CGA

Compressed Gas Association

The Standard For Safety Since 1913

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GUIDELINE FOR COMPLYING WITH DATA INTEGRITY REGULATORY EXPECTATIONS

FIRST EDITION

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1 Introduction

Both the U.S. Food and Drug Administration (FDA) and Health Canada (HC) have developed guidance documents for their respective current expectations for data integrity to comply with respective Current Good Manufacturing Practices (CGMP) requirements. In the United States, see *Data Integrity and Compliance with CGMP Guidance for Industry* and in Canada, see Health Canada Guidance Document GUI-0001, *Good manufacturing practices guide for drug products* [1, 2].[1]

2 Scope and purpose

2.1 Scope

This publication provides guidance and acceptable practices for the medical gas industry to comply with data integrity. It identifies the acquisition and retention of data obtained to assure it is complete, consistent, accurate, attributable, contemporaneously recorded, and auditable regardless of the form in which it is obtained and maintained.

This publication does not address what data is acquired during the manufacturing and testing of medical gases.

2.2 Purpose

The purpose of this publication is to outline how the medical gas industry complies with the data integrity guidance documents.

Data integrity principals apply to both paper-based and electronic records considering the ALCOA concepts (Attributable, Legible, Contemporaneous, Original, Accurate) as further detailed in the following:

- Attributable—It shall be possible to identify the individual who performed the recorded task;
- Legible—All records shall be legible – the information shall be readable;
- Contemporaneous—The evidence of actions, events or decisions should be recorded as they take place serving as an accurate attestation of what was done, or what was decided and why;
- Original—The original record can be described as the first-capture of information or true copy, whether recorded on paper or electronically; and
- Accurate—Error free records are achieved through many elements of the quality management system (QMS).

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.

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

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