Education Guide

WHERE MANUFACTURING MINDS MEET


Join the Conversation
#AdvMfgExpo
Automation & Control Freak?
Same here.

... We carry more automation & control brand names than any other distributor in North America.

It’s true – we checked.

Table of Contents

Center Stage .......................................................... 5
Tech Theater .......................................................... 7
Innovation Tours .................................................... 9
Connection Corner ................................................ 11
WestPack Hub ....................................................... 13
Conference-at-a-Glance ........................................ 14
MD&M West Conference ....................................... 17
3D Printing Innovation Summit ............................... 29
Smart Manufacturing Innovation Summit ................ 31
Conference Floor Plan .......................................... 35
Expo Hall Floor Plan ............................................ 36

PRESENTATION SLIDES
All presentation slides will be available at
http://presentations.canontradeshows.com/events/anaheim/2018

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With the addition of sheet metal fabrication services, we are your single source for the broadest selection of rapid manufacturing services. Visit us at booth #3301 to learn more.

**QUOTES IN HOURS. PARTS IN DAYS.**

3D PRINTING | CNC MACHINING | SHEET METAL FABRICATION | INJECTION MOLDING

Visit go.protolabs.com/PDM2018 to grab a free guide to sheet metal part design.

The Proto Labs logo is shown at the bottom of the page.
3 Ways To Make Your Factory Smarter With IIoT

PRESENTED BY
Christoph Wimmer
Director, Customer Experience and Electronic Vertical, Omron Microscan Systems

FEBRUARY 7, 3:15-4 PM
ROOM 209A

VISIT US IN BOOTH #4395

See our exciting state-of-the-art technology showcase!

Omron Microscan Systems is global leader in automatic identification, barcode verification & machine vision applications.

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**EXPERIENCE FANUC’S NEW SCARA ROBOTS**

FANUC’s new line of SCARA robots are fast, precise, compact, and affordable. Backed by our world-renowned reliability and integrated intelligence, we invite you to experience our SCARAs, and realize higher productivity with the promise of lifetime customer support.

**Innovation Tours**

Navigate the show floor with field experts to point out the newest technology, innovations, and industry trends.

Tours meet at the **Booth 313**.

**TUESDAY, FEBRUARY 6**
- 10:30 am – Innovation Tour: West First-Timers
  Hayley Haggarty, Associate Director, Events, UBM
- 12:00 pm – Innovation Tour: Packaging
  Lisa Pierce, Executive Editor, Packaging Digest, UBM
- 3:00 pm – Innovation Tour: Medtech
  Jamie Hartford, Director of Content, Medtech Brands, UBM

**WEDNESDAY, FEBRUARY 7**
- 12:00 pm – Innovation Tour: Packaging
  Lisa Pierce, Executive Editor, Packaging Digest, UBM
- 2:00 pm – Innovation Tour: 3D Printing
  Chuck Murray, Senior Technical Editor, Design News, UBM

**THURSDAY, FEBRUARY 8**
- 11:00 am – Innovation Tour: Packaging
  Lisa Pierce, Executive Editor, Packaging Digest, UBM
- 12:00 pm – Innovation Tour: 3D Printing
  Rob Spiegel, Senior Editor, Design News, UBM
- 3:00 pm – Innovation Tour: Smart Manufacturing
  Jennifer Campbell, Technical Content Producer, UBM

**THANK YOU TO OUR 3D PRINTING ZONE EXHIBITORS FEATURED ON THE 3D PRINTING INNOVATION TOUR**

- Additive Manufacturing | Booth 4093
- BOFA Americas Inc. | Booth 4091
  - Dekra | Booth 3709
  - Dynamism Inc | Booth 3887
- Hawk Ridge Systems | Booth 3707
- Raise 3D | Booth 3897
- Saratech, Inc | Booth 3614
- Scicon Technologies Corp. | Booth 3864
- Superior 3D Solutions | Booth 3988

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Connection Corner

Connection Corner is your destination for formal and fun networking. Attend our exhibitor-to-attendee matchmaking, meet ups, and peer-to-peer networking, all hosted in this space.

**TUESDAY, FEBRUARY 6**
- 2:00 pm – 3:15 pm: Attendee-to-Exhibitor Matchmaking
- 4:00 pm – 5:00 pm: Developing your Medical Device: From Concept to Completion  
  *Dan Golka, Med Tech Council*

**WEDNESDAY, FEBRUARY 7**
- 11:00 am – 12:00 pm: Peer-to-Peer Speednetworking- Automation, Assembly, & Robotics
- 2:00 pm – 3:15 pm: Attendee-to-Exhibitor Matchmaking

**THURSDAY, FEBRUARY 8**
- 11:00 am – 12:00 pm: Peer-to-Peer Speednetworking- Medical Design & Manufacturing
- 2:00 pm – 3:15 pm: Attendee-to-Exhibitor Matchmaking

**FREE**
OPEN TO ALL ATTENDEES

Take advantage of this effective, efficient, and fun event to establish new connections, gain industry knowledge, learn about new processes and build relationships with your industry peers.

Attend this networking activity and rub shoulders with likeminded attendees within the packaging and medtech industry.

(No need to RSVP. This will be a first come, first served basis.)

No solicitation of services or products please, as this is a peer-to-peer networking session.

There are two events scheduled for your convenience. Choose from:
- **Wednesday**: Automation, Assembly & Robotics: 11:00 A.M.-12:00 P.M.
- **Thursday**: Medical Design & Manufacturing: 11:00 A.M.-12:00 P.M.

Located at the Connection Corner, Booth 184

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New for 2018! Stay on top of the latest packaging industry trends, technologies, and materials at the WestPack Hub on the expo floor. Learn from engaging presentations and live demos conducted by packaging design and manufacturing thought leaders.

**TUESDAY, FEBRUARY 6**

<table>
<thead>
<tr>
<th>Time</th>
<th>Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:30 am</td>
<td>Milacron Presents Klear Can</td>
</tr>
<tr>
<td>11:15 am</td>
<td>Michael Crawford, Corporate Communications Manager, Mold Masters</td>
</tr>
<tr>
<td>11:15 am</td>
<td>Just How Hard Is It to Open a Medical Package Aseptically?</td>
</tr>
<tr>
<td>12:00 pm</td>
<td>Laura Bix, PhD, Associate Director, Michigan State University</td>
</tr>
<tr>
<td>1:30 pm</td>
<td>Mission Possible: Formulating the Right Adhesive Coating for the Application</td>
</tr>
<tr>
<td>2:15 pm</td>
<td>Rick Brady, Technology Manager, Oliver Healthcare Packaging; Kevin Zacharias, Technical Director, Oliver Healthcare Packaging</td>
</tr>
<tr>
<td>2:30 pm</td>
<td>How to Keep Your Packaging Job in the Automation Age</td>
</tr>
<tr>
<td>3:00 pm</td>
<td>Stacy Feiner, PsyD, Business Psychologist &amp; Coach, BDO USA; Andrea MacKenzie, Coach, Lead With Harmony; Lisa Pierce, Executive Editor, Packaging Digest, UBM Americas</td>
</tr>
<tr>
<td>3:30 pm</td>
<td>Trends and Challenges in Today’s Recycling System</td>
</tr>
</tbody>
</table>

**WEDNESDAY, FEBRUARY 7**

<table>
<thead>
<tr>
<th>Time</th>
<th>Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:30 am</td>
<td>Strategically Communicating Your Sustainability Story</td>
</tr>
<tr>
<td>11:30 am</td>
<td>Robert Libenfeld, Consultant</td>
</tr>
<tr>
<td>11:30 am</td>
<td>Utilizing Inline Product Inspection Systems To Meet Compliance and Avoid Recalls While Improving OEE</td>
</tr>
<tr>
<td>12:15 pm</td>
<td>Robert Rogers, Senior Advisor Food Safety &amp; Regulation, Mettler-Toledo</td>
</tr>
<tr>
<td>1:30 pm</td>
<td>Beyond the Baggie: The Future of Cannabis Containers</td>
</tr>
<tr>
<td>2:15 pm</td>
<td>Walter Apodaca, Owner and CEO, Gizmo Beverages</td>
</tr>
<tr>
<td>2:30 pm</td>
<td>Who Wore it Better: Designing Packaging in a Hyper-Visual Age</td>
</tr>
<tr>
<td>3:30 pm</td>
<td>Andrea Olson, CEO, Prag'madik</td>
</tr>
<tr>
<td>3:30 pm</td>
<td>Innovation Hour: WestPack</td>
</tr>
</tbody>
</table>

**THURSDAY, FEBRUARY 8**

<table>
<thead>
<tr>
<th>Time</th>
<th>Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:30 am</td>
<td>Understanding California’s Rigid Plastic Container Law</td>
</tr>
<tr>
<td>11:15 am</td>
<td>Natalie Rainer, Associate, Keller and Heckman LLP</td>
</tr>
<tr>
<td>1:30 pm</td>
<td>California’s Proposition 65: Understanding the Impact on Food Packaging</td>
</tr>
<tr>
<td>2:15 pm</td>
<td>Mitzi Clark, Partner, Keller and Heckman LLP</td>
</tr>
</tbody>
</table>

**THE RECYCLING CHALLENGE**

Tuesday, February 6; Wednesday, February 7; and Thursday, February 8
10:00am - 4:00pm  | Booth 5493
Trina Matta, Senior Manager, Sustainable Packaging Coalition
## Conference-At-A-Glance

### TUESDAY, FEBRUARY 6

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00 am</td>
<td>Registration and Refreshments</td>
</tr>
</tbody>
</table>
| 8:30 am – 5:30 pm | MD&M Track A  
Sponsored by Eastman Chemical, Maxon Precision Motors, and PolyOne 
Room 210A  
MD&M Track B  
Sponsored by Eastman Chemical, Maxon Precision Motors, and PolyOne 
Room 210B  
MD&M Track C  
Sponsored by Eastman Chemical, Maxon Precision Motors, and PolyOne 
Room 210C  
MD&M Track D  
Sponsored by Eastman Chemical, Maxon Precision Motors, and PolyOne 
Room 210D  
3D Printing  
Sponsored by Poly-Med, Proto Labs, & Renishaw, Inc. 
Room 208B  
Smart Manufacturing  
Sponsored by Allied Electronics; Digi-Key; NSK Americas; Omron Microscan Systems, Inc.; PHD Inc.; Renishaw, Inc.; SDP/STI; WinSystems 
Room 209A |
| 8:30 am – 9:10 am | Opening Plenary Session: Let’s Get Real About Consumerizing Healthcare  
Jordan Shlain, MD, Founder and Chairman, HealthLoop 
Room 213 CD |
| 10:00 am – 10:15 am | Refreshment Break                                                     |
| 11:45 am – 1:00 pm | Lunch & Learn  
Sponsored by Eastman Chemical Company 
Room 211AB |
| 11:45 am – 1:15 pm | Lunch & Learn  
Sponsored by Samtec 
Room 211AB |
| 5:00 pm – 6:00 pm | Golden Mousetrap Reception                                           |
| 6:00 pm – 7:00 pm | Golden Mousetrap Awards                                               |

### WEDNESDAY, FEBRUARY 7

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00 am</td>
<td>Registration and Refreshments</td>
</tr>
</tbody>
</table>
| 8:30 am – 5:30 pm | MD&M Track A  
Sponsored by Maxon Precision Motors, Samtec, and NAMSA 
Room 210A  
MD&M Track B  
Sponsored by Maxon Precision Motors, Samtec, and NAMSA 
Room 210B  
MD&M Track C  
Sponsored by Maxon Precision Motors, Samtec, and NAMSA 
Room 210C  
3D Printing  
Sponsored by Poly-Med, & Renishaw, Inc. 
Room 208B  
Smart Manufacturing  
Sponsored by Allied Electronics; Digi-Key; NSK Americas; Omron Microscan Systems, Inc.; PHD Inc.; Renishaw, Inc.; SDP/STI; WinSystems 
Room 209A |
| 10:00 am – 10:15 am | Refreshment Break                                                     |
| 11:45 am – 1:00 pm | Lunch & Learn  
Sponsored by Samtec 
Room 211AB |
| 11:45 pm – 1:00 pm | Lunch & Learn  
Sponsored by Thailand Board of Investment 
Room 212AB |
| 11:45 am – 1:15 pm | Networking Lunch                                                     |
| 3:00 pm – 3:15 pm | Refreshment Break                                                     |

### THURSDAY, FEBRUARY 8

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00 am</td>
<td>Registration and Refreshments</td>
</tr>
</tbody>
</table>
| 8:30 am – 4:30 pm | MD&M Track A  
Sponsored by Maxon Precision Motors 
Room 210A  
MD&M Track B  
Sponsored by Maxon Precision Motors 
Room 210B  
MD&M Track C  
Sponsored by Maxon Precision Motors 
Room 210C  
MD&M Track D  
Sponsored by Maxon Precision Motors 
Room 210D  
3D Printing  
Sponsored by Poly-Med, & Renishaw, Inc. 
Room 208B  
Smart Manufacturing  
Sponsored by Allied Electronics; Digi-Key; NSK Americas; Omron Microscan Systems, Inc.; PHD Inc.; Renishaw, Inc.; SDP/STI; WinSystems 
Room 209A |
| 10:00 am – 10:15 am | Refreshment Break                                                     |
| 11:45 am – 1:15 pm | Networking Lunch                                                     |
| 3:00 pm – 3:15 pm | Refreshment Break                                                     |
| 4:30 pm       | Conference Adjourns                                                   |

### EVENT PRICING:

<table>
<thead>
<tr>
<th>Package</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-Day All-Access Pass</td>
<td>$999</td>
</tr>
<tr>
<td>2-Day Conference Pass</td>
<td>$799</td>
</tr>
<tr>
<td>Expo-Only Pass</td>
<td>$149</td>
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</tbody>
</table>

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Presented by:

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Combining our engineers' knowledge with the experience built up in more than 50 years, maxon motor covers a wide range of medical applications including surgical robots, insulin pumps, prostheses, respirators and much more. We develop, together with our customers, high precision drive solutions that fit their needs.

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Eastman MXF221 copolyester is an opaque and clear polymer that is disinfectant ready and offers toughness uniquely suited for electronic device housings. The toughness of Eastman MXF221 stands up to the daily rigors of hospital environments and aggressive disinfectants while offering increased durability and a reduction in product failures.

At Eastman, we develop specialized polymers with superior chemical resistance, durability, and color stability. For clear and opaque parts alike, our plastics have become the new standards for chemical resistance and toughness in the medical market.

Find out more at MD&M West. Stop by booth 2401, and ask how we can help bring the next generation of medical devices to market.

Eastman.com/medical
MEDTECH OPPORTUNITIES IN THAILAND

- The Thai market (70 million) acts as the medtech hub of the fast growing ASEAN medtech market (640 million), the 3rd largest global market;
- SE Asian healthcare spend is rising faster than most global regions and a large percentage of equipment and supplies are imported from North America;
- A growing local supply chain supports both domestic and international companies operating out of Thailand.

Mr. Chokedee Kaewsang, Deputy Secretary General, Thailand Board of Investment (BOI), speak about:

- The Medtech & Healthcare Market in Thailand, and how the Thailand BOI can support companies growing in the SE Asian Region.

Dr. Rome Jutabha, MD, MD, Professor of Medicine, David Geffen School of Medicine at UCLA and Advisor to the Thailand Ministry of Public Health, speak about:

- Opportunities in the Medtech Sector and the experience of doing business in Thailand.

Hope to see you there to learn and network with Thai representatives. Any questions please call Doug Gray at 1-917-494-5278 or email Doug at ThailandBoi@sectorglobal.com
MD&M West Conference Track
Wednesday February 7  |  Technical Solutions

**TRACK C**

**Room 210C**

**8:25 am – 8:30 am**
Chair's Opening Remarks
Mike Pizzi, Events & Communications Manager, Nelson Laboratories, LLC

**8:30 am – 9:30 am**
Nelson Labs Workshop: Assessing Biocompatibility for Medical Devices
Thor Rollins, Director, Toxicology and E&L, Nelson Laboratories, LLC

**9:30 am – 10:30 am**
Nelson Labs Workshop: Extractable/Leachable Chemistry for Assessment of Medical Device Biocompatibility
Matthew Jorgensen, Chemistry and Materials Scientist, Nelson Laboratories, LLC

**10:45 am – 11:45 am**
Nelson Labs Workshop: Ethylene Oxide Sterilization Validation Overview
Mike Padilla, Manager, SteriPro Consulting

**12:00 pm – 12:45 pm**
Nelson Labs Workshop: Hands-On Biocompatibility Case Studies
Matthew Jorgensen, Chemistry and Materials Scientist, Nelson Laboratories, LLC; Thor Rollins, Director, Toxicology and E&L, Nelson Laboratories, LLC

**1:30 pm – 2:30 pm**
Nelson Labs Workshop: Radiation Sterilization: Selection of a Validation Approach & Updates in the Radiation Industry
Niki Fidopiastis, Director, SteriPro Consulting; Wendy Wangsgard, PhD, Senior Scientist, Nelson Laboratories, LLC

**2:30 pm – 3:30 pm**
Nelson Labs Workshop: Sterile Barrier Packaging Validations
Wendy Mach, Packaging Section Leader, Nelson Laboratories

**3:45 pm – 4:45 pm**
Nelson Labs Workshop: Cleanliness Testing for Medical Devices Including Reusable and Single Use Devices
Emily Mitzel, Consulting Manager and Senior Scientist, Nelson Laboratories, LLC

**TRACK D**

**Room 210D**

**8:25 am – 8:30 am**
Chair's Opening Remarks
Marcelo Trevino, Senior Vice President of Regulatory Affairs and Quality, Applied Medical

**8:30 am – 10:00 am**
Panel: EU MDR & IVDR Implications for Manufacturers & Suppliers
Moderator: Michael A. Swit, Esq., Principal, Law Offices of Michael A. Swit; Vinay Goyal, Project Engineer, Johnson and Johnson Enterprise Product Stewardship; Valynda Machen, Principal Medical Research Manager, Regulatory, NAMSA; Kim Walker, Vice President of Regulatory, Quality, and Clinical Affairs, MyoCutan Biomedical

**10:15 am – 11:45 am**
Implementation: Notified Body Expectations & Readiness
Ibim Tariah, PhD, Technical Director, BSI Medical Devices

**1:15 pm – 2:30 pm**
Panel: Making the Medical Device Single Audit Program (MDSAP) Work for You
Moderator: Marcelo Trevino, Senior Vice President of Regulatory Affairs and Quality, Applied Medical; Jessica Cho, Regulatory Affairs Manger, Applied Medical; Uwe Degenhardt, Director, Quality Compliance, Edwards Lifesciences; Kristy Pollard, Senior Specialist for Quality Compliance in Auditing, Edwards Lifesciences; Lynnette Tones, Quality Director for Critical Care, Edwards Lifesciences

**2:30 pm – 4:00 pm**
Panel: Next Steps for Implementing Global UDI
Moderator: Frank Pokrop, Director, Quality and Regulatory Affairs, BD; Dennis Black, Director, e-Business, Solutions Group, BD; Jay Crowley, Vice President and Practice Lead - UDI Services and Solutions, USDM Life Sciences

**4:00 pm – 5:30 pm**
What the 21st Century Cures Act Means for Medtech
Michael Hoffman, Deputy Director, Division of Neurological and Physical Medicine Devices, FDA; Yarelma Pavlovic, Esq., Partner, Hogan Lovells; Rick White, CEO and Co-Founder, Sure Genomics; Sharee Pew, Director of Quality Assurance, Myriad Genetics Laboratories Inc.

**LUNCH & LEARN**

Wednesday, February 7 | 11:45 am – 1:00 pm | Room 212AB

Medtech Opportunities in Thailand
Rome Jutabha, MD, Professor of Medicine, David Geffen School of Medicine, UCLA; Chokedee Kaewsang, Deputy Secretary General, Thailand Board of Investment (BOI)

Space is limited, with priority given to those that RSVP’d before the event. Please arrive early.
To learn more, visit polyone.com or call 1.866.POLYONE

2018 MD&M West Conference

DAY THREE: THURSDAY, FEBRUARY 8

TRACK A New Technologies & Next-Gen Design

ROOM 210A

9:55 am – 10:00 am  Chair’s Opening Remarks
Jason Wilkins, Senior Design Lead, IDEO

10:00 am – 12:00 pm  IDEO Workshop: Empathy, Insights & Innovation
Farzad Azimpour, MD, Clinical Director of Health, IDEO; Jason Wilkins, Senior Design Lead, IDEO; Alyson Yamada, Principal Designer and Project Lead, IDEO

1:00 pm – 3:00 pm  IDEO Workshop: Prototyping Our Way to Success
Farzad Azimpour, MD, Clinical Director of Health, IDEO; Jason Wilkins, Senior Design Lead, IDEO; Alyson Yamada, Principal Designer and Project Lead, IDEO

3:15 pm – 4:15 pm  IDEO Workshop: IDEO Point of View Panel: Designing Medical Devices with Augmented Intelligence in Mind
Moderator: Chris Wiltz, Senior Editor, Design News, UBM; Farzad Azimpour, MD, Clinical Director of Health, IDEO; Irmak Sirer, Design Director, IDEO; Jason Wilkins, Senior Design Lead, IDEO.

TRACK B Product Development Best Practices

ROOM 210B

8:25 am – 8:30 am  Chair’s Opening Remarks
Siddharth Desai, President, HealthCare Evolution

8:30 am – 10:00 am  Panel: Beating Industry Standards for New Product Development: Getting Your Device to Market Quickly
Moderator: Marc Habib, Executive Director, Labco and Strategic Partnerships, The Innovation Lab; Nadder Sahar, Director of Innovation, MPE, Inc.; Peter Tortorico, Senior Manager, Medtronic; Mark Vreeke, PhD, Co-Founder, Chemical Angel Network

10:15 am – 11:00 am  Choosing How to Invest Advanced Technology Resources
Liam Pender, Senior Director, Research & Development, Dexcom

11:00 am – 11:45 am  Commercializing a Single-Use Electronic Patch
Mark Troutman, Vice President, Design Engineering, Benchmark Electronics

1:15 pm – 2:00 pm  Case Study: A Device with Multiple Technical Areas: Acute Care Covering for Severely Injured Limbs (ACCSIL)
Erik Edwards, Senior Research Scientist, Battelle

2:00 pm – 3:00 pm  Medtech Show Floor Tour: Product Development Tools & Technologies
Jamie Hartford, Director of Content, Medtech Brands, UBM

3:15 pm – 4:30 pm  An Interconnected World, 2027 & Beyond: Future of Medical Devices
Siddharth Desai, President, HealthCare Evolution

CONFERENCE PRESENTATION SLIDES

will be available for download at:
http://presentations.canontradeshows.com/events/anaheim/2018

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MORE THAN MATERIALS

Solutions that help you win, from concept to marketplace.

• Polymer Distribution
• Engineered Polymers and TPEs
• Healthcare Vinyl Solutions
• Pre-certified Polymer Colorants and Additives

Backed by the Power of PolyOne.
<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Speaker(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:25 am</td>
<td>Chair’s Opening Remarks</td>
<td>Gary Tapp, Engineering Manager, Biomerics</td>
</tr>
<tr>
<td>8:30 am</td>
<td>What’s New &amp; How to Get the Best Battery Solution for Your Products</td>
<td>Michael Xie, CEO, Founder, PHD Energy Inc.</td>
</tr>
<tr>
<td>9:15 am</td>
<td>Assuring Component Reliability in Medical Electronic Devices</td>
<td>Ravi Subrahmaniyam, PhD, Executive Director, Advanced Technologies, Micro Systems Engineering, Inc.</td>
</tr>
<tr>
<td>10:15 am</td>
<td>Ensuring Success During Combination Product Testing: Part 1</td>
<td>Frank Bieganousky, Associate Director, Container Qualification &amp; COIT, Whitehouse Laboratories, LLC; John Iannone, Director, Extractables/Leachables &amp; Impurities, Albany Molecular Research, Inc. (AMRI); Brandon Zurawlow, Associate Director, Container Qualification &amp; COIT, Whitehouse Laboratories, LLC</td>
</tr>
<tr>
<td>11:00 am</td>
<td>Ensuring Success During Combination Product Testing: Part 2</td>
<td>Frank Bieganousky, Associate Director, Container Qualification &amp; COIT, Whitehouse Laboratories, LLC; John Iannone, Director, Extractables/Leachables &amp; Impurities, Albany Molecular Research, Inc. (AMRI); Brandon Zurawlow, Associate Director, Container Qualification &amp; COIT, Whitehouse Laboratories, LLC</td>
</tr>
<tr>
<td>1:15 pm</td>
<td>Case Study: Verifying Software &amp; Requirements Using Software Simulation &amp; Automated Scripts</td>
<td>Jason Farnan, User Experience Design Manager, Tandem Diabetes Care</td>
</tr>
<tr>
<td>2:00 pm</td>
<td>Do’s &amp; Don’ts of Testing for Materials Selection</td>
<td>Ryan Siskey, Principal Office Director, Exponent</td>
</tr>
<tr>
<td>3:15 pm</td>
<td>Is Your Medical Device at Risk for Particulates in Coatings?</td>
<td>Sean Stucke, Director of Commercial Development, Surmodics, Inc.</td>
</tr>
<tr>
<td>8:25 am</td>
<td>Chair’s Opening Remarks</td>
<td>Eri Hirumi, Regulatory Affairs Specialist, MicroVention</td>
</tr>
<tr>
<td>8:30 am</td>
<td>Understanding FDA Regulatory Expectations: Keys to Successful 510(k) Regulatory Submissions</td>
<td>Allison Komiyama, PhD, Principal Consultant, AcKnowledge RS, LLC</td>
</tr>
<tr>
<td>9:15 am</td>
<td>Sterility Assurance for Sensitive Combination Products: Defining a Regulatory Path</td>
<td>Byron Lambert, Senior Associate Fellow, Sterilization Science, Abbott Vascular</td>
</tr>
<tr>
<td>10:15 am</td>
<td>When the De Novo Pathway is the Simplest Way to Market</td>
<td>Mike Drues, President, Vascular Sciences; Eric Steuben, Vice President, Operations, PROCEPT BioRobotics</td>
</tr>
<tr>
<td>1:15 pm</td>
<td>What FDA Looks for During Inspection</td>
<td>Marcelo Trevino, Senior Vice President of Regulatory Affairs and Quality, Applied Medical</td>
</tr>
<tr>
<td>2:30 pm</td>
<td>How’s Your Relationship? Working with FDA for Successful Product Launch</td>
<td>Mary Hole, Supervisory Investigator, FDA</td>
</tr>
<tr>
<td>3:45 pm</td>
<td>Panel: Driving Innovation: Getting Innovative Products Through FDA</td>
<td>Grant Bennett, Chief Executive Officer, Brandwood Biomedical; Michael Hoffman, Deputy Director, Division of Neurological and Physical Medicine Devices, FDA</td>
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**8:30-10:00 AM**
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