



FDA Question #7

Are there alternative sterilization methods being developed that can take the place of EtO sterilization processes with respect to scalability and material compatibility? If so can the panel provide a discussion of the path forward for these modalities? If not, what are the barriers and challenges preventing large-scale industrial utilization of these modalities?

FDA Question #8



How can FDA help implement adoption of these EtO reduction or EtO replacement strategies and facilitate reduction of EtO emissions within our regulatory framework?

FDA Question #9



Can the panel identify devices or device types that would be difficult to sterilize without using EtO that may be amenable to the application of alternative sterilization modalities?

FDA Question #10



Does the panel have any other recommendations for reducing EtO risk without causing medical device shortages?