CGA

Compressed Gas Association

The Standard For Safety Since 1913

CGA M-2—2021

STANDARD FOR THE MANUFACTURE OF MEDICAL GASES CLASSIFIED AS DRUGS

THIRD EDITION

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Work Item 17-020
Medical Gases Committee

NOTE—Technical changes from the previous edition are underlined.

NOTE—Appendix A (Informative) is for information only.

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SECOND EDITION: 2013
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1 Introduction

This publication is a standard for compliance with the applicable regulations of the U.S. Food and Drug Administration (FDA) for the manufacture of compressed medical gases (CMG) classified as drugs as described in Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) [1].[1] It outlines the requirements for manufacturing CMGs classified as drugs; however it may not contain all information necessary to comply with FDA regulations. It is the responsibility of each CMG manufacturer to ensure that their standard operating procedures (SOP) comply with all applicable federal, state, and local regulations.

2 Scope

This publication applies to firms that engage in the filling, repackaging, transfilling, mixing, and/or re-labeling of CMG classified as drugs by the FDA and applicable state agencies. Although it is primarily intended for firms engaged in the CMG manufacturing processes, portions may apply to firms that only distribute CMG classified as drugs.

This publication is intended to address current good manufacturing practice (CGMP) requirements for:

- designated medical gases as defined in Section 575(1) of the Federal *Food Drug and Cosmetic Act* (Act) or combinations thereof; and
- other medical gases as defined in Section 575(2) of the Act that may be approved via a new drug application (NDA) or abbreviated new drug application (ANDA) for which the sponsor has shown through a science based risk management plan that this publication provides appropriate CGMPs [2].

Throughout this standard, the terms CMG, medical gas or medical gases are used to refer to these categories of products.

This publication does not apply to:

- bulk air separation (oxygen, USP and nitrogen, NF) manufacturing and distribution facilities;
- bulk carbon dioxide USP manufacturing and distribution facilities;
- bulk helium USP manufacturing and distribution facilities;
- bulk nitrous oxide USP manufacturing and distribution facilities;

  NOTE—For information about bulk medical gases classified as drugs, See CGA M-3, *Standard for the Manufacturer of Bulk Medical Gases* [3].

- refrigerated liquid oxygen USP that is filled at a patient's residence or is filled, repackaged, transfilled, and/or relabeled by home respiratory care companies;
- medical gases classified by FDA as medical devices as defined by the Act [2]; or
- drugs that are defined as Investigational New Drug Applications, e.g., a gas or gas mixture that has never been previously used as a drug, NDAs, or ANDAs by the Act [2].

See the *United States Pharmacopeia and National Formulary (USP–NF)* for information on the USP and NF designations for medical gases [4].

NOTE—Gases such as, diving gases, U.S. Occupational Safety and Health Administration (OSHA) regulated breathing air, aviator's breathing oxygen, although inhaled are not medical gases.

[1] References are shown by bracketed numbers and are listed in order of appearance in the reference section.