

Quality Oversight for Medical Device Manufacturing Summit

Strategies to Create Compliant Medical Devices and Bring Products to Market Faster

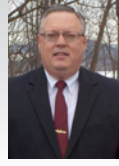
March 12-13, 2012 | Century Plaza Hyatt Regency | Los Angeles, CA

KEYNOTE PRESENTATIONS



QUALITY OVERSIGHT - ENSURE THE BALANCE BETWEEN BUSINESS AND COMPLIANCE

JAVAD SEYEDZADEH, SENIOR VICE PRESIDENT, QUALITY ASSURANCE & REGULATORY AFFAIRS, GAMBRO



CONDUCT SUCCESSFUL COMPLAINT INVESTIGATIONS

SAM BRAYTON, DIRECTOR, GLOBAL QUALITY OPERATIONS, ANGIODYNAMICS, INC

FEATURED PRESENTATIONS



STRATEGIES TO ENSURE COMPLIANCE WITH INTERNATIONAL REGULATORY REQUIREMENTS

MARCELO TREVINO, SENIOR QUALITY SYSTEMS & REGULATORY COMPLIANCE MANAGER, MEDTRONIC



RISK-BASED APPROACHES TO QUALITY SYSTEMS: MANAGE INTERNAL QUALITY AND MAINTAIN LEAN PRACTICES

TERESA CLARK, QUALITY ASSURANCE GENERAL MANAGER, ICU MEDICAL



ESTABLISH AND MAINTAIN AN IRON-CLAD SUPPLIER MANAGEMENT SYSTEM

TERRY VILLARBA, PRINCIPAL DESIGN ASSURANCE ENGINEER, BOSTON SCIENTIFIC NEUROMODULATION



BUILDING A WORLD CLASS CAPA SYSTEM

ROGER JANCZAK, DIRECTOR, CONTINUOUS IMPROVEMENT, ABBOTT

HEAR INDUSTRY EXPERTS FROM:

ABBOTT

ANGIODYNAMICS, INC

BANYAN BIOMARKERS, INC

BOSTON SCIENTIFIC

COVIDIEN

GAMBRO

ICU MEDICAL

MEDTRONIC

OMRON HEALTHCARE, INC.

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Dear Colleague,

As diagnostic tests increase in complexity and as FDA increases their surveillance, companies grapple to keep up to date with regulatory changes and struggle to ensure they continue to meet the strictest of QA standards. Warning letters from FDA have significantly increased, which has resulted in a need for greater due diligence in QA activities, from closer examination of suppliers to stronger design controls.

The Quality Oversight for Medical Device Manufacturing Summit is the foremost event that will bring together senior level quality executives to discuss how to ensure quality and compliance in medical device manufacturing, and offers attendees an unrivaled opportunity for learning and networking.

For any company, reviewing and understanding inspection requirements and manufacturing controls is a primary challenge. In addition, sustaining QA throughout the manufacturing processes and throughout a lifecycle of a product is critical. Through a top-down approach that integrates QA throughout an organization, companies will find fewer compliance infractions.

This event will provide attendees with best practices to improve your CAPA systems, complaint and medical device reporting, and documentation processes to prevent regulatory issues. Your company will stay ahead of the curve by ensuring the quality of suppliers and understand the changing trends of the FDA and other regulatory agencies in enforcing quality oversight. This event will give you the tools to create quality products and bring them to market as quickly as possible while remaining compliant.

This is a must attend event. Register today to reserve your place at the Quality Oversight for Medical Device Manufacturing Summit. We look forward to greeting you in March!



Miriam Feygenson
Conference Director

**CENTURY PLAZA
HYATT REGENCY
2025 AVENUE OF THE STARS
LOS ANGELES, CA 90067
1-888-421-1442**



Room Reservations:

If you require overnight accommodations, please contact the hotel and state that you are with **"ExL's March Meeting"** for information on our discounted room rates. **We encourage conference participants to make reservations by February 20, 2012 with our designated venue as our discounted room rates are limited.**

This Summit is specifically designed for Medical Device professionals with responsibilities in the following areas:

- ▶ Quality Assurance
- ▶ Regulatory Affairs
- ▶ Compliance
- ▶ Manufacturing
- ▶ Quality Systems
- ▶ Quality Engineering
- ▶ Product Development
- ▶ Validation
- ▶ Project Management
- ▶ Risk Management
- ▶ Crisis Management

This conference is also of interest to:

- ▶ Quality Assurance Service Providers
- ▶ Medical Technology Companies
- ▶ Notified Bodies
- ▶ Technology Vendors
- ▶ Speaker Bureaus
- ▶ Consultants
- ▶ Regulators and Policy Makers
- ▶ Health Services Researchers and Academics

Sponsorship and Exhibit Opportunities

Do you want to spread the word about your organization's solutions and services to potential clients who attend this event? Take advantage of the opportunity to exhibit, present an educational session, host a networking event, or distribute promotional items to attendees. ExL works closely with you to customize a package that suits all of your needs.

- 8:00 **Workshop Registration and Continental Breakfast**
- 9:00 **Supplier Quality: FDA Expectations in Documenting Quality in Third Party Manufacturers, Vendors, Suppliers, and Service Provider Controls**
- The following areas will be covered in this workshop:
- Purchasing/supplier requirements under the Quality System Regulation and the GHTF Guidance on supplier controls
 - Who are our suppliers:
 - Evaluation of potential suppliers
 - When should this evaluation start
 - Parties involved in the evaluation and supplier risk based categorization
 - Creating and maintaining a supplier approval list, supplier metrics and supplier certification program
 - Supplier auditing program
 - SCAR implementation/follow-through/closure
 - Quality agreement content and building strong partnerships with suppliers
 - Lessons learned including warning letter examples
- Led by:
VANESSA LOPEZ, SENIOR QUALITY AND REGULATORY CONSULTANT, QUALITY AND REGULATORY CONSULTING SERVICES
- 10:30 **30-minute Networking and Refreshment Break**
- 12:00 **Lunch for Workshop Attendees**

Main Conference Begins

- 12:00 **Conference Registration**
- 12:45 **Chairperson’s Welcome and Opening Remarks**
MICK HOWK, MSN, RAC, COE, HEALTH CARE SALES MANAGER, NORTH AMERICA, SYSTEMS AND SERVICES CERTIFICATION, SGS

1:00 **Quality Oversight - Ensure the Balance Between Business and Compliance**

In this comprehensive keynote presentation, hear how your organization can be ready to meet the rapid changes in the regulatory environment and insure the right balance between financial viability and compliance. The medical device industry faces a significant challenge in this area and this session delves into best practices in reducing risks in order to manufacture quality medical devices

- Understanding the changes in the regulatory environment and the potential impact on business processes
- Preparing for the transitioning landscape and creating flexible business strategy
- Implementing a harmonized quality system that ensures financial success and while maintaining compliance

JAVAD SEYEDZADEH, SENIOR VICE PRESIDENT, QUALITY ASSURANCE & REGULATORY AFFAIRS, GAMBRO

1:45 **Strategies for a Successful Transition of a Class 1 Medical Device Facility to a Class 3 Facility**

- US Regulatory Landscape --device classifications and submission type
- Differences in the classification
- Cost of quality and why classification is irrelevant
- Real world application

KAMBIZ DRAKE, ESQ, DIRECTOR OF QUALITY ASSURANCE AND REGULATORY AFFAIRS, SAKURA FINETEK

2:30 **Preparing for the Revision of the Medical Device Directives in the EU**

The Medical Device Directives in Europe are currently being revised. The revisions will impact all devices that fall under the Medical Device Directive (MDD), Active Implantable Directive (AIMD) and the In Vitro Diagnostics Directive (IVDD). This session covers the anticipated changes of the directives and provides the latest updates concerning these revisions. The time to start preparing is now, and this session will help attendees assess the potential impact of these changes on your organization, specifically:

- The product development process
- Quality management system
- Regulatory submission strategy and business plan

MINDY MCCANN, HEALTH CARE DIRECTOR, NORTH AMERICA, SYSTEMS AND SERVICES CERTIFICATION, SGS

3:15 **Afternoon Networking and Refreshment Break**

3:45 **Strategies to Ensure Compliance with International Regulatory Requirements**

This session will provide attendees with an understanding for the regulatory requirements imposed by the International Agencies and strategies for organizations to create an organized and global approach to regulatory compliance

- Overview of the Australian regulatory model
- Overview of the regulatory requirements for Latin America, Japan and other Asian countries
- Learn about international quality system requirements
- Understand common elements of regulatory requirements in different world regions

MARCELO TREVINO, SENIOR QUALITY SYSTEMS & REGULATORY COMPLIANCE MANAGER, MEDTRONIC

4:30 **Building a World Class CAPA System**

- Setting performance expectations for your CAPA system
- Training and certification of internal staff
- Providing regular feedback on the progress of your CAPA system
- Leverage CAPA data mining to ensure quality
- Growing a strong CAPA Culture

ROGER JANCZAK, *DIRECTOR, CONTINUOUS IMPROVEMENT, ABBOTT*

5:15 **Operationalize Regulation Changes Into Practice – Implementation of a CAPA Process**

- Getting help: warning letters, guidelines, online resources, standards, regulatory and quality associations
- How to read the regulations, language, terminology, interpretation, relevance
- Implementing a CAPA process that works
- Success factors and pitfalls when implementing regulation changes in your CAPA process

DANIEL KUEHLER, *COORDINATOR INTERNAL AUDITS, SMITH & NEPHEW ORTHOPEDICS AG*

6:00 **Close of Day One****Day Two – March 13, 2012**9:00 **Chairperson's Day Two Welcome and Opening Remarks**

MICK HOWK, *MSN, RAC, CQE, HEALTH CARE SALES MANAGER, NORTH AMERICA, SYSTEMS AND SERVICES CERTIFICATION, SGS*

12:45 **Lunch**9:15 **Establish and Maintain an Iron-Clad Supplier Management System**

- Demonstrating compliance with 21 CFR Part 820 and ISO 13485
- Identifying and selecting the right supplier
- Understanding the supplier metrics that count
- Dealing with sole sources and supplier proprietary processes
- How to manage supplier changes

TERRY VILLARBA, *PRINCIPAL DESIGN ASSURANCE ENGINEER, BOSTON SCIENTIFIC NEUROMODULATION*

1:45 **Risk-Based Approaches to Quality Systems: Manage Internal Quality and Maintain Lean Practices**

- Employing risk-based quality systems while maintaining compliance with medical device industry regulations
- Achieving compliance in a lean quality environment
- Learning which quality systems make good candidates for risk-based requirements

TERESA CLARK, *QUALITY ASSURANCE GENERAL MANAGER, ICU MEDICAL*

10:00 **Supplier Quality - Understanding and Meeting FDA Requirements**

- Understand the FDA regulations for supplier quality
- Knowing and avoiding the familiar misconceptions in FDA requirements
- Creating effective quality agreements with suppliers
- Create a process for IVD supplier qualification
- FDA's plans for ensuring medical device supply chain safety

DEVA H. PURANAM, *MS, MBA, DIRECTOR, QUALITY AND BIOSAFETY BANYAN BIOMARKERS, INC*

2:30 **Understanding the Challenges of Product Stability in the Medical Device Industry**

- Accelerated temperature vs. Real time ambient temperature aging
- Stability testing criteria and testing for aging related failure modes
- Stability during new product development
- Stability during sustaining manufacturing

JAMES HEAD, *QUALITY ASSURANCE ENGINEER, COVIDIEN ENERGY-BASED DEVICES*

10:45 **Morning Networking and Refreshment Break**11:15 **Revolutionize your Complaint Handling System - Lessons Learned from a Recent FDA Audit**

- Strategies to avoid FDA 483 forms and warning letters
- Ensure compliance with 21 CFR 820.198 requirements
- Understanding the differences between FDA requirements vs FDA expectations
- Industry best practices to revamp your complaint handling system

MIRNA DIPANO, *DIRECTOR - QUALITY & REGULATORY, OMRON HEALTHCARE INC*

3:15 **Ensuring Quality Through Compressive Documentation Practices**

- Defining and understanding Document Control in a regulated industry
- Understanding GDP (Good Documentation Practices)
- Comparative overview of relevant standards and their documentation requirements
- The compliance challenge through growth and change
- Planning and preparation for EDMS (Electronic Document Management System)

NANCY AUSPELMYER, *DOCUMENT SYSTEMS SUPERVISOR, ANGIODYNAMICS, INC*

12:00 **Conduct Successful Complaint Investigations**

In this interactive session, walk through a step-by-step process for conducting a complaint investigation

- Understand the complaint information and fill the gaps
- Conduct effective complaint investigations based on requirements
- Establish roles and responsibilities for conducting complaint investigations
- Knowing when to stop digging during the investigations
- Managing collected data from post investigations

SAM BRAYTON, *DIRECTOR, GLOBAL QUALITY OPERATIONS, ANGIODYNAMICS, INC*

4:00 **Chairperson's Closing Remarks and Close of Conference**

MICK HOWK, *MSN, RAC, CQE, HEALTH CARE SALES MANAGER, NORTH AMERICA, SYSTEMS AND SERVICES CERTIFICATION, SGS*

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 Conference Code P261

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 Register Before January 27, 2012
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Conference + Workshop	\$1995
Conference Only	\$1695

Standard Pricing
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