FDA Question #1

If EtO sterilization is reduced, eliminated or replaced to a different sterilization modality, how can the impact to healthcare delivery organizations be minimized?

FDA Question #2

What can FDA do to help mitigate and prevent device shortages due to reduced device sterilization capabilities?

FDA Question #3

Can changing EtO sterilization cycles or sterilization loads reduce EtO use while maintaining effective sterilization? Can the panel provide a recommendation for which methods appear to be the most promising?

FDA Question #4

Can new or different methods of validating EtO sterilization cycles potentially result in a reduction of EtO use while still maintaining an effective sterilization process? If so, how?

FDA Question #5

Should sterilization of some medical devices to a less rigorous sterility assurance level (e.g. 10^{-5}, 10^{-4}, etc. instead of 10^{-6}) be considered as part of the approach to reduce sterilant use? How do you see this changing the patient risk profile for sterile devices if a different sterility assurance level is determined to be acceptable?

FDA Question #6

Are there existing large-scale industrial sterilization modalities that can take over a portion of the EtO sterilization performed for medical devices in the short or long term? If so can the panel provide a discussion of the path forward for these modalities? If not, what are the barriers and challenges preventing wider utilization of these modalities?