Ensuring Continued Compliance with Evolving Regulatory Guidelines while Maintaining the Highest Level of Quality Assurance and Reducing Costs in Medical Device & Diagnostic Manufacturing Facilities

DISTINGUISHED PRESENTERS INCLUDE:

- Peter E. Shearstone  
  DVP Global Quality Assurance  
  ABBOTT
- Matthias Bürger  
  VP Quality Assurance & Regulatory Affairs EMEA  
  ZIMMER
- Wolfgang Werner  
  VP Quality Management, Regulatory Affairs & Operations  
  SEQUANA MEDICAL
- Hans Freriks  
  Manager, Quality Assurance & Regulatory Affairs  
  PHILIPS
- Sabine Ohse  
  IVD Expert & Auditor  
  BSI GROUP
- Julia Korus  
  Head of Regulatory Affairs  
  MEDELA
- Ulf Lundgren  
  Head of Quality Assurance & CA  
  TIGRAN TECHNOLOGIES
- Beate Allgeier  
  Sterility Assurance Specialist  
  STRYKER
- Jan Pullen  
  Director Quality & Regulatory  
  OXFORD IMMUNOTEC
- Antonio Fassio  
  Corporate Regulatory Affairs & Quality Assurance Director  
  DIASORIN
- Geoffrey Potter  
  Partner  
  PATTERSON BELKNAP WEBB & TYLER LLP
- Joachim Wilke  
  Director Regulatory Affairs & Policy Europe  
  MEDTRONIC
- Clemens Haas  
  Eucomed ETF & GS1 HLT  
  Member, Product Identification  
  Manager, Global Sourcing & Supply Chain Management  
  FRESENIUS KABI
- Marike van’t Root  
  CEN/CLC TC 3 Secretary & Medical Technology Consultant  
  NEN (DUTCH STANDARDISATION INSTITUTE)
- Hans Freriks  
  Manager, Quality Assurance & Regulatory Affairs  
  PHILIPS
- Sabine Ohse  
  IVD Expert & Auditor  
  BSI GROUP
- Julia Korus  
  Head of Regulatory Affairs  
  MEDELA
- Ulf Lundgren  
  Head of Quality Assurance & CA  
  TIGRAN TECHNOLOGIES
- Beate Allgeier  
  Sterility Assurance Specialist  
  STRYKER
- Jan Pullen  
  Director Quality & Regulatory  
  OXFORD IMMUNOTEC
- Antonio Fassio  
  Corporate Regulatory Affairs & Quality Assurance Director  
  DIASORIN
- Geoffrey Potter  
  Partner  
  PATTERSON BELKNAP WEBB & TYLER LLP
- Joachim Wilke  
  Director Regulatory Affairs & Policy Europe  
  MEDTRONIC
- Clemens Haas  
  Eucomed ETF & GS1 HLT  
  Member, Product Identification  
  Manager, Global Sourcing & Supply Chain Management  
  FRESENIUS KABI
- Marike van’t Root  
  CEN/CLC TC 3 Secretary & Medical Technology Consultant  
  NEN (DUTCH STANDARDISATION INSTITUTE)
- Hans Freriks  
  Manager, Quality Assurance & Regulatory Affairs  
  PHILIPS
- Sabine Ohse  
  IVD Expert & Auditor  
  BSI GROUP
- Julia Korus  
  Head of Regulatory Affairs  
  MEDELA
- Ulf Lundgren  
  Head of Quality Assurance & CA  
  TIGRAN TECHNOLOGIES
- Beate Allgeier  
  Sterility Assurance Specialist  
  STRYKER
- Jan Pullen  
  Director Quality & Regulatory  
  OXFORD IMMUNOTEC
- Antonio Fassio  
  Corporate Regulatory Affairs & Quality Assurance Director  
  DIASORIN
- Geoffrey Potter  
  Partner  
  PATTERSON BELKNAP WEBB & TYLER LLP
- Joachim Wilke  
  Director Regulatory Affairs & Policy Europe  
  MEDTRONIC
- Clemens Haas  
  Eucomed ETF & GS1 HLT  
  Member, Product Identification  
  Manager, Global Sourcing & Supply Chain Management  
  FRESENIUS KABI
- Marike van’t Root  
  CEN/CLC TC 3 Secretary & Medical Technology Consultant  
  NEN (DUTCH STANDARDISATION INSTITUTE)
- Hans Freriks  
  Manager, Quality Assurance & Regulatory Affairs  
  PHILIPS
- Sabine Ohse  
  IVD Expert & Auditor  
  BSI GROUP
- Julia Korus  
  Head of Regulatory Affairs  
  MEDELA
- Ulf Lundgren  
  Head of Quality Assurance & CA  
  TIGRAN TECHNOLOGIES
- Beate Allgeier  
  Sterility Assurance Specialist  
  STRYKER
- Jan Pullen  
  Director Quality & Regulatory  
  OXFORD IMMUNOTEC
- Antonio Fassio  
  Corporate Regulatory Affairs & Quality Assurance Director  
  DIASORIN
- Geoffrey Potter  
  Partner  
  PATTERSON BELKNAP WEBB & TYLER LLP
- Joachim Wilke  
  Director Regulatory Affairs & Policy Europe  
  MEDTRONIC
- Clemens Haas  
  Eucomed ETF & GS1 HLT  
  Member, Product Identification  
  Manager, Global Sourcing & Supply Chain Management  
  FRESENIUS KABI
- Marike van’t Root  
  CEN/CLC TC 3 Secretary & Medical Technology Consultant  
  NEN (DUTCH STANDARDISATION INSTITUTE)

PROGRAM OVERVIEW

Throughout Europe, manufacturers of Medical Devices and Diagnostic Tests are facing tremendous challenges as they work to maintain the quality of their products. As Device companies face ever increasing pressure to reduce operating costs in order to pass these savings onto healthcare systems that are encountering reduced budgets, but that are desirous for new technologies, the challenges only surmount. Coupled with increasing regulatory vigilance in the form of updated Medical Device Directives, ISO regulatory changes and FDA surveillance, and lack of clarity related to the interpretation and implementation of new regulations, device & diagnostic companies are experiencing pressures from every angle.

Certainly the first step in maintaining a high level of quality assurance for medical products and within facilities is having a firm and comprehensive understanding of regulatory guidance. While regulations are clearly aimed at creating a solid framework for quality operations, the actual guidance and implementation can at times be quite open to interpretation. Understanding how to satisfy regulatory requirements from a notified body perspective, as well as maintaining compliance with FDA and ISO regulations is a first step in ensuring quality is consistently achieved. With perspectives that will include regulatory bodies such as standardisation institutes and notified bodies, as well as perspectives from industry executives that have overcome tremendous challenges to maintain and improve their quality assurance, these sessions will provide immediate take-away's for program participants.

As with all Q1 conference programs, keynote presentations, case studies and panel discussions will illuminate the challenges and opportunities within the medical device and diagnostic industries as related to maintaining quality assurance in manufacturing facilities. Speakers will provide attendees with the opportunity to engage with industry experts in a neutral setting. The addition of notified body and standardisation institute speakers, as well as authorized representatives and consultants will round out the program, ensuring that no question is left unanswered. Formal and informal networking opportunities will further the dialogue, creating meaningful connections within the industry.
DAY ONE / MONDAY, NOVEMBER 7

9:00 REGISTRATION & WELCOME COFFEE

9:45 OPENING REMARKS

10:00 STRATEGIES TO FIND THE APPROPRIATE BALANCE BETWEEN LOW COSTS AND HIGH QUALITY

From rigorous quality control and testing to innovation in new products and materials, the cost of designing, manufacturing and launching a medical device is extremely high. Given that the price and integrity of the product must stay in-line with the safety and efficacy required by regulators for clearance, understanding how to balance costs and quality is very challenging for quality assurance teams. Assessing budgets for the different steps in manufacturing processes and implementing adequate strategies to reduce expenses will efficiently achieve an appropriate balance between low costs and high quality.

- Considering outsourced plants in emerging markets
- Investing in design & quality system software to ultimately reduce costs
- Recognizing positive outcomes of automation systems
- Implementing customization options to meet specific customer needs

Peter E. Shearstone, DVP Global Quality Assurance

ABBOTT

10:45 EFFICIENT RISK MANAGEMENT THROUGHOUT THE DEVICE LIFECYCLE

The lifecycle of a medical device includes numerous stages, which incorporate potential risks that must be considered by quality assurance teams. Risk assessment, control and management throughout the product’s utilization is critical to ensure the safety of the end-user, as well as the reliability of the product. Incorporating overall risk management as an integrated component of the quality management system will enhance risk prevention and help reduce costs linked to potential recalls.

- Assessing potential risks in the utilization of the device
- Development team decisions that can impact quality assurance
- Evaluation of overall residual risk acceptability
- Implementation of risk control measures

Hans Freiks, Manager, Quality Assurance & Regulatory Affairs

PHILIPS

11:30 SUCCESSFULLY MAINTAINING COMPLIANCE WITH EVOLVING REGULATIONS

Establishing an efficient plan to successfully develop and launch a medical device on different markets worldwide is extremely challenging. Quality assurance teams must adapt their manufacturing processes with the goal of meeting country-specific regulations in addition to the MDD and FDA guidelines. Given that these standards are in constant evolution, the task of implementing an overall compliant manufacturing plan is very complex. Addressing this issue and examining successful design strategies will help quality assurance teams overcome this critical step of the device manufacturing process.

- Obtaining updated knowledge of relevant regulations and guidelines
- Recognizing country regulations when selecting manufacturing sites
- Strategies to include a variety of requirements in one product design plan

Jan Pullen, Director Quality & Regulatory Affairs

OXFORD IMMUNOTEC

12:15 LUNCHEON FOR ALL SPEAKERS, SPONSORS & ATTENDEES

1:15 RECOGNIZING CHALLENGES IN THE IMPLEMENTATION OF REVISED DIRECTIVES

While the revision of the MDD guidelines has brought more clarity to quality and safety requirements within the European device and diagnostics environment, it has also raised a number of questions to manufacturers. With the forthcoming IVDD Recast, members of the in vitro diagnostics industry are also concerned about imminent changes and adaptive solutions to implement to meet new requirements. Correct interpretation of regulations governing medical products is essential to ensure compliance and it is critical that product design and quality assurance teams understand Notified Bodies expectations for their products to be CE marked and eventually launched on the market.

- Clarification of the MDD revision in 2010
- Class Ila & Iib devices: understanding the revised sampling regime
- Examining the new approach to technical file reviews
- Recast of the IVDD: what to expect?
- Overview of the proposed changes
- Competent Authority concerns and debates
- Overall impact of revisions on quality assurance

Sabine Ohse, IVD Expert & Auditor

BSI GROUP

2:00 SELECTING AND CONTRACTING WITH OUTSIDE MANUFACTURING PARTNERS

Contracting with an external manufacturer offers many advantages to device manufacturers, from cost-savings to access to sophisticated technologies that streamline processes. While the opportunities in successful partnerships are broad, identifying and selecting the most appropriate external manufacturer can be challenging when assessing which company will be most compliant for the desired work. Furthermore, once a potential partner is identified, it is critical that quality assurance teams have authorization to inspect the facility and assess compliance to relevant regulatory standards, as they also apply to outsourced manufacturers and determine the overall compliance of the final product. Addressing these challenges will provide quality executives with perspectives on how to target and contract with the ideal partner.

- Considering cultural synergies when contracting with non-European partners
- Assessing the potential partner’s compliance to relevant regulations
- Inspecting facilities before and after contracting
- Overview of the imperative clauses to have on the contract

Matthias Bürger, VP Quality Assurance & Regulatory Affairs

EMEA ZIMMER


In today’s expanding global market, the necessity of standardised requirements for medical products is critical to ensure compliance with national and country-specific regulations. The ISO 13485:2003 provides a good base model for conformity with the European MDD guidelines and is becoming widely accepted as the international standard to oversee medical devices. Also in-line with the industry is ISO 14971:2007, providing manufacturers with a framework to correctly apply risk management to their product life-cycle. However, some nations strongly oppose to these standards for inconsistency with key essential requirements of the MDD.

- Understanding why Sweden refuses ISO 13485:2003
- Examining European Commission’s formal objection to ISO 14971:2007
- Debate surrounding potential alternatives to both ISOs
- Forecasting of relevant ISO revisions to come

Marieke van’t Root, CEN/CLC TC 3 Secretary & Medical Technology Consultant

DUTCH STANDARDISATION INSTITUTE

Paul Sim, TC 210 Member, Chair of ISO 13485 & 14971 BSI Committees & Regulatory Affairs Manager

BSI GROUP

Matthias Bürger, VP Quality Assurance & Regulatory Affairs

EMEA ZIMMER

Wolfgang Werner, VP Quality Assurance, Regulatory Affairs & Operations

SEQUANA MEDICAL

3:30 COFFEE & NETWORKING BREAK

4:00 EXAMINING POTENTIAL POSITIVE OUTCOMES OF E-LABELING IN EUROPE

With the European Union being composed of a multi-lingual environment, the requirement by national laws to provide instructions for use in paper-format represents a significant challenge for manufacturers. Not only are paper-format instructions difficult to manage logistically, but also extremely costly and difficult to handle for users as manufacturers work to secure labels with full usage instructions in up to 23 languages. While electronic IFUs for medical devices are already authorized in electronic formats in the U.S. and Canada, the European Commission has just released a new regulation, allowing eIFUs. From reducing costs to better presentation to users, the implementation of eIFUs in the European market will certainly prove to be efficient for the health care system.

- Overview of the directive
- Considerations on concerned families of medical products
- Risk assessment and other requirement

Joachim Wilke, Director Regulatory Affairs & Policy Europe

MEDTRONIC

4:45 WHAT TO EXPECT WITH UNIQUE DEVICE IDENTIFICATION GUIDELINES

In the ever-growing medical device field, the need to better follow the utilization of products is critical. Currently, many device executives and organizations as the European Commission, FDA and GHTF are designing UDI specific standards to provide manufacturers with formal guidelines and instructions on this imminent legislation. From tracking of an implantable device to reducing recall probabilities, the forthcoming implementation of unique device identification will improve the overall commitment of device manufacturers to quality assurance.

- EUCOMED perspective on UDI
- What does UDI mean for a manufacturer?
- Considering implementation costs & examining UID/ID content
- Expected time-line before implementation

Clemens Haas, Eucomed ETF & GS1 HLT Member, Product Identification Manager, Global Sourcing & Supply Chain Management

FRESENIUS KABI

5:30 CLOSING REMARKS & DAY ONE CONCLUSION
9:00 RAISING CONCERNS IN COUNTERFEIT MEDICAL DEVICES: HOW TO PREVENT FRAUD

The medical device market has rapidly evolved over the course of the past decade, and shows little sign of potential decline. Medical device opportunities have been recognized not only by manufacturers but also non-official networks which produce counterfeit medical products to be sold through legal supply chains worldwide. Most importantly, counterfeits have no quality testing or risk assessment, directly implicating the manufacturer’s liability in the case of an accident. Being aware of the risks and possible outcomes of counterfeit abuse will help quality executives understand which strategies to adopt to prevent fraud.

- Overview of the most affected families of devices
- Tightening the security and control of the supply chain
- Considering the risks in on-line sales
- Working with anti-counterfeiting agencies

Geoffrey Potter, Partner
PATTERSON BELKNAP WEBB & TYLER LLP

9:45 SUCCESSFUL FDA AUDITS IN DEVICE MANUFACTURING FACILITIES

Medical products intended to be launched in the United States market must meet FDA manufacturing, quality and safety requirements. This regulatory system differs from the European standards, and it is common that FDA representatives thoroughly inspect and audit facilities manufacturing products that will be utilized in the United States. Examining strategies from a device company’s successful experience with FDA audits will provide quality executives with ideas and tactics to remain prepared.

- Maintaining updated knowledge of FDA regulatory framework
- Global centralization of data, knowledge & strategies within the same company
- Internal inspections to prepare for FDA audits

Ulf Lundgren, Head of Quality Assurance & CAQ
TIGRAN TECHNOLOGIES AB

10:30 COFFEE & NETWORKING BREAK

11:00 OVERCOMING CHALLENGES IN STERILIZATION IN DEVICE MANUFACTURING

Products intended to be used in the healthcare setting are required to maintain a very low level of microbes and bacteria in order to prevent contamination and infection risks for end-users. The various stages of manufacturing, processing and ultimately packaging medical devices pose great challenges to quality assurance teams who must assess and ensure that the final product meets sterilization standards and is safe for utilization. From steam over radiation to gas, a number of familiar sterilization methods exist to gather sterilization conformity. Recognizing means of relevant standards to achieve an appropriate sterilization level will ensure quality assurance teams with a better management of this process.

- Overview of reliable standards to manage the sterilization process
- Validation of the sterilization process – what has to be done and how?
- Methods and sterilization assurance
- Working with sterilization sub-contractors

Beate Allgeier, Sterility Assurance Specialist
STRYKER

11:45 IMPLEMENTING AND EXECUTING A USABILITY ENGINEERING PROCESS

With the 2007/47/EC revision of the European Medical Device Directive, manufacturers are facing the challenges of being compliant with the new usability requirements. Following the IEC Standard 62366 does not only mean creating some additional documents for a usability engineering file but can be a chance to lead to safer and better products once you understand and use the advantages of a good usability engineering process. Where do we come from and where do we want to be in future - sharing our learning & experience.

- How to be compliant for devices marketed before March 2010
- Integrating usability engineering into your existing process map
- Creating a usability engineering file according to IEC 62366

Julia Korus, Head of Regulatory Affairs
MEDELA

12:30 LUNCHEON FOR ALL SPEAKERS, SPONSORS & ATTENDEES
SPEAKER SPOTLIGHT:

PETER SHEARSTONE
DIVISIONAL VICE PRESIDENT,
GLOBAL QUALITY ASSURANCE
ABBOTT DIAGNOSTICS

Peter Shearstone is the Divisional Vice President, Global Quality Assurance, responsible for Abbott Diagnostics reagent, instrument and supplier quality across all global manufacturing locations. He is also responsible for the division Compliance, Quality Systems, Medical Events, Customer Care, Supply Chain QA, Learning and Quality Programs teams.

Peter joined Abbott in January 2008 as Senior Director, Quality Systems Design. In mid-2008 he assumed responsibility for R&D QA, Medical Events, Quality Systems and Quality Programs. He was appointed Division Vice President, Quality Systems in April 2010. In December 2010 he assumed responsibility for U.S. Instrument and Reagent manufacturing quality and in February 2011 he assumed responsibility for the International Reagent manufacturing quality operations.

Prior to joining Abbott, Peter held a number of senior positions with Power Medical Interventions, Dade Behring (Siemens), Bayer Diagnostics (Siemens), the Tenax Corporation and Owl Scientific Plastics in Sales, Quality, Technical Support, R&D, Project Management and Regulatory Affairs. Peter earned his bachelor’s degree in Biology from Salem State University in Salem, Massachusetts.

WHO SHOULD ATTEND:

This conference has been designed to bring together top level executives from the medical device and diagnostic industries across Europe to discuss and debate their challenges in driving quality assurance within their organizations. As a result, the job titles of executives that will find this program content of most interest will primarily include Vice Presidents, Directors and Specialists of:

- Quality Assurance
- Quality Systems
- Compliance
- Regulatory Affairs
- Quality Specialists
- Quality Managers
- Product Quality Development
- Quality Engineering

SPONSORSHIP OPPORTUNITIES:

At this time, there are a variety of sponsorship and exhibition opportunities available for companies wishing to increase their visibility and participation in the program, ranging from keynote speaking opportunities through to exhibitor and documentation sponsors. Organizations most suitable for this type of exposure provide services and solutions including:

- Quality Assurance / Quality Control Consultants
- Quality Systems Software Manufacturers
- Contract Manufacturing Companies
- Component Manufacturers
- Analytical Instrumentation
- Auditing Services
- Lean Manufacturing Consultants

PREVIOUS ATTENDEES INCLUDE:

Sr. Manager, Quality Assurance, ABBOTT DIABETES
Director, Quality Engineering, ABBOTT DIAGNOSTICS
Director, Quality Assurance, AUERON LABS
Director, Quality Assurance, AXIS-SHIELD
Group Leader, Product Development, AVIIR
Quality System Supervisor, BD DIAGNOSTICS
Internal Audit & Training Mgr., BD DIAGNOSTICS
Director of Quality CABI, BECKMAN COULTER
Quality Director, BECKMAN COULTER
Director, Quality Systems, BIOMERIEUX
Director, Quality, BIOMERIEUX, INC.
Executive Director, Quality, BIOMERIEUX, INC.
Director, Quality Management, BIOMERIEUX, INC.
Manager, Quality Assurance, CARDIODX
VP Quality Systems, CEPEHE
VP Quality Assurance, CHEMBIO DIAGNOSTICS
Lab Manager, CLARIENT
Quality Assurance Manager, CORGENIX MEDICAL
Director, Quality Systems, CYLEX INCORPORATED
VP Regulatory & Quality, DAKO DIAGNOSTICS
Manager, Quality Systems, DIASORIN
Director, Corporate Quality, DIASORIN
Chief Scientific Officer, DIIOGENIX
Quality Assurance Lead, DYNEX TECHNOLOGIES
Compliance Reviewer, FDA OIVD
Compliance Officer, FDA CHICAGO OFFICE
VP Regulatory Affairs & Quality Assurance, GENBIO
Director, Quality Systems, GEN-PROBE
VP Operations, GREAT BASIN SCIENCE
Director, Quality & Regulatory Affairs, HOLOGIC
VP Business Systems, IDAHO TECHNOLOGY
Director, Quality Assurance, IDAHO TECHNOLOGY
VP Worldwide Regulatory Affairs, IMMUCOR
Quality & Regulatory Manager, INNOGENETICS
VP R&D, INTELLIGEND MDX
VP Quality Assurance & Regulatory, IRIS INT’L
VP & Chief Scientific Officer, LABNOW, INC.
SVP Regulatory & Quality, MERIDIAN BIOSCIENCE
Director, QA, MESOSCALE DIAGNOSTICS
Director of R&D, MIRACULINS
Director, Quality Assurance, MICROPHAGE
Associate Director, MDx QA, NOVARTIS MOLECULAR
Associate Director, Compliance, NOVARTIS
Director, Quality & Regulatory Compliance, NUGEN
Manager, Regulatory Affairs, ORTHO CLINICAL DX
VP Quality & Regulatory, OMNYX
Director, Quality Systems & Compliance, ROCHE
VP Regulatory Affairs, ROCHE
VP Integration, SIEMENS
Sr. Manager, Quality Systems, SIEMENS
Sr. Manager, Quality Systems, SIEMENS
Manager, Quality Assurance, SOMALOGIC
Director, Operations & Quality, SOTERIA
Director, Quality Engineering, SUNTRON CORP
Chief Scientist, SWORD DIAGNOSTICS
Quality Assurance Associate, TETRACORE
Sr. Director, Quality Assurance, THERMO FISHER
Dir., Product Manufacturing, THERMO FISHER
Quality Assurance Lead, TREK DIAGNOSTICS
Director, Quality & Regulatory, VIVACTA