5th Annual
MEDICAL DEVICE GLOBAL REGULATORY INTELLIGENCE

Maintaining Regulatory Compliance throughout the Medical Device Product Lifecycle, from Ensuring Global Product Clearance through Appropriate Clinical Data & Post-Market Surveillance, to the Implementation of UDI Requirements on a Worldwide Scale, all while Evolving with Worldwide Regulatory Frameworks

DISTINGUISHED PRESENTERS INCLUDE:

Kerri-Ann Arnott
WW Vice President, Regulatory Affairs Lifecycle Innovation, Medical Devices Group
JOHNSON & JOHNSON

Tamima Itani
Vice President Global Regulatory Affairs
BOSTON SCIENTIFIC

Kerri-Ann Arnott
Vice President, Regulatory Affairs
LIFECYCLE INNOVATION, MEDICAL DEVICES GROUP
JOHNSON & JOHNSON

Teresa Raich
Senior Director Regulatory Affairs
ABBOTT DIAGNOSTICS

Peter Alvarez
Senior Director Master Data Management
GS1

Darin Oppenheimer
Director of Regulatory Affairs
BAXTER HEALTHCARE

Cassie Scherer
Special Counsel
COVINGTON & BURLING LLP

Tony Piotrowski
Senior Manager, Regulatory Affairs
STERIS CORPORATION

Susan Olinger
Vice President, Regulatory Affairs
MEDTRONIC, TYRX INC

Quynh Hoang
Senior Regulatory Consultant
KING & SPALDING

Marcia Benedict
Senior Director Regulatory Affairs
STERIS CORPORATION

Janet Benson
Director, Regulatory Affairs
ABBOTT VASCULAR

Tim Missios
Dir. Regulatory Affairs International
BOSTON SCIENTIFIC

Thomas Denaro
Dir. Corporate Regulatory Global Systems
BECTON DICKINSON

Louis-Pierre Marcoux
Senior Director Regulatory & Quality
ZELTIQ

Rosanne Yetemian
Manager, Regulatory Affairs
ABBOTT MEDICAL OPTICS

Montoya Love
Regulatory Operations Manager
BECTON DICKINSON

Carol Clark-Evans
VP Regulatory Affairs
BTG INTERNATIONAL INC

Paul Brooks
Vice President, Healthcare Solutions
BSI GROUP

Mark Del Vecchio
Senior Director Regulatory Affairs
BD DIAGNOSTICS

Bill Brodbeck
Director, Regulatory Affairs
STERIS CORPORATION

Roberto Refeca
Associate Director, Regulatory Affairs
HALYARD HEALTH

Robert Steele
VP Quality & Regulatory Affairs
CONVATEC

Pete Scott
Sr. Director Regulatory Affairs
IMMUCOR

Jennifer Newberger
Associate
HYMAN, PHELPS & McNAMARA

CONFERENCER SPONSORS:

RAPS CERTIFICATION:

The 5th Annual Medical Device Global Regulatory Intelligence Conference has been pre-approved by the Regulatory Affairs Professionals Society (RAPS) as eligible for up to 12 credits towards a participant’s RAC recertification upon full completion.
8:45 CREATING A COMPETITIVE MEDICAL DEVICE REGULATORY STRATEGY FOR A GROWING GLOBAL MARKET

Thinking globally has become an expectation within the medical device industry as the healthcare landscape continues to expand based on an aging patient population and improved healthcare services in emerging markets. Regulatory affairs executives are faced with the challenge of formulating strategies based on regional regulatory and clinical requirements while also considering the impact product registrations will make on overall corporate goals and timelines. Developing a regulatory strategy that considers a device’s entire product life cycle including the design, quality assurance, clinical testing and marketing potential is imperative to support a chosen submission pathway.

- Building a flexible and scalable strategy for an evolving global landscape
- Aligning business development and regulatory strategies to maximize corporate objectives
- Execution excellence: training for seamless approval strategy implementation

Janet Benson, Director, Regulatory Affairs, ABBOTT VASCULAR

9:30 PANEL DISCUSSION: THE POSITIVE IMPACT OF A COLLABORATIVE AND TRANSPARENT RELATIONSHIP BETWEEN FDA AND THE MEDICAL DEVICE INDUSTRY

The relationship between FDA and the medtech industry, while at times challenging, has arguably shown favorable advancement in recent years as the agency improves internal training and education while focusing on a risk-based paradigm in evaluating the safety and efficacy of innovative technologies. The implementation of a reformed pre-market review process coupled with the ongoing FDA and industry negotiations on expedited clinical trials and new software technology regulation are examples of forward-thinking and collaborative agency. The continued success of the healthcare landscape will require both the FDA and industry to focus efforts on reducing patient risks while maintaining product innovation.

- Managing FDA/industry constructive dialogue
- The changing regulatory dynamic as FDA shifts towards globalization
- Current trending areas of regulatory concern within the FDA

Tamima Itani, VP Global Regulatory Affairs, BOSTON SCIENTIFIC
Rosalane Yetzemian, Mgr., Regulatory Affairs, ABBOTT MEDICAL OPTICS
Marcia Benedict, Sr. Director Regulatory Affairs, STERIS CORPORATION

10:15 COFFEE & NETWORKING BREAK

10:45 PREPARING FOR THE CONTINUED OVERHAUL OF REGULATORY REQUIREMENTS: CHINA AND JAPAN

Regulatory jurisdictions continue to redefine and overhaul the regulations pertaining to Medical Devices. The Chinese Food and Drug Administration (CFDA) finally released the MDR “650” in June 2014 and the Japanese Ministry of Health Labour & Welfare (MHLW) released the revised PAL November 2014. Both countries are continuing to streamline device review and clearance processes to encourage local innovation and manufacturing. The China medical device market continues to grow and is expected to pass the $55 billion mark this year, according to Access China Management Consulting. While the future of both markets remains strong and desirable for manufacturers (local and MNC), regulatory affairs executives can expect more changes to come as the sub-regulations associated with China’s “650” are implemented. China’s Standardization Administration (SAC) completes the revision of 600 national and industry standards, and reviewers in both countries apply their interpretation of the new regulations to product submissions thus setting the precedence and creating challenges and changes for medical device manufacturers.

Kerri-Ann Amott, WW Vice President, Regulatory Affairs Lifecycle Innovation, Medical Devices Group JOHNSON & JOHNSON

11:30 BEST PRACTICES FOR EXPEDITING PRODUCTS THROUGH BRAZILIAN BUREAUCRACY

Navigating the Brazilian regulatory process can be a timely and frustrating process as it can take anywhere from five months to five years depending on the classification of device risk. In March 2015, Brazil’s medical device regulatory agency, ANVISA, published new clinical testing requirements in an effort to harmonize testing processes and procedures with international standards and agencies. While regulatory executives of the new RDC10/2015 regulation, teams are still faced with bridging the gap between existing FDA or ISO 13485 compliant quality systems to meet BGMQ requirements, along with lengthy BGMP audit queues delaying new product registration timelines.

- Tools and techniques for expedited product registration
- Identifying QP process gaps for BGMP compliance
- Review of lessons learned from successful product registration in Brazil

Roberto Refeca, Associate Director, Regulatory Affairs, HALYARD HEALTH

9:30 CASE STUDY: ROADMAP TO A SUCCESSFUL UDI IMPLEMENTATION PLAN

The UDI project has been a monumental undertaking for medical device manufacturers throughout the industry and will continue to be high priority as the project moves into the next phase of class II devices. Regulatory affairs executives preparing organizations for class II compliance have the unique opportunity to leverage predecessor knowledge to identify potential roadblocks and rework strategies to mitigate implementation challenges. By reviewing strategies, FDA interactions and best practices from industry peers, practical lessons will be learned allowing regulatory affairs executives still working towards UDI implementation the tools to proactively anticipate and prepare teams for execution excellence.

- Best practices for preparing for and implementing UDI
- Execution of direct marking and expiration date formatting
- Downstream effects of UDI on organizational processes and procedures

Thomas Denaro, Dir. Corporate Regulatory Global Systems BECTON DICKINSON
Montoya Love, Regulatory Operations Manager, BECTON DICKINSON

10:15 COFFEE & NETWORKING BREAK

10:45 THE FUTURE OF A GLOBAL HARMONIZED UDI STANDARD

As the medical device industry continues to implement FDA UDI requirements, regulatory affairs executives find challenges in managing varying international regulatory standards for labeling compliance. Executives are also concerned with the international future of the UDI program, including the compatibility of the standards and systems for implementing and reporting medical device labeling. Staying abreast of the changing international labeling requirement is essential in order to ensure UDI labeling compliance is maintained globally.

- Overview of the global UDI landscape
- Strategies for implementing UDI on a global basis
- Managing data at global and local level

Peter Alvarez, Senior Director Master Data Management, GS1

11:30 CHANGES TO EN ISO 14971:2012 AND INTEGRATING NEW STANDARDS INTO QUALITY SYSTEM

In the medical device industry, there is still much confusion surrounding risk management and the standards required to comply with EN ISO 14971: 2012 and how to efficiently integrate current system processes into the new standard. Regulatory affairs executives also specifically face the challenge of regulatory and reporting requirements of the new standard related to QSR and MDR. Best practices of implementing the new EN ISO 14971:2012 requirements into existing quality systems will be discussed as well as lessons learned throughout the integration process.

- Key elements of a risk management plan identified
- Strategies for enhancing risk management performance

Tony Piotrowski, Sr. Mgr., Regulatory Affairs, STERIS CORPORATION
12:15 LUNCHEON FOR ALL ATTENDEES, SPEAKERS & SPONSORS

1:30 PREPARING FOR THE TRANSITION TO ISO 13485:201X
As medical device manufacturers continue to expand into global markets, where regulatory structures vary greatly, the implementation and adoption of ISO standards has allowed many firms a framework for globally accepted regulatory practices. As the ISO TC 210 working group continues to work with industry and regulators in the revisions of ISO 13485 standards, many in the industry are looking for clarification on new risk-based paradigms that will impact the total product lifecycle. With changes forecast to come online in the first quarter of 2016, understanding what revisions to standard practices will need to be made, especially as related to supplier controls, software validation and technical file requirements, is of paramount importance for regulatory executives.

- Review of major ISO13485:201X revisions
- Strategies for incorporating risk in Q&S Processes
- Timelines of anticipated ISO 13485: 201X changes

Darin Oppenheimer, Director of Regulatory Affairs
BAXTER HEALTHCARE

2:15 A REGULATORY PERSPECTIVE ON COMBINATION PRODUCTS
Combination products pose additional challenges for the regulatory affairs executives as CDRH and CDER operate under separate regulations, processes and timelines. A clear understanding of the factors that influence the determination of CDRH as the lead Center, CDRH regulatory process and the applicable CDER regulatory requirements will streamline the approval process for combination product submissions.

- Assignment of lead Center with case studies
- CDRH premarket process
- CDER/CDRH collaboration on combination product premarket review
- Other regulatory challenges (e.g., cGMP)

Quynh Hoang, Senior Regulatory Consultant, KING & SPALDING

3:00 COFFEE & NETWORKING BREAK

3:30 ELEMENTS OF AN EFFECTIVE POST MARKET SURVEILLANCE STRATEGY
Regulation has focused our industry on developing Post market systems that monitor the safe and effective use of Medical devices. As an industry we have to leverage this same process, data and information to drive improvement in our products, reduce patient risk and improve outcomes, this necessitates a data led approach that must drive forward to New product development and LCM. The processes that provide objective evidence to support regulatory compliance are clear but management focus and senior leadership has to view this process differently to see the business value.

Robert Steele, VP Quality & Regulatory Affairs, CONVATEC

4:15 UNDERSTANDING REGULATORY IMPLICATIONS IN THE REVOLUTION OF MOBILE MEDICAL HEALTHCARE
More than ever before, the world is craving the ability to remain constantly connected through technology, and key stakeholders including healthcare professionals, consumers, and patients will be soon be expecting this convenience for medical care. Recently the FDA has made strides in communicating mobile device regulatory expectations by releasing updated draft guidance on mobile medical applications along with a working list of regulated and non-regulated device examples. Regulatory affairs executives embarking on digital innovation projects will benefit from this session focused on reviewing the FDA's intended risk-based oversight of mobile medical applications and experiences navigating emerging digital health landscape.

- Updates to MAA and MDDS guidance
- Identifying mobile device app classification
- Future regulatory concerns of cyber security

Carol Clark-Evans, VP Regulatory Affairs, BTG INTERNATIONAL INC
Cassie Scherer, Special Counsel, COVINGTON & BURLING LLP

END OF CONFERENCE DAY ONE
As patient centric healthcare continues to be one of the main drivers behind healthcare reform, medical device manufacturers have had to realign product development strategies to fit the needs of the current and future market. Regulatory affairs executives must actively be involved in the development process early on to avoid costly setbacks due to regulatory roadblocks. Understanding market trends and the variables affecting the regulatory landscape will allow regulatory teams to proactively work with product development teams in developing strategies for successful product launches.

- Predicting the future regulatory landscape through market analysis
- Designing regulatory strategies for an ever-evolving regulatory landscape
- Aligning strategies throughout a dynamic and cross-functional organization

**Teresa Raich**, Senior Director Regulatory Affairs
ABBOTT DIAGNOSTICS

**9:45 PANEL DISCUSSION: MAXIMIZING THE VALUE OF PRE-SUBMISSION MEETINGS**

With the Pre-Submission Program guidance finalized in February 2014, many regulatory affairs executives have utilized this resource as a method of collecting valuable feedback from the FDA regarding IDE applications and other premarket submissions such as 510(k), PMA, HDE, and de novo petitions. For successful interactions to occur, regulatory affairs executives must develop a robust plan to prepare for a pre-submission meeting which includes outlining specific attendees, discussion points and meeting agenda. By examining recent pre-submission meeting experiences, regulatory teams can identify if a pre-submission meeting is necessary and review lessons learned from pre-submission meeting setbacks to capitalize on these agency interactions.

**Teresa Raich**, Senior Director Regulatory Affairs
ABBOTT DIAGNOSTICS

Louis-Pierre Marcoux, Senior Director Regulatory & Quality
ZELTIQ

Mark Del Vecchio, Senior Director Regulatory Affairs
BD DIAGNOSTICS

**10:30 COFFEE & NETWORKING BREAK**

**11:00 THE FUTURE OF THE 510K PROGRAM**

In 2011 the FDA began the reform of the 510(k) submission process after Congressional criticism of device safety concerns due to a high rate of recalls and industry confusion of agency expectations. Since then the FDA has published several important guidance documents to clarify substantial equivalence, RTA policy, and communication timeline expectations however regulatory affairs executives are still seeking clarity regarding the FDA’s modification policy as well as seeking guidance on how to prepare for potential future changes to the 510k process. While the 510k process remains the most popular submission pathway for regulatory teams, the future of the program and a discussion surrounding recent submission experiences will benefit even the most seasoned executives.

- Overview of recent changes to the 510(k) submission pathway
- Best practices and lessons learned from recent 510(k) submissions
- FDA expectations of bench testing and animal studies for 510(k) SE
- Anticipated changes to 510(k) program in 2015 and beyond

Susan Olinger, Vice President, Regulatory Affairs
MEDTRONIC, TYRX INC

**11:45 PREPARING FOR INDIA’S DRUG AND COSMETICS (AMENDMENT) BILL 2015**

Currently, the Indian medical device market lacks distinctive regulations with only 22 notified devices regulated through the Central Drug Standard Control Organization (CDSCO). With the rapid rise of the Indian middle class and the availability and affordability of healthcare, the Indian market will continue to increase at a rate of 16% through 2017 according to Indian Medical Device Market reports, prompting the Department of Health and Family Welfare to submit proposed changes to Parliament regarding current medical device laws. The proposed Drugs and Cosmetics (Amendment) Bill 2015 coincides with the release of CDSCO regulatory initiatives 2015 and include changes such as revised GMP quality management system standards, implementation of online submission for clinical trials, pre-submission consulting, and finalized accreditation standards for clinical trials. Regulatory affairs executives will benefit from this session focused on addressing the changing Indian regulatory landscape as well as review successful device registration best practices.

Tim Missios, Dir. Regulatory Affairs International, BOSTON SCIENTIFIC

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

**1:30 PANEL DISCUSSION: OVERCOMING INCONSISTENCIES IN FDA REVIEWER FEEDBACK TO AVOID UNNECESSARY CLEARANCE DELAYS**

In recent years, the FDA has arguably made a substantial effort to improve the speed and reliability of the agency through the release of numerous guidance documents, some of which include: updates to 510K substantial equivalence evaluation, implementation of pre-submission meetings, and 510K policy modifications. While these actions are a step in the right direction, executives continue to struggle with inconsistent reviewer feedback throughout the agency. This discussion will examine various experiences surrounding reviewer disparities and proactive steps regulatory executives took to ensure clearance and approval despite inconsistencies in reviewer feedback.

- Trends amongst reviewer feedback inconsistencies
- Decision-making based on various reviewer recommendations
- Mitigating communication challenges with agency reviewers

Marcia Benedict, Senior Director Regulatory Affairs
STERIS CORPORATION

Darin Oppenheimer, Director of Regulatory Affairs
BAXTER HEALTHCARE

**2:15 FDA AUDIT STRATEGIES TO MEET INCREASING REGULATORY DEMANDS**

For regulatory affairs executives the management of regulatory audits is an ongoing and considerable concern especially as the FDA continues to be a fluid organization; increasing the risk of noncompliance due to changing agency expectations and regulations. Executives must not only implement SOP’s but also diligently track and manage product-associated events to ensure complaints are appropriately handled to satisfy auditors expectations. Through ongoing organizational improvement, appropriate preparation of technical files can be maintained and successful audits achieved.

- Best practices in audit preparation
- Current industry inspections trends
- Development of a robust audit strategy

Pete Scott, Sr. Director Regulatory Affairs, IMMUCOR

**3:00 CLOSING REMARKS & CONFERENCE CONCLUSION**