



TOMORROW'S CONNECTION TODAY

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

PROGRAM · DAY 1

OCTOBER 13th, 2020

10:15 am - 10:45 am EST

LOG-IN AND WELCOME

10:50 am - 11:00 am EST

CHAIR'S OPENING REMARKS



BRIAN I AWRENCE

SVP and Chief Technology Officer

11:05 am - 11:40 am EST

OPENING KEYNOTES

DESIGN



TERRY TALBOT

SVP, Digital Health
Siemens Healthineers

UNDERSTANDING THE ROLE OF ARTIFICIAL INTELLIGENCE IN IMPROVING GLOBAL PATIENT DIAGNOSTICS AND TREATMENT

- What is the importance of AI in making imaging products more intelligent and easier to use?
- Transforming clinical support for diagnostic and therapeutic decisions through Al
- Leveraging digital twin technology to guide physicians through the entire clinical pathway
- Partnering with providers to advance precision medicine

PRODUCT DEVELOPMENT



NICK WEST

Chief Medical Officer and DVP, Global Medical Affairs, Abbott Vascular Abbott

LEADING CUTTING-EDGE TOOLS AND TECHNOLOGIES FOR A LARGE PORTFOLIO

- What are the industry's biggest drivers of disruptive technology?
- Exploring how disruptive technologies are redefining our approach to health, cardiovascular diseases and vascular care
- Leading transformative and accessible, hightechnology medical device companies
- Navigating the blending of healthcare and technology how this convergence has categorically transformed the diagnosis and management of vascular care

QUALITY



AMI SIMUNOVICH

EVP and Chief Regulatory Officer Becton Dickinson



ADRIENNE BROTT

VP, Quality Management Becton Dickinson

UNRAVELLING THE SCIENCE BEHIND LEADERSHIP IN THE QA/RA SPACE

- New, actionable strategies to effectively manage a diverse workforce
- Discussing how teammates within an organization can become greater allies to female leaders
- Overcoming imposter syndrome when leading and managing teams
- How BD is attracting and retaining top talent in quality and regulatory, and clearing roadblocks for female leadership
- Out of office: Achieving your goals both within and beyond your workplace

REGULATORY



KLAUS MOOSMAYER

Member of the Executive Committee and Chief Ethics Risk and Compliance Officer Novartis

DIRECTING A HOLISTIC ETHICS, RISK AND COMPLIANCE ORGANIZATION

- Best practices for reshaping your company's compliance strategy to bring ethics, risk and compliance together
- How to develop and implement a new Code of Ethics co-created by the employees and based on behavioral science
- How to build a holistic Third Party Risk Management including Human Rights
- Leveraging digital innovation as a cornerstone to achieving a compliant program

INNOVATION



LINDA PETERS

VP, Quality, Regulatory, Safety and Trust Google Health

REMAINING AGILE AND BUILDING MOMENTUM DURING TIMES OF UNCERTAINTY

- Discussing change of pace in operations during COVID-19 pandemic, and how Google Health remained agile and proactive
- Rethinking quality and regulatory, prioritizing safety and trust during a pandemic
- Transitioning from idea to execution in your production and operations strategy
- Case study: Updates on the partnership between Google Health and Apple to create contact tracing technology

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

12:50 pm - 1:25 pm EST

PLENARY



PADMAPRIYA PUTREVU

Associate General Manager HCL America, Inc.

EU MDR: CLINICAL EVALUATION REPORT

- Sufficient Clinical Evidence PMCF
- Clinical Evaluation vs Clinical Investigations
- Role of Automation in Clinical Documentations

1:30 pm - 2:00 pm EST

LUNCH & LEARN ROUNDTABLE DISCUSSIONS

Benefit from additional learning by joining a moderated roundtable discussion on pressing issues in the industry. Spots are limited. Choose from:



PHILLIP SIMULIS

CEO Simtelligent



VIRGINIA VICKERS

Senior Technical Specialist *HCL America Inc.*



CHUCK SERRIN

VP, Industry Marketing, Med-Tech and Life Sciences *Propel*

ACCELERATE AUTOMATION AND REMOTE DATA ACCESS



ENSURING GLOBAL REGULATORY COMPLIANCE OF MEDICAL DEVICES THROUGH NPD, NPI AND POST-MARKET



KEVIN BOCKELMAN

Senior Staff Engineer Logikos, Inc.





JAMES GIANOUTSOS

Founder and CEO Rimsys

HOW TO COMMUNICATE WITH VARIOUS STAKEHOLDERS ABOUT THE IMPORTANCE OF REGULATORY

WORKSHOPS

WORKSHOP



SCOTT BABLER

Principal Consultant Integrated Project Management Company, Inc.



TIM EHR

Director

Integrated Project Management

MANAGING DISRUPTIVE COMPLIANCE PROGRAMS

- Recognizing the benefits of increased compliance requirements like MDR and IVDR
- Transforming from a reactive organization to a proactive one
- Exceeding the compliance challenge through enhanced organizational approaches
- Preventing the compliance program from becoming a crisis management program
- Recovering when programs are running late

WORKSHOP



EMILY STEPHENS

CEO

Global Regulatory Writing & Consulting



JAMIE HIJMANS

Senior MDR Specialist Global Regulatory Writing & Consulting

MDR-MAGEDDON: HOW TO SURVIVE YOUR DATA GAPS WITH COST-SAVING PRE-MARKET & PMCF SOLUTIONS

- How to identify critical clinical data gaps: processes and case studies
- How to develop clear safety and performance outcome measures and "thresholds" aka "acceptance criteria"
- How to build robust rationale that will convince Notified Bodies to keep your device on the market while you're still collecting missing clinical data
- Understand your options: the pros, cons and costs of pre-market and PMCF activities
- Best strategies for choosing pre-market and PMCF activities for new devices, legacy devices, and devices with no data or literature
- Get the most bang for your buck! How to leverage PMCF activities for clinical data AND marketing claims gaps

2:45 pm - 3:45 pm EST

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

SESSIONS

DESIGN



ASHISH ATREJA, M.D., MPH, FACP Chief Innovation Officer The Mount Sinai Hospital

BEYOND SMART DEVICE DESIGN: LEVERAGING A USER-CENTERED DESIGN TO ACHIEVE NEW LEVELS OF PATIENT INTIMACY

- Disrupting current patient engagement models to drive innovation
- Highlighting breakthroughs in the smart device ecosystem and addressing where medical devices are lagging behind
- Software/Hardware: Combining the best of both worlds to create a wholesome experience for patients and providers
- Complementing hardware processes with digital hubs
- Why the blending of patient engagement combined with software is an ongoing journey to improve healthcare

PRODUCT DEVELOPMENT



STEVEN NAGEL Medical Officer FDA

TRENDS AND INNOVATION IN CANCER TREATMENT DEVICES

- Exploring the past, present and future of cancer treatment devices
- Discussing federal, state, local and industry roles in collaborating to improve the quality and functionality of treatment devices
- Leveraging technological innovations in treatment devices

OUALITY

Medtronic

PRAKASH PATWARDHAN

Director, Global Quality Program Medtronic

VIPUL SHETH

Medtronic

VP, Global Quality Operations and Supplier Quality *Medtronic*

BEST PRACTICES FOR INTEGRATING AN OPTIMIZED QUALITY CULTURE

- How has Medtronic adapted to global challenges and uncertainty and how does it affect overall quality?
- Transforming your QMS and changing your organization's quality culture to address pressing corporate needs
- Key tools and techniques for successful integration of a QMS
- Case study: Highlighting Medtronic's Quality Begins With Me initiative as it relates to creating a quality culture

REGULATORY



NATHAN CARRINGTON

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

GAINING REGULATORY APPROVAL FOR SOFTWARE AS A MEDICAL DEVICE (SAMD)

- Guidelines for how software as a medical device fits into the regulatory framework for medical devices
- Determining when software is subject to regulations
- Exploring go-to-market strategies for software as a medical device, software for a medical device and software in conjunction with non-MedTech digital health offerings
- Highlighting unexpected nuances, challenges and timelines for approval

INNOVATION



MISTY WILLIAMS

EVP, Regulatory and Clinical Affairs
Neauvia North America

DEFINING THE MERITS AND BENEFITS OF MDSAP

- Discussing evolvement of Global Medical Device Regulations as devices become more diverse and sophisticated
- Understanding the scope of MDSAP, how to apply, the rating system developed and what to expect when signing onto the program
- Document movement and timeline expectations
- Key takeaways for auditing tips and tricks to make the audit process less stressful
- Expediting speed-to-market of innovative products and assisting patients needing access to life-saving products and technologies

4:30 pm - 5:30 pm EST

EXPO HALL NETWORKING

PROGRAM · DAY 2

OCTOBER 14th, 2020

10:30 am - 10:45 am EST

LOG-IN AND WELCOME

10:50 am - 11:00 am EST

CHAIR'S OPENING REMARKS



MARK WEHDE

Chair, Mayo Clinic Engineering Mayo Clinic

11:05 am - 11:40 am EST

OPENING KEYNOTES

DESIGN



JIJO JAMES. M.D.

Chief Medical Officer, Medical Devices Johnson & Johnson

BALANCING SAFER PATIENT OUTCOMES WITH THE NEED TO BRING SURGICAL INNOVATIONS TO MARKET

- Addressing unmet patient needs and creating new markets through surgical innovations
- Revitalizing our guiding principles for medical safety
- Facilitating optimized device performance using the HCP surgeon perspective
- How a device briefing tool can increase confidence and bring safety to the environment
- Case study: Pulling insight from the perspective of the patient

PRODUCT DEVELOPMENT



KEN SKODACEK

Deputy Ombudsman, Center for Devices and Radiological Health

UPDATES ON HOW TO SUPPORT MEDICAL DEVICE INNOVATION THROUGH COLLABORATION

- Updating and reviewing special programs to address critical and unmet needs
- Taking a hybrid approach to address industry and FDA
- Improving staff collaboration, bridging the gap between industry and the FDA

QUALITY



CYNTHIA HOUGUM, PH.D.SVP, Global Quality and Business

Transformation
Terumo Blood and Cell Technologies

RETHINKING THE VISION FOR QUALITY TO IMPROVE THE FUTURE OF MEDICAL DEVICES

- Strategically reshaping the meaning and definition of quality
- Embracing technology transformations in a compliant way
- Managing financial and employee bandwidth, building a compliant infrastructure for continued growth
- Prioritizing patients when it comes to quality

REGULATORY



JOSEPH SAPIENTE

VP, Quality Assurance and Regulatory Affairs *Hologic, Inc.*



CISCO VICENTY

Program Manager, Case for Quality FDA



PAMELA GOLDBERG

President and CEO Medical Device Innovation Consortium (MDIC)

CREATING AN UNCOMPROMISING QUALITY CULTURE: BEST PRACTICES FOR DEFINING, INSTITUTING AND MAINTAINING A CULTURE OF QUALITY

- Placing quality and compliance as the core strength of your organization and the industry
- Ensuring a strong quality focus with CMOs, partners and suppliers for medical devices
- Establishing strong operational control and quality processes to drive and ensure compliance
- Improving integrity across supply operations through Continuous Improvement, on-going training and audits

INNOVATION



BRIAN LAWRENCE

SVP and Chief Technology Officer Hillrom

MANAGING A SUSTAINABLE DEVICE-ENABLED DIGITAL ECOSYSTEM

- Addressing the importance of sustainability in digital health and devices
- Utilizing sustainable digital platforms to drive breakthrough patient outcomes
- Steps to achieve a complete and sustainable deviceenabled digital ecosystem
- Overcoming limitations to digital healthcare
- Highlight reel: Updates on Hillrom's roadmap to a sustainable device-enabled digital ecosystem

REGULATURY

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

12:50 pm - 1:25 pm EST

WORKSHOPS

WORKSHOP

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DON SCHLIDT

President and CEO

Dedicated Computing

A.I. ENABLED MEDICAL PLATFORMS AND THE PARTNERSHIPS FOR DELIVERY

- This workshop focuses on the partner ecosystem for delivering A.I. centric applications, from start-up to mass-distribution
- How to avoid costly blind spots commonly missed in the Research and Development process
- Improving system performance while reducing timeto-market
- Case study: OEM/ODM collaboration drives innovation and competitive advantage

WORKSHOP

Inmark

KENNETH LUKES

Manager, Business Development - Life Science Division Inmark

BEST PRACTICE IN THE DEVELOPMENT AND MEASUREMENT OF A GLOBAL RETURN PROCESS FOR USED MEDICAL DEVICES

- Finding complaint packaging that meets the needs of our industry.
- Matching packages to devices for field reps and end users
- Global harmonization and consolidation
- Monitoring on-going returns and measuring compliance

WORKSHOP



SLAVKO JOVANOVIC

Partner Minerva USA

BEST IN CLASS DESIGN CONTROL AND PRODUCT DEVELOPMENT PROCESSES: CONCLUSIONS FROM OPTIMIZING MEDICAL DEVICES COMPANIES ACROSS THE GLOBE FOR MORE THAN 15 YEARS

- Exploring how quality, traceability, deliverable matrix and more are tied to best-in-class processes as set forth by FDA, EUDAMED, etc (or by global regulatory bodies)
- Diving into optimization of connected processes including how change impacts your ability to sell in varied markets.
- Join us after the session to pick up the report and schedule your free best-in-class benchmark

1:30 pm - 2:00 pm EST

LUNCH & LEARN ROUNDTABLE DISCUSSIONS

Benefit from additional learning by joining a moderated roundtable discussion on pressing issues in the industry. Spots are limited. Choose from:



FRED LITTLE

Business Development (Technology Evangelist) Providence Enterprise USA, Inc.



JULIAN DIXON

Director, Human Factors Team Consulting

MAXIMIZING YOUR CONTRACT MANUFACTURING CAPABILITIES



DAVID NICKELSON

VP, Client Growth Nerdery

LEVERAGING A DYNAMIC MEDICAL DEVICE SOFTWARE-DEVELOPMENT LIFECYCLE FOR COMPETITIVE ADVANTAGE USABILITY, HUMAN FACTORS, UX/UI: WHAT'S THE DIFFERENCE AND WHY DOES IT MATTER?

2:05 pm - 3:05 pm EST

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

SESSIONS

DESIGN

FRESENIUS MEDICAL CARE

MICHAEL ANGER, M.D.

SVP and Chief Medical Officer, Fresenius Renal Therapies Group (RTG) Fresenius Medical Care

HOW TO BE AGILE, FLEXIBLE AND INNOVATIVE TO IMPROVE RENAL THERAPY DEVICES (CONFESSIONS OF A CLOSET CLINICIAN)

- Establishing an agile approach to renal therapy devices that empowers project managers to refine their products
- Using agile project management as a strategy to drive faster feedback cycles within the business
- Avoiding complexity of agility: Ensuring that a flexible strategy does not over-complicate the development cycle
- Explore the transition from practicing clinical nephrologist to renal product development

PRODUCT DEVELOPMENT



MARK WEHDE

Chair, Mayo Clinic Engineering Mayo Clinic

HOW THE COVID-19 PANDEMIC HAS DISRUPTED HEALTHCARE

- Managing a shortage of ventilator and respirator parts
- Addressing the PPE (personal protective equipment) shortage
- Increasing patient throughput and staff and patient safety by certifying aerosol clearance time in operating and procedure rooms
- Preliminary results from studies of the impact of masking on transmission of the virus through droplets

QUALITY



ANN VII

VP, Quality and Regulatory Compliance Zimmer Biomet

GETTING YOUR BUSINESS ON BOARD TO UPDATE YOUR QUALITY MANAGEMENT SYSTEM

- Proactive considerations for mature and new quality systems
- How to use your Quality Management System (QMS) as a tool for simplification, and how to pitch this to your business as a means for change
- Updates to European Union Medical Device Regulation (EU MDR) and how it impacts your simplification journey
- Case study: A step-by-step guide to measure your quality system implementation effectiveness

REGULATORY



LISA GRANEY

VP, Regulatory Affairs Cardinal Health

DEVELOPING A CULTURE THAT VALUES REGULATORY LEADERSHIP

- Managing compliance with worldwide quality and regulatory requirements with FDA and other regulatory bodies
- Utilizing people, processes and technologies to develop the leaders of tomorrow and enable better decision-making overall
- Why 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
- Case study: Highlighting Cardinal Health's company's journey of leadership development

INNOVATION



NORBERT LEINFELLNER

Senior Director and Head, PMO Element Science

MANAGING INNOVATIONS IN SCIENCE, MEDICINE AND TECHNOLOGY TO BETTER THE MEDICAL DEVICE INDUSTRY

- Taking a holistic approach to the medical device industry: Away from selling boxes to building an ecosystem
- Current challenges to the MedTech industry
- Leveraging sensors, connectivity, and data for better outcomes
- Balancing resources needed for Innovation and Life-Cycle Management
- Achieving operational excellence in a fast-paced world

3:50 pm - 4:50 pm EST

EXPO HALL NETWORKING

PROGRAM · DAY 3

OCTOBER 15th, 2020

9:45 am - 10:00 am EST

LOG-IN AND WELCOME

10:05 am - 10:45 am EST

WOMEN IN LEADERSHIP ROUNDTABLE



JILL WINTERS

Managing Director, Sales



LINDA PETERS

VP, Quality, Regulatory, Safety and Trust Google Health



ZIMMER BIOMET

MICHELLE BLEVINS

Senior Director, Global Quality Systems Smith & Nephew

ANN VU

VP, Quality and Regulatory Compliance Zimmer Biomet



ANNLEA RUMFOLA

SVP, Medical Segment IT Cardinal Health

stryker

JODY POWELL

VP, Regulatory, Quality, Clinical

Su ykei

WOMEN IN LEADERSHIP ROUNDTABLE

We invite our attendees to network at a Women in Leadership roundtable with a discussion from inspirational leaders in the medical device industry. Seating is limited.

BREAKFAST BRIEFS



EMILY STEPHENS

CEO

Global Regulatory Writing and Consulting

PMCF STUDY DESIGN: CLINICAL GAPS TO ENDPOINT SOLUTIONS

10:50 am - 11:00 am EST

CHAIR'S OPENING REMARKS



MAC MCKEEN

Fellow, Regulatory Science Boston Scientific Corporation

OPENING KEYNOTES

DESIGN

Medtronic

WIKE HESS

VP, Engineering and Medtronic Fellow Medtronic

ADVANCES IN MEDICAL DEVICE ENGINEERING TO SUPPORT THE EVOLUTION OF LEGACY DEVICES

- What upstream and innovation activities is Medtronic working on?
- Disrupting the legacy market through engineering innovations
- Discussing the evolution of legacy devices: How Medtronic is upgrading research and concept development to support the era of connected devices
- Leveraging R&D development for emerging markets and devices
- Considering complexities for disrupting the legacy market as a large company vs. small company vs. a start-up

PRODUCT DEVELOPMENT



BEN LOCWIN

SVP, Quality Lumicell

PORTABLE, WEARABLE, IMPLANTABLE: DRIVING TECHNOLOGICAL INNOVATIONS TO IMPROVE PATIENT CARE

- Navigating the landscape of portable, wearable and implantable medical devices
- Balancing early adopters and health maintenance
- Addressing challenges in technology transformations and their ability to improve patient care

OUALITY



ELIZABETH BLACKWOOD

Chief Quality Officer, Medical Devices Johnson & Johnson

NAVIGATING THE IMPACT OF COVID-19 ON THE EU MDR

- How COVID-19 has impacted the EU MDR
- Reviewing the process of becoming EU MDR compliant
- Understanding bottleneck locations
- Addressing the extent of reliance on transitional provisions
- Overcoming the stumbling blocks and discussing lessons learned throughout the process

REGULATORY



JENNIFER STEVENSON, MBE, RAC,

Deputy Director, Office of Surgical and Infection Control Devices

ROBOTICALLY ASSISTED SURGICAL DEVICES: PAST, PRESENT, AND FUTURE

- Exploring regulatory side of robotic-assisted surgery devices
- Embracing robotic-assisted surgery devices in a compliant manner
- Implementing robotic-assisted surgery devices into your facility and training employees for successful and safe implementation

INNOVATION



ELIZABETH BAKER

SVP and Head, Manufacturing Medical Devices Philins

THE CHANGING LANDSCAPE OF DEVICE MANUFACTURING

- Delving into the landscape of device manufacturing, digitalization and digital platforms
- Using analytics and greater digitalization capabilities to improve manufacturing outcomes
- The Philips Journey: Transforming to a healthtechnology focused company

11:45 am - 12:45 pm EST

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

12:50 pm - 1:25 pm EST

WORKSHOPS

WORKSHOP



JOHN QUIRKE

Director, Connected Manufacturing Seabrook Technology Group

ENABLING OPERATIONAL EXCELLENCE THROUGH CONNECTED MANUFACTURING FOR MEDTECH 4.0

- How to strategize and implement Connected Manufacturing for MedTech 4.0
- How Connected Manufacturing helps organizations to achieve maximum operational efficiency through intelligence, integration and identification
- Discussing the value of Connected Manufacturing for MDD
- Eliminating pain points and improving competitive position with automation, integration, IIoT, MES, analytics, and ManuApps

WORKSHOP



WILLIAM STAMM

VP, Product Development and Software Services General Digital

PRODUCT DESIGN FOR LONG-TERM FINANCIAL AND TECHNICAL SUSTAINABILITY

- Design for rapid ROI
- Design for long-term technical safety, stability, and compliance
- Design in future enhancements and functionality
- Design success into the product with control of profitability

LUNCH & LEARN ROUNDTABLE DISCUSSIONS

Benefit from additional learning by joining a moderated roundtable discussion on pressing issues in the industry. Spots are limited. Choose from:



MICHELLE HACKMANN

Head, Quality, IGTD

RISK MANAGEMENT AND CLOSED-LOOP

FEEDBACK FOR POST-MARKET

SURVEILLANCE/EU MDR

ΔVΔΝΟS

LEE BURNES

FRIC CARDWELL

SVP, Global R&D, Clinical and Medical Affairs Avanos Medical Vyaire

COLLEEN WATSON

Director, Regulatory Affairs Vyaire Medical

USING OPEN INNOVATION TO BUILD A HEALTHY R&D PORTFOLIO

OVID 40 LOOK BAOK

COVID-19 LOOK BACK: CHALLENGES, OBSTACLES AND SUCCESS STORIES



ROBERT STEELE

EVP, Quality Assurance and Regulatory Affairs ConvaTec



Director, Regulatory Information Management and Application Lifecycle Management AphVie



RAJESH KASBEKAR

Global VP, Regulatory and Clinical Affairs Helen of Troy

DRIVING PROCESS EXCELLENCE AND IMPROVE AGILITY WITHIN REGULATORY AFFAIRS

IMPLEMENTING WORLD-CLASS QUALITY SYSTEMS AND STANDARDS FOR DEVICES

LEVERAGING QARA STRATEGIES TO ENSURE PRE-MARKET AND POST-MARKET COMPLIANCE

2:05 pm - 2:45 pm EST

PANEL DISCUSSION



PAUL UPHAM

Head, Smart Devices Genentech



MIKE DORSEY

Director, R&D



DAN PERREAULT

Director, Quality Engineering *Philips*



BRIAN BRUCKNER

Director, R&D Engineering Boston Scientific



BLAYNE ROEDER

Global Director, R&D New Ventures Cook Medical



MICHELLE MORAN

Director, Takeda BioLife Device Strategy Takeda

EMERGING TOOLS & TECHNOLOGIES: CREATING PATHWAYS FOR EARLY DEVICE DEVELOPMENT

- Best practices for emerging technologies and manufacturability of early device development
- Design for reimbursement strategies
- $\blacksquare \quad \text{Managing expectations in speed-to-commercialization and how to stay abreast of PreMarket priorities}$
- Considering market dynamics in medtech and how to strive for innovation amidst competition, economic and environmental changes
- Addressing the plenitude of unmet healthcare needs begging for medtech solutions, and what the future may hold for device development

2:50 pm - 2:55 pm EST

CLOSING REMARKS & PRIZE ANNOUNCEMENTS

2:55 pm - 3:55 pm EST

EXPO HALL NETWORKING