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Engaging wiht the FDA - Submission Review

Thursday, 21 September 2023 11:20 (30 minutes)

Engaging with FDA: Radiation Master File Pilot, Submission Review, Responses, & Misconceptions

This session will build on last year's FDA mock Q-Submission session and cover several topics related to engaging with FDA.

1) The first topic will be an overview of FDA's Radiation Sterilization Master File Pilot Program. This program was initiated in April 2023 to pilot a novel way for FDA to support sterilization changes to PMA approved devices such as changing from gamma or ethylene oxide sterilization to x-ray or e-beam sterilization.

2) Next, there will be a panel discussion of some common questions and things to consider when submitting a premarket submission to FDA for a sterilization change to a medical device. The panel discussion will continue for the last set of topics in the session:

3) responding to FDA requests for information during submission review and some common questions and misconceptions about this part of the premarket review process.