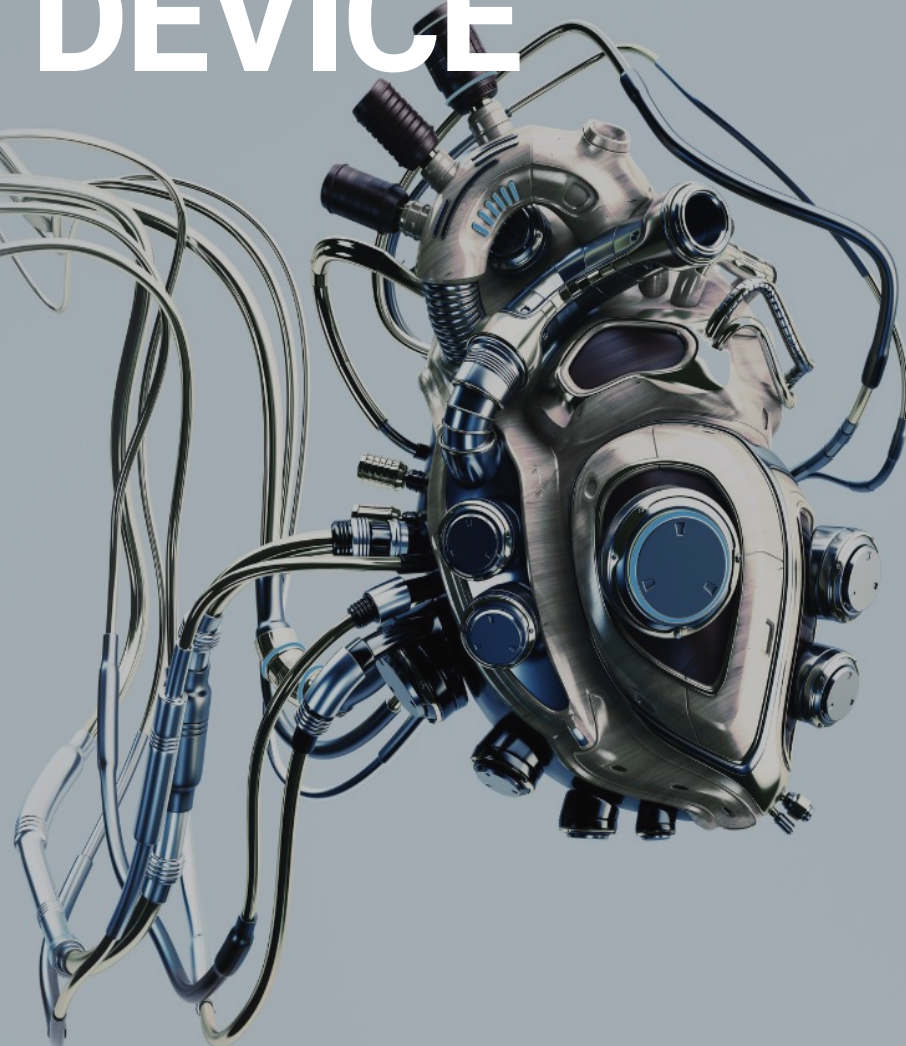




AMERICAN MEDICAL DEVICE SUMMIT 2021


October 26–28, 2021


amdsummit.com



TOMORROW'S CONNECTION TODAY

Designing a new future for manufacturing, quality and supply chain leaders

 +1-416-298-7005

 info@generisgp.com

PROGRAM

PROGRAM • DAY 1

OCTOBER 26th, 2021

10:00 am - 10:30 am EST

LOG-IN AND WELCOME

10:35 am - 10:45 am EST

CHAIR'S OPENING REMARKS



AMI SIMUNOVICH
EVP and Chief Regulatory Officer
Becton Dickinson

10:45 am - 11:20 am EST

OPENING KEYNOTES



ELIZABETH BLACKWOOD
Chief Quality Officer, Medical Devices
Johnson & Johnson

OPTIMIZING PATIENT CARE, QUALITY AND COMPLIANCE WITH EVOLVING REGULATORY LANDSCAPE

- Highlighting Johnson & Johnson's Quality Standards
- Updates to the ever-changing regulatory landscape (EU MDR compliance, Brexit's role on compliance, APAC, and more)
- Practicing Protectionism: What we learned over the last year while serving the world critical medical supplies (PPE, ventilators) to suit evolving regulations
- Why quality extends beyond device design and into the optimization of patient care



AMIT PHADNIS
Chief Digital Officer
GE Healthcare

INVESTING IN ARTIFICIAL INTELLIGENCE AND PAVING THE WAY FOR HEALTHCARE TRANSFORMATION

- Calling attention to the rising need for AI both in healthcare and outside of the operating room
- Moving beyond ambitious plans for AI and into actionable execution
- Why an agile organization is the vital foundation for digital transformation success
- Case study: Organizational adoption of innovations in AI and success stories

11:25 am - 12:00 pm EST

PLENARY

SPEED-TO-MANUFACTURABILITY: OPTIMIZATION TACTICS FOR POST-PANDEMIC SUCCESS

- Building a nimble and responsive organization that applies Lean thinking amidst COVID-19 pressures
- Disrupting the legacy market through engineering innovations
- Assessing your organization for gaps in speed-to-manufacturability and planning your COVID-19 exit strategy
- Why linking our people, processes and technologies leads to greater collaboration

12:05 pm - 1:05 pm EST

PRE-ARRANGED 1-2-1 BUSINESS MEETINGS AND NETWORKING

1:10 pm – 1:50 pm EST

LUNCH & LEARN ROUNDTABLE DISCUSSIONS

Benefit from additional learning by joining a moderated roundtable discussion on pressing issues in the industry. Registration is required, and attendance is limited. Choose from:



FRED LITTLE
Business Development (Technology Evangelist)
Providence Enterprise

HOW WORKING WITH A FULLY INTEGRATED CM CAN HELP MANAGE THE EXPLOSION IN USE CASES FOR REMOTE PATIENT MONITORING



ERIK HILLIARD
Director, Business Development
Sterling Medical Devices

STREAMLINING THE ENGINEERING PROCESS TO SPEED REGULATORY APPROVAL OF CLASS II AND III DEVICES



SPEAKER TBA
RAUMEDIC

HIGHLIGHTING THE USE-VALUE IN SILICONE PROCESSING FOR MEDICAL DEVICES



SPEAKER TBA
Tempo Automation

DELIVERING QUICK-TURN PROTOTYPES AND LOW-VOLUME PRODUCTION OF HIGH-COMPLEXITY, HIGH-QUALITY BOARDS FOR MEDICAL DEVICES AND OTHER CRITICAL SYSTEM APPLICATIONS



SPEAKER TBA
RWS Life Sciences

TESTING & DATA TRAINING STRATEGIES TO ENSURE PRODUCT SUCCESS



SPEAKER TBA
Cyient

VIRTUAL HEALTH AND REMOTE CARE: HOW THE CRISIS IS CHANGING DIGITAL HEALTH



PETER MATTHEWSON
Head of Electronic Engineering
Team Consulting

FUTURE PROOFING YOUR SMART MEDICAL DEVICE



JAMES RICHTER
Managing Partner
Compliance Architects LLC

RISK-PRIORITIZING AND ADDRESSING QUALITY AND COMPLIANCE GAPS/OPPORTUNITIES: A PROPRIETARY, ANALYTICAL APPROACH FOR MEDICAL DEVICE COMPANIES

1:55 pm – 2:30 pm EST

WORKSHOPS

DESIGN



ANDY RICHARDSON
SVP, Sales
Xcentric

3D PRINTING AND INJECTION MOLDING: SAME TEAM, DIFFERENT ROLES

- 3D Printing and Injection Molding work well together to prove out new products, reduce costs, and accelerate time to market
- Efficient, effective manufacturing depends on choosing the right process for the right step
- Understanding how 3D Printing and Injection Molding can be used optimally at different points of development and production leads to a more successful product development process
- The trend of promoting 3D Printing in place of Injection Molding can have a devastating impact on project success
- Learning how and when to use each process will optimize your product development

QUALITY AND REGULATORY

CACTUS

VERA EDGEWORTH
Medical Director
Cactus Life Sciences



RONAK DUNUNG
Manager, Risk Management
COOK Medical

DATA-DRIVEN QMS ALIGNMENT

- Defining and understanding the similarities and differences between various types of QMS data
- Impact of EU MDR on the type, quality, and quantity of post-market data
- Recycling data and aligning key QMS processes via Risk Management

PRODUCT DEVELOPMENT



SHIRLEY FURESZ, PH.D., RAC
Director, Regulatory Affairs Medical Devices
Innomar Strategies

STRATEGIC CONSIDERATIONS FOR US AND CANADIAN MEDICAL DEVICE REGISTRATIONS

- A look at the similarities and differences between jurisdictions
- Agency Interface meetings – Q meetings vs pre-submission meetings
- Device Classification – substantial equivalence vs risk based
- Regulatory Pathways including timelines, cost, and QMS requirements
- Special Options/Designations; Small Business Designation and Breakthrough Designation

INNOVATION

Within3

SPEAKER TBA
Within3

USING VIRTUAL COLLABORATION STRATEGIES TO ADVANCE AND ACHIEVE YOUR MEDICAL DEVICE GOALS

- How the COVID-19 pandemic has charted a path for the future of virtual work in the medical device world
- Highlighting Within3's virtual platform: delivering seamless collaboration and communication to improve study design, training, and trial execution
- Case study: How Med Device teams accomplished many of their COVID-era achievements through virtual collaboration strategies
- Discussing the 2021 Medical Device Virtual Engagement Field Guide

2:35 pm – 3:35 pm EST

PRE-ARRANGED 1-2-1 BUSINESS MEETINGS AND NETWORKING

3:40 pm – 4:15 pm EST

SESSIONS

DESIGN



LIANE TEPLITSKY
VP and GM, Worldwide Robotics
Zimmer Biomet

SURGICAL ROBOTICS: CREATING TANGIBLE VALUE FOR THE FUTURE OF MEDICAL DEVICES

- Designing turnaround strategies for mission-critical businesses
- Discussing the manufacturability of global surgical robotics and steps to design implementation
- Exploring how to make medical interventions smarter, less invasive and more personalized
- Case study: How Zimmer Biomet is changing the standard of care for now and for the future

QUALITY AND REGULATORY



ILANA SHULMAN
Chief Compliance Officer
Hillrom



JOANNE THOMPSON
Director, Compliance
Hillrom

DIRECTING AN AGILE COMPLIANCE ORGANIZATION

- Best practices for reshaping your company's compliance strategy to adhere to regulatory and compliance changes
- Overcoming increasing complexities of the material supply chain and manufacturing operations
- Addressing new FDA quality and regulatory guidelines
- Leveraging innovation as a cornerstone to achieving a compliant program

4:20 pm – 5:20 pm EST

EXPO HALL NETWORKING

PRODUCT DEVELOPMENT



Edwards

TODD BRINTON, M.D., F.A.C.C.
CVP, Advanced Technology and Chief Scientific Officer
Edwards Lifesciences

INNOVATIONS AND ADVANCEMENTS IN MEDICAL DEVICE ENGINEERING

- Allowing design intention to be clearly communicated and showcasing the overall form of a concept
- Best practices for developing and prototyping devices
- Assessing risk of new technology implementation in the engineering process
- Discussing customization in medical device creation: Providing part consolidation and topology optimization for custom medical devices

INNOVATION



SNEHAL DESAI
VP, Augmented Intelligence
Cardinal Health

USING AI TO MAKE A DIFFERENCE IN QUALITY

- Getting quality in our DNA
- Strategies for automating in the quality space
- Discussing Cardinal Health's AAA Initiative: Automation, Analytics and Artificial Intelligence
- Leveraging people + talent combined with data + analytics for optimal outcomes

PROGRAM • DAY 2

OCTOBER 27th, 2021

9:45 am – 9:55 am EST

LOG-IN AND WELCOME

10:00 am – 10:50 am EST

EMPOWER HOUR



REGINALD PORTER
SVP, CSR and Chief Diversity Officer
St. Jude Children's Research Hospital-ALSAC



MICHAEL JOHNSON
SVP, Diversity and Inclusion
Abbott



SALLY SABA
Chief Inclusion and Diversity Officer
Medtronic



PAMELA ABNER
VP and Chief Diversity Operations Officer
The Mount Sinai Hospital



MIRNA DIPANO
VP, Quality Assurance and Regulatory Affairs
NanoString Technologies, Inc.



JAMES CHENG
Global Head, Diversity, Equity, and Inclusion
Zimmer Biomet

DIVERSITY AND INCLUSION ROUNDTABLE

We invite attendees to network at the Diversity and Inclusion Roundtable with discussions from inspirational leaders in design, product development, quality, regulatory, technology and more.

10:55 am – 11:05 am EST

CHAIR'S OPENING REMARKS



AMI SIMUNOVICH
EVP and Chief Regulatory Officer
Becton Dickinson

11:05 am – 11:40 am EST

OPENING KEYNOTES



LISA EARNHARDT
EVP, Medical Devices
Abbott



COLLEEN RILEY
Global SVP, Innovation and Development
Terumo Blood and Cell Technologies

SHAPING THE FUTURE OF HEALTHCARE CALLS FOR NEW APPROACHES TO INNOVATION

- The world faces immense health threats and major issues in confronting them. For healthcare innovators, "business as usual" won't get it done; cutting-edge innovation alone is not enough
- The best healthcare solution is the one that can reach the most people who need it – one that is accessible and affordable, transforms care, breaks down barriers to access
- How Abbott is designing access and affordability into every aspect of product development to create more impact for more people in more places and shaping the future of healthcare
- Case studies/examples: FreeStyle Libre, BinaxNOW COVID-19 Rapid Test, Ultreon OCT system, NeuroSphere Virtual Clinic

REDESIGNING THE FUTURE OF MEDICAL TECHNOLOGY AND DEVICES

- Automating complex processes and help researchers and clinicians unlock the potential of an individual's genetic material
- Embedding products into the cell therapy manufacturing process
- Why it's important to build infrastructure in growth geographies and expand beyond devices into patient data
- Case study: How Terumo BCT diversifies its portfolio to fund continued innovation in a cost-conscious healthcare environment

11:45 am – 12:20 pm EST

PLENARY

CREATING AND EXECUTING AN ENGINEERING ROADMAP ACROSS A LARGE DEVICE PORTFOLIO

- Setting the technology strategy and direction for the business in each engineering discipline
- Driving continuous improvement of systems, products and processes to enable execution of that technology strategy
- Creating an engineering roadmap definition, and integration of technologies across the portfolio
- Leading change through creative solutions to unstructured product and system design issues
- Optimizing your team's participation in all phases of product development
- Supporting existing products within Manufacturing, Sourcing, Service and Supplier Quality Engineering


12:25 pm – 1:25 pm EST

PRE-ARRANGED 1-2-1 BUSINESS MEETINGS AND NETWORKING

1:30 pm – 2:10 pm EST

LUNCH & LEARN ROUNDTABLE DISCUSSIONS

Benefit from additional learning by joining a moderated roundtable discussion on pressing issues in the industry. Registration is required, and attendance is limited. Choose from:



MONICA NAKIELSKI
Associate Director and Health Care
Sector Lead
Anthesis



JACKIE LESLIE
Category Specialist Life Sciences
Esko | Brand Solutions



MILTON YARBERRY
Director, Medical Programs
Integrated Computer Solutions (ICS)

HOW SUSTAINABILITY INNOVATION SUPPORTS COST CONTAINMENT, RISK MITIGATION, AND GROWTH OPPORTUNITIES




ED WALSH
VP Global Sales
Sigmatrx

E2E LABELING AND PACKAGING ARTWORK BEST PRACTICES IN MEDICAL DEVICE



KELLY STANTON
Director, Quality
Qualio

THE VALUE PROPOSITION OF MACHINE LEARNING IN MEDICAL DEVICES



JOSEPH-RICHARDSON LARBI
Consultant, Medical Device Regulatory
Affairs
Celegence

UNDERSTANDING SYSTEM VARIATION TO DEVELOP MORE INNOVATIVE PRODUCTS AND ADHERE TO FDA 21 CFR 820.30 AND 501(K) REQUIREMENTS

UNITING YOUR TEAMS, PROCESS, AND DATA USING EQMS

THE POST BREXIT LANDSCAPE FOR MEDICAL DEVICE COMPLIANCE

2:15 pm – 2:50 pm EST

WORKSHOPS

DESIGN

DRIVING SUSTAINABLE SUCCESS IN MEDICAL DEVICE DEVELOPMENT AND ADVANCEMENT

- Tips and tricks for optimizing product value in medical device development (i.e. new indications, new formulations, improving market penetrance)
- Examining external landscape concerning Medical Devices, Electronic Data Capture, Human Factors Studies, and all R&D aspects of eHealth
- Navigating the development and utilization of future eHealth platforms in a highly competitive and rapidly changing market

QUALITY AND REGULATORY



MARTY SMYTH
SVP, Go-To-Market Strategy
MasterControl

DEBUNKING THE MYTH THAT DIGITIZATION IS COSTLY AND TIME-CONSUMING

- While paperless plant initiatives have been commonplace for years, many manufacturers still haven't digitized production processes due to the cost and complexity of traditional solutions
- Expensive, complex MES isn't necessarily the path to automating the shop floor, when new technologies provide smarter, faster, and affordable paperless manufacturing opportunities
- Modern SaaS applications available today allow you to digitize and manage all your production records, training documents, SOPs, and more on a single platform that is fast to implement, simple to configure, easy to use, and able to deliver results today – not a year from now
- As organizations look to increase production capacity, efficiency, and profitability coming out of the latest disruption cycle, leaders in manufacturing operations, technology, and quality should be asking themselves if they can really afford not to finally eliminate paper-based processes from their shop floors – especially when doing so is faster and cheaper than ever before

PRODUCT DEVELOPMENT

KEEPING UP WITH THE DIGITAL HEALTH REVOLUTION

- What technologies and trends are revolutionizing the industry?
- Navigating cost, regulatory challenges, and how to decide which technologies are worth the investment
- Getting your team on board with tech transformations
- Planning beyond the device and into the data ecosystem
- Investing in capabilities that will deliver future value

INNOVATION



SPEAKER TBA
Simtelligent

SECURE IOT INTEGRATION TACTICS FOR CONNECTED DEVICES

- Allowing device manufacturers to connect to a secure cloud environment that provides immediate alerts, real-time health information and historical data to identify trends and potential issues
- Addressing surgical delays and inventory issues: How IoT can enable hospital staff to ensure surgeries are performed on time by tracking current usage and allowing the planning phase to lock in needed equipment
- Uncovering the value in data collection during surgery and using historical data for future planning

2:55 pm – 3:55 pm EST

PRE-ARRANGED 1-2-1 BUSINESS MEETINGS AND NETWORKING

4:00 pm – 4:35 pm EST

SESSIONS

DESIGN



RANDY SCHIESTL
VP, R&D and Global Technology
Boston Scientific Corporation



KEVIN FU
Acting Director, Medical Device Cybersecurity
FDA Center for Devices and Radiological Health



PAMELA GOLDBERG
President and CEO
Medical Device Innovation Consortium (MDIC)

STRATEGIES TO ENHANCE YOUR DIGITAL HEALTH, DATA AND CYBERSECURITY JOURNEY

- Reviewing the importance of data in the medical field to enhance digital health and patient experience
- How to have a world-class cybersecurity program in the medical device industry
- Designing safety risk management programs for device design and development
- Reframing device vulnerabilities and enabling resources to protect patients from security risks

QUALITY AND REGULATORY



JACKIE KUNZLER
Chief Quality and Regulatory Officer
Baxter

BALANCING QUALITY AND SPEED-TO-COMMERCIALIZATION ACROSS THE PORTFOLIO

- Balancing complexities of today's speed-to-commercialization needs with global quality and EU MDR requirements
- New, actionable strategies to manage speed-to-commercialization across the portfolio
- Achieving cross-functional organizational alignment for standardized quality and results
- Highlighting innovative technologies to maximize quality without compromising on efficiency

4:40 pm – 5:40 pm EST

EXPO HALL NETWORKING

PRODUCT DEVELOPMENT



BRIAN PETERSON
CTO and VP, Engineering
Garwood Medical Devices, LLC

CREATING AND EXECUTING AN ENGINEERING ROADMAP ACROSS A LARGE DEVICE PORTFOLIO

- Setting the technology strategy and direction for the business in each engineering discipline
- Driving continuous improvement of systems, products and processes to enable execution of that technology strategy
- Creating an engineering roadmap definition, and integration of technologies across the portfolio
- Championing the FDA submission process and successfully achieving Breakthrough Device Designation for the BioPrax product
- Optimizing your team's participation in all phases of product development
- Sharing tips for launching new documentation system for being FDA, ISOP 14971, 13485 compliant
- Supporting existing products within Manufacturing, Sourcing, Service and Supplier Quality Engineering

INNOVATION



JORIE SOSKIN
VP and General Manager, Procedure Innovations
Medtronic

LEVERAGING INNOVATIVE MODELS FOR VALUE-BASED HEALTHCARE

- Exploring the current state of the industry: Where are we and where do we need to go?
- Examining industry drivers and trends, and their impact on operations: Evolution of technology, capacity and complexity, cost pressures, etc.

PROGRAM • DAY 3

OCTOBER 28th, 2021

9:45 am – 10:00 am EST

LOG-IN AND WELCOME

10:00 am – 10:50 am EST

EMPOWER HOUR



VALERIE OBENCHAIN
 Founder and CEO
Advanced Interactive Response Systems (AIRS)



ILANA SHULMAN
 Chief Compliance Officer
Hillrom



CYNTHIA WALKER
 SVP, Global Medical Education
Smith & Nephew



TANYA KLASLO
 Senior Director, Quality, Regulatory,
 Safety and Trust (QRST)
Google Health



CELINE MARTIN
 Global President, Digital Surgery
Johnson & Johnson



NINA GOODHEART
 SVP and President, Structural Heart
 and Aortic
Medtronic

WOMEN IN LEADERSHIP ROUNDTABLE

We invite our attendees to network at a Women in Leadership Roundtable with discussion from inspirational leaders in design, product development, quality, regulatory, technology and more.

SPONSORED BY:

Integrity Development



BREAKFAST BRIEFS



NATALIE WEIR
 Human Factors Consultant
Team Consulting



SPEAKER TBA
Nova Biologicals

SAVE MONEY AND STRESS BY INTRODUCING HUMAN FACTORS EARLY

DEVICE TESTING STRATEGIES FOR STERILITY VALIDATION AND ENVIRONMENTAL MONITORING

10:50 am – 11:00 am EST

CHAIR'S OPENING REMARKS



AMI SIMUNOVICH
 EVP and Chief Regulatory Officer
Becton Dickinson

11:05 am – 11:40 am EST

OPENING KEYNOTES



GIANLUCA PETTITI
SVP and President, Specialty Diagnostics
Thermo Fisher Scientific

PROCESS AND PEOPLE: BALANCING PERSPECTIVES ON A CHANGING CULTURE IN MEDICINE AND DEVICES

- Managing a large portfolio of projects on a national and international scale
- Empowering teams to focus on excellence and innovation
- Driving a high performance culture that is agile and thrives off of innovation
- Highlighting available and implementable processes that help with managing a changing culture



JODI EDDY
SVP and Chief Information and Digital Officer
Boston Scientific

MAXIMIZING YOUR DIGITAL INNOVATION BY LEVERAGING ITS ROLE THROUGHOUT OPERATIONS

- What are the necessary steps required to lead design, product development and quality operations in your organization?
- Addressing obstacles when integrating emerging tools and technologies across the enterprise
- Leading teams through process optimization - how Boston Scientific standardizes and ensures quality in design and product development
- Establishing systems to ensure the workforce is trained to successfully implement new technologies into the product development process

11:45 am – 12:45 pm EST

PRE-ARRANGED 1-2-1 BUSINESS MEETINGS AND NETWORKING

12:50 pm – 1:25 pm EST

SESSIONS

DESIGN



DAN WOLF
VP and General Manager, Intelligent Data Solutions (IDS)
Medtronic

DIGITIZING SURGERY USING DATA & AI: TRANSFORMING THE OPERATING ROOM

- How can a digital operating room bring value into a complex hospital setting?
- Digitizing surgical workflows and operations using artificial intelligence driven surgical planning, personalized spinal implants, and robotic assisted surgical delivery
- How the digitization of medical devices continues to shape and reshape the operating room
- Streamlining device and information usage and enrich clinical data before, during and after surgery
- Advancing your toolset to improve documentation, communication, integration, and ultimately patient outcomes

QUALITY AND REGULATORY



JODY POWELL
VP, Regulatory, Quality, Clinical
Stryker

HOW DATA AND ACCESS TO DATA IS CHANGING THE RA/QA FUNCTION

- Exploring the current state of the industry: Where are we in the data journey and where do we need to go?
- Examining industry drivers and trends, and their impact on operations: Evolution of medical device RA/QA automation and how data is changing the game
- How data visualization and understanding can increase speed-to-market

PRODUCT DEVELOPMENT



BRIAN MILLER
Chief Digital Officer
Intuitive Surgical

SUPPORTING CONTINUOUS IMPROVEMENT IN PRODUCT DEVELOPMENT AND PROCESSES

- What continuous improvement initiatives can be implemented to support and sustain product development?
- Ensuring transparency across design and manufacturing to ensure top quality
- Tips and tricks for launching new robotic systems, vision systems, instruments and accessories
- Case study: Discussing the movement from a start-up to becoming a global leader in surgical robotics

INNOVATION



NATHAN CARRINGTON
Head, Digital Health and Innovation, Global Regulatory Policy and Intelligence
Roche Diagnostics

EVOLVING AND INNOVATIVE APPROACHES IN THE GLOBAL REGULATION OF SAMD

- Reviewing the importance of SaMD in the healthcare community
- Describe approaches for determining when software is a medical device
- Software classification and clinical evidence requirements
- Regulatory approaches to software with multiple functions
- Approaches to the regulation of artificial intelligence-based SaMD
- Assessing what regulators are doing to evolve regulatory frameworks for software products

1:30 pm – 2:10 pm EST

LUNCH & LEARN ROUNDTABLE DISCUSSIONS

Benefit from additional learning by joining a moderated roundtable discussion on pressing issues in the industry. Registration is required and attendance is limited. Choose from:



DEREK SWAN
Chief Technology Officer
Optos

OPTIMIZING R&D PERFORMANCE IN MEDICAL DEVICES



JEFF MARKSBERRY
Chief Medical Officer
Oska Wellness

STIMULATING INNOVATION: DEVELOPING AND IMPLEMENTING PORTABLE DEVICES



PABLO BARIOLA
Head, Design and Director, Product Design
Glooko

USING DESIGN AS A CORNERSTONE TO ACHIEVE REMOTE PATIENT MONITORING



MAC MCKEEN
Fellow, Regulatory Science
Boston Scientific Corp

ETHYLENE OXIDE STERILIZATION OF MEDICAL DEVICES - THE JOURNEY TO REDUCE ETO LEVELS: IS YOUR COMPANY READY?

OVERVIEW OF IVD REGULATIONS



JUDY FONG
Associate Director, Medical Device and Combination Product Quality
Merck

LET'S TALK DESIGN TRANSFER AND POST-MARKET DESIGN CHANGES

2:15 pm – 2:50 pm EST

WORKSHOPS

DESIGN

INNOVATIVE MODELS FOR PRODUCT DESIGN AND DEVELOPMENT

- What are the key drivers that influence which projects to invest in early-on, and how do you work to de-risk certain activities?
- Emphasizing speed-to-manufacturability: How to be efficient with the budget yet drive device development, manufacturing and innovation forward
- Case study: New product design and development insight

QUALITY AND REGULATORY

HARNESSING THE POWER OF HARMONIZATION IN THE MEDICAL DEVICE INDUSTRY

- Taking a broad look at the need for change and the risk of not engaging in medical device regulatory harmonization
- Strategically influencing global regulations through direct interaction with Global Regulators
- How the harmonization of medical devices can facilitate trade and expand access to new and emerging markets
- Case study: Looking at EU MDR requirements into global quality systems and deploying throughout the facility system

PRODUCT DEVELOPMENT

UNDERSTANDING DIGITAL INNOVATION AND IT'S ROLE THROUGHOUT OPERATIONS

- What are the necessary steps required to lead regulatory, quality, and manufacturing operations in your organization?
- Addressing obstacles when integrating emerging tools and technologies across the enterprise
- Leading teams through process optimization - how to standardize and ensure quality in manufacturing
- Establishing systems to ensure the workforce is trained to successfully implement new technologies into the manufacturing process

INNOVATION

TIPS AND TRICKS FOR DEVICE SOURCING BEST PRACTICES

- Procuring materials for medical device development
- Integration and sourcing challenges due to compliance and regulatory changes
- Discussing test methods for device proof of functionality

2:55 pm – 3:35 pm EST

PANEL DISCUSSION



BRADLEY LEIBOVICH, M.D.,
Medical Director, Mayo Clinic Center
for Digital Health
Mayo Clinic



TESHTAR ELAVIA
VP, R&D Medical Segment
Becton Dickinson



LISA GRICE
Executive Director
Anthesis



PABLO BARIOLA
Head, Design and Director, Product
Design
Glooko



JOHN ZACHARIA
Senior Director, Product, Digital
Health
Quidel



TERRY TALBOT
SVP, Digital Health
Siemens Healthineers

BRINGING HUMAN CENTERED DESIGN TO MEDICAL DEVICE DEVELOPMENT

- Discussing the value of telemedicine and reshaping rules and regulations to offer more flexibility and access to information
- How human-centric design can help medical device manufacturers reduce risks and development costs and maximize market acceptance
- Understanding the factors that drive medical device adoption among modern healthcare providers
- Exploring how to make medical interventions smarter, less invasive and more personalized
- Case study: Changing the standard of care for now and for the future

3:40 pm – 3:45 pm EST

CLOSING REMARKS & PRIZE ANNOUNCEMENTS

3:45 pm – 4:45 pm EST

EXPO HALL NETWORKING