

FDA Public Workshop
Medical Gas Regulation: Public Workshop I
 February 9, 2018

FDA White Oak Campus, Great Room (*Building 31 Conference Center, Room 1503*)
 10903 New Hampshire Avenue, Silver Spring, MD 20993
 (UPDATED: webcast URL: <https://collaboration.fda.gov/mgrpw2018/>)

Final Agenda

Time	Activity	Speaker(s)
8:00-9:00am	<i>Registration</i>	N/A
9:00-9:05am	Welcome and Opening Remarks	Christine Kirk Regulatory Counsel Office of Regulatory Policy, CDER, FDA
9:05-9:15am	Goals for Second Public Workshop	
9:15-9:30am	Introduction of FDA panel (morning panelists)	FDA Moderator and Panelists
9:30-10:45am	Post-Market Reporting of Adverse Drug Experiences	
	--Moderator Overview	FDA Moderator
	--Stakeholder Presentation(s) and Panel Reaction	<ul style="list-style-type: none"> ◦Michael Tiller President and CEO ◦John Willenbrock Technical Manager ◦Compressed Gas Association (CGA)* (*Also presenting on behalf of the Gases and Welding Distributors Association (GAWDA); additional CGA members may provide portions of the presentation). ◦Other Stakeholder Comments, if any (no other registered presenters) ◦FDA Panelists
10:45-11:00am	<i>Morning Break</i>	
11:00am-12:00pm	Other Post-Market Reporting and Certification Process for Designated Medical Gases	
	--Moderator Overview	FDA Moderator
	--Stakeholder Presentation(s) and Panel Reaction	<ul style="list-style-type: none"> ◦Mr. Tiller and Mr. Willenbrock, CGA ◦Other Stakeholder Comments ◦FDA Panelists
12:00-1:00pm	<i>Lunch</i>	
1:00-1:10pm	Introduction of FDA panel (afternoon panelists)	FDA Moderator and Panelists
1:10-2:30pm	Registration and Listing and Other Issues (e.g., Medical Gases and Medical Devices; Medical Gases for Use in Animals; Workshop I Follow-Up)	
	--Moderator Overview	FDA Moderator
	--Stakeholder Presentation(s) and Panel Reaction	<ul style="list-style-type: none"> ◦Mr. Tiller and Mr. Willenbrock, CGA ◦Other Stakeholder Comments ◦FDA Panelists
2:30-2:45pm	<i>Afternoon Break</i>	
2:45-4:30pm*	Continue Discussion	Stakeholders and FDA Panelists
4:30-5:00pm*	Next Steps and Closing Remarks	
5:00pm*	<i>Adjourn</i>	

*The last discussion session may end early. If so, the next steps, closing remarks, and adjournment will also be earlier.