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**FRANKFURT, GERMANY**
**December 8-9, 2014**

*3rd Annual*

# EUROPEAN QUALITY ASSURANCE IN DEVICE & DIAGNOSTIC MANUFACTURING CONFERENCE

**Best Practices in Handling Regular & Unannounced Audits, Addressing MDR & IVDR Developments & Impact on Quality Assurance Operations, all while Exploring Efficient Strategies in Change Control Management & Process Validation**

## PROGRAM OVERVIEW:

As new regulatory requirements continue to evolve across Europe, quality assurance teams within medical device and diagnostic manufacturing firms are continually looking to stay ahead of the curve and prepare facilities and teams for changes in requirements. Of particular concern at this time is the launch of unannounced audits by Competent Authorities across Europe; from understanding new areas of inspection, to effective ways to communicate with authorities both before, and after the audit. As the Medical Device Regulation (MDR) comes into effect, there is also much uncertainty surrounding the potentially expanded role of Notified Bodies in handling audits, and the ongoing impact this will have on quality systems and procedures.

Additional issues to be addressed during this third annual program will include advanced methods for handling change control, internally as well as with external supplier partners, as well as process validation, a continual concern for quality teams. Taking monitoring of quality to a higher degree, executives will address challenges in working to oversee sales and marketing quality as products are sold via distribution partners throughout the world. Understanding how to monitor these relationships as well as handling complaints and follow-up on quality assurance matters is critical.

Through perspectives from high level key opinion leaders from the industry, academia and regulatory bodies, clarity will be provided on many challenging aspects of quality assurance management in Europe.

**CONFERENCE SPONSORS:**

MEDICAL ENGINEERING TECHNOLOGIES
EXCELLENCE IN DEVICE TESTING

Michael Schaefer
Quality Management and Regulatory Affairs

## DISTINGUISHED PRESENTERS INCLUDE:

**Frédérique Pedretti-Abel**
*Vice President International Quality*
**EDWARDS LIFESCIENCES**

**Matthias Bürger**
*Vice President of Quality Assurance & Regulatory Affairs EMEA*
**ZIMMER**

**Erik Raadsheer**
*Senior Director Quality & Regulatory Affairs, Market Group EMEA*
**PHILIPS HEALTHCARE**

**Melissa Finocchio**
*Director, Global Product Labeling & Documentation*
**BIOMÉRIEUX**

**Gert Bos**
*President*
**TEAM NB**
*Head of Regulatory & Clinical Affairs*
**BSI HEALTHCARE**

**Yves Ohandja**
*Manager Quality & Regulatory, Europe*
**IMMUCOR**

**Joachim Wilke**
*Director Regulatory Affairs & Policy Europe*
**MEDTRONIC**

**Toni Kennet Jorgensen**
*Head of Operations, Quality & Regulatory Affairs*
**SORIN GROUP**

**Frank Meyer**
*Quality Management – Head of Documentation*
**B. BRAUN MEDICAL**

**Karina Hellbert**
*Attorney-at-Law & Head of Life Sciences/Pharmaceutical Law*
**FIEBINGER POLAK LEON ATTORNEYS**

**Fàtima Dionisio**
*Sr Manager Regulatory/Quality Latin America & Canada International Regulatory Affairs/ Division Labeling*
**ABBOTT**

**Tim Whitchurch**
*Staff Engineer, Safety Risk Management & Surveillance*
**ORTHO CLINICAL DIAGNOSTICS**

**Nicolas Guignet**
*Senior Quality/Regulatory Program Manager, CRHFM Global Supplier Quality*
**MEDTRONIC**

**Kristine Vandierendonck**
*Quality Systems Manager*
**TERUMO EUROPE**

**Vicki Snow**
*Senior Manager, Global Regulatory Audit & Compliance*
**SMITHS MEDICAL**

**Michael Schaefer**
*Quality Management & Regulatory Affairs Expert in Medical Devices*
**MICHAEL SCHAEFER QUALITY MANAGEMENT & REGULATORY AFFAIRS**

**Marta Carnielli**
*Safety Risk Management & Surveillance Manager*
**ORTHO CLINICAL DIAGNOSTICS**

**Erik Schwanbom**
*Professor of Risk Management*
**UNIVERSITY OF LÜBECK**

**Vincent Westenberg**
*Quality & Regulatory Lead, Commercial Operations*
**PHILIPS HEALTHCARE**

**Nick Gould**
*Principal Engineer, Safety Risk Management & Surveillance*
**ORTHO CLINICAL DIAGNOSTICS**

# 3rd EU QUALITY ASSURANCE IN DEVICE & DIAGNOSTIC MANUFACTURING

## *DAY ONE / MONDAY, DECEMBER 8*

**8:00 REGISTRATION & WELCOME COFFEE**

**8:50 CHAIRPERSON'S OPENING REMARKS**

**9:00 KEYNOTE - IMPROVING QUALITY VS DECREASING RESOURCES: UPDATING QUALITY STRATEGIES TO FIT EVOLVING MANUFACTURING ENVIRONMENTS**

In the currently tight European economic environment, device and diagnostic corporations are increasingly faced with budget cut-backs and downsized staff requirements from upper management, impacting manufacturing processes and quality assurance teams. To ensure quality assurance is maintained at the highest level, quality executives must continuously revise and update strategies to address this evolving work environment and identify new ways of operating within imposed constraints all while remaining in compliance with health authority requirements. Examining a practical approach to quality assurance in manufacturing with restrained resources will certainly provide participants with insightful ideas to make all ends meet and remain at the forefront of quality excellence.

- Identifying areas in which expenditure may be contained
- Addressing concerns in downsizing QA teams
- Continuously improving quality regardless of constraints
- Efficiently updating quality assurance & manufacturing strategies

**Matthias Bürger**, *VP of QA & Regulatory Affairs EMEA,* **ZIMMER**

**9:45 EXPLORING INSIGHTFUL PRACTICES IN QUALITY PROCESS (RE)VALIDATION**

In order to prove compliance and consistency in production to regulators, quality executives must develop a thorough and detailed validation process which clearly highlight operations and documentation related to product performance and consistent quality levels. When a product undergoes a modification or a new component is added to the manufacturing process, the validation process must be revised as well, increasing the overall complexity for quality teams in developing a new process validation protocol to present to authorities. Furthermore, when revalidation is necessary, handling and specifically documenting the transition is a time consuming task for quality executives, currently on the lookout for strategies to compliantly expedite validation operations.

- Addressing process validation challenges
- Gauging the need for revalidation
- Step by step approach to revalidation
- Lean Six Sigma application to revalidation
- Successfully expediting revalidation

**Kristine Vandierendonck,** *Quality Systems Manager,* **TERUMO EUROPE**

**10:30 COFFEE & NETWORKING BREAK**

**11:00 EXAMINING EFFICIENT & COMPLIANT CHANGE CONTROL MANAGEMENT STRATEGIES**

When updates to a Quality Management System (QMS) must be implemented, device and diagnostic manufacturers are required to carefully supervise the shift through change control procedures. In theory, operations must not slow down and furthermore, the QMS under revision must remain compliant and efficient during the transition period. Quality executives are at times unsure of where and how to launch such a process all while maintaining high production rates of pristine quality. Examining this real life change control management experience will provide attendees with a clear idea of common paths and pitfalls as well as how to ensure a smooth and compliant transition to an updated QMS.

- Choice of change control software & tools
- Appropriate development & filing of change control documentation
- Efficient management of the transition period
- Reporting the QMS update to healthcare authorities
- Common non-compliances & lessons learned

**Frank Meyer,** *Quality Management – Head of Documentation*
**B. BRAUN MEDICAL**

**11:45 CLARIFYING THE INTEGRATION OF THE QUALIFIED PERSON IN DEVICE & DIAGNOSTIC CORPORATIONS**

Within the scope of new measures introduced in the upcoming MDR and IVDR, device and diagnostic manufacturing corporations are required to appoint a Qualified Person, responsible for the overall compliance of a medical product and serving as primary person of contact in communications with health authorities and auditors. At this time, both industries have yet to become familiar with this new role and underlying responsibilities, and are screening profiles to find the most appropriate executives for the function. Obtaining a thorough understanding of the Qualified Person responsibilities and how to fit this new role in current operations to meet compliance is pivotal to ensure a smooth transition towards the MDR and IVDR.

- Scope of responsibilities and overall liability of the QP
- Profile target: required qualification & preferred experience
- Identifying & addressing implementation challenges

**Karina Hellbert,** *Attorney-at-Law & Head of Life Sciences/Pharmaceutical Law*
**FIEBINGER POLAK LEON ATTORNEYS**

**12:30 LUNCHEON FOR ALL SPEAKERS, SPONSORS & ATTENDEES**

**1:45 EXAMINING HOW THE MDR & IVDR ARE SHAPING THE NEW NOTIFIED BODY ROLE IN EUROPE**

In reaction to the PIP breast implant scandal and further recall cases, the European Commission released a formal proposal in 2012 for new rules to apply to the device and diagnostic industries, focused towards improving patient safety through increased vigilance and scrutiny. European notified bodies are strongly impacted by this regulatory shift as the level of examination in reviews and inspections is increasing and a new code of conduct has been developed to ensure all notified bodies operate with the same level of quality. While device and diagnostic manufacturers welcome this setting, several grey areas require clarification in the real life application of the new notified body role and overall collaboration with the industry.

- MDR/IVDR impact on European notified bodies
- Obtaining the CE stamp: areas of change
- Notified body inspections: new areas of scrutiny

**Gert Bos,** *President,* **TEAM NB**
*Head of Regulatory and Clinical Affairs,* **BSI HEALTHCARE**

**2:30 EXPLORING THE EVOLUTION OF AUDITS & INSPECTIONS IN EUROPEAN MANUFACTURING FACILITIES**

Among the device and diagnostic industries' greatest concerns at this time is the evolution of manufacturing plant audit and inspection processes in Europe. Undergoing a thorough inspection is commonly a stressful experience as it is very challenging for quality executives to continuously remain abreast of increasingly stringent regulations on an international level and implement changes timely. Furthermore, with the emergence of unannounced audits from European regulators, quality executives are anxious to understand the practical application of this new type of inspection. Through this thorough overview addressing not only best practices in regular audits from various healthcare regulatory bodies but also the very first industry experiences with unannounced audits, clarity will be provided on what lies ahead for European manufacturing inspections.

**PREPARING FOR & HANDLING REGULAR AUDITS & INSPECTIONS:**

- Conducting regular internal mock inspections
- Composure & overall collaboration with auditors
- Handling audits without slowing down operations
- Lessons learned from real life experience

**Yves Ohandja,** *Manager Quality & Regulatory, Europe,* **IMMUCOR**

**3:00 MEETING FDA EXPECTATIONS WHEN BEING AUDITED:**

- Remaining abreast of FDA requirements
- Specific FDA areas of examination
- Expediting communications with the FDA
- FDA audit lessons & common pitfalls

**Tim Whitchurch,** *Staff Engineer, Safety Risk Management & Surveillance*
**ORTHO CLINICAL DIAGNOSTICS**

**3:30 COFFEE & NETWORKING BREAK**

**4:00 MDR IMPACT: FIRST INDUSTRY EXPERIENCES WITH UNANNOUNCED AUDITS:**

- The European unannounced audit pilot program
- Practical insight: when, what & how
- New areas of scrutiny & unannounced audit setting specifics
- Focus on product sampling review in unannounced audits

**Nicolas Guignet,** *Senior Quality/Regulatory Program Manager, CRHFM Global Supplier Quality,* **MEDTRONIC**

**4:45 OPENING DISCUSSION WITH NOTIFIED BODIES & INSPECTORS ON THE EVOLUTION OF AUDITS:**

- How to best prepare for unannounced audits
- Financial considerations with regular & unannounced audits
- Addressing grey areas & concerns from the industry

**Nicolas Guignet,** *Senior Quality/Regulatory Program Manager, CRHFM Global Supplier Quality,* **MEDTRONIC**
**Joachim Wilke,** *Director Regulatory Affairs & Policy Europe,* **MEDTRONIC**
**Gert Bos,** *President,* **TEAM NB**
H*ead of Regulatory and Clinical Affairs,* **BSI HEALTHCARE**
**Karina Hellbert,** *Attorney-at-Law & Head of Life Sciences/Pharmaceutical Law*
**FIEBINGER POLAK LEON ATTORNEYS**

**5:15 CLARIFYING & PREPARING FOR ISO 13485 & ISO 9001 UPDATES**

The International Standard Organization (ISO) has been working on updates to both ISO 13485 and ISO 9001 to address new areas of standardization and to modernize obsolete guidelines. As both standards are widely utilized in device and diagnostic corporations to enhance good quality system management, consistency in quality product manufacturing and to harmonize operations on a global level, the industry is eager to understand differences between previous and forthcoming editions as well as how to efficiently implement multiple standards in a single organization. More specifically, quality assurance executives seek clarification on expected timelines for impact and how to proactively prepare for implementation of revised standards.

**EVOLUTION OF ISO 13485:**

- 2013 committee draft & comments
- 2014 draft international standard
- Timeline & impact on operations
- Becoming of EN ISO 13485 Annex Z

**ISO 9001 UPDATE SPECIFICS:**

- Clarifying & utilizing Annex SL
- Risk based thinking & new concepts
- Timeline for implementation

**Vicki Snow,** *Senior Manager, Global Regulatory Audit & Compliance*
**SMITHS MEDICAL**

**6:00 CLOSING REMARKS & DAY ONE CONCLUSION**

# 3rd EU QUALITY ASSURANCE IN DEVICE & DIAGNOSTIC MANUFACTURING

## *DAY TWO | TUESDAY, DECEMBER 9*

**7:30 REGISTRATION & WELCOME COFFEE**

**7:50 CHAIRPERSON'S OPENING REMARKS**

**8:00 PRACTICAL APPLICATION OF UDI: PATHS & PITFALLS IN CORPORATE IMPLEMENTATION**

With the release of the FDA UDI Final Rule late 2013 and the upcoming implementation of a similar rule in Europe and beyond, device and diagnostic manufacturers are required to develop and implement a robust UDI strategy in order to mark all products with a unique identifier. While the industry is looking forward to improving product traceability, many challenges reside in the overall development and implementation of a UDI process within facilities as it involves many resources including funds, software and qualified personnel. This thorough overview provides a hands-on approach to the establishment of UDI within a life science corporation, hurdles encountered and savvy strategies to contain costs for a successful product traceability launch.

- Overview of UDI requirements & US-EU harmonization efforts
- Foreseeing implementation costs & establishing a budget
- Areas of primary concern in corporate UDI development
- Implementation challenges & first steps with UDI

**Melissa Finocchio,** *Director, Global Product Labeling & Documentation*
**BIOMÉRIEUX**

**8:45 FOCUS ON INTERNATIONAL LABELING REQUIREMENTS & ACCOMPLISHING ELABELING CORPORATE IMPLEMENTATION**

In the ever growing worldwide healthcare market, labeling is of the utmost importance to health authorities as it contains important information about the product and conveys utilization and safety messages to users. Labeling requirements on an international scale are constantly updated to address a variety of requirements, differing from one market to another. Quality assurance executives involved in labeling operations and validation must remain abreast of this rapidly evolving regulatory landscape to guarantee labels are developed and edited according to regulations. More specifically for products launched on the EU market, from March 2013 manufacturers are welcome to provide labels and IFUs in an electronic format. While this opportunity is beneficial to the industry, many corporations struggle with the development and implementation of a cost-efficient and compliant elabeling strategy. Through this dual perspective on labeling, participants will gain a thorough understanding of how to meet compliance with evolving international requirements as well as practical ideas to establish or enhance elabeling strategies.

**LABELING COMPLIANCE IN THE INTERNATIONAL SETTING:**

- Latest major developments in international requirements
- Integration of UDI in labeling strategies
- Addressing trade compliance regulations

**Fàtima Dionisio,** *Sr Manager Regulatory/Quality Latin America & Canada International Regulatory Affairs/Division Labeling,* **ABBOTT**

**9:15 ACHIEVING SUCCESSFUL ELABELING IMPLEMENTATION:**

- Key considerations for implementation
- Practical insight in corporate implementation
- Lessons learned with notified body submissions

**Joachim Wilke,** *Director Regulatory Affairs & Policy Europe,* **MEDTRONIC**

**9:45 COFFEE & NETWORKING BREAK**

**10:05 ESTABLISHING SUCCESSFUL SUPERVISION OF SUPPLY CHAIN QUALITY**

Quality assurance executives are working closely with supply chain teams throughout the industry in order to monitor and validate product and component quality throughout the lifecycle of the product, an increasingly difficult challenge as component parts are sourced from a diverse group of suppliers, and with products being distributed worldwide. In order to ensure product quality is maintained, quality control measures are implemented throughout the supply chain, creating a high level of visibility related to product quality. As the need for total product quality continues to increase, quality executives must implement fresh tactics throughout the supply chain in order to maintain quality and efficiently track and monitor products on a global scale, allowing for rapid feedback and correction when required.

- Overview of Total Quality Management tools
- Utilization of ISOs to strengthen supply quality
- Implementing supply chain risk assessment & mitigation
- Benchmark tests on supply chain processes

**Toni Kennet Jorgensen,** *Head of Operations, Quality & Regulatory Affairs*
**SORIN GROUP**

**10:50 BEST PRACTICES IN CAPA STRATEGY DEVELOPMENT & IMPLEMENTATION**

Quality assurance executives in device and diagnostic organizations are required to collect and analyze product data in order to detect recurring problems linked to the overall quality of the device. When defects are identified, it is necessary to rapidly address the issue and establish measures to remove the underlying root causes and bring the product back to conformity to ensure compliance with relevant regulations. While CAPA guidelines are available for the industry, implementing a CAPA strategy can be challenging and time consuming for quality executives.

- The importance of proactive failure investigation
- Establishing a specific and targeted CAPA strategy
- Concerns with increasing documentation requirements
- Maximizing the utility & added value of CAPA results

**Michael Schaefer**
*Quality Management & Regulatory Affairs Expert in Medical Devices*
**MICHAEL SCHAEFER QUALITY MANAGEMENT & REGULATORY AFFAIRS**

**11:35 WORKSHOP: SHARING STRATEGIES TO SUCCESSFULLY HANDLE & EXPEDITE COMPLAINT MANAGEMENT**

As the number of product complaints received by device and diagnostic companies continues to expand, QA executives need to define & deploy the appropriate processes and procedures for investigating and addressing product complaints in a timely and compliant manner. Compounding the complexity of the task, various markets have differing definitions of "complaint" and health authority perspectives vary, creating confusion among the industry and difficulties in establishing a process that fits all requirements. Through this interactive workshop in which the audience will be divided into small groups and work on short assignments diving into specific topics such as complaint gathering, evaluation, investigation and timely closure as well as the proper documentation of these, participants are given the opportunity to share experience and sharpen skills on compliant handling and how to implement a robust corporate strategy ensuring all issues are promptly addressed.

**Erik Raadsheer,** *Sr. Director Quality & Regulatory Affairs, Market Group EMEA*
**PHILIPS HEALTHCARE**

**12:20 LUNCHEON FOR ALL SPEAKERS, SPONSORS & ATTENDEES**

**1:30 MARKETING QUALITY FOCUS: CONNECTING QUALITY ASSURANCE TO DISTRIBUTION PARTNER MANAGEMENT**

Collaborations between local distribution partners and device and diagnostic organizations are common in areas with a promising patient population in which the corporation is not established and therefore has no team on site to handle quality related issues. While contracting with a distribution partner is beneficial for industry, regulators are increasingly focusing on the overall collaboration process especially in areas related to post-market surveillance and maintaining quality throughout the product life cycle. Distributors as well as local sales representatives are seldom trained on quality requirements and have little understanding of the necessity to report product defects to the manufacturing corporation, resulting in extended timelines in addressing quality issues in distributor markets.

- Obtaining insight on product defects in distributor markets
- Training sales representatives & distributors
- Corporate quality standards in distribution networks
- Ongoing monitoring of distributor quality

**Frédérique Pedretti-Abel,** *VP International Quality,* **EDWARDS LIFESCIENCES**

**2:15 RISK MANAGEMENT & POST MARKET SURVEILLANCE FOCUS: HOW TO EFFICIENTLY ADDRESS RISK IN QA OPERATIONS**

When utilizing a device or diagnostic, patients encounter potential risks that must be seriously taken into account by QA teams from the very inception of the product. Exhaustive and robust risk assessment and control measures initiated by quality teams are therefore vital to obtain regulatory clearance for production, market release and eventually distribution. In addition, quality executives must continuously monitor the efficiency of products while being utilized by patients and are required to implement post-market surveillance plans in order to address quality issues throughout the product life cycle in a timely manner. Through short case studies delivered by peers, participants in this session will gain insight on how to establish sturdy risk control and post-market surveillance plans to meet regulator and patient expectations.

**CASE 1: QUALITY & RISK MANAGEMENT: FRIENDS & FOES**

- The origin of risk – the distinction between source & cause
- The FMEA, a simple tool with pitfalls & certain options
- Risk & numbers – whether to verify or validate
- Prospective & retrospective risk criteria
- The "overall residual risk" – a fallacy & a hoax that went awry

**Erik Schwanbom,** *Professor of Risk Management,* **UNIVERSITY OF LÜBECK**

**2:45 COFFEE & NETWORKING BREAK**

**3:05 CASE 2: ASSESSMENT OF RISK & IMPLEMENTATION OF PMS PROCESSES FOR A DIVERSE PRODUCT RANGE**

- Of what should Post Market Surveillance consist? What is the objective?
- The assessment of current risk level for products already on the market
- Development of a Risk Assessment Matrix
- Developing PMS Plans based on Risk Level
- Continuous assessment of PMS output data & feedback to Risk Management Plans

**Nick Gould,** *Principal Engineer, Safety Risk Management & Surveillance*
**Marta Carnielli,** *Safety Risk Management & Surveillance Manager*
**ORTHO CLINICAL DIAGNOSTICS**

**3:35 ENSURING QUALITY & COMPLIANCE WHEN WORKING WITH EXTERNAL SUPPLIERS**

Many device and diagnostic products are partially made of components developed by suppliers external to the manufacturing corporation. While this is common practice in both industries, it is nonetheless critical to carefully select the supplier and examine manufacturing processes as well as quality assurance efforts to ensure the components are developed and produced in compliance with relevant legislation and standards. Furthermore, once the partner is selected and the contract is established, it is highly recommended that quality executives regularly audit suppliers to verify ongoing compliance and therefore safeguard the conformity of the overall end product.

- How to select the most appropriate & compliant supplier
- Focus on monitoring supplier quality efforts
- Implementing quality control measures & audits
- Lessons learned from real-life collaborations

**Vincent Westenberg,** *Quality & Regulatory Lead, Commercial Operations*
**PHILIPS HEALTHCARE**

**4:20 CLOSING REMARKS AND CONFERENCE CONCLUSION**

# 3rd EU QUALITY ASSURANCE IN DEVICE & DIAGNOSTIC MANUFACTURING

***DECEMBER 8-9, 2014 I FRANKFURT, GERMANY***

## WHO SHOULD ATTEND:

Participants in the 3rd Q1 Quality Assurance in Device & Diagnostic Manufacturing conference will include executives from a wide range of corporations currently manufacturing products across the European market, from small to very large organizations operating on a multi-national level. With presenters delivering case-studies and panel discussions aimed at high level quality, regulatory and compliance issues, the executives participating in the program will have a strategic role within their organizations. Job functions that will be of the greatest relevance for this program include:

VPs, Directors and Managers of:

- Quality Assurance
- Quality Systems
- Quality Management
- Quality & Regulatory Affairs
- Operations
- Validation

## SPONSORSHIP OPPORTUNITIES:

With a range of sponsorship opportunities available for companies looking to increase their visibility and prominence in this marketplace, Q1 has designed a wide variety of packages and solutions, available to all sizes of budget. The primary focus of any sponsorship package will of course center on creating value and interest in products and services, as well as ensuring a high number of networking opportunities. Initial program research has indicated that the following products and services are currently of interest to this target audience:

- Quality Assurance and QMS Consultants
- Global Regulatory Compliance Consultants
- Validation Software & Consultation
- CAPA Software & Consultation Services
- Compliance & Quality Training Solutions

## ABOUT THE ORGANIZERS:

Q1 Productions designs and develops webinars, training courses, conference programs and forums aimed at specifically targeted audiences in order to provide strategic and timely information. Through a rigid production process focused on end-user research and design, our team is able to understand the immediate business concerns of today's leading executives. Whether focusing on new or pending legislative issues, enhanced business processes or technologies that will drive efficiency and customer service, our programs provide solutions to the urgent needs of our attendees. To learn more, visit our website at www.q1productions.com.

## PREVIOUS ATTENDEES INCLUDE:

Director, Supply Chain QA, **Abbott**
DVP Global Quality Assurance, **Abbott Diagnostics**
Regulatory Affairs Manager, **Axis-Shield**
Post-Market QA & RA Manager, **Beckman Coulter**
Director, Product Labeling & Documentation, **BioMerieux**
Quality Manager, **Biom'Up**
Global Director Regulatory Affairs, **Biosensors**
VP Quality & Regulatory Management, **BoneSupport**
Manager of Quality Assurance, **Boule Medical**
Head of Clinical & Regulatory Affairs, **BSI Group**
IVD Expert & Auditor, **BSI Group**
Manager of Quality Assurance, **Copan Italia**
Compliance & Quality Manager, **DePuy France**
VP Quality & Regulatory Affairs, **Devicor Medical Products**
Quality Assurance Manager, **DiaSorin**
EU Regulatory Compliance Manager, **Edwards Lifesciences**
VP International Regulatory Affairs, **Edwards Lifesciences**
Associate EU Director of Quality Assurance, **ExonHit**
QA Manager Surveillance, **Gambro Dialysatoren**
Director QA/RA, **Gambro Dialysatoren**
Regulatory Affairs Leader EMEA, **GE Healthcare**
Public Policy Manager, **GS1 Global Office**
Director of Quality & Regulatory Management, **HemoCue**
Director, Regulatory Affairs, **Hemoteq**
Quality & Regulatory Director, **Inion**
Head of QA & RA, **JenaValve Technology**
International Manager of Quality Assurance, **Karl STORZ**
VP RA & QA, **Leica Microsystems**
Quality Assurance Engineering Supervisor, **Medtronic**
Senior Global Quality Assurance Manager, **Medtronic**
Quality & Regulatory Manager, **Nox Medical**
Quality Manager, **OrbusNeich Medical**
Director, Quality & Regulatory Affairs, **Philips-Medisize**
Director Quality Assurance & RA, **Polyganics**
Head of Quality Assurance, **Coloplast**
Director Quality Assurance, **Ranier Technology**
Sr QA & RA Engineer, **RaySearch Laboratories**
Head of Quality Management & RA, **Roche Diagnostics**
Director Quality Systems, **Siemens**
Director Quality Management, **Siemens**
Director of Quality Assurance, **Symetis**
Quality Assurance & Regulatory Affairs Director, **Systelab**
Director RA/QA, **Teleflex Medical**
QA/RA Director, **The Magstim Company**
Design Quality & Compliance Manager, **Thermo Fisher**
Quality/ Regulatory Affairs Manager, **Venner Medical**
Director, International QA & RA, **Welch Allyn**
VP Quality Mgmt & Environmental Affairs, **Wellspect**
Group QA/RA Director, **Werfen Life Group**
Quality Assurance Manager EMEA, **Wright Medical**
Head of Quality Assurance, **Ypsomed**
Manager Quality Systems Engineering, **Zimmer**
Director Quality Systems, **Zimmer**

**... AND MANY MORE!**