

VIRTUAL WORKSHOP

MEDICAL DEVICE RISK MANAGEMENT: IMPLEMENTING ISO 14971:2019



Tuesday, Dec. 1, 2020 · 10:00 a.m. - 4:30 p.m. EST | Presented by FDAnews and Ombu Enterprises

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10:00 AM **Overview of standards**

10:00 AM – 12:30 PM EST

The risk management file

10:00 AM – 12:30 PM EST

The risk management plan

10:00 AM – 12:30 PM EST

12:30 PM **Break**

12:30 PM - 1:30 PM EST

1:30 PM **Defining acceptable risk – the risk matrix**

1:30 PM - 2:45 PM EST

Risk analysis

1:30 PM - 2:45 PM EST

Risk evaluations

1:30 PM - 2:45 PM EST

Risk control

1:30 PM - 2:45 PM EST

2:45 PM **Break**

2:45 PM - 3:00 PM EST

3:00 PM

Overall residual risk evaluation

3:00 PM - 4:30 PM EST

Risk management review

3:00 PM - 4:30 PM EST

Production and post production

3:00 PM - 4:30 PM EST

Linkage to the EU-MDR

3:00 PM - 4:30 PM EST