FDA CDRH General Hospital and Personal Use Devices Panel Advisory Committee Meeting

November 6 – 7, 2019
DoubleTree by Hilton Grand Ballroom
Washington DC North/Gaithersburg
620 Perry Pkwy.
Gaithersburg, MD 20877

The Food and Drug Administration (FDA) is convening the General Hospital and Personal Use Devices Panel (the Panel) for the purposes of obtaining recommendations about strategies to reduce or eliminate environmental ethylene oxide (EtO) emissions secondary to medical device sterilization. EtO emissions are an environmental health concern and emissions greater than EPA allowable limits may trigger EtO sterilization facility closure limiting sterilization processing capacity for medical devices. This could potentially lead to medical device shortages. FDA is holding this panel meeting to obtain input on how to reduce EtO environmental emissions without compromising assurance of sterility of medical devices.

AGENDA Day 1 – Reduction or Elimination of Ethylene Oxide Emissions for Medical Device Sterilization

8:00 a.m.	Call to Order, Opening Remarks, and Introduction of the Committee	Frank Lewis, M.D., FACS Panel Chair
8:10 a.m.	Conflict of Interest Statement	CDR Patricio Garcia, M.P.H. Designated Federal Officer

Introduction and International Perspective

8:15 a.m.	FDA/CDRH Opening Remarks	Ryan Ortega, Ph.D. Center for Devices and Radiological Health (CDRH) Food and Drug Administration (FDA)
8:25 a.m.	EPA/OAQPS Opening Remarks	Mike Koerber Deputy Director, Office of Air Quality Planning and Standards (OAQPS) Environmental Protection Agency (EPA)
8:35 a.m.	CDC/ATSDR Opening Remarks	Chris Reh, Ph.D. Associate Director, Agency for Toxic Substances and Disease Registry (ATSDR) Centers for Disease Control and Prevention (CDC)
8:45 a.m.	UK perspective on industrial EtO medical device sterilization	Andrew Bent BEng (Hons), CSci, MTOPRA Devices Division Medicines & Healthcare products Regulatory Agency (MHRA)

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AGENDA – Reduction or Elimination of Ethylene Oxide Emissions for Medical Device Sterilization

FDA's Oversight of Medical Devices and their Sterility

8:55 a.m.	Shortage of Ethylene Oxide Sterilized Medical Devices: CDRH's Role	Adam Saltman, M.D., Ph.D. US FDA/CDRH
9:05 a.m.	Shortage of Industrial Ethylene Oxide Sterilized Medical Devices: Clinical Impact	Karoll Cortez, M.D. US FDA/CDRH
9:15 a.m.	Overview of Industrial Ethylene Oxide Sterilization	Steven Elliott, M.S. US FDA/CDRH
9:25 a.m.	How FDA reviews sterilization information in premarket regulatory submissions for medical devices	Christopher Dugard, M.S. US FDA/CDRH
9:35 a.m.	Clarifying questions from the Panel	
9:55 a.m.	*Break*	

Impact of contract sterilization on medical device supply chains

10:10 a.m.	Manufacturer perspective of medical device supply chains and device sterilization	Mark Leahy, J.D. Medical Device Manufacturers Association (MDMA)
10:20 a.m.	Group purchasing organization perspective of medical device supply chains and shortages due to loss of sterilization capacity	David Gillian Vizient
10:30 a.m.	Healthcare delivery organization perspective of potential impact on patients due to loss of medical device sterilization capacity	Kara Mascitti, M.D. St. Luke's University Health Network

Reducing Ethylene Oxide Emissions for Medical Device Sterilization

10:40 a.m.	Overview of EtO sterilization process and engineering to optimize EtO use	Phil Cogdill Medtronic
11:00 a.m.	Reduction of EtO emissions by changing cycle design and validation methods	Brian McEvoy B.Sc., MBA and William Brodbeck, Ph.D. STERIS Applied Sterilization Technologies

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11:20 a.m.	Reducing EtO use in sterilization cycles by changing sterilization load configuration	Denny Christensen SVC Inc.
11:40 a.m.	Flexible chamber EtO sterilization	A. E. Ted May Andersen Sterilizers, Inc. and William Andersen, M.D., FAAOS Andersen Products, Inc.
12:00 a.m.	Clarifying questions from the Panel	
12:30 p.m.	*Lunch*	

Open Public Hearing

1:30 p.m.	Open Public Hearing
2:00 p.m.	Clarifying questions from the Panel

Elimination of Ethylene Oxide Emissions for Medical Device Sterilization: Modalities with Existing Industrial Infrastructure

2:10 p.m.	Gamma sterilization of medical devices	Emily Craven Mevex
2:30 p.m.	X-ray and e-beam based industrial sterilization methods	Thomas Kroc, Ph.D. Fermilab
2:50 p.m.	Moist and dry heat sterilization of medical devices	Jonathan Wilder, Ph.D. Quality Processing Resource Group, LLC
3:10 p.m.	Clarifying questions from the Panel	
3:40 p.m.	*Break*	

Open Public Hearing

3:50 p.m.	Open Public Hearing
4:20 p.m.	Clarifying questions from the Panel

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FDA questions regarding impact to the medical device ecosystem and optimization of EtO (reducing emissions), followed by panel deliberation

4:30 p.m.	FDA Questions 1 - 6
4:35 p.m.	Panel Deliberation
6:00 p.m.	Adjourn Day 1

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AGENDA – Reduction or Elimination of Ethylene Oxide Emissions for Medical Device Sterilization

AGENDA Day 2 – Reduction or Elimination of Ethylene Oxide Emissions for Medical Device Sterilization

8:00 a.m.	Call to Order and Opening Remarks	Frank Lewis, M.D., FACS Panel Chair
8:05 a.m.	Conflict of Interest Statement	CDR Patricio Garcia, M.P.H. Designated Federal Officer
8:15 a.m.	Day 1 Summary and Overview of Day 2	Clarence Murray, III, Ph.D. US FDA/CDRH
	Elimination of Ethylene Oxide Sterilization Emissions for Medical Device Sterilization: Modalities with Unknown Industrial Infrastructure	
8:20 a.m.	Hydrogen Peroxide	Sylvie Dufresne, Ph.D. Partner, IM3 Consulting Group
8:40 a.m.	Nitrogen Dioxide	David Opie, Ph.D. Noxilizer
9:00 a.m.	Chlorine Dioxide	Paul Lorcheim, P.E. ClorDiSys Solutions Inc
9:20 a.m.	Vaporized Peracetic Acid and Other Chemicals	Joe McDonald, Ph.D. Life Sciences Division Cantel Medical
9:40 a.m.	Healthcare sterilization of medical devices	Sue Klacik International Association of Healthcare Central Service Materiel Management
10:00 a.m.	Clarifying questions from the Panel	
10:20 a.m.	*Break*	
	FDA questions regarding possible alternatives to EtO, followed by panel deliberation	
10:30 a.m.	FDA Questions 7 - 10	
10:35 p.m.	Panel Deliberation	
11:35 p.m.	Lunch	

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Agenda Day 2 - Reducing the Risk of Infections from Reprocessed Duodenoscopes

12:30 pm	FDA Presentation	Shani Haugen, PhD
1:10 pm	Clarifying Questions from the Panel	
1:20 pm	Open Public Hearing	
	• Combined Nursing Professional Societies – Association of perioperative Registered Nurses (AORN); Society of Gastroenterology Nurses and Associates (SGNA)	Erin Kyle, DNP, RN, CNOR, NEA-BC and Catherine Bauer, MSN, MBA, RN, CGRN, CFER
	• Healthmark Industries	Jahan Azizi, Mary Ann Drosnock, and John Whelan, BSN, RN
	• Providence St. Joseph Health System	Rebecca Bartles, MPH, CIC, FAPIC and Jack Brandabur, MD
	• The Joint Commission	Sylvia Garcia-Houchins, MBA, RN, CIC
1:50 pm	Guest Speaker Presentation – Endoscopes: Reprocessing Challenges and Quality Assurance	Michelle Alfa, PhD, FCCM
2:05 pm	Guest Speaker Presentation – Human Factors and Quality Assurance	Cori L. Ofstead, MSPH
2:20 pm	Clarifying Questions from the Panel	
2:30 pm	*Break*	
2:40 pm	Perspectives from Stakeholder Professional Societies	
	• Combined Physician Gastrointestinal Professional Societies – American College of Gastroenterology (ACG); American Gastroenterological Association (AGA); American Society for Gastrointestinal Endoscopy (ASGE); Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)	Michael L. Kochman, MD, and Bret T. Petersen, MD
	• International Association of Healthcare Central Service Materiel Management (IAHSCMM)	Susan Klacik
	• Combined Infection Management Professional Societies – Association for Professionals in Infection Control and Epidemiology (APIC); Infectious Diseases Society of America (IDSA); Society for Healthcare Epidemiology of America (SHEA)	Michael Anne Preas, MS, RN, CIC, FAPIC

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AGENDA Day 2 – Reducing the Risk of Infections from Reprocessed Duodenoscopes

3:10 pm	Perspectives from Device Manufacturers	
	• FUJIFILM Medical Systems U.S.A., Inc.	Randy Vader
	• Olympus Corporation of the Americas	Ross Segan, MD, MBA, FACS
	• PENTAX Medical	J. Hudson Garrett Jr., PhD, MSN, MPH, FNAP
	• Ambu Inc.	Patrick Hurley, PhD
	• Boston Scientific Corporation	Brian J. Dunkin, MD
3:50 pm	Clarifying Questions from the Panel	
4:00 pm	Panel Deliberation	
5:30 pm	Adjourn	