

Consultants Update

COVID-19

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July 15, 2020

Discussion Topics

- FDA Inspections
- New Medical Gas Regulations
- Medical Gas Shortages

FDA Inspections

- FDA announced its plans for resumption of domestic inspections
 - New risk assessment system – Phase of the state, county level statistics and intensity of infection
 - Three stages:
 - Mission critical inspections
 - Staff protection who have self-identified as being in a vulnerable population
 - Resumption of all regulatory activities.
 - Mostly preannounced – staff and employee safety
 - <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-prepares-resumption-domestic-inspections-new-risk-assessment-system>

Appropriate Medical Gas Regulations

- The new target deadline for a proposed rule is August 2021

Shortages

- US Public Health Service – revisiting the medical gas supply survey
 - Are you currently able to meet demand for your product(s) ?
 - Do you anticipate any demand increases and have you adjusted production or delivery schedules as a result ?
 - Is there an unavoidable supply disruption or a supply disruption that may be preventable?
 - What is the estimated date of onset of the interruption in manufacturing or supply disruption for this product? If a supply disruption has occurred, what is the estimated duration?
 - Is this product manufactured on multiple lines or in multiple facilities?
 - How much current inventory of product is at your facility or warehouse?
 - When will the last batch of finished product be released into distribution? Based on the current demand, how long do you expect the supply to last in the market without additional releases?

Contact Info

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