AMERICAN MEDICAL DEVICE SUMMIT 2017

OCTOBER 4–5, 2017
THE WESTIN LOMBARD YORKTOWN CENTER • LOMBARD, IL

amdsummit.com

TOMORROW’S CONNECTION TODAY
Driving Business performance through process and technological innovation

+1-416-298-7005
info@generisgp.com

PROGRAM
PROGRAM DAY ONE

PRE-EVENT HAPPY HOUR
JOIN US FOR THE PRE-EVENT HAPPY HOUR OCTOBER 3RD, 2017 AT 6:00PM–7:00PM

7:00 am – 7:55 am

REGISTRATION & GROUP BREAKFAST

8:00 am – 8:10 am

CHAIR’S WELCOME ADDRESS

JOHN PEYTON
VP, Global Design Quality

MARCUS SCHABACKER
Former CVP & Chief Scientific Officer

STEPHEN FULTON
Director, Manufacturing

8:10 am – 8:50 am

KEYNOTE
RESTORING THE HEALTH OF A POPULATION: TRANSFORMING THE FUTURE OF NEW MEDICAL DEVICE INNOVATION

• The Carol Malnati story: The hard is what makes it great
• How to grow an initial defibrillator start-up to the current multi-billion dollar business
• Case Study: The evolution of the pacemaker
• Improving healthcare for more people in more ways: How failure acts catalyst to future breakthroughs in new product development
• Improving leadership capabilities: How to take intelligent risks and lead into disruptive and innovative businesses and technologies to advance business results

CAROL MALNATI
VP, Product Development

8:50 am – 9:30 am

PLENARY
STREAMLINING THE PATH FROM DESIGN TO MANUFACTURING

• Looking at how the 21st century presents new challenges to patients, healthcare providers, payor and industry
• How demographics are changing dramatically
• Why demand for better, more complex and affordable healthcare is exploding
• The systematic utilization of ever increasing data pool for goal-directed diagnosis and therapy provide huge opportunities
• Who will be the winner in the digital health care race

MARCUS SCHABACKER
Former CVP & Chief Scientific Officer
# PLENARY

**INNOVATION INSIGHTS AND GUIDED COMPLIANCE**
- From lunch meat to Teslas to medical device development, innovation is alive—and Excel Hell is over
- We’ll explore the “product behind the product” and see how guided compliance can profoundly help your efforts
- We’ll get a glimpse into a case study of guided compliance in action and see how 483’s in our past can be addressed in a manner that sets us up for success in subsequent NPD

<table>
<thead>
<tr>
<th>9:30 am – 10:10 am</th>
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<tbody>
<tr>
<td><strong>DESIGN</strong></td>
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<tr>
<td>INNOVATIVE MODELS OF PRODUCT DEVELOPMENT TO DE-RISK TECHNOLOGIES FASTER AND CHEAPER</td>
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<tr>
<td>- Business case drivers that influence which projects to invest in early, and key de-risking activities</td>
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<tr>
<td>- Emphasizing speed to market: how to be efficient with budget yet drive device development and innovation forward</td>
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<td>- A new case study on product development at Cleveland Clinic</td>
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**KELLY EMERTON**
Senior Director, Product Development & Commercialization

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<thead>
<tr>
<th>10:15 am – 11:45 am</th>
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<tbody>
<tr>
<td><strong>PRE-ARRANGED ONE-TO-ONE NETWORKING &amp; REFRESHMENTS</strong></td>
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<th>11:50 am – 12:25 pm</th>
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<tr>
<td><strong>QUALITY</strong></td>
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<tr>
<td>GENERATING RELIABLE RISK MANAGEMENT PROCESSES ACROSS THE ENTIRE QUALITY MANAGEMENT SYSTEM</td>
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<tr>
<td>- Decrease cost of quality by allowing your resources to focus on the areas of highest risk</td>
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<td>- Visibility into the critical supply chain processes, starting with the raw material suppliers and vendors through point-of-sale is a major factor to success</td>
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<td>- Increases the efficiency of supplier and vendor selection by both tracking and managing the qualification and approval process for new potential vendors and parts while avoiding redundant evaluations</td>
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<td>- Increases accountability through assignments, process step sign-offs, and automated audit trails</td>
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**MAUREEN BERNIER**
Biomedical Engineer, Recall Coordinator

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<td><strong>TECHNOLOGY</strong></td>
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<tr>
<td>A PROACTIVE APPROACH FOR SECURING MEDICAL DEVICES NOW AND IN THE FUTURE</td>
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<tr>
<td>- Applying concepts of security risk management to medical device design</td>
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<td>- Proactive and reactive program capabilities</td>
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<td>- Collaborative approaches with health delivery organizations</td>
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<td>- Lessons learned from the WannaCry attack</td>
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**STEVE ABRAHAMSON**
Senior Director, Product Cybersecurity

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<td><strong>MITCH HAYES</strong></td>
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Chief Technology Officer

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<tr>
<td><strong>RYAN WARD</strong></td>
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Director

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<td><strong>COGNITION</strong></td>
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12:30 pm – 1:05 pm

**DESIGN**
A DETAILED CASE STUDY OF GUIDED COMPLIANCE IN ACTION
- This will be a detailed look at the case study of guided compliance in action
- We’ll explore the “product behind the product” and see how guided compliance can profoundly help your efforts
- We’ll see how 483’s in our past can be addressed in a manner that sets us up for success in subsequent NPD

**MITCH HAYES**
Chief Technology Officer

**PRODUCT STRATEGY**
WHEN YOU HAVE A COMPLIANCE CRISIS: RESPONDING TO CHALLENGES IN A WAY THAT BEST MANAGES EXPOSURE TO RISK
- Responding to an FDA 483 inspection
- Responding to an FDA Warning Letter
- Meeting with the FDA to resolve disputes
- Implementing corrective and preventive action (CAPA) programs-including development, execution, monitoring, and project management

**RICKI A. CHASE**
Director, Compliance Practice

**QUALITY**
SMART FACTORY, SMART QUALITY MANAGEMENT: THE IMPACT OF INDUSTRY 4.0 ON QUALITY MANAGEMENT SYSTEMS
- Understand Smart Factory 4.0/Industry 4.0 and what it means to production, Quality Management Systems, and the extended supply chain
- Review the new role of technology, the challenges of that technology, and required changes in Quality Management
- Evaluate the need for automated, Operational Quality Risk Management today and in the future for Industry 4.0 and the extended supply chain
- Examine the potential Impact of Industry 4.0 on Regulatory Quality Compliance
- The business case Quality Leaders will need to present to gain organizational support for the technology journey required for Industry 4.0

**KARI MILLER**
VP, Regulatory and Product Management

**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

**KHOREN SAHAGIAN**
Chief Process Engineer and Applications Manager
American Medical Device Summit 2017 Program • Page 4

1:10 pm – 2:10 pm

LUNCH & LEARN ROUND-TABLE DISCUSSIONS

HOW TO AUTOMATE AND STREAMLINE REPETITIVE OR POTENTIALLY UNSAFE PROCESSES
DOUGLAS PETERSON
General Manager, Universal Robots’ Americas Division

BEST PRACTICE APPROACHES IN MANUFACTURING FOOTPRINT OPTIMIZATION AND LOCATION SELECTION AROUND THE GLOBE
JOHAN BEUKEMA
Managing Partner

MEDICAL DEVICE SECURITY AS AN ENABLER FOR INNOVATION
ROD SCHULTZ
Chief Product Officer

ADVANTAGES & OPPORTUNITIES WITH THE NEW EU MEDICAL DEVICE REGULATION
JEFFREY D. GERHARDT
Partner

HOW TO STAY ON TOP OF GLOBAL REGULATORY REQUIREMENTS
EVA L. PETERSEN
VP, International Sales

HOW MANUFACTURERS AND PROVIDERS WORK TOGETHER ON IMPROVING PATIENT CARE AND SAFETY
WILLIAM PARKINSON
Global Senior Director

A STRUCTURED APPROACH FOR QUALITY SYSTEM IMPROVEMENT
LARRY MAGER

LOWERING COST FOR MEDICAL DEVICE TESTING THROUGH EFFICIENT SOFTWARE ARCHITECTURE
TODD VANGILDER
VP, Sales

HOW TO IMPROVE THE QUALITY AND TIME TO MARKET WHILE MITIGATING RISK AND COSTS FOR YOUR MEDICAL DEVICE PRODUCT DEVELOPMENT LIFECYCLE. WITH FOCUS ON SOFTWARE DESIGN, TESTING (IV&V) AND DOCUMENTATION
BILL STAMM
Sales and Business Manager

STORAGE AND DISTRIBUTION OF TEMPERATURE SENSITIVE MEDICAL DEVICES. HOW DO YOU KNOW WHAT’S HAPPENING TO YOUR PRODUCT AFTER IT HAS LEFT YOUR FACILITY?
MIKE MONTANA
Senior Business Development Manager

RECENT DEVELOPMENTS IN THE USE OF FLEXIBLE PRINTED CIRCUIT BOARDS IN IMPLANTABLE DEVICES
KATHLEEN NARGI-TOTH
President

IMPROVED PRODUCTION SCHEDULING AS A COMPETITIVE ADVANTAGE
GABOR KOERTVELYESY
COO & Senior Consultant

PROVEN METHODS FOR SUCCESSFUL INNOVATION OUTCOMES
JOE GORDON
Director of Innovation

COMMON OBSTACLES IN RECEIVING PRODUCT APPROVALS FOR GLOBAL MARKETS
ROB DIETER
VP, Healthcare

1:25 pm – 2:00 pm

PLENARY
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 the quality culture and adopting change management

LIZ IVERSEN
SVP, Chief Quality & Regulatory Officer
3:00 pm – 3:35 pm

**DESIGN**

**DESIGN FOR EXCELLENCE (DFX) — DRIVING PRODUCT OPTIMIZATION THROUGH EARLY STAGE VALUE ENGINEERING DEVELOPMENT**

- The key benefits to performing DFX on your product: reducing lead time and material costs (DFSC)
- How to improve PCB yield, cost (DFF), assembly yield, reduced labour content (DFA), coverage, final yield, reduced RMA and field failures (DFT)
- Key opportunities for reducing engineering development and resources while improving time to market
- Working to enhance production stability and predictability (DFM)
- How to build a culture of continuous improvement (Post-DFM, ROI)

**PRODUCT STRATEGY**

**ESTABLISHING THE RIGHT CHECKS AND BALANCES TO PROTECT YOUR BUSINESS**

- End to end assessment
- Future-proof your business
- Culture of accountability
- Quality by design strategies

**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

**TECHNOLOGY**

**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?

3:40 pm – 5:10 pm

**PRE-ARRANGED ONE-TO-ONE NETWORKING & REFRESHMENTS**

5:15 pm – 5:55 pm

**PLENARY**

**MANAGING THE BUSINESS TO MANAGE THE AUDIT**

- Culture: What are the “Must-haves” to succeed in an audit
- Logistics: What is required to support and execute seamlessly
- People: Who should be there and what roles should they have
- Systems: How do you set up your quality system so it can show well
CHAIR’S CLOSING REMARKS

JOHN PEYTON  
VP, Global Design Quality

MARCUS SCHABACKER  
Former CVP & Chief Scientific Officer

STEPHEN FULTON  
Director, Manufacturing

NETWORKING DRINKS RECEPTION

Sponsored By:
PROGRAM  DAY TWO

7:00 am – 7:55 am

NETWORKING & BREAKFAST BRIEF

STRATEGIC QUALITY: ACHIEVING THE PROMISE OF YOUR MEDICAL DEVICE BUSINESS MODEL
JOHN GARVEY
CEO

SAAS GOVERNANCE; ACCOUNTABLE VS RESPONSIBLE
KOSAL KEO
CEO

HOW TO ACHIEVE COST SAVINGS WHEN USING FLEXIBLE CIRCUITS?
CAREY BURKETT
VP, Business Development

7:55 am – 8:05 am

CHAIR’S OPENING REMARKS & REVIEW OF DAY ONE
JOHN PEYTON
VP, Global Design Quality

MARCUS SCHABACKER
Former CVP & Chief Scientific Officer

STEPHEN FULTON
Director, Manufacturing

8:05 am – 8:45 am

KEYNOTE
CDRH STRATEGIC PRIORITIES: HOT TOPICS FOR AN EVOLVING REGULATORY CLIMATE
• Update on 2016-2017 priorities and preview of 2018-2019
• Case for quality: Realizing what we can achieve when we work together
• Benefit: Risk guidance: Impact on compliance and enforcement decisions
• Inside CDRH: Organizing to enhance knowledge management and operational excellence across the total product lifecycle
CAPT SEAN BOYD
Deputy Director for Regulatory Affairs

8:45 am – 9:25 am

PLENARY
DEMOCRATIZATION OF HEALTHCARE TECHNOLOGIES
• Affordability and accessibility of healthcare is a great concern, as our population worldwide grows and ages
• Products designed for developed healthcare markets miss the mark in serving unmet needs in developing markets
• In our interconnected world with leap frogging technologies—such as accessible internet, wearables, drones, inexpensive sensor technologies—healthcare is being democratized
• Concepts such as Reverse Innovation, Jugaad Innovation and GEMBA impact product design for the underserved market of 5 billion people
• Telemedicine and digital medicine are moving general and even some critical care from centralized hospitals into the hands of the masses as in-home healthcare
• Necessity is the mother of invention; constraints open up creative solutions
• Recognizing these constraints and the potential has given rise to new models of innovation, creating thriving businesses
PALANI PALANIAPPAN
EVP, Innovation & Development
BRIAN LAWRENCE  
SVP & Chief Technology Officer

**PLENARY**

**DESIGN THINKING: USER-CENTERED DESIGN TO DRIVE BREAKTHROUGH PATIENT OUTCOMES**

- Dealing with today’s dynamic healthcare environment must start with a new understanding of the customer
- We must disrupt current customer engagement models with new levels of customer intimacy to drive new innovation
- These techniques translate to breakthroughs in new products: the next-generation hospital bed and airway clearance device
- Customer engagement is an ongoing journey to truly deliver breakthroughs in patient outcomes

**9:25 am – 10:05 am**

**10:10 am – 10:45 am**

**DESIGN**

**CONCEPT TO COMMERCIALIZATION: OPTIMIZING YOUR PRODUCT DEVELOPMENT STRATEGY**

- Pathways to connect designers with manufacturing for improved downstream risk management
- Design strategy that incorporates supply chain sustainability
- When to employ external expertise in the concept to commercialization process
- Critical considerations in medical device design and development

**PRODUCT STRATEGY**

**HOW TO EFFECTIVELY ASSESS TRANSFERS, INTEGRATION, MERGERS AND ACQUISITIONS**

- How to take charge of your quality system success
- Comparing keeping things stand alone vs. integrating
- The pros and cons of standardizing
- Examining the notified body differences
- The impacts of significant regulatory changes in your approach – MDSAP, MDR, ISO 13485:2016
- How to prevent casualties along the way

**REGULATORY**

**LEADERSHIP INSIGHTS: MANAGING RISK FROM A LEGAL-REGULATORY STANDPOINT**

- What are the real world challenges
- What are the overarching principles
- Nuts and bolts of managing risk including
  - Written procedures
  - Emails
  - Contracts
  - Working in the grey zone
  - Reducing silos
  - Whistleblowers
  - Communicating with FDA
  - Handling Post-Market Quality Issues

**10:50 am – 11:50 am**

**NETWORKING & REFRESHMENTS**
11:55 am – 12:30 pm

**DESIGN**

BUILD IT RIGHT AND COMMUNICATE WELL: BREAKING ENTERPRISE SILOS IN THE PRODUCT DEVELOPMENT PROCESS

- Define a requirements approach that guides your product development strategy
- Benefits of creating a central hub to coordinate stakeholders, engineers, partners, data, conversations and decisions
- Opportunities in creating a central data source for ongoing iteration, real-time reporting and clarity across the organization
- Structure product variants from requirements for accelerated new product development

**PRODUCT STRATEGY**

TO RESHORE OR NEARSHORE: OPPORTUNITIES TO DECREASE COST IN DEVELOPMENT AND MANUFACTURING

- Key checklist in deciding when and where to locate your operations in order to drive strong bottom line results
- Focusing on site selection: How do I understand what to look for when deciding to shift operations
- Labor, logistics, utilities and real estate costs: establishing a strong cost comparison between different cities
- Why Mexico: assessing advantages that operating in Mexico could create for your business

**QUALITY**

STRATEGIC QUALITY – ACHIEVING THE PROMISE OF YOUR MEDICAL DEVICE BUSINESS MODEL

- Developing operational systems and practices
- Establishing your company’s “risk balance point”
- Exploring risk mitigation objectives and approaches
- Looking at new product introduction facilitation
- Assessing knowledge management/organizational connections

**REGULATORY**

DECRYPTING FDA CYBERSECURITY EXPECTATIONS FOR MEDICAL DEVICES

- See how the new standards, including UL 2900 correspond to FDA guidance
- Understand security design considerations recommended by the FDA Guidance
- Discover key processes assuring security risks are managed for products currently in the market

**speakers**

DAVID REAUGH  
Project Manager

SERGIO ALMADA  
Marketing & Business Development Manager

JOHN GARVEY  
CEO

LAURA ÉLAN  
Cybersecurity Practice Lead

WENDY KENNEDY  
CTO

![UL](ultra.png)  
![INTERMEX](intermex.png)
12:35 pm – 1:10 pm

**DESIGN**

**MAXIMIZING MEDICAL DEVICE ROI**
- New technologies are constantly being developed to help ensure patients well-being. With a widely dispersed fleet of medical devices, how are hospitals and healthcare systems optimizing the investment they are making in these medical devices?
- Medical device manufacturers and healthcare providers face many challenges. Do they have that single source of truth for critical information, such as total cost of ownership, device location, status, utilization, costs, software updates/patches, alerts, and availability of spare parts? Do they know how much they are spending on compliance?
- New security threats are directly affecting medical devices today. How do you know that your medical devices are really secure?

**WILLIAM PARKINSON**
Global Senior Director

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**PRODUCT STRATEGY**

**AUTOMATING DAY TO DAY FDA COMPLIANCE IN 20 GLOBAL MEDICAL MANUFACTURING FACILITIES - ADVANCED MANUFACTURING SYSTEMS**
- How equipment connectivity to MES "forces" day to day regulatory compliance
- Case study will cover global I.T. systems for 20 medical factories with 500+ production lines, shipping 35M+ top level assemblies per year
- Medical production lines range from those producing highly complex instruments to high volume "lights out" production lines
- Discussion of UDI and GAMP5 Compliance Requirements

**GELSTON HOWELL**
SVP

**SRIVATS RAMASWAMI**
CTO

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**QUALITY**

**BEYOND COMPLIANCE: REACHING IDEAL QUALITY & BUSINESS PERFORMANCE OBJECTIVES**
- Integrated – Un-siloed approach to driving end-to-end business performance
- Maturity – Clear, complete and repeatable processes designed to get it right the first time
- Visibility – Correct key indicators for executive level visibility for quality and business performance
- Efficiency – Integration technology, processes, methodology and the right people to increase process speed and effectiveness

**ROB HARRISON**
Director, Market Strategy

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**REGULATORY**

**BE READY FOR THE EU MDR LABELING AND USE THE LESSONS LEARNT FROM UDI**
- Understand what EU MDR compliance means for your business and how it will affect your labeling processes
- Develop an understanding of the market's perceptions of EU MDR
- Recognize what the biggest labeling compliance challenges ahead are and how to proactively overcome them
- Embrace the lessons learned from UDI to work smarter in meeting the implementation deadlines of MDR by May 2020 and IVDR by May 2022
- Learn about a labeling system that can adapt to regulations

**TIM FISCHER**
Sales Manager
LUNCH & LEARN

MEDICAL DEVICE IOT: SHARING LESSONS LEARNED FROM MINING THE NON-CLINICAL DATA OF THOUSANDS OF ONLINE THERAPEUTIC DEVICES
JOHN VAN HETEREN
Director, System Engineering

THE RISK MANAGEMENT BOARD (BALANCING PATIENT RISK, REGULATORY REQUIREMENTS, LEGAL RISK, AND BUSINESS NEEDS FOR PRODUCT ISSUES AND NEW PRODUCT INTRODUCTIONS)
MICHAEL BACA
VP, Quality / Regulatory / Clinical

STUART KOZLICK
VP, Medical Robotics

HOW TO DISRUPT THE PARADIGM OF HEALTHCARE AND HEALTH ECONOMICS
CARLOS URREA
Hill-Rom

EXPANDING PRODUCT DEVELOPMENT AND PIPELINE STRATEGIES

DISCUSSING ONGOING EFFORTS TO PROTECT THE PUBLIC HEALTH FROM CYBERSECURITY
STEVE ABRAHAMSON
Senior Director, Product Cybersecurity

EXPANDING ON OPERATIONAL MATURITY JOURNEY AND HOW TO ADVANCE THE SUPPLY CHAIN TO CREATE REQUIRED CONNECTIONS FROM MANUFACTURING TO PATIENT
STEPHEN FULTON
Director, Manufacturing

1:15 pm – 2:15 pm

2:20 pm – 2:55 pm

PRODUCT STRATEGY

THE BENEFITS AND ADVANTAGES OF AUTOMATING YOUR QUALITY MANAGEMENT SYSTEM FOR A MEDICAL DEVICE MANUFACTURER
BRANT ENGELHART
President

QUALITY

NEW AGE DIGITAL HEALTHCARE
PHANI BIDARAHALLI
GM, Global Engineering & Practice Head

REGULATORY

CONNECTED ASSETS IN REGULATED ENVIRONMENT (CARE)
PARTHA MARELLA
SVP & Global Head of Medical Services

DESIGN

PAVING THE WAY FOR PRODUCT INNOVATION
KRISTIN KINSCHERFF
Director of Operations

DEANA PAPE
Director
3:00 pm - 3:40 pm

PLENARY

DRIVING LEAN THROUGH THE END-TO-END VALUE CHAIN

- Understanding the lost opportunities of not applying lean: Leak analysis
- What is the missing link between functional support areas and daily operations?
- Lessons learned on driving lean through the organizational culture
- Lean and its impact on organizational speed: Short term and long term

WILLIAM OWAD
SVP, Operational Excellence

3:40 pm - 4:20 pm

CLOSING PANEL

ADDRESSING THE 2017 OBSTACLES: EXPLORING REGULATORY CHALLENGES & OPPORTUNITIES

- Assessing real-time detection, the resolution of compliance and quality events
- Understand International market activities and quality events, creating streamline procedures that adapt to all regions
- Enabling markets outside the United States to take ownership of quality and compliance

MAUREEN BERNIER
Biomedical Engineer, Recall Coordinator

CARLOS URREA
VP, Medical Affairs

DVORAH RICHMAN
VP, Chief Regulatory Counsel

MAUREEN BERNIER
Biomedical Engineer, Recall Coordinator

WILLIAM PARKINSON
Global Senior Director

LIZ IVERSEN
SVP, Chief Quality & Regulatory Officer

MARCUS SCHABACKER
CVP & Chief Scientific Officer

DONNA HAIRE
VP, Head of Medical Care Global Regulatory Affairs

4:20 pm - 4:25 pm

CHAIR’S CONCLUDING REMARKS & CLOSE OF SUMMIT

JOHN PEYTON
VP, Global Design Quality

MARCUS SCHABACKER
Former CVP & Chief Scientific Officer

STEPHEN FULTON
Director, Manufacturing