

Consultants Update

COVID-19

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Discussion Topics

- COVID-19 Resources
- Change of Grade (e.g. O₂ industrial -> USP)
- State Pharmacy Law Waivers
- Medical Oxygen Quick-Start
- Surveys

Resources

- GAWDA COVID-19 Resources
 - <https://www.gawda.org/member-only-documents/#128-covid-19>
 - Safety Alerts, Roundtables, White Papers, etc.
- CGA COVID-19 Online Toolkit
 - <https://www.cganet.com/resources/cga-covid-19-toolkit/>
- GAWDA/CGA Safety Program
 - <https://www.gawda.org/resources/cga-subscription-program/>
 - Free publications and eLearning resources

Change of Grade

- It **IS** possible to convert industrial grade oxygen to medical grade oxygen (HP & Liquid).
- The details are in CGA M-18, *Standard for the Change of Product and Change of Grade for High Pressure and Refrigerated Liquid Containers*.
 - <https://portal.cganet.com/Publication/Details.aspx?id=M-18>
- For example - section 6.2 in M-18 has the process steps for converting from industrial grade oxygen to medical grade oxygen service:
 - Identification
 - Odor test
 - Valve removal, internal inspection and revalving
 - Purging/evacuation/pressurization
 - Filling
 - Testing for conformance
- See CGA M-18 for the details/specifications of each step.

State Pharmacy Law Waivers

- Out-of-State Suppliers - ability to receive drugs from a legitimate out-of-state supplier (not licensed in CA, OH, PA)
 - Details and conditions vary
- Ohio
 - Expedited out-of-state licensing

Medical Gas Quick-Start

- If you need to start pumping or distributing medical oxygen...
 - Distribution Only:
 - Written SOPs
 - CGMP Training
 - State Licensure
 - Pumping (Manufacturing), all above plus:
 - FDA Registration/Listing
 - Labels
 - Liquid O₂ USP in your bulk tank

Surveys

Survey

1. IPA/EA Suppliers

- If you are having difficulty sourcing isopropyl alcohol or ethanol, email tom@asteriskllc.com
- If you have a reliable source, email tom@asteriskllc.com

2. CGA Survey Link:

<https://www.surveymonkey.com/r/GAWDACovid19>

Surveys

CGA Survey - Identify potential and emerging issues

1. Are you anticipating the inability to **meet the demand** for medical or food gases (e.g., oxygen, nitrogen, carbon dioxide, etc.)?
2. Are you anticipating a **shortage of critical equipment** (e.g., cylinders, valves, regulators, other cylinder apparatus, liquid containers, tanks, vaporizers, etc.)?
3. Are you experiencing any **regulatory roadblocks** with the manufacture, transportation or use of your products?
4. Are there any **issues related to the COVID-19 crisis in which CGA is currently not engaged** with, but which you believe CGA should engage?

Contact Info

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