Important Notice
The information provided in this course represents the personal opinions of the instructors and does not necessarily represent the opinions of AdvaMed staff. Companies relying on the information do so at their own risk and assume the risk of any subsequent liability that results from relying on the information. The information does not constitute legal advice.
1:45 – 2:45 pm Human Factors Engineering: How integration propels the development process
Linda Chatwin, Esq, RAC, Manager Medical Regulatory Advisory Services North America Life and Health, UL LLC
Merrick Kossack, Research Director, Human Factors Engineering, UL-Wiklund
- Best practices and demonstrated case studies that support the value of a truly integrated approach, covering:
  - What successful integration looks like and what it accomplishes
  - How an integrated approach improves: time to market, cost of development, regulatory approval and market adoption

2:45 – 3:00 pm Break

3:00 – 4:00 pm Human Factors Benefits Beyond End Users
Bob Marshall, Senior Principal Engineer, R&Q
Ryan Kasun, PMP, Project Engineer, R&Q
- Impact on clinical trials outcomes
- Better data speed the product development
- Competitive advantage
- Market acceptance
- Patient safety

4:00 – 5:00 pm Effectively Managing Change During Development
Bob Marshall, Senior Principal Engineer, R&Q
Ryan Kasun, PMP, Project Engineer, R&Q
- User needs that dictate required functionality
- Design issues that impact other system components

5:00 – 6:00 pm Reception

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Wednesday, June 8

8:00 – 8:30 am  Continental Breakfast

8:30 – 10:30 am  Integrating Human Factors Engineering into Medical Product Development - hands on interactive session
  Rebecca Miron, Senior Human Factors Engineer, Ximedic
  Susan McDonald, Senior Human Factors Engineer, Ximedic
  - Teams will systematically document required use steps and use tasks through the development of a task analysis; then work through the use tasks to develop a use error analysis and system design spec.
  - How these documents feed the product development process, risk management process, verification and validation testing.

10:30-10:45 am  Break

10:45 – 12:30 pm  Integrating Human Factors Engineering into Medical Product Development - hands on interactive session (continued)
  Rebecca Miron, Senior Human Factors Engineer, Ximedic
  Susan McDonald, Senior Human Factors Engineer, Ximedic
  - Teams will systematically document required use steps and use tasks through the development of a task analysis; then work through the use tasks to develop a use error analysis and system design spec.
  - How these documents feed the product development process, risk management process, verification and validation testing.

12:30 pm  Adjournment