

# Consultants Update

## *COVID-19*

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# Discussion Topics

- FDA Update – CARES Act update
- Q&A – Why does the FDA send me registration and password reminders?
- Q&A – What grade of oxygen should be provided to a Life-Flight?
- Q&A – What are the requirements for medical gas liquid container connections?

# Coronavirus Aid, Relief, and Economic Security Act

- **Reporting –**
  - “...shall report annually to the Secretary on the amount of each drug listed...that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution.”
  - We are working with CGA and FDA to make this appropriate for medical gases
- **“Redundancy Risk Management Plan”** – We are also seeking clarification on this requirement.
- **Action needed?** - None right now

# Why does the FDA send me registration and password reminders?

- You are the official contact for important and routine communications
  - Food registration - password reminders
  - Drug and food registration – reminders about the registration period
- The official contact may also be notified to schedule an inspection or survey
- States may use a different official contact

# What grade of oxygen should be provided to a Life-Flight?

- Three Scenarios

- Pilots – Aviator Breathing Oxygen
  - Be sure you know the customers' requirements and they know your specifications (MilSpec, SAE, other)
- Patients – Medical Oxygen (USP)
  - Sold to a licensed healthcare provider
  - Patient prescription
- Emergency Use

# What grade of oxygen should be provided to a Life-Flight?

- Emergency Use

- 21 CFR 201.161 Medical gases.
- (a)(1)(i) In the case of oxygen, a warning statement providing that uninterrupted use of high concentrations of oxygen over a long duration, without monitoring its effect on oxygen content of arterial blood, may be harmful; that oxygen should not be used on patients who have stopped breathing unless used in conjunction with resuscitative equipment; and, in the case of oxygen that may be provided without a prescription for use in the event of depressurization or other environmental oxygen deficiency, or for oxygen deficiency or for use in emergency resuscitation when administered by properly trained personnel, a warning statement providing that oxygen may be used for emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation, and that for all other medical applications a prescription is required.

# What are the requirements for medical gas liquid container connections?

- FDA requirements 21 CFR 211.94 Drug product containers and closures.
  - (e) Medical gas containers and closures must meet the following requirements—(1) Gas-specific use outlet connections. Portable cryogenic medical gas containers that **are not manufactured with permanent** gas use outlet connections (e.g., those that have been **silver-brazed**) must have gas-specific use outlet connections that are attached to the valve body so that they **cannot be readily removed or replaced** (**without making the valve inoperable and preventing the containers' use**) except by the manufacturer.
  - For the purposes of this paragraph, the term “**manufacturer**” includes any individual or firm that **fills** high-pressure medical gas cylinders or cryogenic medical gas containers.

# What are the requirements for medical gas liquid container connections?

- CGA V-23—2020 (Formerly SB-26), *Standard For Cylinder Connections On Portable Cryogenic Liquid Cylinders*
  - Threaded or socket connection
  - Brazed (lead-free solder)
  - Welded
  - Attached by other tamper-resistant methods to the valve body in a manner that prevents removal or would render the connection or valve body outlet unusable if removal was attempted or accomplished
  - Permanent and integral part of the valve body.



# Examples



*This valve outlet connection is destroyed when it is removed*



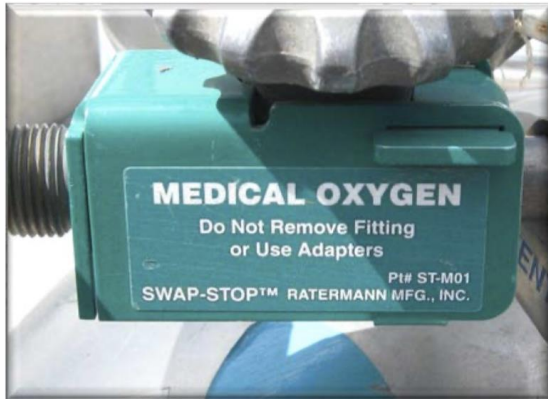
*OK for medical containers*



*OK for medical containers*

*This valve outlet connection is permanently silver-brazed*

# Examples



*OK for medical containers*

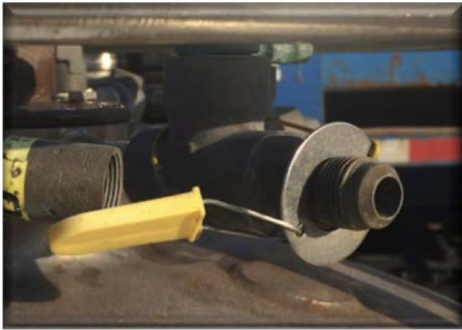
*This valve outlet connection is destroyed when it is removed*



**NOT** acceptable for  
medical containers

*Non-Compliant - This valve outlet connection can be removed with scissors*

# Examples



*NOT acceptable for  
medical containers*

*Non-Compliant - This valve outlet connection can be easily removed/damaged*



*NOT acceptable for  
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*Non-Compliant - This valve outlet connection can be easily removed/damaged*

# Examples



*NOT acceptable for  
medical containers*

*Non-Compliant - This valve outlet connection can be easily removed with a wrench*



*NOT acceptable for  
medical containers*

*Non-Compliant - This valve outlet connection can be easily removed with a wrench*

# Contact Info

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