You can still save 15% off of each registration.

To find out more on how you can take advantage of these group discounts, please call 866-207-6528.

A RISK-BASED APPROACH TO ACHIEVE REGULATORY COMPLIANCE, PRODUCT SAFETY AND AVOID DEATH BY CAPA

- Discuss strategies to determine which issues should be escalated/de-escalated to a CAPA status in the manufacturing phase
- Hear ways to address incidents that arise in the manufacturing process and the implementation of preventive actions through risk-based assessments
- Efficiently document the data required by the FDA to assess the effectiveness of a CAPA in the medical devices industry

Julii Lindquist, CAPA and Audit Manager, Bayer Healthcare (Medrad)
Prevent Non-Compliance and Achieve Successful Root Cause Analyses and CAPA System Implementation from Clinical to Post-Market

What's new for the 2015 event?

- 2 TRACKS covering clinical and post-market CAPAs
- CAPAs for medical device companies
- INTERACTIVE SESSIONS on root cause analysis, signal detection and CAPAs development
- 10+ unique perspectives on CAPA systems implementation and management
- 4+ interactive panel sessions and group discussions

TO REGISTER call 866-207-6528 or visit www.exlevents.com/CAPA