Presents

GENERIS

AMERICAN MEDICAL DEVICE SUMMIT 2016

October 5th & 6th, 2016

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: October 5th, 2016

GENERIS

7:00-8:00

Registration & Group Breakfast

8:00-8:10

Chair's Welcome Address

Dale Gallaher
President

COGNITION

8:10-8:50

KEYNOTE
Applying Human Centered Design to Medical Device Development
- 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
- Why medical device manufacturers should focus on developing a better product at a lower cost

Dr. Marco Costa
VP & Chief Innovation Officer

University Hospitals

8:50-9:30

PLENARY
Accelerating your Journey from Concept to Commercialization
- How the best companies are using performance, safety, business economics, risk management, and regulatory requirements as a basis for device design
- 'Design thinking' as a driver for new medical device development
- Building quality into your device early in the design process to avoid costly missteps in the future
- Ensuring the design of a medical device can be cheaply and easily modified to meet different international regulatory standards

Palani Palaniappan
EVP, Innovation and Development

TERUMOBCT
Unlocking the Potential of Blood

9:30-11:10

Pre-Arranged One To One Networking & Refreshments

DESIGN
A Look into the History of Design Controls, Why we do what we do!

- Examining the evolution of system engineering architecture
- Looking beyond the FDA 21CFR 820.30 to develop an effective design control program
- Cutting through the clutter of regulations in a complex system to ensure your systems don't overlook common sense engineering
- Ensuring that there are multiple viewpoints and layers to assess the systems robustness
- Managing how to remove cost, time, publicity and other business priorities from the stage gate reviews

Joseph Sener
VP Quality Device Engineering

Hospira

QUALITY
Developing a Proactive Quality Culture

- Evaluating and assessing the culture continuum, challenges and risks
- Quantifying the business value of a culture of quality
- Creating and streamlining effective models for evaluating the culture of quality
- Developing and sustaining the gains of a quality culture and adopting change management

Joseph Hutson
VP, Quality Management

BD

TECHNOLOGY
Winning the Innovation Race: How to Leverage Operations & Technology to get to market faster with higher quality, lowest cost product solutions

- Acquiring and agreeing on stable and sufficient product requirements before embarking on development
- Contrasting short time-frame needs for the product development environment and long-term needs of ramp-up and steady manufacturing
- Ensuring machine design that allows for changing materials, specifications and energy requirements/laws
- Improving precision for medical components and disposable parts

Michael Maszy
VP, Manufacturing

Endologix

DESIGN
Easing Regulatory Compliance using a Guided Approach

- Efficiently demonstrate system safety and efficacy
- Gaining compliance faster with a guided approach to completing submission deliverables
- Gaining and sustaining system maturity by integrating risk management seamlessly into the design control process
- Driving creativity by enforcing process constraints

Mitch Hayes
Chief Technology Officer

COGNITION

QUALITY
The Case for Quality System Transformation

- The value of thinking globally: identify, diagnose, predict and prevent quality problems across the organization's value chain
- Harmonization: the process DNA strand that is at the heart of every quality process - consistent and measurable
- Creating a single source of quality truth: properly structuring data sets to establish a common language for the organization
- Facilitating global communication: enable proactive risk mitigation and identification of opportunities for improvement
- Making the case for transformation: securing executive support for an enterprise-wide quality system

Kari Miller
VP of Regulatory &
Product Management
Pilgrim Quality Solutions

pilgrim

TECHNOLOGY
Innovations in Manufacturing Functional Surfaces

- Direct Bonding: Joining dissimilar materials without the use of primer, solvents or adhesive chemistry
- Biocompatibility: Barrier coatings which are safe for contact or implantation
- Antimicrobial: Rapid inline coatings
- Osteogenesis: Structured topographies promoting bone growth and healing
- Tailored Surface Chemistry: Customized solutions for R&D and process development

Andy F. Stecher
CEO / President

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solutions on top

PLENARY

Innovate for Health: Leveraging 3D design and collaborative platforms to support digital health and personalized care initiatives and improve therapeutic outcomes

- Enhance open scientific innovation initiatives such as the Living Heart Project for superior patient health experiences
- Embrace "In-silico" medical device design and testing to advance regulatory science and accelerate the best products to market faster
- Encompass genomic, behavioral and environmental for phenotype analysis to achieve personalized predictive, preventive, and participatory therapies
- Advance towards evidence-based medicine to improve clinical diagnosis and patient outcomes

Dr. Steve Levine
Senior Director, Product Strategy / Executive Director, Living Heart Project

Lunch & Learn Round-Table Discussions * On-site registration required

Hands-on with Seismic's Sales enablement tools: Medical Device Use Case

Andrew Cohen
Senior Product Marketing Director

Automating Day-to-Day FDA Compliance in 20 Global Medical Manufacturing Facilities - Advanced Manufactruing Systems

Gelston Howell
Senior Vice President

Getting your products right using optimized global processes

Scott Babler
Principal Consultant

Combination Product Quality Management System Requirements: Drug or Device

Bob Parsons
VP Quality & Medical Devices, Life Sciences

Key Sourcing, Quality & Regulatory Issues in Asia

Ames Gross
President

Ensuring your Medical Device Design Remains within the Prescribed Regulatory Framework

Bill Brodbeck
Director, Regulatory Affairs

PLENARY

Understanding the Impact of Increased 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
- Exploring how the harmonization of medical devices can facilitate trade and expand access to new and emerging markets
- Examining how the MDSAP addresses the need for a global approach to auditing and monitoring the manufacturing of medical devices
- An in-depth look of the potential risk and rewards of a harmonized medical device audit program

James Dennison
SVP, QARA

DESIGN
Leveraging Digital Manufacturing to Accelerate Time to Market and to Reduce Risk

- Overview of recent advances in manufacturing technologies geared at facilitating iterative design and development
- Reducing up-front investment and market risk through effective and frequent prototyping early in the development cycle
- Getting to market faster by using quick-turn manufacturing to bridge between prototyping and high-volume production
- Managing the volatility of demand and reducing inventory costs with on-demand manufacturing

Peter Havel
SVP, MHS Global &
Regional Director MHS US

QUALITY
The ROI Of Good Quality & Compliance

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

Ed Roach
Managing Director

MAΞTRICS+

TECHNOLOGY
Product Realization: Optimization & Sustainability to Reach Ideal Quality & Business Performance Objectives

- Integrated approach to driving end-to-end business performance (breaking down Silos)
- Maturity – Clear, complete and repeatable processes designed to "get it right the first time."
- Visibility – Do we have the correct key indicators for executive level visibility for quality and business performance?
- Efficiency – Integration Technology, Processes, Methodology and People to Increase Speed and Effectiveness of the process

Gregory Pierce
President

ENGI SYSTEMS
LIFE SCIENCES
COMPLIANCE & ENGINEERING

Pre-Arranged One To One Networking And Refreshments

PLENARY
Utilizing the Risk Management System (RMS) & Risk Management File (RMF) to Manage the Medical Device Lifecycle

- Using New Product Development (NPD) elements as input to the RMS and RMF (Design Input/ Design Output/ Process Validation/ Product Validation)
- Creation of "Top Down" and "Bottom up" elements to the RMF
- Establishing Product Performance Thresholds based on NPD and Validation Data
- Using Corrective and Preventive Action (CAPA) system, Manufacturing Systems, and Customer Complaint System as input for CAPA and escalation of Post Market issues
- Continued update of RMF for input to NPD and Product Rationalization

Mike Baca
VP, QA/RA/Clinical Sciences

stryker

PLENARY
Closing the Loop: Using your post-market surveillance system to feed your Risk Management and Product Lifecycles

- Recognizing that medical device risk management is not a one-time project, but rather an ongoing process of review and risk assessment throughout the life of the device
- Developing a systematic process to evaluate products on a continuing basis
- Analyzing feedback to determine whether corrective and preventative action needs to be taken to fix the problem
- Determining if changes must be made to the original medical device risk assessment

John Daley
VP Quality Assurance and Regulatory Affairs

IBM Watson Health

CLOSING KEYNOTE
Developing a Strategic Medical Device Clearance & Approval Plan

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

Marjorie Shulman
Director, Premarket Notification [510(k)] Program

FDA

Chair's Closing Remarks

Dale Gallaher
President

COGNITION

Networking Drinks Reception

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PROGRAM
DAY TWO: October 6th, 2016

GENERIS

Networking & Breakfast Brief

Debunking the Mystery of the Value Analysis Committee (VAC): What they are Looking for from Medical Device Companies

Medical Device Reporting Challenges On & Off Site

Phillip Brown
Partner

plante moran
audit · tax · consulting · wealth management

Pat Schaumann
Senior Director of Healthcare Compliance

Maritz TRAVEL®
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Chair's Opening Remarks & Review Of Day One

Dale Gallaher
President

COGNITION

PLENARY
Case for Quality and Benefit Risk: Hot Topics in Compliance

- Update on the ongoing Case for Quality and Benefit Risk Initiatives
- Analyzing FDA device quality related initiatives that move beyond the inspect-and-cite regulatory model
- How the case for quality initiative works and how you can benefit from it
- Benefit Risk: a new paradigm in compliance enforcement

Robin Newman
Director of the Office of Compliance, CDRH

FDA

PLENARY
Staying up-to-date on Global Regulatory Changes: An IMDRF perspective

- Understanding the role of the IMDRF in accelerating international medical device regulatory harmonization and convergence
- Current outlook and agenda for the IMDRF in 2016/2017
- Developing a role for Recognized Standards in a global landscape
- Reviewing the increased focus on device registries and post-market data sharing programs

Michael Morton
VP, Corporate Regulatory Affairs

Medtronic

DESIGN
Networked Medical Device Cybersecurity and Patient Safety

- Understanding Medical Device Cyber Security and the security risks associated with medical devices
- Reviewing the FDA Pre-Market and Draft Post-Market Guidance documents on managing cybersecurity for medical devices
- Structuring an integrated manufacturer program for addressing risks from the perspectives of the various stakeholders: business, customer, regulator, others
- Supporting medical device cyber security throughout the product lifecycle

Steve Abrahamson
Director, Product Security Engineering

QUALITY
Medical Device Recalls: Unique Challenges and Opportunities

- Current recall classification trends, recall policy and expectations
- When reporting Corrections and Removals may or may not be required to include discussions regarding Medical Device Enhancements
- Best practices for effectively communicating with the FDA and consignees to include discussion of press releases and customer notifications
- The new 806 electronic submissions process introduction and pilot program

Ron Brown
Chief, Recall Branch, CDRH

REGULATORY
A Top-Level View of Key Upcoming Changes in European Medical Device Regulations

- Are you prepared for unannounced audits of your facilities? How could unannounced audits affect your ability to market medical devices in Europe?
- Handling the challenges in compliance and transition across different jurisdictions
- Examining the use of DELTA's for near real-time active safety surveillance and medical device regulation in the EU
- Best practices in ensuring alignment across many regions (IMDRF)

Elisabeth George
VP, Global Government Affairs, Standards & Regulations

Networking & Refreshments

DESIGN
Innovation in workforce development for the Medical Industry "Colorado's Bold Move"

- Learn how the Swiss apprenticeship system is influencing workforce development in the United States, and how potentially it can revolutionize how we educate our youth
- Learn how Colorado is building a youth apprenticeship system that is being looked at as a national model
- How youth apprenticeship can improve innovation and profitability within your business
- Learn what the necessary elements are for your company to benefit from this movement
- Why building innovation into our education system is essential for the US to compete in a global economy. Have we already lost our edge?

Noel Ginsburg
Chairman & CEO

QUALITY
Keys to Collaborative Medical Device Design: Managing Development Across Quality Systems

- Best practices for integrating client/ partner quality systems while minimizing compliance risk
- Establishing processes for requirements management, traceability, and regression testing across multiple systems
- Avoiding surprises through proper planning: project plans, risk management, and documentation
- Carrying quality through to manufacturing: the role of the design team during production

Dave Strandberg
Director, Engineering Solutions

REGULATORY
ERP Business Application Solution: Electronic System of Record

- Are you in a position to easily prove compliance to all the data integrity and auditability requirements of 21 CFR Part 11?
- Can you absorb the overhead of FDA reporting and concurrently gain efficiencies in your manufacturing operations?
- How do you monitor GMP risk items that need to be documented and controlled in a FDA regulated organization?
- Are you still utilizing paper based regulatory documentation? Now is the time to take your electronic records (computer system) through the IQ process
- Does your regulatory department have the time to redefine an entire validated system? Learn how predefined test cases can lead you through the OQ & PQ process

Robert Lane
CEO

DESIGN
Design for Excellence (DFx) - Driving Product Optimization Through Early Stage Value Engineering Development

- What are the key benefits to preforming DFx on your product?
- How to work with your CMO in order to create products that are more cost effective, have increased manufacturability and quality, coupled with a higher reliability over the product life-cycle
- Key opportunities for cost reduction and feedback, driving successful product introduction
- Working shoulder-to-shoulder with the appropriate stakeholders in order to better manage risk over the product life-cycle

Brian Morrison
Director, Value Engineering & Technology

QUALITY
Solutions for Product Content Management Challenges in a Regulated Environment

- In today's environment of strict regulation, are you feeling the pressure to reduce operational costs, increase efficiency and provide greater value?
- Discover how sales asset management technology can optimize the seller's journey through sales enablement
- Learn how to collaborate on content creation across the organization, manage and distribute content, and expertly analyze the ROI of marketing programs

Andrew Cohen
Senior Product Marketing Director

REGULATORY
The Changing Landscape of Medical Device Regulations and Compliance

- Examining the rapidly changing world of medical device manufacturing
- Handling the changes in regulatory requirements and the looming deadlines for implementation
- Investigating current compliance trends through the evolving FDA structure

Ricki A. Chase
Director

Lunch & Learn * On-site registration required

Taking the Leap: how to build your organization into a global player

Brett Gopal
Senior Director, Strategic Initiatives, Global Operations

Medical Startup Challenges from Idea to Exit

Chris Stepanian
President & CEO

Risk Management & Human Factors: Incorporating Human Factors Engineering Early in the Design Process to Manage Risk

John Stone
Director, Advanced Engineering

Lean Manufacturing Strategies for Low to Mid Volume Disposables

Adam Prime
President

Managing a Successful Partnership with a Design Manufacturer & Supply Chain Solution Provider

Robert Berger
VP, Contract Manufacturing, MITG

Derek Kane
Business Unit Director

DESIGN
Harmonizing Processes Across Your Organization to Reduce Complexity

- Reducing the disconnect throughout the value chain to optimize product performance through its lifecycle
- Achieve successful collaboration: examining best-in-class operations to synchronize your processes, people and technologies
- Establishing digital processes as an opportunity to improve end-to-end process control, enforcement and visibility
- Examining challenges and opportunities in improving design cycles

Larry Dube
VP PLM Strategy
Fresenius Medical Care

FRESENIUS
MEDICAL CARE

QUALITY
A Case for Quality System Integration: The DENTSPLY SIRONA Story

- Understanding the case for a harmonized quality system, particularly when acquisitions result in different levels of maturity
- Taking an in-depth look at challenges in harmonization of quality processes
- Examining use of IT enabling tools to overcome the differences between sites, while ensuring uniform quality workflows and practice
- Key considerations in deployment of harmonized quality workflows to increase efficiency and compliance at the same time

Ajay Kumar
VP, QA/RA DENTSPLYSIRONA Prosthetics

Dentsply
Sirona

PLENARY
CTQ flow down & eCPDP - Design to Value

- Enterprise framework
- Supports and improves the efficiency of CPDP Execution
- Using CTQ flow down as the electronic backbone to complete the process

David Enck
Director of DtV and QE

Janssen

PLENARY
Building a High Impact Product Launch Organization: breaking silos, incorporating stakeholders and driving customer value

- Identify appropriate decision-makers, clearly define roles and responsibilities, and ensure accountability and ownership
- Moving beyond the design team: Incorporating your customers in your design and product development strategy
- Create a sense of urgency about the launch from the top, and mobilize the company toward this goal
- Build for future success: Develop processes that effectively disseminate best practices from launch to launch and country to country

J. Gustavo Perez
President, Surgical Division

LIVE CASE PANEL
Postmarket Regulatory challenges around HRA's, field action determination including softwares

FDA

Donna Haire
VP, Head of Medical Care
Global Regulatory Affairs

BAYER

Elisabeth George
VP, Global Government
Affairs, Standards &
Regulations

PHILIPS

Ron Brown
Chief, Recall Branch,
CDRH

Chair's Concluding Remarks & Close Of Summit

Dale Gallaher
President

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