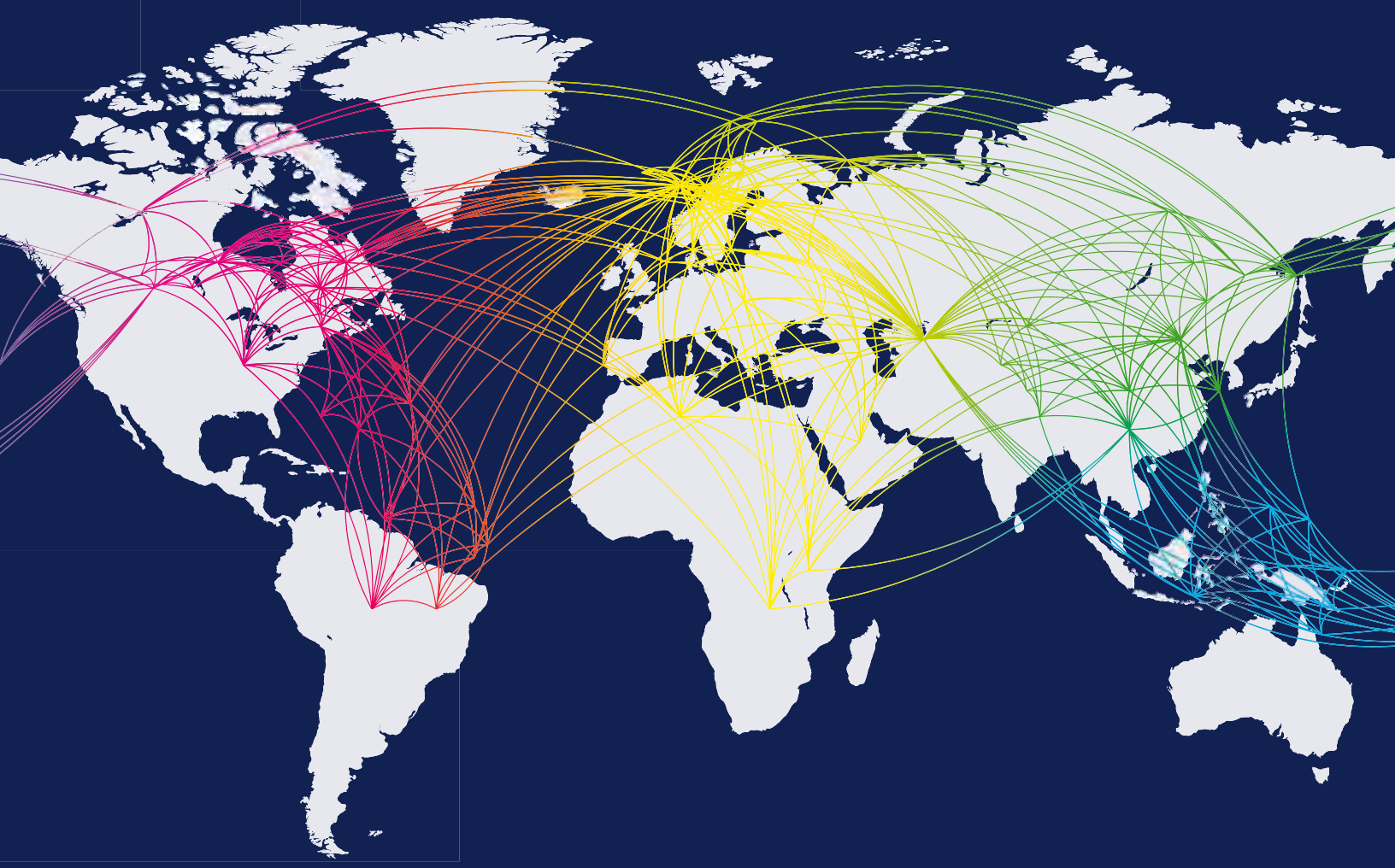
AAMI
Advancing Safety in Health Technology

# The Quality System Compendium

## *CGMP Requirements and Industry Practice*

FOURTH EDITION



*Jack Ward, Technical Editor*
*With contributions from FDA and Industry*

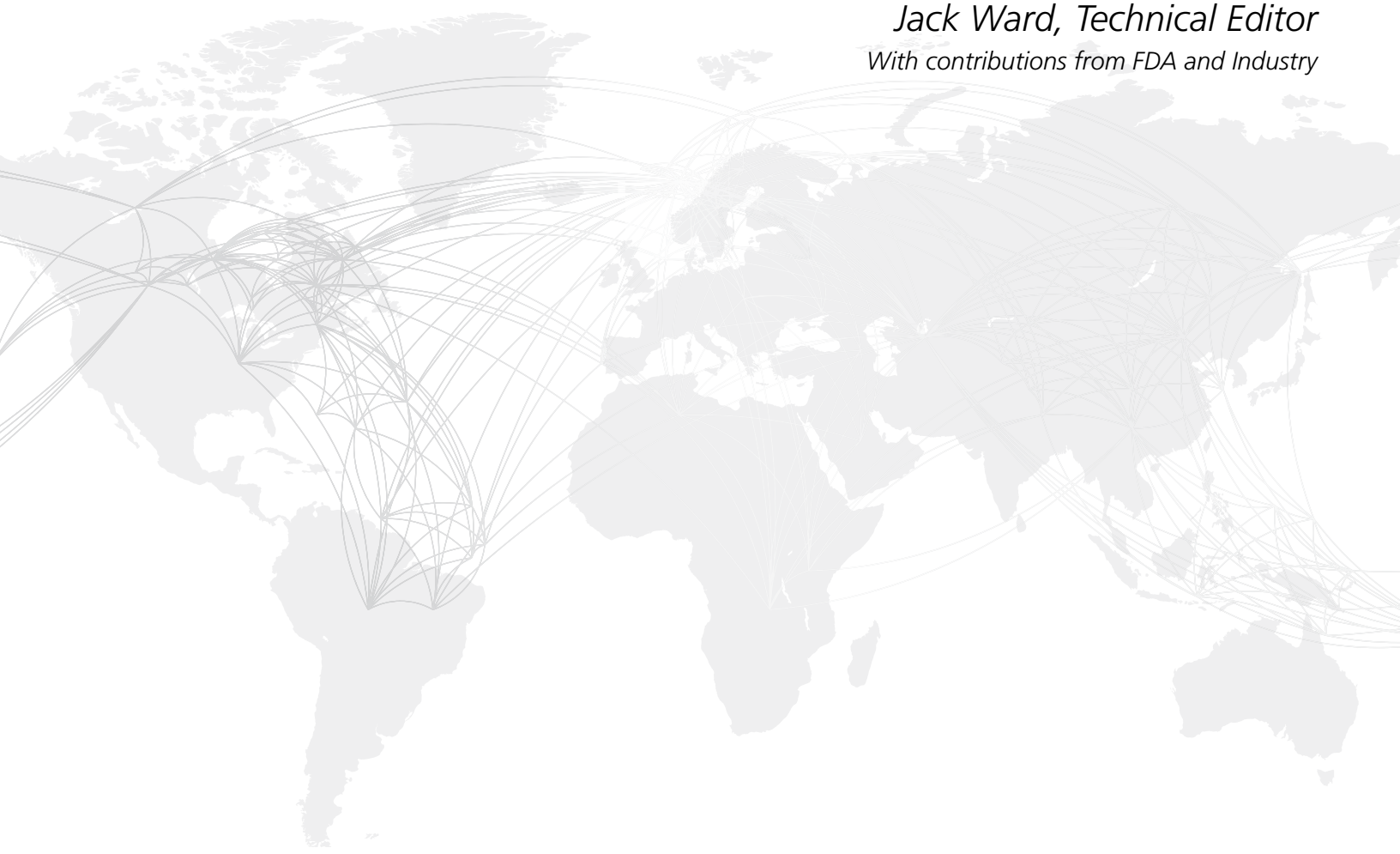
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# Foreword and Acknowledgments

The Association for the Advancement of Medical Instrumentation (AAMI) is a diverse community of nearly 7000 healthcare technology professionals united by one important mission—supporting the healthcare community in the development, management, and use of safe and effective medical technology. As a part of its mission, AAMI offers numerous courses on various aspects of the safe design, manufacturing, and use of medical devices. *The Quality System Compendium: CGMP Requirements and Industry Practice* serves as the basis for AAMI's intensive course titled "The Quality System Regulation 21 CFR 820 and ANSI/AAMI/ISO 13485: Navigating Regulatory Requirements," which presents the requirements of the Quality System (QS) Regulation, ISO 13485:2016, and the Medical Device Single Audit Program (MDSAP).

The first edition of *The Quality System Compendium: CGMP Requirements and Industry Practice* was published in 1996. That edition presented the best industry practices at the time and was based on the collective wisdom of the foremost experts on the QS Regulation from all related disciplines, including Food and Drug Administration (FDA) staff, corporate representatives, and leading industry consultants. The *Supplement to the Quality System Compendium* was published in 2004. It provided updated information on FDA's organizational structure, international quality system standards, and new information concerning industry practices for managing electronic records and signatures, process validation, and software validation. The second edition of the *Compendium* combined the previous two books and expanded on their content.

The 2015 third edition of the *Compendium* documented the substantial changes in medical device technology, medical device regulatory approaches, and FDA and international guidances and standards that had occurred since the 2007 publication of the second edition. For example, the use of software in medical devices increased greatly and this trend shows no sign of abating. Mobile medical apps and Internet access are now commonplace and many companies have implemented new development methodologies such as agile. Other notable areas of substantial change in the medical device environment include combination products, personalized medicine/companion diagnostics, risk management, and worldwide corporate outsourcing of products and services.

This new 2019 fourth edition of the *Compendium* has been developed to provide accurate and useful information to the medical device community and includes substantially updated content to reflect the current status of the many rapidly evolving areas of the medical device environment. Areas of focus include such important topics as ISO 13485:2016, MDSAP, the EU Medical Device Regulation/In Vitro Diagnostic Regulation, and the continuing evolution of standards and best practices for software validation and risk management.

AAMI wishes to gratefully acknowledge the many individuals who contributed to this and the previous editions of the *Compendium*. The expert authors and technical editors have each provided immeasurable value in producing a text that is a fair and comprehensive treatment of this broad topic: the QS Regulation and current industry practice. AAMI thanks each of the contributors to this and previous editions:

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# Introduction

*The Quality System Compendium: CGMP Requirements and Industry Practice*, fourth edition, provides a comprehensive explanation of the Food and Drug Administration (FDA) Quality System (QS) Regulation (21 CFR Part 820). The *Compendium* is organized in logical "subsystems," where related aspects of the QS Regulation are presented in sequence to facilitate a system-based understanding of the regulatory requirements. The specific requirements are grouped into eight major subject areas: general provisions, quality management, design controls, acceptance activities, production and process controls, product controls, monitoring and feedback, and documents and records. The text presents each section of the QS Regulation followed by a discussion of the requirements, which presents a regulatory perspective, and a review of current industry practice.

This edition retains the same format and organization as the 2015 third edition of the *Quality System Compendium*, which has proven to be a useful and highly regarded resource for the medical device industry. The fourth edition provides new and seasoned professionals with an important resource that presents the "current" implementation approaches of the Current Good Manufacturing Practices (CGMPs), as defined in the QS Regulation. This resource is now based on more than 20 years of industry experience.

In addition, several updated chapters present current practice for specific regulatory areas that have matured in the years since the earlier editions of the *Quality System Compendium* were published, notably the international regulatory landscape, software validation, and risk management for medical devices. A new chapter has been added to provide readers with current information on the Medical Device Single Audit Program. Finally, the updated appendices provide a bibliography, an extensive list of relevant Internet websites, a complete copy of the Final Rule for the QS Regulation, a comparison of 21 CFR Part 820 to ISO 13485:2016, and an index.

In the October 7, 1996, issue of the *Federal Register,* FDA published the Final Rule for the QS Regulation. The basic quality system requirements remain in effect more than 20 years later, although a few technical amendments have been published in the intervening years. These amendments address issues such as title or address changes for various FDA offices specifically cited in the QS Regulation. The most substantive amendment to the QS Regulation is reflected in the April 1, 2014, revision and includes updates related to the 2013 final rule for unique device identification (UDI).

Furthermore, industry and FDA have adopted additional strategies for compliance since the publication of the Final Rule for the QS Regulation. FDA's efforts to harmonize U.S. regulations with international medical device regulations, coupled with efforts by various independent standards organizations, have resulted in a better understanding and implementation of key quality system areas.