2nd Annual

Sustaining Effective CAPA Systems

Developing a Timely and Effective CAPA System to Uphold Quality and Maintain Compliance

July 30 - 31, 2014
Westin San Diego | San Diego, CA

Promote CAPA efficiency through the application of a risk-based approach.

marcusevans®

Overcome the struggle between corrective and preventative actions.

Conference Chairperson:

James Wabby
Director, Quality Systems and Risk Management
Allergan

Attending this premier marcus evans conference will enable you to:

- **Define** and measure a timely CAPA to optimize the allocation of available resources
- **Establish** a risk based approach to prioritize the investigation of CAPAs based on significance
- **Navigate** the intersection of nonconformities and CAPAs to determine when action is required
- **Assess** the potential impacts of product field actions on CAPAs
- **Establish** a joint system that allows for multinational CAPA reporting
- **Design** an enterprise-wide CAPA curriculum to boost participation and productivity

Who Should Attend:

marcus evans invites C-Level Executives, Managing Directors, EVPs, SVPs, VPs, Directors, Heads and other Senior Executives from the Medical Device and Pharmaceutical industries to attend.

- CAPA
- Quality Assurance / Quality Control / Quality Systems
- Regulatory Affairs
- Compliance
- Quality Engineer
- GCP, GLP or GMP professionals
- Product / Process Development

Current Speakers Include:

Carlos E. Lugo-Ponce
Director, Quality Assurance
Merck Sharp & Dohme

Patricia A. Lancos
World Wide CAPA Process Owner
Ethicon Inc., a Johnson & Johnson Company

Luz I. Collado
Vice President, Global Quality
Roche Diagnostics

Ryan Magee
Corporate Senior Manager, Risk Management, Renal Therapies Group
Fresenius Medical Care

Chris Hoag
Director, Global CAPA and Quality eSystems
Stryker

Denise Nazario
Global CAPA Manager
Stryker

Vishaka Rajaram
Associate Director, CAPA
Zimmer

Regina Fullin
Product Surveillance Leader
GE Healthcare

Richard A. Lubin
Senior Manager, Supplier Quality & Quality Engineering
Boston Scientific Neuromodulation

Julii Lindquist
Manager, CAPA, Audit & Training
Bayer HealthCare

Sherri Robbins
Director, Compliance
Edwards Lifesciences

James Wabby
Director, Quality Systems and Risk Management
Allergan

Will Ferguson
Senior Quality Systems Project Leader
Kinetic Concepts

Ken Peterson
Director, Business Development, Professional Services
MasterControl Inc.

Collis Laton
Training Director
PathWise Inc.

Debara R. Reese
Vice President Quality and Compliance
Maetrics

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7:30 Registration and Morning Coffee

8:15 Chairperson's Opening Remarks

DEFINING AND MEASURING A TIMELY CAPA TO OPTIMIZE THE ALLOCATION OF AVAILABLE RESOURCES

8:30

CAPA and the Drive to Continuous Improvement

- Embedding CAPA throughout the enterprise to meet increased requirements for continuous improvement
- Addressing difficulties inherent to the efficiency and effectiveness of the CAPA process that helps drive organizational excellence
- Using CAPA efficiently to minimize costs while continuously increasing product quality
- Striving for continuous improvement by linking actions taken in CAPA with problems that arise to create a closed-loop, quality process

Will Ferguson
Senior Quality Systems Project Leader
Kinetic Concepts

9:15

Establishing a Joint System that Allows for Multinational CAPA Reporting

- Promoting compliance efficiencies under the increased scrutiny of both the FDA and international regulators
- Embedding quality systems to keep pace in the increasing globalization of the market
- Increasing competitive advantage through the application of proven CAPA reporting technologies

Patricia A. Lancos
World Wide CAPA Process Owner
Ethicon Inc., a Johnson & Johnson Company

10:00

Balancing the Concerns of Regulators with those of the Organization to Determine the Proper Focus of CAPAs

- Considering all of the feeder processes and ensuring that appropriate filters are implemented before entering the formal CAPA system
- Avoiding "death by CAPA" by ensuring CAPAs are opened only in appropriate circumstances
- Using a risk-based assessment to evaluate the impact of potential scenarios in order to elicit the proper response

Julii Lindquist
Manager, CAPA, Audit & Training
Bayer HealthCare

10:45 Networking Break

11:15

Establishing Risk Based CAPA Systems to Avoid "Death by CAPA"

- Managing your Quality Event Resolution process faster and with better affectivity
- Learning how to respond with the appropriate action based upon risk
- Matching the depth of the investigation with the significance of the problem
- Comparing best practices for Quality Event Management (QEM) and CAPA to your company system
- Understanding "what to do" and "what not to do" under regulatory oversight
- Learning what management must do to facilitate a risk based process.

Ken Peterson
Director, Business Development, Professional Services
MasterControl Inc.

12:45 Networking Lunch Welcome

1:00 Networking Lunch

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PRODUCER INFO:

I would like to thank everyone who has assisted with the research and organization of the event, particularly the speakers for their support and commitment. **Justin Guinn,** justing@marcusevansch.com

ESTABLISHING A RISK BASED APPROACH TO PRIORITIZE THE INVESTIGATION OF CAPAS BASED ON SIGNIFICANCE

2:00

Verifying Safety and Effectiveness to Determine Successful CAPAs

- Implementing the right process to ensure CAPA effectiveness
- Developing repeatable procedures to ensure the consistent collection of correct data
- Establishing a level of effectiveness that is adequate based on risk tolerances and organizational goals
- Utilizing key process indicators to measure efficiency and effectiveness

Ryan Magee
Corporate Senior Manager, Risk Management, Renal Therapies Group
Fresenius Medical Care

2:45

CAPA: Challenges, Pitfalls…and How to Overcome Them

- Key CAPA traps companies frequently overlook
- Root cause analysis, tools, techniques, and other best practices
- Real world monitoring tips for CAPA programs
- Pitfalls in creating a positive CAPA culture within a conventional organization paradigm

Debara R. Reese
Vice President Quality and Compliance
Maetrics

3:30 Networking Break

4:00

Highlighting the Differences between Corrective and Preventive Actions to Ensure Proper Actions

- Drawing attention to common misconceptions and mistakes about corrective and preventive actions
- Evaluating quality data sources for the proper identification of corrective and preventive actions
- Common Challenges associated with corrective and preventive actions

Luz I. Collado
Vice President, Global Quality
Roche Diagnostics

4:45

Avoiding Recurrence by Performing a Root Cause Analysis to Accurately Identify all Solutions to a Problem

- Facts behind CAPA
- Implementing processes for identification of CAPA
- Examining methodologies to determine investigation root cause

Carlos E. Lugo-Ponce
Director, Quality Assurance
Merck Sharp & Dohme

5:30 Chairperson's Closing Remarks

5:40 Drinks Reception Welcome

5:45 Drinks Reception

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6:45 End of Day One

DISCLAIMER:

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8:30 Registration and Morning Coffee

8:55 Opening Remarks by Conference Chairperson

DESIGNING AN ENTERPRISE-WIDE CAPA CURRICULUM TO BOOST PARTICIPATION AND PRODUCTIVITY

9:00

Promoting an Improvement Oriented Management Culture to Create Buy-In at all Levels of the Organization

- Understanding CAPA as a necessary quality assurance tool used to maintain quality standards and sustain a learning organization
- Incorporating CAPA into the business model to promote CAPA as "good business" rather than a one-off exercise
- Utilizing the CAPA system in the larger risk management framework to enhance risk management capabilities

Regina Fullin
Product Surveillance Leader
GE Healthcare

9:45 Interactive Panel Discussion

Minimizing Scope Creep to Allow for Efficiency in the CAPA Request

- Attempting to define the scope of the CAPA from the onset to avoid wasting resources
- Ensuring CAPA owners document the focus during initial filings to enhance stakeholder awareness
- Gauging whether it is necessary to open additional CAPA requests when the scope of the original becomes too large

Facilitator:
James Wabby
Director, Quality Systems and Risk Management
Allergan

Panelists:
Richard A. Lubin
Senior Manager, Supplier Quality & Quality Engineering
Boston Scientific Neuromodulation

Patricia A. Lancos
World Wide CAPA Process Owner
Ethicon Inc., a Johnson & Johnson Company

Luz I. Collado
Vice President, Global Quality
Roche Diagnostics

10:45 Networking Break

11:15

Instituting a Robust Qualification Program to Support the CAPA System

- Determining roles in the CAPA system
- Defining qualification expectations
- Comparing qualification options
- Examining independent performance criteria
- Establishing effective documentation expectations

Collis Laton
Training Director
PathWise Inc.

12:00

Educating CAPA Owners on the Proper Documentation of CAPAs to Promote Complete and Sound Results

- Standardizing the content of CAPAs to allow for efficient and intuitive documentation
- Ensuring CAPA owners are familiar with the regulatory language contained within the CAPA
- Demonstrating the strategic benefits of opening a CAPA to maintain organizational quality and compliance standards

Sherri Robbins
Director, Compliance
Edwards Lifesciences

12:45 Networking Lunch Welcome

1:00 Networking Lunch

PathWise

NAVIGATING THE INTERSECTION OF NONCONFORMITIES AND CAPAS TO DETERMINE WHEN ACTION IS REQUIRED

2:00

Leveraging Management Responsibility and Quality System Internal Audit Practices to Reduce the Cost of CAPA

- Using risk management principles to reduce internal audit and CAPA costs
- Linkage between Management Responsibility and CAPA Management
- Challenges and Opportunities noted during CAPA Surveillance audits and regulatory inspections

James Wabby
Director, Quality Systems and Risk Management
Allergan

2:45

CAPA Engagement Model:

- The Problem – CAPA is often regarded as a documentation activity for compliance's sake, CAPA organization often avoided as the bearer of bad news, CAPA timeliness is an increasing focus from the FDA
- Factors – People working on CAPA do so beside their "normal" job, often after hours, and rarely do goals, objectives, and incentives for the organization include any around CAPA
- Model – Top Down (executive management buy in, etc.), Middle Level (these are the resource owners, exec level buy in needs to be translated through them), and Grass Roots (CAPA leads and owners)
- Lessons learned – What has worked and what hasn't, Recognition Model around CAPA

Vishaka Rajaram
Associate Director, CAPA
Zimmer

3:30 Networking Break

4:00

Defining and Measuring a Timely CAPA to Optimize the Allocation of Available Resources

- Aligning the CAPA system with quality and business objectives
- Making the CAPA process and systems as efficient and effective as required for organizational priorities
- Integrating systems to allow for the seamless and accurate retrieval of data
- Ensuring that complete data is entered into systems as timely as possible

Denise Nazario
Global CAPA Manager
Stryker

Chris Hoag
Director, Global CAPA and Quality eSystems
Stryker

4:45 Chairperson's Closing Remarks

5:00 End of Conference

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PathWise

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PharmaVOICE

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BioPortfolio

BioPortfolio is a leading news, information and knowledge resource covering the global life science industries impacted on by biotechnology. The site aims to provide the lay person, the researcher and the management executive with a single location to source core information on specific bio-related topics, to collate relevant data associated with each topic and to point the user to relevant knowledge resources.

Journal of Medical Device Regulation

The Journal of Medical Device Regulation is intended to educate, provide professional guidance, develop core competence of regulatory professionals, and promote debate on fundamental and topical matters within the medical device industry. In addition to publishing review and discussion articles by opinion leaders from the device community, it summarizes the international news headlines and provides useful reference information.
www.globalregulatorypress.com

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WHY YOU SHOULD ATTEND:

Maintaining a robust corrective and preventative action (CAPA) system remains one of the top priorities of medical device and pharmaceutical companies. Not only is such a system needed to keep up with increasing regulatory scrutiny, but the implementation and documenting of CAPAs is an essential step in ensuring products are upheld to a level of quality that is necessary to remain competitive in the industry.

The 2nd Annual Sustaining Effective CAPA Systems Conference offers timely, innovative insight from leaders within the medical device and pharmaceutical industries – all with a level of detail and clarity that comes from firsthand experience. Attendees will leave well prepared to ensure their CAPAs are closed in a timely and prioritized way, while also being able to assess the effectiveness of the CAPA system as a whole and any individual corrective or preventative actions that arise. Attendees will also explore the intersection of nonconformities and CAPAs and define the entry point into a CAPA to maintain efficiency and get the most out of the enterprise's systems.

SPONSORSHIP INFO:

Does your company have solutions or technologies that the conference delegates would benefit from knowing? If so, you can find out more about the exhibiting, networking and branding opportunities available by contacting: **Faraz Tafti** at 416 304 7990or FarazT@marcusevansto.com