CGA

Compressed Gas Association

The Standard For Safety Since 1913

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GUIDELINE FOR DETERMINING PHARMACOVIGILANCE REPORTING REQUIREMENTS IN NORTH AMERICA (FOR THE U.S. & REFERENCE FOR CANADA)

FIRST EDITION

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1 Introduction

In many countries, mandatory regulatory worldwide systems for companies manufacturing medicinal products or manufacturing/providing medical devices, e.g., European Union (EU), United States, and Canada, require an effective pharmacovigilance system within the company.

For globally based medical gas organizations, these systems typically involve coordination within an applicable company to have a centrally located department that manages the global reporting requirements and coordinates the flow of information from the field to each region, then supports the decision making and reporting efforts of the regions to their local regulatory agencies and globally, if appropriate.

A detailed explanation of the reporting requirements in North America (U.S. & Canada) will show the regional responsibilities for global organizations as well as specific reporting requirements for independent companies operating within one country that are not part of a global organization.

In Canada, medical gases considered drugs require a marketing authorization that is similar to the European model.

In the United States, with the passage of the *Food and Drug Administration Safety and Innovation Act* (FDASIA) in 2012, most of these medical gases became approved drugs under a "certification" process. These newly designated drugs were never evaluated through a traditional Clinical Trial New Drug Application (NDA) process and therefore do not technically fit the criteria of 21 CFR Part 314 "Applications for FDA Approval to Market a New Drug" and more specifically, the U.S. reporting requirements of Section 314.80 "Postmarketing reporting of adverse drug experiences" and Section 314.81 "Other postmarketing reports" [2].

The medical gas industry understands the intent of both the U.S. Food and Drug Administration (FDA) and Health Canada to maintain an awareness of potential adverse events that might indicate a need for special focus and attention. To satisfy this intent, CGA has developed this guideline for the industry to provide guidance on how to satisfy the U.S. reporting requirements of 21 CFR Parts 314.80 and 314.81 [2]. This publication will also serve as a reference for reporting similar events in Canada.

2 Scope

This publication provides guidance for pharmacovigilance reporting to FDA and acts as a reference for Health Canada pharmacovigilance reporting. This guidance is intended to aid companies that market medical gases classified as drugs in the United States or Canada in setting up a pharmacovigilance (drugs) reporting system that satisfies local and regional regulatory requirements, bearing in mind any global requirements when applicable.

Although both reporting for drugs and devices is required, this publication only addresses medical gases classified as drugs (pharmacovigilance) and does not address reporting requirements for gases or medical gas equipment classified as medical devices (materiovigilance).

2.1 United States

In the United States, this publication should be used as a guideline for companies to comply with 21 CFR Part 314 [2].

2.2 Canada

In Canada this publication may only be used for a reference.

The *Food and Drug Regulations*, more specifically sections C.01.016 to C.01.020, C.08.007 (h) and C.08.008 (c), set forth regulatory requirements for manufacturers, including but not limited to, the reporting of adverse drug reactions (ADR) and the reporting of unusual failures in efficacy of new drugs to Health Canada [3].

In 2004 Health Canada implemented an inspection program for Good Pharmacovigilance Practices (GVP) (known at that time as Post-Market Reporting Compliance). The GVP inspection program is intended to verify that the manufacturer meets the requirements of sections C.01.016 to C.01.020, C.08.007 (h) and C.08.008 (c)