

Consultants Update

COVID-19

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Discussion Topics

- *SB-26, Cylinder Connections on Portable Liquid Cryogenic Cylinders & CGA SA-36, Safety Alert, Cylinder and Cryogenic Container Issue Related to Cylinder Conversion and Filling During the COVID-19 Crisis*
- **FDA Food Production Inquiries**

Tamper Proof Connections – Cryogenic Containers

- CGA Safety Alert 36 introduced pandemic related considerations for temporarily adjusting our practices about using tamper-proof connections on medical cryogenic containers
- Increased the availability of containers for the anticipated medical oxygen requirements

Tamper Proof Connections – Cryogenic Containers

- If you implemented CGA SA-36 for medical oxygen containers, consider when to return to standard practices
- Self-audit



OK for medical containe

This valve outlet connection is destroyed when it is removed



OK for medical containers

This valve outlet connection is destroyed when it is removed



OK for medical containers

This valve outlet connection is permanently silver-brazed



NOT acceptable for medical containers

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



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/damaged

Resources

Medical Gas – CGMP Training for Drivers -

- 23 minute video presentation
- The FDA regulations (21 CFR 211) pertaining to medical gas container deliveries
- Recognizing medical gas labels
- Medical gas tamper-proof connections
- Quiz
- Certificate of participation.



Recognizing Tamper-Proof Fittings

- PDF with photos
- Quiz and Answer Sheet

FDA Food Production Inquiries

- Email from FDA
 - Subject: Re: Food and Drug Administration - Food Facility Registration questions
- Some simple questions and some intrusive questions
 - What is the number of full time/part time employees ...
 - What is the total annual sales for this facility (gross)?

FDA Food Production Inquiries

- In the past, the FDA has de-registered facilities... temporarily
- If you are not comfortable answering the questions, consider waiting two weeks
 - CGA/GAWDA communication with the agency

Contact Info

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