GENERIS

AMERICAN MEDICAL DEVICE SUMMIT 2018

OCTOBER 24–25, 2018
THE WESTIN LOMBARD YORKTOWN CENTER • LOMBARD, IL

amdsummit.com

TOMORROW'S CONNECTION TODAY

Driving business performance through process and technological innovation

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PROGRAM

PROGRAM DAY ONE

PRE-EVENT HAPPY HOUR

JOIN US FOR THE PRE-EVENT HAPPY HOUR OCTOBER 23RD, 2017 AT 6:00PM–7:00PM

7:00 am – 7:55 am

REGISTRATION & GROUP BREAKFAST

8:00 am – 8:10 am

CHAIR'S WELCOME ADDRESS

MICHAEL BACA
Former VP, Quality/ Regulatory/ Clinical
stryker

MAC MCKEEN
Fellow, Regulatory Science
Boston Scientific

ROBERT WOOD
VP, WW Manufacturing
VARIAN medical systems

8:10 am – 8:50 am

OPENING KEYNOTE

PATIENT OUTCOMES THROUGH VALUE-BASED HEALTHCARE: DELIVERING THE NEXT GENERATION OF MEDICAL DEVICES:

- Reforming your future business model for disruption: transitioning from volume-to-value-based care
- Striking a healthy balance between external vs. internal organizational growth: relying on multiple sources to achieve design innovation
- Eliminate the cost burden stigma through driving valued based healthcare as an economic growth driver
- Implement design processes that drive cost-efficiency, speed-to-market and user friendly devices

MICHAEL HILL
VP, Corporate Science, Technology and Clinical Affairs
Medtronic
Medtronic

8:50 am – 9:30 am

LEADERSHIP SPOTLIGHT

TRANSFORMING THE QUALITY PROFESSIONAL: THE TOM WESTRICK STORY

- The transition from finance to Chief Quality Officer: The Tom Westrick story
- Innovating the quality ecosystem from the perspective of the regulator and the patient
- Build quality into processes at every step of the value chain to lower costs, risks and design better products
- Driving better business results and improving your bottom line through a patient-centric approach

TOM WESTRICK
VP, Chief Quality Officer and Head of Regulatory Affairs
GE Healthcare

9:30 am – 10:10 am

WORKSHOP

A TURNKEY APPROACH TO HARMONIZE R&D STANDARDS

- How to develop a structured approach and resource plan
- Implementing gap assessments and prioritizing to manage potential actions required
- Case study: How we constructed a plan and executed on-time and on budget

WILLIAM SCHMIDT
Co-Founding Partner

10:15 am – 11:45 am

PRE-ARRANGED ONE-TO-ONE NETWORKING & REFRESHMENTS

11:50 am – 12:25 pm

DESIGN

BLURRING THE BOUNDARIES BETWEEN ENGINEERS AND PHYSICIANS: PULLING BACK THE CURTAINS ON INNOVATION AT MAYO CLINIC

- A look at how engineers at Mayo Clinic have teamed with physicians for over 100 years and found new ways to better care for our patients
- How this dedicated engineering group is unique and allows innovation to be intentionally driven by the organization's strategic plan
- A historical perspective on medical device innovation at Mayo Clinic

MARK WEHDE
Section Head of Technology Development
Mayo Clinic Division of Engineering

MAYO CLINIC

PRODUCT DEVELOPMENT

CONCEPT TO COMMERCIALIZATION: OPTIMIZING YOUR PRODUCT DEVELOPMENT STRATEGY

- Pathways to connect designers with manufacturing for improved downstream risk management
- Design strategy that incorporates supply chain sustainability
- When to employ external expertise in the concept to commercialization process
- Critical considerations in medical

ROBERT WOOD
VP, WW Manufacturing

VARIAN medical systems

QUALITY

SOFTWARE PRE-CERT PILOT PROGRAM STATUS UPDATE

- Pre-Cert pilot goals and objectives
- FDA perspective
- Pre-Cert pilot program logistics
- Point of contact
- Engagement plan and schedule
-
- Site visits and data collection: excellence principles and common validating perspectives

CATHERINE BAHR
Digital Health Expert
CDHR/ OCD

FDA

INNOVATION

A PROACTIVE APPROACH FOR CYBERSECURITY FOR MEDICAL DEVICES NOW AND IN THE FUTURE

- Applying concepts of security risk management to medical device design
- Proactive and reactive program capabilities
- Collaborative approaches with health delivery organizations
- Lessons learned from the WannaCry attack

STEVE ABRAHAMSON
Senior Director, Product Cybersecurity

GE

12:30 pm – 1:05 pm

WORKSHOP

MODERNIZING QUALITY MANAGEMENT SYSTEMS FOR MEDICAL DEVICE MANUFACTURERS

- The QT9 Quality Management Software's easy approach to a full eQMS implementation
- How to invest and see a return on investment
- Innovation in quality management technology
- End frustration through paperless quality automation

BRANT ENGELHART
President

WORKSHOP

WHY MEDICAL DEVICE MANUFACTURERS NEED TO DELIVER INNOVATIVE PRODUCTS TO CREATE EFFICIENCIES IN THE DELIVERY OF CARE

- This will be a detailed look at the case study of guided compliance in action
- We'll explore the "product behind the product" and see how guided compliance can profoundly help your efforts

DAVE GUZZI
SVP, Sales & Marketing

WORKSHOP

REDUCE SUPPLIER RISK, REDUCE ORGANIZATIONAL RISK: THE IMPACT OF SUPPLIER MANAGEMENT ON THE ORGANIZATION AND THE ROLE OF QUALITY

- Gain an understanding of supplier risk, and its role in broader enterprise risk ecosystem
- Review the medical device regulatory landscape regarding supplier control
- Review how appropriate supplier management processes reduce risk and the critical role that quality management plays in that process

KARI MILLER
Regulatory and Product Management Leader

WORKSHOP

MODEL-BASED DESIGN, DEVELOPMENT & TESTING: AN APPROACH TO SPEED, SAFETY & ENHANCED QUALITY

- Learn about a better design for complex, safety critical and distributed systems
- A look at the overall improvement in the quality of the product, better documentation and evidence of compliance with standards
- How you can have a faster time to market by reusing a verified model

HARIKRISHNAN RAMARAJU
Sr. Business Development Manager

NOLAN WANNER
Principal System Engineer

1:10 pm – 2:10 pm

LUNCH & LEARN ROUND-TABLE DISCUSSIONS

BEST PRACTICES FOR VOICE-OF-CUSTOMER INSIGHTS FOR EARLY STAGE TECHNOLOGIES

NICHOLAS MOURLAS
Senior Director New Ventures

AI BASED DEVICES: ADDRESSING DESIGN CHALLENGES AND LOOKING AT THE EVOLUTION NEXT 5 YEARS AND BEYOND

LUIS LASALVIA, MD
VP & Global Medical Officer

HOW ADDITIVE MANUFACTURING WILL REVOLUTIONIZE THE MEDICAL DEVICE INDUSTRY

ROBERT WOOD
VP, WW Manufacturing

DRIVING AGILE ADOPTION FOR THE DEVELOPMENT OF MEDICAL DEVICES

BESAINT MEHTA SAHNI
Senior Program Manager

HOW TO CREATE AN ORGANIZATION OPEN, CURIOUS, AND COMMITTED TO LEARNING

MARK WEHDE
Section Head of Technology Development
Mayo Clinic Division of Engineering

IMPLEMENTATION AND EXECUTION OF MAJOR REGULATORY CHANGES WITH A SPECIFIC FOCUS

LAILA GURNEY
Senior Executive, Global Regulatory Affairs

THE BIGGEST CHALLENGE FOR SMALL-TO-MID-SIZE MEDICAL DEVICE MANUFCATURERS

WHY THE MEDICAL DEVICE INDUSTRY SHOULD CARE ABOUT BLOCKCHAIN?

2:15 pm – 2:55 pm

DESIGN

BUILDING THE FUTURE OF HEALTHCARE STARTING NOW

- Sharing high-value drivers of the future
- Expanding precision in medicine, while joining an upcoming transformation of care delivery (from precise diagnosis and prevention up to individualized treatment)
- Improving patient experience, while setting patients as consumers

LUIS LASALVIA, MD
VP & Global Medical Officer

SIEMENS Healthineers

PRODUCT DEVELOPMENT

THE IMPACT OF R&D AND MEDICAL DEVICE TRENDS ON SMALL TO MID-SIZE ORGANIZATIONS

- How to simply take advantage of changing industry dynamics as a small to the mid-size medical device company
- How to increase strategic relationships
- Developing an approach to increase focus on R&D and understanding outsourcing as an opportunity within the medical device industry

GRACE HSIA
Co-Founder & CEO

warmilu

QUALITY

A CULTURE THAT VALUES REGULATORY LEADERSHIP

- Why leadership remains the No. 1 talent issue facing organizations around the world
- Exploring the need for "leaders at all levels" as a critical issue identified in the Global Human Capital Trends survey
- How developing leaders in the face of new challenges, such as development within various generations, demand for global influence, and rapidly changing technologies can be daunting

RAINA DAURIA
VP, WW Regulatory Affairs

Johnson & Johnson

INNOVATION

EMBRACING THE DIGITAL REVOLUTION OF MEDICAL DEVICE MANUFACTURING: GAINING MOMENTUM WITH IOT

- Robotics is creating new value for manufacturers across the value chain
- Identify and eradicate global manufacturing and quality problems with an IoT transformation
- Reduce and eliminate defects and optimize productivity and localize supply chains in a cost-effective manner

TBD

3:00 pm – 3:35 pm

WORKSHOP

LEVERAGING REAL-TIME TECHNOLOGY & ANALYTICS TO FOSTER PLANT FLOOR OPTIMIZATION

- Gathering machine-level data real-time to improve OEE and reduce manufacturing costs
- Integrate machine data with ERP systems to provide enhanced scheduling and inventory control of raw
- Provide complete product traceability to each cycle of the machine

ROB DIETER
VP, Healthcare

CSA Group

WORKSHOP

BE READY FOR THE EU MDR LABELING AND USE THE LESSONS LEARNT FROM UDI

- Understand what EU MDR compliance means for your business and how it will affect your labeling processes
- Develop an understanding of the market's perceptions of EU MDR
- Recognize what the biggest labeling compliance challenges ahead are and how to proactively overcome them

TIM FISCHER
VP, Healthcare

PRISYM ID

WORKSHOP

HIGHLIGHTING MEDICAL DEVICE MANUFACTURING FACILITIES

- Case study: A look at global I.T. systems for 20 medical factories with 500+ production lines, shipping 35M+ top level assemblies per year
- Medical production lines range from those producing highly complex instruments to high volume "lights out" production lines
- Discussion of UDI and GAMP5 Compliance Requirements

BRYAN BRADY
VP, Sales

MPI MICROBOARD PROCESSING INC.
"excellence across the board since 1983"

WORKSHOP

WHEN YOU HAVE A COMPLIANCE CRISIS: RESPONDING TO CHALLENGES IN A WAY THAT BEST MANAGES EXPOSURE TO RISK

- Responding to an FDA 483 inspection
- Responding to an FDA Warning Letter
- Meeting with the FDA to resolve disputes
- Implementing corrective and preventive action (CAPA) programs-including development, execution,

RICKI A. CHASE
Director, Compliance Practice

Lachman CONSULTANTS

3:40 pm – 5:10 pm

PRE-ARRANGED ONE-TO-ONE NETWORKING & REFRESHMENTS

5:15 pm – 5:55 pm

WORKSHOP

CONNECTED ASSETS IN REGULATED ENVIRONMENT (CARE)

- Key considerations for driving connectivity in a regulated environment
- Ways to generate value from analytics and decision-making systems to drive business and clinical objectives
- Steps to quantify ROI for smart-connected devices

PARTHA MARELLA
SVP & Global Head of Medical Services

5:55 pm – 6:35 pm

LEADERSHIP SPOTLIGHT

DEVELOPING A STRATEGIC MEDICAL DEVICE CLEARANCE & APPROVAL PLAN

- Identify benefits and challenges of various regulatory markets, alongside an analysis on potential modifications to 510k policy
- FDA perspective on predicate device criterial: examining predicate device selection tools and techniques
- Understanding checklists and timelines for FDA refuse-to-accept policy, best practices for internal submission review
- Overcoming rejection in 510k submissions; examples of successful appeal pathways

MARJORIE SHULMAN
Director, Premarket Notification Program

6:35 pm – 7:15 pm

INTERACTIVE SPOTLIGHT

THE DESIGN INNOVATION BEHIND HEALTHCARE TECHNOLOGIES

- Affordability and accessibility of healthcare is a great concern, as our population worldwide grows and ages
- Products designed for developed healthcare markets miss the mark in serving unmet needs in developing markets
- In our interconnected world with leapfrogging technologies—such as accessible internet, wearables, drones, inexpensive sensor technologies—healthcare is being democratized

PALANI PALANIAPPAN
EVP, Innovation & Development

7:15 pm – 7:20 pm

CHAIR'S CLOSING REMARKS

MICHAEL BACA
Former VP, Quality / Regulatory / Clinical

7:20 pm – 8:20 pm

NETWORKING DRINKS RECEPTION

Sponsored by:

PROGRAM DAY TWO

7:00 am – 7:55 am

NETWORKING & BREAKFAST BRIEF

WOMEN IN LEADERSHIP BREAKFAST BRIEF

*WE INVITE OUR ATTENDEES TO NETWORK AT A WOMEN IN LEADERSHIP BREAKFAST BRIEF WITH DISCUSSION FROM INSPIRATIONAL LEADERS IN THE MEDICAL DEVICE INDUSTRY. SEATING IS LIMITED.

LIZ IVERSEN
SVP, Chief Quality & Regulatory Officer
PHILIPS

GRACE HSIA
Co-Founder & CEO
warmilu

RAINA DAURIA
VP, WW Regulatory Affairs
Johnson & Johnson

7:55 am – 8:05 am

CHAIR'S OPENING REMARKS & REVIEW OF DAY ONE

MICHAEL BACA
Former VP, Quality / Regulatory / Clinical
stryker

8:05 am – 8:45 am

OPENING KEYNOTE

CDRH STRATEGIC PRIORITIES: HOT TOPICS FOR AN EVOLVING REGULATORY CLIMATE

- Update on 2016-2017 priorities and preview of 2018-2019
- Case for quality: Realizing what we can achieve when we work together
- Benefit: Risk guidance: Impact on compliance and enforcement decisions
- Inside CDRH: Organizing to enhance knowledge management and operational excellence across the total product lifecycle

CAPT SEAN BOYD
Deputy Director for Regulatory Affairs
FDA

8:45 am – 9:25 am

INNOVATION SPOTLIGHT

SMART DEVICE DESIGN THINKING: USER-CENTERED DESIGN TO DRIVE BREAKTHROUGH PATIENT OUTCOMES

- Dealing with today's dynamic healthcare environment must start with a new understanding of the patient
- We must disrupt current patient engagement models with new levels of patient intimacy to drive new innovation
- These techniques translate to breakthroughs such as smart devices
- Patient engagement is an ongoing journey to truly improve lives

ASHISH ATREJA, MD, MPH
Chief Innovation Officer, Medicine
Icahn School of Medicine at Mount Sinai

9:25 am – 10:05 am

LEADERSHIP SPOTLIGHT

REDESIGNING HEALTH CARE: HOW AI WILL TRANSFORM THE MEDICAL DEVICE INDUSTRY

- Managing patient expectations in a digital world and the need for unifying experiences
- A deep dive into the evolving healthcare ecosystem & its implications for medical device companies
- How to build a digital core and framework for patient-centric healthcare solutions
- Exploring technology drivers transforming digital healthcare

GUSTAVO PEREZ-FERNANDEZ
President & CEO

10:10 am – 10:45 am

DESIGN

A BALANCED MATRIX IN YOUR R&D ORGANIZATION

- Identify the need for Organizational Change Management
- The 5 strategic pillars of OCM
- Organizational Change Management as a strategic growth initiative: Why it works so well
- Working on the right things: The basics of Project

NORBERT LEINFELLNER
VP, Product Development Engineering

FRESENIUS MEDICAL CARE

PRODUCT DEVELOPMENT

ADVANCING NEW MEDICAL DEVICE INNOVATION THROUGH COLLABORATION

- A focus on growth factors that help you achieve the creation of value through innovation and global reach
- Lead with innovation and make it a core component of your business success
- Excellence in execution starts with quality across the entire spectrum from operational procedures to the

NICHOLAS MOURLAS
Senior Director, New Ventures
Johnson & Johnson Innovation

Johnson & Johnson

REGULATORY

GLOBAL REGULATORY INTELLIGENCE: EVALUATING THE DEVELOPMENTS TO THE EU MDR

- Exploring regulatory challenges regarding the tracking, monitoring and interpretation of new regulations of the ever-changing global regulatory landscape, specifically the new EU MDR
- Advice for companies to help them to ensure that they have the right resources and support to appropriately interpret and implement the new EU MDR

MICHAEL SANTALUCIA
VP, Global Regulatory Affairs

TERUMOBCT
Unlocking the Potential of Blood

INNOVATION

ENTERING AN ERA OF VALUE BASED HEALTH CARE: A CASE STUDY ON THE TYRX DEVICE

- A case study on how the TYRX absorbable antibacterial envelope will reduce infection and reduce costs
- A look at how innovation leads to better quality standards through accountability and a patient-centric focus
- Examining the future of health care through the partnership with the Lehigh Valley Hospital Network

JORIE SOSKIN
Sr. Director & General Manager, Medtronic Infection Control

Medtronic

10:50 am – 11:50 am

NETWORKING & REFRESHMENTS

11:55 am – 12:30 pm

WORKSHOP

A PROGRAMMATIC APPROACH TO EU MDR COMPLIANCE

- Assess your product portfolio to determine priority
- Develop a plan that takes into account prioritization of your current products and pipeline
- Execute the plan and ensure that project controls are in place to manage and monitor your progress
- Revise processes and procedures to ensure a sustainable process

TOM RYNKIEWICZ
VP, RA/ QA

raland COMPLIANCE PARTNERS

WORKSHOP

SUCCESSFULLY NAVIGATING COMMON PRODUCT COMMERCIALIZATION PITFALLS

- When the difficult and costly development process is coming to fruition, the pressure is on to deliver the product to patients in need
- Navigate the complexities of the commercial launch process - the complex regulatory submission process, market access barriers, supply chain challenges, and many other challenges
- Mitigate risks that, if mismanaged, can result in missed opportunities for patients and loss of market share to competitors

EYAL GOLAN
Project Management Consultant

IPM INTEGRATED PROJECT MANAGEMENT

WORKSHOP

STRATEGIC QUALITY – ACHIEVING THE PROMISE OF YOUR MEDICAL DEVICE BUSINESS MODEL

- Developing operational systems and practices
- Establishing your company's "risk balance point"
- Exploring risk mitigation objectives and approaches
- Looking at new product introduction facilitation
- Assessing knowledge management/ organizational connections

JAMES BANKO
VP, Sales

PACUR

WORKSHOP

DESIGN FOR EXCELLENCE (DFX) — DRIVING PRODUCT OPTIMIZATION THROUGH EARLY STAGE VALUE ENGINEERING DEVELOPMENT

- The key benefits to performing DFX on your product: reducing lead time and material costs (DFSC)
- How to improve PCB yield, cost (DFF), assembly yield, reduced labor content (DFA), coverage, final yield, reduced RMA and field failures (DFT)
- Key opportunities for reducing engineering development and resources while improving time to market

BILL STAMM
Sales & Business Manager

GD GENERAL DIGITAL SOFTWARE SERVICES

12:35 pm – 1:10 pm

WORKSHOP

MAXIMIZING MEDICAL DEVICE ROI

- With a widely dispersed fleet of medical devices, how are hospitals and healthcare systems optimizing the investment they are making in medical devices?
- Do medical device manufacturers have that single source of truth for critical information, such as total cost of ownership, device location, status, utilization, costs, software updates/patches, alerts, and availability of spare parts?
- Knowing how much is spent on compliance
- New security threats are directly affecting medical devices today: How do you know that your medical devices are really secure?

TBD

WORKSHOP

BALANCING BUSINESS GOALS WITH PATIENT SAFETY

- The importance of efficient quality management systems
- Best practices to successfully integrate quality and corporate compliance
- How to avoid typical costly pitfalls associated with poor quality management and non-compliance
- The ROI of proactive vs. reactive efforts

ED ROACH
SVP, Strategic Accounts

MAETRICS

WORKSHOP

BEYOND COMPLIANCE: REACHING IDEAL QUALITY & BUSINESS PERFORMANCE OBJECTIVES

- Integrated – Un-siloed approach to driving end-to-end business performance
- Maturity – Clear, complete and repeatable processes designed to get it right the first time
- Visibility – Correct key indicators for executive level visibility for quality and business performance
- Efficiency – Integration technology, processes, methodology and the right people to increase process speed and effectiveness

TBD

WORKSHOP

DECRYPTING FDA CYBERSECURITY EXPECTATIONS FOR MEDICAL DEVICES

- See how the new standards, including UL 2900 correspond to FDA guidance
- Understand security design considerations recommended by the FDA Guidance
- Discover key processes ensuring security risks are managed for products currently in the market

TBD

1:15 pm – 2:15 pm

LUNCH & LEARN ROUND-TABLE DISCUSSIONS

HOW TO STAY ON TOP OF GLOBAL REGULATORY REQUIREMENTS

EVA L. PETERSEN
VP, International Sales

HOW TO AUTOMATE AND STREAMLINE REPETITIVE OR POTENTIALLY UNSAFE PROCESSES

BRAD SCHULTZ
VP, Sales & Marketing

RECENT DEVELOPMENTS IN THE USE OF FLEXIBLE PRINTED CIRCUIT BOARDS IN IMPLANTABLE DEVICES

BRYAN BRADY
VP, Sales

MEDICAL DEVICE SECURITY AS AN ENABLER FOR INNOVATION

DEON LEWIS
Sr. Marketing Director

PROVEN METHODS FOR SUCCESSFUL INNOVATION OUTCOMES

TCATHERINE CERASUOLO
Manager

HOW DO YOU KNOW WHAT'S HAPPENING TO YOUR PRODUCT AFTER IT HAS LEFT YOUR FACILITY?

MIKE MONTANA
Senior Business Development Manager

ADVANTAGES & OPPORTUNITIES WITH THE NEW EU MEDICAL DEVICE REGULATION

STEVEN LEPKE
President

DEVELOPING SMARTER, MORE COST-EFFECTIVE MANUFACTURING

JUDSON VANN
VP, Sales & Marketing

IMPROVED FLEXIBLE AND ADAPTABLE OUTSOURCING MODELS FOR LIFECYCLE

SATHISHBABU RAMACHANDRAN
Medical Technology & Healthcare, Mechanical System

HOW TO RAMP UP ROI FOR SMART-CONNECTED DEVICES

PARTHA MARELLA
SVP & Global Head of Medical

ADVANTAGES & OPPORTUNITIES WITH THE NEW EU MEDICAL DEVICE REGULATION

JEFF CHAMPAGNE
VP

RISK MANAGEMENT STRATEGIES FOR MEDICAL DEVICE DESIGN AND PROCESSES

MITCH HAYES
CEO

HOW TO RAMP UP ROI FOR SMART-CONNECTED DEVICES

PARTHA MARELLA
SVP & Global Head of Medical

2:20 pm – 3:00 pm

LEADERSHIP SPOTLIGHT

DEVELOPING A PROACTIVE QUALITY CULTURE

- Evaluating and assessing the cultural continuum, challenges, and risks
- Quantifying the business value of a culture of quality
- Developing and sustaining the gains of a quality culture and adopting change management

LIZ IVERSEN
SVP, Chief Quality & Regulatory Officer

3:00 pm – 3:35 pm

DESIGN

CONNECTING DESIGN TO EXECUTION IN A LEAN SYSTEM

- Understanding the lost opportunities of not applying lean: Leak analysis
- What is the missing link between functional support areas and daily operations
- Lessons learned on driving lean through the organizational culture
- Lean and its impact on organizational speed: Short-term

WILLIAM OWAD
SVP, Operational Excellence

CardinalHealth™

PRODUCT DEVELOPMENT

EXPANDING MARKET LEADERSHIP WITH INNOVATIVE PRODUCTS WITH A CUSTOMER FOCUS

- Opportunities for more inclusive innovations models, collaborate more frequently and with a broader range of partners and pursue greater integration
- The time to collaborate is now: Driving a strategy that complies with a global emphasis to drive down healthcare costs
- Partnerships rather than in-house efforts as a accelerator to innovation and increase speed to market

REGULATORY

CONNECTED ASSETS IN REGULATED ENVIRONMENT (CARE)

- Key considerations for driving connectivity in a regulated environment
- Ways to generate value from analytics and decision-making systems to drive business and clinical objectives
- Steps to quantify ROI for smart-connected devices
- Latest updates from the FDA and EU on connected medical device regulations, cybersecurity and mobile medical apps

CARLOS URREA
VP, Medical Affairs

Hill-Rom

INNOVATION

ADDRESSING AN UNMET NEED:TRANSITIONING ADULT DEVICES TO ACCOMMODATE THE PEDIATRIC POPULATION; A LOOK AT CHALLENGES AND TRENDS

- Examining device and design consideration
- An outline of key factors specific to the pediatric population
- How to acquire funds for pediatric devices; battling the return on investment hurdle
- Tips for clearing your pediatric device through FDA pathways

LISA BECKER
Associate Director, Clinical Quality Assurance

Abbott

3:40 pm – 4:20 pm

CLOSING PANEL

ADDRESSING THE 2018 OBSTACLES: EXPLORING REGULATORY CHALLENGES & OPPORTUNITIES

- Assessing real-time detection: What measures can regulators, healthcare providers, and device manufacturers take to protect the public from malware attacks?
- With the "Emerging Signals" guidance issued by FDA, what are some of the challenges and benefits to the early notification to the public of potential adverse events?
- With upwards of over 100 countries with local regulatory requirements for medical devices, what are some of the greatest challenges

CAPT SEAN BOYD
Deputy Director for Regulatory Affairs

FDA

MICHAEL BACA
Former VP, Quality/ Regulatory/ Clinical

stryker

ASHISH ATREJA, MD, MPH
Chief Innovation Officer, Medicine

Icahn School of Medicine at Mount Sinai

4:20 pm – 4:25 pm

CHAIR'S CONCLUDING REMARKS & CLOSE OF SUMMIT

MICHAEL BACA
Former VP, Quality/ Regulatory/ Clinical

stryker