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Rajaram Balasubramanian, RAC-US, RAC-EU, PMP
Director, Regulatory Affairs and Quality Assurance, TIMEA
Elekta Medical Systems India Pvt Ltd
India
Chapters 9 and 10

Karen Fan, MSc, RAC, Peng, PMP
EU MDR Consultant
Johnson & Johnson Surgical Vision Inc.
Canada
Chapter 3

Anu Gaur, PhD, MBA, MSRA, RAC-US, RAC-Global
President
SYNERGY Global Regulatory Affairs Consultancy, Inc.
US
Lead Editor, Preface, and Chapter 1

Michelle Jump, MSc, RAC
CEO
MedSec
US
Chapter 18

Barbara Leukers, Dipl. Chem (FH), RAC
Consultant
Leukers-Consulting
Germany
Chapter 8

Shikha Malik, MPharm, MS, RAC-Devices
Senior Regulatory Affairs Specialist
Medtronic
US
Chapter 2

Cathy Matthews, MSc
Regulatory Affairs Specialist
Edwards Lifesciences Canada Inc.
Canada
Chapter 4

Sharon Perez, PhD
Vice President, Global Medical Safety
Novocure
US
Chapters 11 through 17

Sharad Mi Shukla, RAC-US, RAC EU
Director Regulatory Affairs MedTech
Johnson & Johnson
Singapore
Chapters 9 and 10

Julia Stindl, PhD
Head of Global Post-Market Safety
Novocure
Germany
Chapters 11, 12, 13, 16, and 17

Ana Subramanian, MSc, PhD, RAC
Canada
Chapters 6 and 8

Echo Yu, MSc, RAC-Global
QA/RA Director
Sinocare Meditech, Inc.
Canada
Chapter 7

Karen Zhou, JD, MS, RAC-Devices, RAC-Global
Faculty, MS Regulatory Affairs Program
Northeastern University
Canada
Lead Editor, Preface, and Chapter 5

SECTION

I

North America: United States and Canada

1 Postmarket Compliance and Product Changes: US

By Anu Gaur, PhD, MBA, MSRA, RAC-US, RAC-Global

Introduction

In the US, the legislative requirements set forth in Section 522 of the Food, Drug, and Cosmetics Act (FD&C Act) mandate postmarket surveillance for medium (Class II) and high-risk (Class III) medical devices. The US Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) is responsible for protecting and promoting the public health by ensuring timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products for healthcare.[1]

In general, postmarket surveillance refers to the monitoring process for legally marketed medical products, which constitutes an active, systematic, and scientifically valid collection of data related to their intended clinical use, data analysis, and its interpretation for safety and performance outcomes. In this process, the monitoring of postmarket product-related adverse events (AEs), including their frequency, occurrence, and severity, applies to any product-related safety concerns, public health impact, and justification for a medical device's safety, performance, and efficacy.

FDA requirements for medical device reporting were enacted in December 1984. However, the US Congress first granted FDA the authority to enforce and require certain medical device manufacturers to conduct postmarket surveillance, per Section 522 of the Safe Medical Devices Act (SMDA) of 1990. The SMDA further provided FDA with two additional postmarket activities, including:

1. Postmarket surveillance for the monitoring of products after their market clearance
2. Device tracking for maintaining traceability of certain devices to the user level

Section 212 of the Food and Drug Modernization Act (FDAMA) of 1997 further amended the Section 522 in part to stipulate that the postmarket surveillance may be required by order for any Class II or Class III device the failure of which would be reasonably likely to have serious adverse health consequences, which is intended to be implanted in the human body for more than one year, or which is a life-sustaining or life-supporting device used outside a device user facility.[2-4]

Under Section 212 of FDAMA, FDA is authorized to require a prospective surveillance period of up to 36 months, unless FDA determines a longer period is necessary, and there is a mutual agreement between FDA and the