7:00-8:00 am Registration and Continental Breakfast

8:00-8:30 am Welcome and Workshop Introduction

8:30-9:00 am Risk Management Requirements 21 CFR 820, ISO 14971, EU MDR/IVDR

9:00-9:15 am Case Study Introduction and Overview – Instructions for first working session

9:15-10:00 am First Working Session – Using FDA database to identify potential product risks, failure modes and patient problems

10:00 – 10:30 am Refreshment Break

10:30-10:45 am Share Results of First Working Session

10:45 am-11:15 am Instructions for second working session

11:15-12:00 pm Second Working Session – Linking the RMF to labeling/IFU, Design Validation and Clinical Evaluation

12:00-1:00 pm Lunch Break

1:00-1:30 pm Share Results of the Second Working Session and Recap of Morning

1:30-1:45 pm Instructions for third working session

1:45-2:30 pm Third Working Session – Using the RMF in a Risk-based Approach to QMS and Operations

2:30-3:00 pm Refreshment Break

3:00-3:15 pm Share Results of Third Working Session

3:15-3:30 pm Instructions for third working session

3:30-4:15 pm Final Working Session – Linking Post-market Data to the RMF and Using RMF for Post-Market Decisions

4:15-4:30 pm Share Results of Final Working Session

4:30-5:00 pm Review of the Day: Tying It All Together

5:00 pm Adjourn