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CGA M-11—2021

GUIDELINE FOR COMPLIANCE WITH THE QUALITY SYSTEMS APPROACH TO CURRENT GOOD MANUFACTURING PRACTICES

THIRD EDITION

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Work Item 19-059
Medical Gases Committee

NOTE—Technical changes from the previous edition are underlined.

THIRD EDITION: 2021
SECOND EDITION: 2014
FIRST EDITION: 2008

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1 Introduction

This publication is intended to help manufacturers implement modern quality systems and risk management processes and to incorporate quality by design principles that meet the current good manufacturing practices (CGMP) requirements in Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) Parts 210, 211, 820 [1].[1] An effective quality system helps to ensure compliance to guidance and regulation.

While the FDA's *Guidance for Industry Quality Systems Approach to Pharmaceutical CGMP Regulations* does not contain regulatory requirements, it represents the FDA's latest thinking on quality systems and provides recommendations for compliance with the CGMP regulations [2]. Companies shall refer to 21 CFR to ensure they are in full compliance with the regulations [1]. The guidance is also aligned with the medical devices quality system's regulations (21 CFR Part 820).

2 Scope

This publication provides guidance on how a medical gas, device gases, and device manufacturers can implement the quality systems approach to meet requirements of 21 CFR Parts 210, 211, and 820 [1].

3 Definitions

For the purpose of this publication, the following definitions apply.

3.1 Publication terminology

3.1.1 Shall
Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should
Indicates that a procedure is recommended.

3.1.3 May
Indicates that the procedure is optional.

3.1.4 Will
Is used only to indicate the future, not a degree of requirement.

3.1.5 Can
Indicates a possibility or ability.

4 Current good manufacturing practices and modern quality system principles

4.1 Quality

Medical drug and device gas quality is achieved by establishing and following policies and procedures to ensure the identity, strength, purity, and other quality requirements for a medical gas product. The quality attributes for designated medical gas products (oxygen, nitrogen, medical air, nitrous oxide, carbon dioxide, helium) are defined in the *United States Pharmacopeia* (USP) and *National Formulary* (NF) monographs [3].

Medical device quality is achieved by establishing and following policies and procedures to ensure the totality of features and characteristics impacting the ability of a device are met in a way that satisfies the intended use of the device, including safety and performance requirements.

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