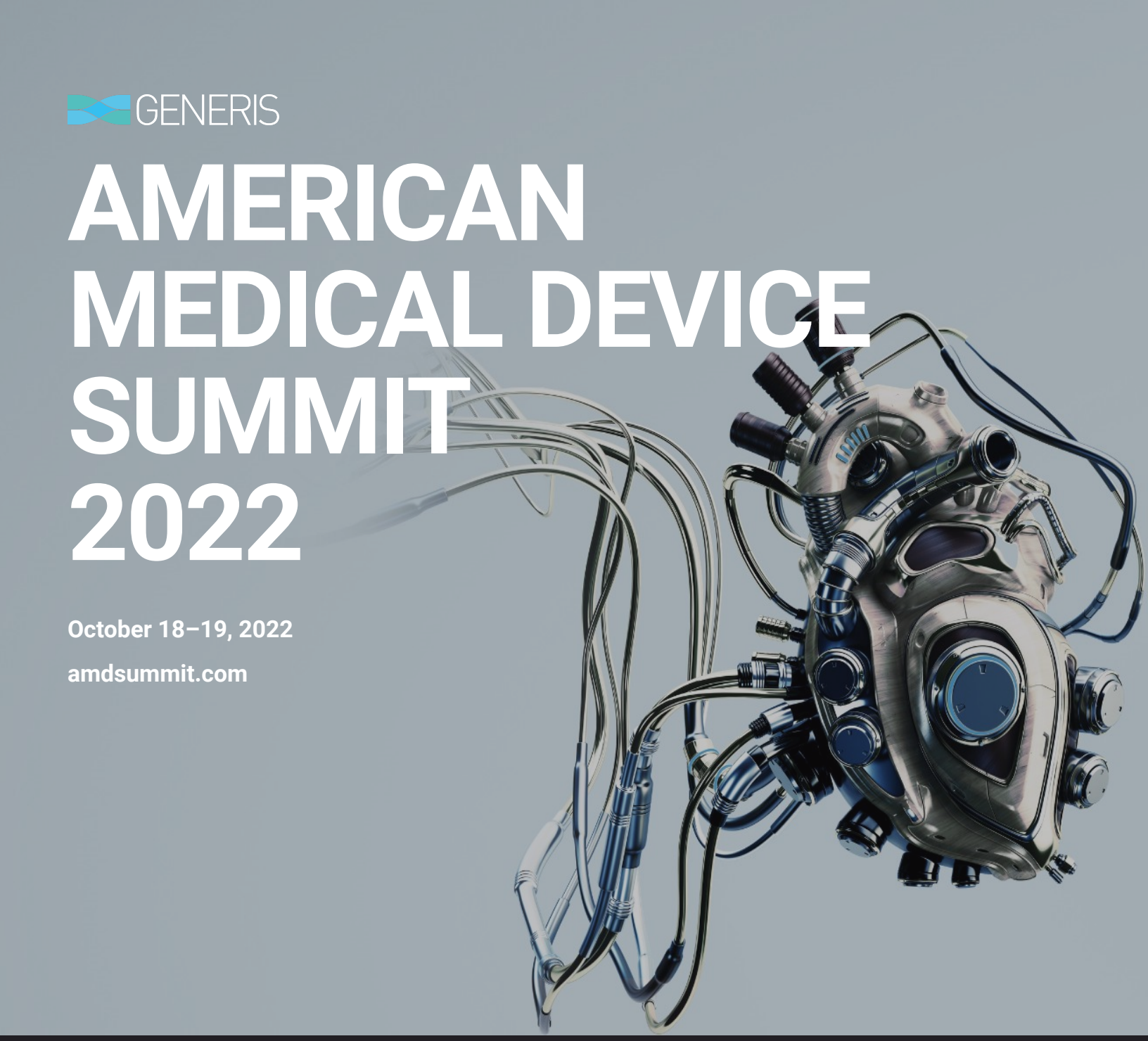
GENERIS

AMERICAN MEDICAL DEVICE SUMMIT 2022



October 18–19, 2022

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 18, 2022

* JOIN US FOR THE PRE-EVENT HAPPY HOUR ON OCTOBER 17, 2022 FROM 6:00 PM – 7:00 PM

7:00 am – 7:55 am CST

DELEGATE REGISTRATION AND NETWORKING BREAKFAST

8:00 am – 8:10 am CST

CHAIR'S WELCOME AND OPENING REMARKS

DESIGN

Medtronic

NINA GOODHEART
SVP and President, Structural Heart and Aortic
Medtronic

PRODUCT DEVELOPMENT

Abbott

NICOLE YOUNG
Director, R&D Program Management, Core Diagnostics, IACC
Abbott

QUALITY & REGULATORY

stryker

JODY POWELL
VP, Regulatory Affairs, Quality Assurance & Clinical
Stryker

INNOVATION

MY PENTAX MEDICAL

ALIND SAHAY
VP, Research & Development
Pentax Medical

8:10 am – 8:45 am CST

OPENING KEYNOTE

CardinalHealth™

STEVE C DE BACA
EVP, Quality and Regulatory Affairs Enterprise
Cardinal Health

DEFINING YOUR COMPETITIVE EDGE THROUGH COLLABORATION AND INTEGRATION

- Uncovering the latest technologies that improve speed-to-manufacturability while exceeding clinical and regulatory standards in the medical or invitro diagnostic (IVD) device industry
- Using urgency and agility to fuel device development and authorization
- A deep dive into Cardinal Health's transformative journey
- Case study: Looking back on the role that the coronavirus pandemic played in reshaping industry operations: rise in telehealth, managing third party relationships, and addressing regulatory changes and challenges

8:45 am – 9:20 am CST

PLENARY

GE Healthcare

JOLANTA ZADLO
Director, Program Management Business Model Transformation
GE Healthcare

CREATING A DEVICE-ENABLED DIGITAL ECOSYSTEM FOR BREAKTHROUGH PATIENT OUTCOMES

- Discussing the key drivers for digital transformation
- Driving “Product + Service + Edison artificial intelligence platform” based business model transformation and go-to-market strategy across GE Healthcare
- Examining the roadmap to your device-enabled digital ecosystem
- Leveraging devices to create unique data and identify unique opportunities to drive patient outcomes
- Effectively tackling pressing challenges and counterbalancing the bottom line to scale your digital operations

9:20 am – 9:55 am CST

PLENARY

KAMEL ALZARKA
Chairman and Founder
Falcon Group

BUILDING MEDICAL DEVICE SUPPLY CHAIN RESILIENCE

- Industry update
- Achieving effective collaboration: third party inventory ownership and Asset-as-a-Service solutions
- Leveraging existing commercial terms with suppliers while improving balance sheet efficiency
- Lessons learned from COVID-19 pandemic supply chain disruptions
- Innovative methods for mitigating future challenges
- Identifying vulnerabilities along the supply chain lifecycle

10:00 am – 11:40 am CST

REFRESHMENTS, NETWORKING, AND PRE-ARRANGED 1-2-1 MEETINGS

11:45 am – 12:20 pm CST

SESSIONS

DESIGN

VICTORIA E. CARR-BRENDEL, PH.D.
GVP, Cochlear Implants and President
Advanced Bionics at Sonova

DEVICE TALK: POWERING THE FUTURE OF PRODUCT DEVELOPMENT

- Leveraging technology transformation for cochlear implant design and development
- Tips and tricks for getting first-to-market
- Discussing the value of bluetooth-enables devices: CI sound processors designed for children
- Ensuring design and manufacturing process transparency

PRODUCT DEVELOPMENT

VINAY MALUR
Director, Program Management
Intuitive

FROM GOOD TO EXCEPTIONAL: HOW TO BUILD AND SUSTAIN A SUCCESSFUL R&D ORGANIZATION

- Mind mapping what a successful R&D organization looks like: Tools, Tech, and Teams
- How can you find opportunities to lower costs, shorten timelines, and add agility to your work
- Addressing shorter timelines
- How to lead and retain high-performing global talent and teams
- Building a culture of ownership and transparency: Goal planning and review practices

QUALITY & REGULATORY

KHAUDEJA BANO, M.D.
VP, Combination Product Quality
Amgen

EXECUTING POST MARKET REQUIREMENTS FOR COMBINATION PRODUCTS

- Enhancing organizational effectiveness in combined pharmaceutical and device vigilance
- What is expected from medical device regulators when it comes to risk management and how the device is being used?
- Feedback on DDCP companies related to handling PMS
- Why risk management is key to the post market phase of lifecycle management
- Future thoughts: What's next in post market safety?

INNOVATION

NITYA NARAYANAN
Senior Director, Regulatory Affairs
Bigfoot Biomedical

A ROADMAP FOR LEADING REGULATORY COMPLIANCE AND QUALITY PROCESSES

- Developing innovative insulin delivery products for people with type-1 and type-2 diabetes
- Streamlining production, inventory, and increasing speed-to-market without compromising on quality
- Overviewing tips and success stories to achieve our 510k FDA clearance for the Bigfoot Unity™ System, which features connected smart pen caps for disposable insulin pens that recommend doses for people relying on multiple daily injection therapy

12:25 pm – 1:00 pm CST

WORKSHOPS

DESIGN

JACKIE LESLIE
Category Specialist Life Sciences
Esko

REDUCE RISK & GAIN EFFICIENCIES IN ARTWORK & LABELING WITH DIGITAL TRANSFORMATION

- Learn how technology can streamline artwork and labeling processes
- Reimagine the change process with content re-use, automation and rules-based processing
- Achieve End-to-End visibility with integration

PRODUCT DEVELOPMENT

JUSTIN WESTENDORF
Manager, Product Development
Phillips-Medisize, a Molex company

JEREMY ODEGARD
Principal Industrial Designer
Phillips-Medisize, a Molex company

BRIDGING THE GAPS - INNOVATIVE LEADERS CAN SMASH STEREOTYPICAL BOUNDARIES BY FOSTERING A CULTURE OF CONNECTION OVER CONFLICT

- Discovering mutually-beneficial solutions to complex problems will demand courage, creativity, and commitment
- Studying a problem from multiple perspectives may reveal a more complete vision of success
- Expecting cross-functional collaboration will encourage diversity of thought and promote respectful challenge
- An authentic sense of empathy can highlight shared objectives and transform opponents into partners

QUALITY & REGULATORY

KELLY STANTON
Director, Quality
Qualio

THE SHIFT TO DIGITAL: LEVERAGING CLOUD-BASED QUALITY MANAGEMENT SYSTEMS

- Why uniting your teams, processes, and data is the key to get to market quickly and scale successfully
- Tips for migrating from a paper-based QMS with case studies
- Audit best practices and gotchas to avoid mistakes with cloud-based quality software
- Open Q&A on digital QMS best practices

INNOVATION

TONY BRENNAN
Commercial Director, Healthcare
CSA Group

INTERNATIONAL APPROVALS FOR MEDICAL EQUIPMENT WITH WIRELESS CAPABILITIES

- Advancements in wireless technologies have led to a new generation of medical devices requiring wireless and other radio approvals and certifications
- Learn about the leading certification schools for radio approvals and how they relate to product approvals and certifications in other countries
- Gain an understanding of the certification processes in selected markets

1:05 pm – 2:05 pm CST

LUNCH & LEARN ROUNDTABLE DISCUSSIONS AND OPEN SEATING LUNCH

Benefit from additional learning by joining a moderated roundtable discussion on pressing issues in the industry. Registration is required, and attendance for moderated roundtables on Day 1 is limited to attendees and speakers.

Choose from:

KELLY STANTON
Director, Quality
Qualio

CLOUD-BASED QUALITY MANAGEMENT: A DEEP DIVE INTO ACTUAL IMPLEMENTATION, PROJECT AND CHANGE MANAGEMENT, AND DELIVERABLES

JOSEPH-RICHARDSON LARBI
Medical Device Regulatory Consultant
Celegence

PROCESS AND TECHNOLOGY EFFICIENCY IN POST-MARKET SURVEILLANCE DOCUMENTATION FOR EU MDR

JENNIFER SIPPEL
VP, Strategic Relationships
oneSOURCE, an RLDatix Company

ONESOURCE DOCUMENT SITE, SAFER TOGETHER MANUFACTURER'S PROGRAM

NATHANIEL HENRIOD
Product Manager
MasterControl

WHERE CAN I INVEST IN TECHNOLOGY AND INNOVATION TO HAVE A SIGNIFICANT IMPACT ON MY BUSINESS?

ED WALSH
VP, Global Sales
Sigmetrix

EFFECTIVE COLLABORATION ACROSS MULTIPLE FUNCTIONAL GROUPS THROUGHOUT A MEDDEV PRODUCT'S LIFECYCLE - IS IT A REALITY

CORBETT FRENCH
Laboratory Director
Nova Biologicals, a Tentamus company

CONSIDERATIONS FOR SELECTING A THIRD-PARTY QUALITY LAB

JOHN FOX
Manager, Sales and Client Success
ResoluteAI

THE HITCHHIKER'S GUIDE TO THE DATAVERSE: A SHORTCUT TO BETTER PRODUCT DESIGN AND DECISION MAKING

JOHN WELLS
Account Director, Industrial and Healthcare
Locus Robotics

THE RIGHT ROBOT FOR THE RIGHT JOB: SELECTION CRITERIA FOR AUTONOMOUS MOBILE ROBOTS

ELIZABETH MCCULLOUGH
Senior Director, Linguistic Validation Operations
RWS

PUTTING THE PATIENT FIRST: THE IMPACT OF RECENT FDA RECOMMENDATIONS ON MEDICAL DEVICE DEVELOPMENT

BRETT FREEMAN
President
Providence Enterprise USA, Inc.

MEDICAL DEVICE MANUFACTURING IN THE EAST AND WEST

SABITHA ABOO
Director, Regulatory Services
Indegene

CONNECTING THE DOTS ACROSS CLINICAL EVALUATION, POST MARKET SURVEILLANCE & RISK MANAGEMENT FOR EU MDR COMPLIANCE

MAZIAR ADL
Co-founder and CTO
Gocious

SETTING VALUE-BASED OUTCOMES FROM WITHIN YOUR PRODUCT STRATEGY

2:10 pm – 2:45 pm CST

WORKSHOPS

DESIGN

ED WALSH
VP, Global Sales
Sigmetrix

BETTER MEDICAL DEVICES THROUGH BETTER UNDERSTANDING AND MANAGEMENT OF MECHANICAL VARIATION

- Considering variation in FDA 21 CFR Part 820.30, ISO 16142-1:2016, ISO 13485:2016 throughout the entire product lifecycle vs mostly during verification & validation in the design phase
- Discussing and addressing variation across multiple functional groups in an organization
- Making the management of variation insightful and valuable to multiple levels of authority in an organization
- Trends and how this may influence MedDev success

PRODUCT DEVELOPMENT

JAMIE HIJMANS, PH.D.
Program Director, Global Regulatory Technology Operations
GLOBAL CRO

ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING: FACTS, FICTION, AND POSSIBILITIES FOR THE FUTURE

- Common myths and misrepresentations surrounding artificial intelligence (AI) and machine learning (ML) technologies
- Setting realistic expectations for current AI and ML technologies
- Tips for evaluating AI and ML solutions – how to cut through the hype, marketing, and messaging
- Less may be more: rethinking how we approach the development and implementation of AI and ML technologies

QUALITY & REGULATORY

PRIYA BHUTANI
Founder and CEO
RegDesk, Inc.

PIONEERING THE USE OF AI FOR REGULATORY INFORMATION MANAGEMENT SOFTWARE

- AI applications for regulatory information management software (RIMS); what they are, what they've contributed to regulatory affairs so far, and how they will affect the future of the industry
- How streamlining regulatory processes with AI RIMS has altered the regulatory affairs landscape for pharma and MedTech
- Overviewing the role of AI in an increasingly automated industry

INNOVATION

RAGHVENDRA SAHAI, PH.D.
President and CEO
ARL-EuTech, a Tentamus company

ENSURING CHEMICAL AND BIOLOGICAL SAFETY OF MEDICAL DEVICES

- Material Selection and relevant information
- Chemical Safety including extractable and leachable
- Biosafety: Sterility and endotoxin testing
- Biocompatibility
- ARL-EuTech can help

2:50 pm – 3:25 pm CST

SESSIONS

DESIGN

DEEPAK GADDIPATI
Founder and CTO
VirtuSense Technologies

ACCELERATING ACCESS TO HEALTHCARE USING ARTIFICIAL INTELLIGENCE

- How VirtuSense's AI-powered fall prevention solutions cater to each patient's needs
- Using AI to predict which patients are at an increased risk for health complications or negative outcomes
- Paying for medical AI: reimbursement and funding opportunities
- Key considerations: pacing your organization with new device technologies along key workflows and data sources

PRODUCT DEVELOPMENT

MANEESH SHRIVASTAV, PH.D.
Senior Director, Strategic Innovation, Technical Fellow
Medtronic

DEVELOPING A VISION AND STRATEGY FOR PRODUCT INNOVATION

- Focusing on the art and science of global medical device market development
- Formulating and implementing long-term strategies with respect to new and emerging technologies that advance organizational goals
- Commercialization schemes: How do they differ between startups and well-established organizations?
- Overseeing multiple international product launches

INNOVATION

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

SMALL MEDTECH, BIG IDEAS: EARLY STAGE INNOVATION PLANS FOR SMALL COMPANIES

- How can you be proactive and have an entrepreneurial mindset as a team-oriented leader?
- Sharing leadership characteristics that define business success besides resilience (setting by example, compassionate leadership)
- Key considerations for protecting your intellectual property
- Finding your niche in a competitive medical device market
- Case study: Zeroing in on unmet needs in oxygen therapy

3:30 pm – 4:50 pm CST

HAPPY HOUR, NETWORKING AND PRE-ARRANGED 1-2-1 MEETINGS

4:55 pm – 5:30 pm CST

INNOVATION SPOTLIGHT

JOHN MASTROTOTARO, PH.D.
CEO
Movano

WEARABLES: POWERING THE FUTURE OF HEALTHCARE INNOVATION

- Overviewing the intersection of medical devices and consumer devices
- Redefining personal health to fit seamlessly into existing daily routines
- Ensuring design, prototyping and process transparency
- Leading global product management and design operations
- Navigating the future of health tech wearable devices (chip innovation, AI, connected devices, and more)

5:35 pm – 6:10 pm CST

CLOSING KEYNOTE

JIJO JAMES, M.D.
Chief Medical Officer, MedTech & External Innovation
Johnson & Johnson

THE IMPORTANCE OF CLOSED-LOOP SYSTEMS: LEVERAGING DATA AND TECHNOLOGY TO ELEVATE PATIENT SAFETY

- Driving MedTech innovation with patient safety at the core
- Strengthening pre and post-market surveillance and risk management of medical devices
- Proactively sharing data in collaboration with industry organizations to align with industry best practices
- Working with regulatory agencies (e.g. FDA) on using RWD/RWE to support clinical trial designs that can inform regulatory decisions

6:10 pm – 6:15 pm CST

CHAIR'S CLOSING REMARKS

DESIGN

NINA GOODHEART
SVP and President, Structural Heart and Aortic
Medtronic

PRODUCT DEVELOPMENT

NICOLE YOUNG
Director, R&D Program Management, Core Diagnostics, IACC
Abbott

QUALITY & REGULATORY

JODY POWELL
VP, Regulatory Affairs, Quality Assurance & Clinical
Stryker

INNOVATION

ALIND SAHAY
VP, Research & Development
Pentax Medical

6:15 pm – 7:15 pm CST

NETWORKING DRINKS RECEPTION

Sponsored by ALKU

PROGRAM · DAY 2

OCTOBER 19, 2022

7:00 am – 8:00 am CST

EMPOWER HOUR

ELIZABETH BALTHROP
VP, Transfusion Medicine
Abbott

JESSICA SHEN, M.D., M.S.
VP, Global Medical Device Sector Preclinical, Clinical, Medical Strategy and Operations
Johnson & Johnson

LISA WARD
Chief Scientific Officer
STERIS

KATE STEWART
President, Stryker's Women's Network and VP and General Manager, ENT
Stryker

REBECCA BORTOLOTTI
SVP and General Counsel
Terumo Blood and Cell Technologies

STEPHANIE TSALES
VP, Education Partnership Development
InStride

WOMEN IN LEADERSHIP ROUNDTABLE

- What's one leadership lesson you've learned in your career?
- As a leader, what has been the most significant barrier in your career?
- How do you and your organization empower the next generation of skilled professionals?
- What is the best piece of advice you've received from leadership?
- What advice would you give to the next generation of leaders?

BREAKFAST BRIEF

SANJAY BHARTIYA
Chief Commercial Officer
HARMAN Digital Transformation Solutions (DTS)

ROLE OF DATA IN SHAPING THE FUTURE OF MEDICAL DEVICES AND PATIENT EXPERIENCES

8:00 am – 8:10 am CST

CHAIR'S WELCOME AND OPENING REMARKS

DESIGN

NINA GOODHEART
SVP and President, Structural Heart and Aortic
Medtronic

PRODUCT DEVELOPMENT

NICOLE YOUNG
Director, R&D Program Management, Core Diagnostics, IACC
Abbott

QUALITY AND REGULATORY

JODY POWELL
VP, Regulatory Affairs, Quality Assurance & Clinical
Stryker

INNOVATION

ALIND SAHAY
VP, Research & Development
Pentax Medical

8:10 am – 8:45 am CST

OPENING KEYNOTE

ADAM N. VASQUEZ, J.D.
Head, Quality, Regulatory, & Health Compliance, Google Devices & Services
Google

NAVIGATING DIGITAL DISRUPTION IN A RAPIDLY EVOLVING MARKET LANDSCAPE

- Tapping into an expanding and evolving ecosystem that features new competitors, new stakeholders, and entirely new possibilities for connected health care
- Building a unified strategy for digital health, software, and emerging technologies
- Leveraging innovative technologies within the context of a broader strategic vision
- Closing the gap between consumer electronics and medical devices

8:45 am – 9:20 am CST

PLENARY

JOE TURK
Global Head, Home Therapies
Fresenius Medical Care

MAPPING THE FUTURE OF HOME THERAPIES

- Giving life back to patients with kidney failure through home therapies
- Insights on R&D activities in the Renal Care Continuum and beyond
- Case study: Simplifying renal care with NxStage System One and connected health

9:25 am – 10:00 am CST

WORKSHOPS

DESIGN

MONICA SWINNEY, PH.D.
VP, Biomedical Product Development
LiquiGlide

IMPROVING PATIENT OUTCOMES WITH FRICTIONLESS TECHNOLOGY

- Enhancing the performance of a wide range of medical products, including vascular access and implantable devices, surgical equipment, and biotechnology applications
- Unlocking high viscosity and silicone-free drug delivery
- Cutting costs and minimizing waste in chemical and pharmaceutical manufacturing
- Designing durable slippery coatings based on the science of liquid-impregnated surfaces
- How LiquiGlide's slippery coatings can withstand rigorous sterilization and environmental conditions while meeting applicable regulatory requirements

PRODUCT DEVELOPMENT

MIKE SAVARD
Senior Project Management Consultant
Integrated Project Management (IPM)

FROM STRATEGY TO EXECUTION: USING AGILE IN MEDICAL DEVICE DEVELOPMENT

- What is Agile project management, and why would you want to use it?
- How to continuously deliver value in medical device development
- How Agile approaches can work with design controls
- Real-world examples of Agile applied in Life Sciences programs

QUALITY AND REGULATORY

NATHANIEL HENRIOD
Product Manager
MasterControl

MODERN, FLEXIBLE QUALITY PAIRED WITH THE POWER OF AI

- How to take practical steps toward modernizing your quality systems
- The benefits of connected quality and the business insights you will gain
- How new technologies save time and money in expediting products to market
- What we can do with AI/ML now and where it is headed

INNOVATION

ANKUR NAIK
Managing Director
IZiel Healthcare

TODD JOHNSON
Technical Director
IZiel Healthcare

INNOVATION VIA ACQUISITIONS – OPPORTUNITIES & CHALLENGES

- Post-Acquisition Assessment
- Engineering Design & Documentation
- Process Development and Scale Up
- Supplier Quality Management
- Quality Systems Integration & Regulatory Compliance
- Production and Line Transfers
- Resource Allocation & Progress Tracking
- Unique Onshore-Offshore Model

10:05 am – 11:25 am CST

REFRESHMENTS, NETWORKING, AND PRE-ARRANGED 1-2-1 MEETINGS

11:30 am – 12:05 pm CST

SESSIONS

DESIGN

VISH CHARAN
DVP, Product Development, Cardiac Rhythm Management
Abbott

THE ADVANCEMENT OF MINIMALLY INVASIVE DEVICE DESIGN

- Current state of minimally invasive devices and a snapshot of demand trends
- Overcoming cost-prohibitive challenges of new technologies
- Enhancing the accuracy of complex surgeries while reducing patient trauma and recovery time
- Driving never-before-seen solutions for patients with cardiac arrhythmias
- Case study: Aveir™ VR, the world's only leadless pacemaker with unique mapping capabilities

QUALITY AND REGULATORY

BRAD SPRING
Global Head, Regulatory Policy and Intelligence
Roche Diagnostics

REGULATORY INTELLIGENCE AND POLICY: SHAPING THE GLOBAL LANDSCAPE

- Managing regulatory intelligence for medical devices: a roadmap
- Tips for keeping up-to-date with regulatory intelligence primarily with US Food and Drug Administration (FDA) and European Union (EU) medical device regulations
- Tools to ensure risk management lives throughout your entire product life cycle
- Why proactive regulatory intelligence communication is the key to success
- Case study: Keeping a pulse on the emerging role of AI in healthcare and how this infiltrates into new regulatory policies

INNOVATION

IRA SOLOMON, M.D., FACP
Chief Safety Officer, External Innovation
Johnson & Johnson

ADDRESSING HEALTH DISPARITIES AND IMPROVING ACCESS TO CARE: FOR NOW AND FOR THE FUTURE

- How the COVID-19 pandemic has reinforced the need for transformative change and rapid progress across our industry to address disparities in care
- Closing gaps in patient safety
- How can we increase our understanding and awareness of health disparities?
- Developing solutions to improve health equity and implement actions to end inequities in health
- Making meaningful progress in the medical device industry to address health disparities and improve access to care
- Working with government and other public agencies to propel change

12:10 pm – 12:45 pm CST

WORKSHOPS

DESIGN

SHAWN KNOPP
SVP, Product, Pharmaceuticals and Medical Devices
Prasaga

BLOCKCHAIN APPLICATIONS FOR MEDICAL DEVICES: TECHNOLOGY, VALUE AND COMPLIANCE DRIVERS OF INDUSTRY ADOPTION

- Key blockchain technology must haves for the regulated industry
- Compliance drivers: mapping current requirements to blockchain solutions
- Value drivers for products, applications and data sharing

QUALITY AND REGULATORY

KIM KAPLAN
Senior Product Manager
ISACA

BUILDING SUSTAINABLE CAPABILITIES THAT IMPROVE MEDICAL DEVICE QUALITY

- Advancing performance and patient safety with ISACA's Medical Device Discovery Appraisal Program
- Evaluating current work against a proven set of best practices to identify opportunities for improvement
- Prioritizing systemic, holistic, and long-term solutions aligned with business objectives and time to implement
- Tracking progress over time and against industry while receiving guidance from expert consultants
- Improving relationships with the Agency while also learning from peers

INNOVATION

YVETTE STOTT
Director, Corporate Partnerships
InStride

AMY WILSON
Director, Global Talent Acquisition
Medtronic

CREATING PATHS TO MOVE THE MEDICAL DEVICE INDUSTRY FORWARD

- Achieving transformative business growth and social impact by unlocking the power of education
- Providing employees with top-rate educational opportunities to improve patient care and retain a high quality workforce
- Meeting diverse healthcare workforce needs
- New strategies to confront long-term skill shortages facing the industry

12:50 pm – 1:50 pm CST

LUNCH & LEARN ROUNDTABLE DISCUSSIONS AND OPEN SEATING LUNCH

Benefit from additional learning by joining a moderated roundtable discussion on pressing issues in the industry. Registration is required, and attendance for moderated roundtables on Day 2 is limited, but open and available to all.
Choose from:

VISHVAS GARG, PH.D.
Senior Director and Head, Health Economics and Outcomes Research, Dermatology
AbbVie

THE CONVERGENCE OF MODERN REGULATIONS AND TECHNOLOGY: TRANSFORMING HEALTHCARE DECISION-MAKING THROUGH REAL-WORLD EVIDENCE

SONA SHAH
Co-Founder and CEO
Neopenda

STARTUP SUCCESS: HOW TO BRING A NOVEL, GROUNDBREAKING PRODUCT TO EMERGING MARKETS

SCOTT THIEL
Global Head, Regulatory Policy and Intelligence
Hologic

THE IMPORTANCE OF TALENT DEVELOPMENT IN REGULATORY INTELLIGENCE

ASHLEY MOY
Co-Founder and CEO
Cast21

INNOVATION THROUGH PARTNERSHIP: LEVERAGING NETWORKS TO SOURCE, BUILD, AND INTRODUCE NEW TECHNOLOGY

ALIND SAHAY
VP, Research & Development
Pentax Medical

AI IN ENDOSCOPIC APPLICATIONS: CURRENT STATUS AND THE FUTURE

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

DESIGNING THE REMOTE MONITORING SYSTEMS OF THE FUTURE

1:55 pm – 2:50 pm CST

EMPOWER HOUR

LYNN PAWELSKI
VP, Global Regulatory Affairs
Baxter Healthcare

MIGNON EARLY
VP, Diversity, Equity, and Inclusion
Fresenius Medical Care

JAZMINE WILLIAMS-MCCOY
Senior Director, Inclusion and Diversity
Medline Industries

WILLARD MCCLOUD III
VP, Diversity, Equity and Inclusion
Zimmer Biomet

MARYSA CHIU
Chief Diversity & Inclusion Officer
Integra LifeSciences

DIVERSITY AND INCLUSION ROUNDTABLE

- How do you define diversity and inclusion in an ever-changing work environment?
- Where are we now and where is the conversation headed?
- How does your organization build diversity and inclusion into its structure?
- What can you do in your career and organization to continue to improve?

2:55 pm – 3:30 pm CST

CLOSING KEYNOTE

NITIN GOYAL, M.D.
Chief Science, Technology and Innovation Officer
Zimmer Biomet

FUELING MEANINGFUL INNOVATION: EXPLORING THE IMPORTANCE OF COLLABORATION BETWEEN INDUSTRY AND HEALTH CARE PROVIDERS

- Understanding why meaningful and impactful innovation in healthcare requires collaboration between industry and the health care providers and patients they serve
- Defining what HCPs are seeking to optimize patient care and explore how digitally enabled delivery of care can transform the patient journey
- How to build a corporate culture that promotes creative problem-solving with the goal of advancing patient-focused innovation

3:30 pm – 4:05 pm CST

PANEL DISCUSSION

KEN NELSON
Head, Digital Health, Diagnostics, & Monitoring
BIOTRONIK

STANISLAV GLEZER, M.D.
EVP and CTO
Inogen

WAQAAS AL-SIDDIQ, D.B.A.
Founder and CEO
Biotricity

ANTONIO SÁNCHEZ-CORDERO
VP, Strategy & Business Development (M&A), Specialty Diagnostics Group
Thermo Fisher Scientific

THE EVOLVING ROLE OF MEDICAL DEVICES IN DELIVERING AT-HOME PATIENT CARE

- How has the COVID-19 pandemic changed the way that medical device companies approach patient monitoring?
- Discussing the value of delivering care in home and community-based settings
- Outlining the challenges associated with making health technologies accessible and widespread
- Navigating the evolving regulatory landscape of at-home medical devices
- Leveraging real-time data to enable better care from practitioners and better outcomes for patients

4:05 pm – 4:15 pm CST

CHAIR'S CLOSING REMARKS AND SURVEY PRIZE GIVEAWAY

DESIGN

NINA GOODHEART
SVP and President, Structural Heart and Aortic
Medtronic

PRODUCT DEVELOPMENT

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