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**RECORDINGS:**

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   Speaker: Dan O’Leary, President, Ombu Enterprises

2. **Requests for Off-label Information – The FDA Guidance and Its Implications**  
   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

6. **EU Language Requirements for Medical Device Labels: Regulation, Exception, and Risk**  
   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

10. **Technical Documentation Requirements for Device Approval in the EU**  
    Speaker: Tamas Borsai, Division Manager, MHS - Customer Service and Quality,