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?
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?
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?