CGA

Compressed Gas Association

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GUIDELINE FOR COMPLIANCE WITH THE QUALITY SYSTEMS APPROACH TO PHARMACEUTICAL CGMPS

SECOND EDITION

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1 Introduction

The last major revision to the current good manufacturing practices (CGMP) occurred in 1978. Since then quality standards, manufacturing techniques, and quality systems have evolved significantly. To encourage the pharmaceutical industry to use modern manufacturing techniques and quality system methodologies, the U.S. Food and Drug Administration (FDA) introduced its Pharmaceutical CGMPs for the 21st Century Initiative in August 2002.

The quality systems guidance is intended to help manufacturers implement modern quality systems and risk management processes and to incorporate quality by design principles that meet the CGMP requirements in Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) Parts 210 and 211 [1].[1] An effective quality system will reduce the risk of manufacturing problems resulting in inspections that are shorter and less frequent.

The guidance does not contain regulatory requirements. It represents the FDA's latest thinking on quality systems and provides recommendations for compliance with the CGMP regulations. The guidance is not meant to replace the CGMP requirements. Companies shall refer to 21 CFR to ensure they are in full compliance with the regulations [1].

The guidance is harmonized with the medical devices quality system's regulations (21 CFR Part 820) as well as other quality standards such as ISO 9001:2008, *Quality management systems–Requirements* [2]. The guidance mirrors the ISO 9001:2008 standard. If a medical gas manufacturer is currently ISO 9001:2008 registered, that manufacturer most likely satisfies the quality systems approach of the guidance.

The quality system model of the guidance is organized into four sections that are similar to the ISO 9001:2008 sections. Table 1 contains a listing of the four sections of the model and the corresponding ISO 9001:2008 sections.

Table 1—Quality system's model related to ISO 9001:2008 sections

Sections of the quality system model	ISO 9001:2008 section
Management responsibilities	Section 5 – Management responsibility
Resources	Section 6 – Resource management
Manufacturing operations	Section 7 – Product realization
Evaluation activities	Section 8 – Measurement, analysis, and improvement

2 Scope

This publication provides guidance on how a medical gas manufacturer can implement the quality systems approach to meet requirements of 21 CFR Parts 210 and 211 [1]. It is based on a review of the FDA's September 2006 *Guidance for Industry Quality Systems Approach to Pharmaceutical CGMP Regulations* [3].

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. Shall is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should

Indicates that a procedure is recommended.

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