CGA

Compressed Gas Association

The Standard For Safety Since 1913

CGA M-16—2022

STANDARD FOR FOOD, DRUG, & MEDICAL DEVICE GAS & GAS EQUIPMENT MANUFACTURERS ON ELECTRONIC RECORDS & SIGNATURES

SECOND EDITION

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NOTE—Technical changes from the previous edition are underlined.

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Contents **Page**

1 Introduction

This publication discusses the general requirements for bulk and packaged gas operations manufacturing and filling medical (drug or device) or food grade gases that are required to comply with the electronic record and electronic signature requirements found in Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) Part 11 and Pharmaceutical Inspection Co-operation Scheme (PIC/S) *Guide for good manufacturing practice for medicinal products*, Annex 11 "Computerised Systems" [1, 2].[1] Additional publications may be developed to address in greater detail the requirements of certain sub-systems that utilize electronic records and electronic signatures.

2 Scope

This publication is based on FDA's August 2003 *Guidance for Industry Part 11, Electronic Records; Electronic Signatures—Scope and Application* and satisfies the criteria of 21 CFR Part 11, § 11.1 (a) "The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper" [3, 2].

This publication also harmonizes with PIC/S *Guide for good manufacturing practice for medicinal products*, Annex 11 "Computerised Systems" (as adopted in Canada) [2].

NOTE—These regulations and guidance will be referred to as e-Regs in this publication.

In addition to the guidance in this publication, see CGA M-27, *Guideline for Complying with Data Integrity Regulatory Expectations,* for more information on compliance with data integrity requirements for medical gases [4].

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 whenever 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.

3.2 Technical definitions

3.2.1 Computer system
Includes hardware, software, and firmware.

3.2.2 Computerized systems
Includes computer system plus the function or process that is being controlled.

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