# MedTech Summit US

**November 19-20, 2019**
Renaissance Chicago Downtown Hotel
Chicago, IL, US

# EU MDR IMPLEMENTATION, US FDA UPDATES AND SOFTWARE REGULATIONS

Bringing together industry, FDA and Notified Body experts to share the very latest on EU MDR implementation, FDA policy and digital health


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## *PRE-CONFERENCE WORKSHOP:*
# MEDICAL DEVICE REGULATORY PROJECT MANAGEMENT

*Led by:* **Heikki Pitkanen,** CEO & Founder, Digital Regulatory Runways, **Lean Entries**

8:00am — *Registration*

9:00am

### AN INTRODUCTION TO PROJECT MANAGEMENT

1. Early development stages in a project
   - Timelines and considerations on the device life cycle
   - Capturing the value proposition
   - Early validation through feasibility studies
   - Regulatory strategy
2. Planning and initiating the project
   - Assigning roles and responsibilities in-house and across boundaries
   - Team communication, collaboration and leadership
3. Document and records management, logs and traceability

10:40am — *Morning coffee*

11:10am

### APPLYING REGULATORY REQUIREMENTS TO PROJECT MANAGEMENT

1. The role of global regulations and standards in medical device project management
2. Key regulatory considerations throughout the medical device lifecycle:
   - General Safety and Performance Requirements
   - Clinical Evaluation
   - Risk Management
3. Other regulatory considerations for project management:
   - Quality system requirements (ISO 13485, FDA QSR)
   - Design Control
   - Vendor control

12:10pm — *Lunch*

1:10pm

### APPLYING CLINICAL EVALUATION IN A PROJECT

- The importance of conducting a literature review
- Clinical investigations and post-market activities

2:10pm

### APPLYING RISK MANAGEMENT IN A PROJECT

- Risk management practicalities
- ISO 14971 and Design FMEA (Failure Modes & Effects Analysis)
- Relation to Biocompatibility, Electrical safety, Software life cycle and Usability

3:10pm

### MANAGING MEDICAL DEVICE PROJECT CYCLES

1. Product life cycle thinking: Does the project have an end?
   - Design Control as the middle cycle: The typical project cycle
   - Design Inputs, Outputs, Verification, Validation, Process Validation, Transfer, Changes and Reviews
2. The micro cycles of project management: The daily work
   - Plan-Do-Check-Act / Build-Validate-Learn / Agile methodologies
3. Maintaining alignment and adapting to change
   - Corrective and preventive actions and methods
   - Project metrics

4:10pm — *End of workshop*

# DAY ONE: TUESDAY, NOVEMBER 19

| | EU MDR IMPLEMENTATION | US FDA UPDATES |
|---|---|---|
| 8:00am | *Registration* | |
| 9:00am | **Opening Remarks** | **Opening Remarks** |
| 9:10am | **Competent Authority feedback: Implementing the MDR**<br>• Highlighting remaining areas of uncertainty<br>• Ensuring a harmonised approach to compliance<br>• Addressing key industry challenges associated with implementation and advice to overcome them<br>**Graeme Tunbridge,** Group Manager – Devices Regulatory Affairs, **MHRA** | **FDA KEYNOTE: Medical Device Regulatory updates from the FDA: An update on the FDA Super Office**<br>• Why has the Super Office been created?<br>• What does the Super Office aim to achieve?<br>• How will it change the way industry works with the FDA? |
| 9:45am | **Presentation to be delivered by BSI** | **Streamlining global quality requirements: Moving away from the CFR 820 guides to align with ISO 13485**<br>• Examining reasons for moving to IS0 13485<br>• Adopting ISO 13485 to replace QSR 820 for the FDA's quality system legislation: what is the status of the project?<br>• Challenges and opportunities for industry<br>**Ann Vu,** Director, Premarket Notification Program, **Zimmer Biomet** |
| 10:20am | **INDUSTRY CASE STUDY: Practically implementing the MDR (large company perspective)**<br>• Understanding what is required to have a successful product submission under the MDR<br>• Strategies for continually monitoring the latest requirements and ensure progress despite uncertainty<br>• Training and explaining: Communicating the key differences between the MDD and the MDR to staff in a meaningful way<br>**Maria Orozco,** Associate Director, **Alcon** | **Understanding the Changes Affecting 510K Device Approval**<br>• Examining the FDA's expectations from industry<br>• Understanding the steps industry should take to ensure approval/ compliance<br>• FDA future plans |
| 10:55am | *Morning Coffee & Networking* | |
| 11:25am | **INDUSTRY CASE STUDY: Practically Implementing the MDR (small company perspective)**<br>• Understanding what is required to have a successful product submission under the MDR based on our interpretation of the regulation<br>• Strategies for continually monitoring the latest requirements and ensure progress despite uncertainty<br>• Training and explaining: Communicating the key differences between the MDD and the MDR to stakeholders in a meaningful way<br>**Mira Leiwant,** Vice President, Regulatory Affairs, **BTG International Inc.** | **Scrutiny and inspection-readiness: Success strategies to prepare for FDA inspections**<br>• Examining inspection and compliance trends: where is the FDA focusing their efforts?<br>• Assessing available databases to access investigator hot spots<br>• Understanding BIMO inspections vs. general quality systems inspections<br>• Practical tips for preparing and running audits<br>**Mercedes Bayani,** Global Director Clinical Research and Regulatory Affairs, **Bioness** |
| 12:00pm | **PANEL DISCUSSION: Sharing experiences of implementing the MDR**<br>• Assessing common implementation challenges faced by manufacturers<br>• Strategies for engaging all stakeholders in the implementation project<br>• Understanding how best to gain senior management buy-in<br>• Lessons learnt<br>**Tanya Klaslo,** Vice President, Global Regulatory Operations**, BD**<br>**Mira Leiwant,** Vice President, Regulatory Affairs, **BTG International Inc.**<br>**Maria Orozco,** Associate Director, **Alcon**<br>**Caroline Byrd,** Director, Commercial RAQA, **Leica Biosystems**<br>**Hugo Xi, MD, MBA,** Director, Medical Affairs, Abbott Quality & Regulatory, **Abbott Laboratories** | **PANEL DISCUSSION: How to use Real World Evidence to get your product on the market and to support your reimbursement strategy**<br>• Clarifying what Real World Evidence can be used for<br>• How to use Real World Evidence to position your product and fulfil requirements for data<br>• Leveraging Real-World Evidence to fulfil reimbursement requirements<br>• How can Real World Evidence be used to reduce the burden to get new products onto the market?<br>**Pamela Goldberg,** President and CEO, **Medical Device Innovation Consortium (MDIC)**<br>**Joseph Sierra,** Global Reimbursement Manager, **Medtronic**<br>**Shilpa Mehendale,** Senior Director , Global Clinical and Medical Affairs, **Intuitive Surgical** |
| 1:00pm | *Networking Lunch* | |

| | EU MDR IMPLEMENTATION | US FDA UPDATES |
|---|---|---|
| 2:00pm | **Notified Body Designation: Where are we now?**<br>• An update on Notified Body designation: Scope, resource and timelines<br>**Tarik Krim,** CEO, **GMED North America** | **Reimbursement: Assessing strategies for developing clinical evidence to demonstrate an effective product**<br>• Understanding how to gain reimbursement for your product sooner after FDA approval<br>• Being smart about clinical trial set up to speed up reimbursement<br>• Challenging the clinical and regulatory strategy at an early stage to ensure reimbursement<br>• Considering "State of the Art" when planning the reimbursement strategy<br>**Joseph Sierra,** Global Reimbursement Manager**, Medtronic** |
| 2:35pm | **Optimizing Data Collection, Triage and Output for EUMDR Compliance** | **Spotlight presentation**<br>Please contact linda.cole@knect365.com, Tel +44 (0) 20 7017 6631 if you are interested in participating as a speaker, panellist, moderator or hosting a webinar. |
| 3:10pm | *Networking Refreshment Break* | |
| 3:40pm | **ISO13485:2016 – Quality Management Systems (QMS) and the MDR: what's new and how can industry prepare?**<br>**Greg Jones,** Business Sector Manager Medical Devices, **SGS** | **An update on the Medical Device Single Audit Program (MDSAP)**<br>• Providing clarity on how the FDA is using MDSAP reports<br>• Advice for industry: How can managers prepare for this process?<br>**Maham Ansari,** Director of Regulatory Affairs, **Synaptive Medical,** *Canada* |
| 4:15pm | **PANEL DISCUSSION: Developing a successful global regulatory strategy: Best practice for gaining product approval in the US and the EU**<br>• Creating an efficient clinical strategy to gain global product approval<br>• Clinical requirements<br>• Key differences between FDA requirements and the EUMDR<br>• Examining the best strategy for entering the market in the US and EU<br>**Judith Svarczkopf,** Principal Technical Advisor, **Genentech**<br>**Maham Ansari,** Director, Regulatory Affairs, **Synaptive**<br>**Mercedes Bayani,** Global Director Clinical Research and Regulatory Affairs, **Bioness** | |
| 5:50pm | **Strategies for maintaining your products on a global market**<br>• Assessing the differences between FDA & EU MDR post market surveillance requirements<br>• PSUR and Summary of Safety Performance reports for the EUMDR – understanding what is acceptable for the FDA<br>• Comparing RWE with PMCFU studies<br>• Examining approaches to handling lifetime data of a device from a global perspective<br>o Data harmonization: An update on the EUDAMED database: what is the status, and will the US be able to take advantage of it?<br>o Managing UDI and product lifecycle data on a global basis<br>**Caroline Byrd,** Director, Commercial RAQA, **Leica Biosystems**<br>**Jennifer Bolton,** Regulatory Fellow, **Boston Scientific** | |
| 5:35pm | *End of conference day one* | |

# DAY TWO: WEDNESDAY, NOVEMBER 20

| | EU MDR IMPLEMENTATION | SOFTWARE AND DIGITAL HEALTH REGULATIONS |
|---|---|---|
| 8.00am | *Registration* | |
| 9.00am | **Opening Remarks** | (8.50 am) **Chairs Extended Opening Remarks: An Update on FDA Regulatory Initiatives for Software and Digital Health**<br>**Diane Johnson,** Senior Director, Strategic Regulatory MD&D, **Johnson & Johnson** |
| 9.10am | **Clarifying expectations for clinical evaluations and investigations under the MDR**<br>• Highlighting the key differences between MDD and the MDR requirements for clinical evaluations and investigations<br>• Examining the interpretation and definition of "Sufficient Clinical Evidence"<br>• Clarifying the pre-market processes for Class III devices: what is the timeline from Competent Authorities for registering Class III devices?<br>• Key challenges and opportunities with the new clinical requirements<br>**Matthias Fink,** Clinical Reviewer, Clinical Centre of Excellence, **TÜV SÜD** | **INDUSTRY PANEL: Gaining regulatory approval for software devices**<br>• Examining the boundaries of software as a medical device and determining when software is subject to the regulations<br>• Exploring go-to-market strategies: software as a medical device, software for a medical device and software in conjunction with non-MedTech digital health offerings<br>• Addressing the regulatory approach for incremental software product changes<br>• Assessing time and resources required to ensure sufficient clinical evidence is gathered<br>• Changing mindsets: incorporating agile working into your regulatory practices<br>• Unexpected nuances, challenges, and timelines for approval<br>**David Amor,** VP, Quality and Regulatory Affairs, **Pear Therapeutics**<br>**Danelle Miller,** Vice President, Global Regulatory Policy & Intelligence, **Roche Diagnostics**<br>**Kirsten Paulson,** Senior Director, Global CMC - Medical Devices, **Pfizer**<br>**Diane Johnson,** Senior Director, Strategic Regulatory MD&D, **Johnson & Johnson** |
| 9.45am | **CASE STUDY: Clinical evidence and legacy products under the MDR: examining the pitfalls and opportunities**<br>• Assessing the requirements for legacy devices under the MDR<br>• Exploring available sources of clinical evidence<br>• Understanding the role of clinical investigators and registries in gathering evidence<br>• Assessing the financial burden of gathering clinical evidence for legacy devices<br>• Evaluating and rationalising product portfolios<br>**Kimberly Thomas-Pollei,** Senior Manager Clinical Evidence and Risk Management, Rhythm Management Division, **Boston Scientific** | |
| 10:20am | *Morning Coffee & Networking* | |
| 10.55am | **CASE STUDY: Performing clinical evaluations in context of the new EU MDR**<br>• Understanding how clinical evaluations should be completed<br>• Assessing difficulties when clinical evaluations get started<br>• Sharing lessons learned and what to avoid<br>**Sara Montminy Paquette,** Medical Writing Manager, **Medtronic - MITG** | **Progress on Regulating Artificial Intelligence and Machine Learning**<br>• Update on the FDA White paper on regulating artificial intelligence<br>• Identifying European and Chinese intentions related to the regulation of artificial intelligence<br>• Overview of standardization initiatives related to artificial intelligence<br>**Pat Baird,** Regulatory Head of Global Software Standards, **Philips** |
| 11.25am | **Presentation to be delivered by GMWT** | **Spotlight on European Medical Device Regulation: classification of medical device software**<br>• Analyzing the definitions for medical device software, software that drives or influences the use of a medical device and independent software<br>• Identifying which classification rules apply to medical device software and how to interpret them<br>• Learning how to apply the IMDRF scheme on software as a medical device for the interpretation of classification Rule 11<br>• Assessing the impact of the classification of software<br>**Heikki Pitkänen,** CEO & Founder, Digital Regulatory Runways, **Lean Entries Ltd** |
| 12.00pm | *Networking Lunch* | |

| | EU MDR IMPLEMENTATION | SOFTWARE AND DIGITAL HEALTH REGULATIONS |
|---|---|---|
| 1:20pm | **Quality Documentation Excellence: An opportunity to leverage the regulations to your advantage**<br>• Upstream changes to impact the quality of the documentations<br>• Industry best practices<br>• Think globally not just for remediation<br>**Tanya Klaslo,** Vice President, Global Regulatory Operations**, BD** | **FDA Security Priorities: Cybersecurity, Cloud Applications and Hosting Compliance**<br>• How insecure are our medical devices?<br>• FDA priorities and plans for cybersecurity<br>• Favoured approaches to reduce vulnerability and maximize patient safety<br>**Steven Abrahamson,** Senior Director, Product Cyber Security, **GE Healthcare** |
| 1.55pm | **PMCF under the MDR: What are the Expectations and How Should This Be Carried Out?**<br>• What are Competent Authorities' PMCF expectations?<br>• Clarifying the meaning of "active" PMCF<br>• Leveraging existing databases and electronic health records to provide evidence<br>• Clarifying the term "lifetime of the device"<br>**Caroline Byrd,** Director, Commercial RAQA, **Leica Biosystems** | **Clinical Evaluation of Medical Device Software**<br>• Outlining methodology and the role of clinical evaluations, validation, and usability<br>• Investigating the use of real-world evidence and best practices to ensure the quality of the data<br>**Loretta K. Dorn,** Director of Nursing Consultants, **Fresenius Kabi USA LLC** |
| 2.30pm | *Networking Refreshment Break* | |
| 3:00pm | **Examining interactions between Risk Management, Clinical Evaluation and Post-Market Surveillance under the EU MDR**<br>• Assessing interactions by product development phase between RM, CE and PMS alongside other functions<br>• Understanding the key inputs and expected outputs for an effective and compliant system<br>• Documenting the interactions and completed evaluations<br>• Documenting disclosures of residual risk<br>**Adam Grimshaw,** Corporate EU MDR Risk Management Lead, **Hillrom** | **INDUSTRY PANEL: Operationalizing Security, Quality and Risk Best Practice**<br>• Understanding risk related to software and security: defining acceptable levels of risk<br>• The importance of developing and integrated QMS, risk and security governance structure to delivery best practice and compliance<br>• Developing processes across the organization: documenting and formalize medical device security processes via policies and procedures<br>• Developing processes across the organization: documenting and formalize medical device security processes via policies and procedures<br>• FDA requirements for a structured human factor process throughout the device design lifecycle and validation testing to assess residual device risk<br>• Embedding FDA compliant quality management and design control practices<br>• Challenges in patch management<br>**Dana Fashina,** Manager of Software Quality, **Sanofi Medical Devices**<br>**Adam Grimshaw,** Corporate EU MDR Risk Management Lead, **Hillrom**<br>**Tyrone Heggins,** Global Security Consultant, **Becton Dickinson**<br>**Brian Shoemaker,** Principal Consultant, **ShoeBar Associates** |
| 3.35pm | **Implementing the EU MDR within the Context of Combination Products**<br>**Judith Svarczkopf,** Principal Technical Advisor, **Genentech** | |
| 4:10pm | **Chair's closing remarks** | **Chair's closing remarks** |
| 4:30pm | *Close of MedTech Summit US* | |