GENERIS

AMERICAN MEDICAL DEVICE SUMMIT 2020

OCTOBER 19-20, 2020
THE WESTIN LOMBARD YORKTOWN CENTER• CHICAGO, 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 18TH, 2020 AT 6:00 PM – 7:00 PM

Sponsored By: Inmark

6:45 am – 7:45 am

REGISTRATION AND NETWORKING BREAKFAST

7:45 am – 7:55 am

CHAIR'S WELCOME AND OPENING REMARKS

DESIGN CHAIR

BRIAN LAWRENCE
SVP and Chief Technology Officer

Hillrom

PRODUCT DEVELOPMENT CHAIR

MARK WEHDE
Section Head, Technology Development, Division of Engineering

Mayo Clinic

QUALITY & REGULATORY CHAIR

MAC MCKEEN
Fellow, Regulatory Science

Boston Scientific

INNOVATION CHAIR

SPEAKER TBA

ELMAS certification and management systems

7:55 am – 8:30 am

KEYNOTE

REDEFINING INNOVATION IN MEDICAL TECHNOLOGY AND DEVICES

- Improving quality of life through innovation
- Creating value and minimizing risk in your innovation tactics
- Technology transformations in Medical Devices: Maximizing value for patients
- How your organization is working to solve the problems faced by clinicians in today's healthcare systems

8:30 am – 9:05 am

PLENARY

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

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

TERUMOBCT Unlocking the Potential of Blood

9:05 am – 10:05 am

PLENARY

IMPROVING PATIENT EXPERIENCE THROUGH CONNECTED HEALTH PLATFORMS

- Balancing digital integrations in health platforms with quality and safety
- Using connected medical equipment to better patient experience for home therapies and remote monitoring capabilities
- Overcoming obstacles when it comes to connected health platforms

SPEAKER TBA

HCL

10:10 pm—11:50 am

PRE-ARRANGED 1-2-1 NETWORKING AND REFRESHMENTS

11:55 am—12:30 pm

DESIGN

AGILE MANUFACTURNG FOR MEDICAL DEVICE PRODUCT DEVELOPMENT

- Establishing open bilateral communication
- Ensuring design and manufacturing process transparency
- How well your contract manufacturer adapts to changes in customer demands, advances in applicable technology and new standards/regulations

PRODUCT DEVELOPMENT

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 surgical systems, vision systems, instruments and accessories
- Case study:
  Discussing Intuitive's movement from a start-up to becoming a global leader in surgical robotics

MAGGIE NIXON
VP, Product Quality

INTUITIVE SURGICAL

QUALITY & REGULATORY

UNRAVELLING THE SCIENCE BEHIND LEADERSHIP

- 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, and clearing roadblocks for female leadership
- Out of office: Achieving your goals both within and beyond your workplace

AMI SIMUNOVICH
SVP and Chief Regulatory Officer

BD

TANYA KLASLO
VP, Global Regulatory Operations

BD

INNOVATION

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

BEN LOCWIN
SVP, Quality

LUMICELL

12:35 pm—1:10 pm

WORKSHOP

BENEFITS OF AUTOMATING DOCUMENT CONTROL FOR MEDICAL DEVICE MANUFACTURERS

- Exploring the benefits of paperless approval routings with electronic signatures
- Embracing collaboration with users and other quality records
- Reducing training gaps through automatic trigger training events
- Streamlining change control with document integration

SPEAKER TBA

QT9™ Software
Automating Business Processes

WORKSHOP

THE ART OF THE SCIENCE: CLINICAL EVALUATION REPORT (CER) AS A COMPELLING NARRATIVE

- Understanding the CER as more than a static, fact-driven document
- Communicating a multi-level, multi-stranded narrative message that resonates - it's a conscious effort
- Exploring the characters, conflicts, connections, audience, and narrative strands of the report
- Proactively addressing objectives and objections
- Creating a conceptual framework for the development of the narrative in the post-market phase and for the MDR

SPEAKER TBA

CACTUS

WORKSHOP

REGIONAL CONTROL OF YOUR LABEL PORTFOLIO FOR GLOBAL ORGANIZATIONS

- Using EU MDR labeling implementation to unlock the power of a global platform
- How a 'Regulatory Rules' engine aids compliance and reduces tribal knowledge roadblocks
- Gaining an understanding of how out-of-the-box print processes give businesses the power to deploy a labeling strategy quickly
- Leveraging your existing network and IT assets using the right labeling solution

SPEAKER TBA

PRISYM ID

WORKSHOP

ASSESSING OVERALL ORGANIZATIONS CYBERSECURITY MATURITY ACROSS THE PRODUCT LIFECYCLE

- Providing an overview of a maturity model process and its benefits
- How best practices are integrated into a cybersecurity maturity
- Over-viewing recommended domains and practice areas
- Assessing your organization's current cybersecurity maturity
- Planning for continued security maturity improvement

SPEAKER TBA

CSA GROUP™

1:15 pm—2:15 pm

LUNCH & LEARN ROUNDTABLE DISCUSSIONS AND OPEN SEATING LUNCH

2:20 pm—2:55 pm

DESIGN

INNOVATIONS AND BEST PRACTICES TO ACHIEVE A STREAMLINED SURGERY

- Integrating patient data from diagnostic, surgical planning and surgical navigation software platforms for alignment between healthcare providers
- Advantages of robotically controlled surgical microscopy: Enabling the surgeon's expertise
- Brain structure visualization on a per-patient basis, with automated tractography segmentation
- Transforming point-of-care MRI innovations with a focus on improving patient safety and bringing high-quality scan data to the OR

CAMERON PIRON
President and Co-Founder

Synaptive

PRODUCT DEVELOPMENT

LEADING THE CHANGE TO STREAMLINED SURGERY

- Integrating patient data from diagnostic, surgical planning and surgical navigation software platforms for alignment between healthcare providers
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QUALITY & REGULATORY

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

DANELLE MILLER
VP, Global Regulatory Policy and Intelligence

Roche

INNOVATION

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

KEN SKODACEK
Deputy Ombudsman, Center for Devices and Radiological Health

FDA

3:00 pm—3:35 pm

WORKSHOP

THE FUTURE OF QUALITY MANAGEMENT AND FDA CASE FOR QUALITY INITIATIVES

- Discussing innovation in quality management amidst the emergence of cutting-edge solutions
- Utilizing the FDA Case for Quality program
- Tapping opportunities to align regulatory, enforcement and compliance approaches
- Streamlining practices that support consistent quality management and manufacturing methods
- Case studies on unique approaches to innovation in quality management
- Leveraging the latest advancements in AI, cloud-based analytics and computer software assurance

SPEAKER TBA

WORKSHOP

5 CRITICAL REQUIREMENTS FOR DEVICE MANUFACTURERS AS THEY TRANSITION OR GO-TO-MARKET

- How to avoid costly blind spots commonly missed in the Research and Development process
- Improving system performance while reducing time-to-market
- Case study: OEM/ODM collaboration drives innovation and competitive advantage

SPEAKER TBA

WORKSHOP

SOURCING AND SELECTING THE BEST REGULATORY WRITERS AND CONSULTANTS FOR YOUR MEDICAL DEVICE OPERATIONS

- Where to begin: Conducting your research
- Best practices for sourcing regulatory writers that are the right fir for your medical device operations
- Navigating the selection process and vetting accordingly

SPEAKER TBA

WORKSHOP

SYSTEMATIC LITERATURE REVIEW: HOW TO EMPOWER DATA-DRIVEN DECISION MAKING

- Reviewing currently accepted SLR best practices and how the use of published data can support regulatory expectations
- Providing practical guidance for designing and conducting a rigorous literature review
- Best practices for conducting a methodologically-sound SLR
- Use of available tools and technology
- Case study: How data identified through the SLR process helped to inform the decision-making process

SPEAKER TBA

3:40 pm—5:00 pm

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

Sponsored By:

5:05 pm—5:40 pm

DESIGN

HOW TO BE AGILE, FLEXIBLE AND INNOVATIVE TO IMPROVE RESTORATIVE THERAPY DEVICES

- Establishing an agile approach to restorative 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

PRODUCT DEVELOPMENT

STIMULATING INNOVATION: DEVELOPING AND IMPLEMENTING PORTABLE DEVICES

- Harnessing the power of PEMF, innovation and technology to develop a safe and clinically backed treatment
- Why helping patients across the globe who suffer from pain and chronic conditions matters
- Case study: Highlighting Oska Pulse, an innovative portable, shareable and affordable device

DR. JEFF MARKSBERRY
Chief Medical Officer

OSKA

QUALITY & REGULATORY

REGULATORY DOCUMENTATION EXCELLENCE: AN OPPORTUNITY TO LEVERAGE THE REGULATIONS TO YOUR ADVANTAGE

- What are some of the upstream changes that can impact the quality of documentation?
- Best practices for reshaping your company's compliance strategy to adhere to regulatory and compliance changes
- Overcoming increasing complexities of the material supply chain
- Addressing new FDA quality and regulatory guidelines
- Leveraging innovation as a cornerstone to achieving a compliant program

ILANA SHULMAN
Chief Compliance Officer

Hillrom

INNOVATION

ANTICIPATING 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 selling a therapy
- Creating value and minimizing risk in your innovation tactics
- How to balance resources needed for Innovation and Life-Cycle Management
- Using data for better outcomes
- Going small: The inevitable trend to wearables and miniaturization
- Why cybersecurity is the new "tax" in product development

NORBERT LEINFELLNER
VP, Product Development Engineering

FRESENIUS MEDICAL CARE

5:45 pm—6:20 pm

PLENARY

THE POWER OF ROBOTIC-ASSISTED SURGERY DEVICES

- 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

JENNIFER STEVENSON, MBE, RAC, CCSYB
Deputy Director, Office of Surgical and Infection Control Devices

FDA

6:20 pm—6:55 pm

PANEL

EMERGING TOOLS & TECHNOLOGIES: CREATING PATHWAYS FOR EARLY DEVICE DEVELOPMENT

- Best practices for emerging technologies and manufacturability of early device development
- Managing expectations in speed-to-commercialization and how to stay abreast of Pre and PostMarket 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

6:55 pm—7:00 pm

CHAIR'S CLOSING REMARKS

DESIGN CHAIR

BRIAN LAWRENCE
SVP and Chief Technology Officer

Hillrom

PRODUCT DEVELOPMENT CHAIR

MARK WEHDE
Section Head, Technology Development, Division of Engineering

MAYO CLINIC

QUALITY & REGULATORY CHAIR

MAC MCKEEN
Fellow, Regulatory Science

Boston Scientific

INNOVATION CHAIR

SPEAKER TBA

ELMAS
certification and management systems

7:00 pm—8:00 pm

NETWORKING DRINKS RECEPTION

Sponsored by: ALKU FROM START TO FINISH

PROGRAM DAY TWO

7:00 am – 8:00 am

NETWORKING BREAKFAST

WOMEN IN LEADERSHIP ROUNDTABLE

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

JODY POWELL
VP, Regulatory, Quality, Clinical

ANN VU
VP, Quality and Regulatory Compliance

SPEAKER TBA

SPEAKER TBA

8:05 am—8:15 am

CHAIR'S OPENING REMARKS

DESIGN CHAIR

BRIAN LAWRENCE
SVP and Chief Technology Officer

PRODUCT DEVELOPMENT CHAIR

MARK WEHDE
Section Head, Technology Development, Division of Engineering

QUALITY & REGULATORY CHAIR

MAC MCKEEN
Fellow, Regulatory Science

INNOVATION CHAIR

SPEAKER TBA

8:15 am—8:50 am

KEYNOTE

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

JIJO JAMES, M.D.
Chief Medical Officer, Medical Devices
Johnson & Johnson

8:50 am—9:25 am

PLENARY

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 AI
- Leveraging digital twin technology to guide physicians through the entire clinical pathway
- Partnering with providers to advance precision medicine

TERRY TALBOT
SVP, Digital Health
SIEMENS Healthineers

9:30 am—10:05 am

WORKSHOP

REINVENTING YOUR PRODUCT LIFECYCLE

- Streamlining end-to-end processes to drive operational efficiency and stay ahead of competitors
- Creating a unified environment across jurisdictions to better manage device registration
- Gaining heightened transparency and control for healthcare professional engagement
- Enabling effective regulatory automation and monitoring with advanced process management capabilities

WORKSHOP

RIGID PACKAGING FOR MEDICAL DEVICES

- Rethinking your medical device packaging solutions
- Inventory management best practices: How packaging can aid in the process
- Case study: Medical Device client packaging success story

SPEAKER TBA

Inmark LIFE SCIENCES

WORKSHOP

EU MDR: ACHIEVING ON-TIME COMPLIANCE WITH LASTING BENEFITS

- Building a program structure and scoping the work to meet critical requirements
- Balancing short- and long-term risks to establish priorities
- Assessing your product portfolio to identify changed product risk classifications and applying strategic decision making to eliminate underperforming products
- Revising processes and procedures to meet new QMS requirements and streamline product development to ensure a sustainable compliance program

SPEAKER TBA

IPM

WORKSHOP

DIGITAL DHRS: MODERNIZING YOUR DEVICE HISTORY RECORDS IN THE 21ST CENTURY

- How will Industry 4.0 affect Device History Records (DHRs)?
- Understanding the hidden costs of paper-based or partially electronic DHRs
- Examining what a truly paperless DHR environment looks like
- Reviewing real-world benefits of digitizing the DHR process reporting, and drill-down features for your connected devices

SPEAKER TBA

MasterControl

10:10 am – 11:30 am

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

11:35 am – 12:10 pm

DESIGN

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 device-enabled digital ecosystem
- Overcoming limitations to digital healthcare
- Highlight reel: Updates on Hillrom's roadmap to a sustainable device-enabled digital ecosystem

BRIAN LAWRENCE
SVP and Chief Technology Officer

Hillrom

PRODUCT DEVELOPMENT

MANAGING QUALITY FROM CONTRACT MANUFACTURERS AND MATERIAL SUPPLIERS IN A GLOBAL NETWORK

- Examining threats to quality from suppliers of manufactured materials to medical device companies
- Tips and tricks to ensure end-to-end quality, reliability and regulatory compliance, from development through manufacturing, distribution and end-customer use
- Overcoming increasing complexities of the material supply chain
- Addressing new FDA quality and regulatory guidelines
- Leading cross divisional teams to execute business strategy in a complex environment

QUALITY & REGULATORY

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

ANN VU
VP, Quality and Regulatory Compliance

ZIMMER BIOMET

INNOVATION

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 AI
- Leveraging technology to guide physicians through the entire clinical pathway
- Partnering with providers to advance precision medicine

12:15 pm—12:50 pm

WORKSHOP

ASSESSING OVERALL ORGANIZATIONS CYBERSECURITY MATURITY ACROSS THE PRODUCT LIFECYCLE

- Providing an overview of a maturity model process and its benefits
- How best practices are integrated into a cybersecurity maturity
- Overviewing of recommended domains and practice areas
- Assessing your organization's current cybersecurity maturity
- Planning for continued security maturity improvement

SPEAKER TBA

WORKSHOP

MEDICAL DEVICE MATERIAL STRATEGIES: MOVING BEYOND "OFF-THE-RACK" POLYMERS

- Discussing multi-discipline requirements for the development of soft-solid systems in biomedical applications
- Reviewing design processes for soft -solids from product requirements to final device
- How to track soft-solids in vivo

SPEAKER TBA

WORKSHOP

EU MDR: ACHIEVING ON-TIME COMPLIANCE WITH LASTING BENEFITS

- Building a program structure and scoping the work to meet critical requirements
- Balancing short- and long-term risks to establish priorities
- Assessing your product portfolio to identify changed product risk classifications and applying strategic decision making to eliminate underperforming products
- Revising processes and procedures to meet new QMS requirements and streamline product development to ensure a sustainable compliance program

SPEAKER TBA

WORKSHOP

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

12:55 pm—1:55 pm

LUNCH & LEARN ROUNDTABLE DISCUSSIONS

HOW TO MONITOR IOT DATA AND IDENTIFY ANY RED FLAGS

PHILIP SIMULIS
CEO
SIMTELLIGENT

A DEEP DIVE INTO LIFECYCLE MANAGEMENT

SPEAKER TBA
HCL

BUILDING A TRANSPARENT METHOD TO KEEP ENGINEERS, SUPPLIERS AND CUSTOMERS ON THE SAME PAGE

SPEAKER TBA
propel

MOBILE APPLICATIONS FOR MEDICAL DEVICES

SPEAKER TBA
logikos

ENSURING COMPLIANT, EFFECTIVE AND EFFICIENCY EXECUTION OF QUALITY SYSTEM REQUIREMENTS

SPEAKER TBA
ALKU
FROM START TO FINISH

LEVERAGING EU MDR CONSULTING

SPEAKER TBA
FANGCONSULTING
REGULATORY AFFAIRS & QUALITY ASSURANCE

MAINTAINING QUALITY AND DELIVERING EXCELLENCE IN MDR STANDARDS, CERTIFICATION AND ASSESSMENT

SPEAKER TBA
bsi.

DISCUSSING THE VALUE OF HIGH QUALITY POLYMER PRODUCTS

SPEAKER TBA
RAUMEDIC
Lifeline to Health

INCREASING OPERATIONAL EFFICIENCY TO SUPPORT OUTSOURCING OR PRODUCTION SWITCHING

SPEAKER TBA
PRISYM ID

DIGITAL SOLUTIONS FOR REGULATORY COMPLIANCE: MDR, UDI AND TRACK-AND-TRACE

SPEAKER TBA
CYIENT

2:00 pm—2:35 pm

FIRESIDE CHAT

CREATING AN UNCOMPRIMISING 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

MIRNA DIPANO
VP, Quality Assurance and Regulatory Affairs

2:40 pm—3:15 pm

KEYNOTE

WATCHING PROCESSES AND PROFITS: THE INCREASING DEMAND FOR NEW AND INNOVATIVE SURGICAL TECHNOLOGIES

- How non-traditional technology is merging with medical devices
- Why innovative surgical robotics and treatments are flourishing
- Calling attention to the rising geriatric population demanding surgeries, less pain, rapid recovery, and better surgical results
- Case study: Organizational adoption of surgical innovations and success stories

3:15 pm—4:00 pm

PANEL DISCUSSION

BUILDING THE FACTORY OF THE FUTURE: 3D PRINTING, MOBILE MANUFACTURING AND BEYOND

- How can you leverage additive in your facility and for your medical devices?
- Rapid prototyping using computational modeling and additive manufacturing
- Moving to point of care additive manufacturing of anatomical models, cutting guides and patient-specific implants
- Discussing the value of mobile manufacturing technologies and what is keeping you from implementation
- Optimizing your existing workforce to be agile among changes in medical device design and product development

4:00 pm—4:10 pm

CHAIR'S REMARKS AND DELEGATE SURVEY PRIZE DRAW

DESIGN CHAIR

BRIAN LAWRENCE
SVP and Chief Technology Officer

PRODUCT DEVELOPMENT CHAIR

MARK WEHDE
Section Head, Technology Development, Division of Engineering

QUALITY & REGULATORY CHAIR

MAC MCKEEN
Fellow, Regulatory Science

INNOVATION CHAIR

SPEAKER TBA