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   Speakers: Wendy Blackburn, Executive Vice President, Intouch Solutions, & Dr. Darshan Kulkarni, Principal Attorney, The Kulkarni Law Firm

3. EU Medical Device Vigilance Reporting Requirements Under MEDDEV 2.12-1 Rev 7
   Speaker: Helen Colquhoun, Senior Vice President, Cromsource

4. Centralized vs Onsite Monitoring – Applying FDA’s Risk-based Approach
   Speaker: Sandra Maddock, President & CEO, IMARC Research, Inc.

5. An Overview of Recent Risk-based Monitoring Guidance from the FDA
   Speaker: Dr. Joy Frestedt. President & CEO, Frestedt Incorporated

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   Speaker: Cheryl Hill, Regulatory Manager, CROMSOURCE, Inc.

7. The Revised RoHS Directive and What It Means for Device Manufacturers
   Speaker: Dr. Joachim Wilke, Director, Regulatory Affairs & Policy, Europe, Medtronic

8. Taking the Literature Route for EU Medical Device Clinical Evaluations
   Speaker: Helen Colquhoun, Senior Vice President, Cromsource

9. Following the 510(k) and 505(b)(2) Pathways to Regulatory Approval
   Speaker: Dr. Joy Frestedt. President & CEO, Frestedt Incorporated

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    Speaker: Tamas Borsai, Division Manager, MHS - Customer Service and Quality,
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