Technical Information Report

AAMI/ISO TIR20416: 2020

Medical devices—
Post-market surveillance
for manufacturers

AAMI
Advancing Safety in Health Technology

Medical devices—Post-market surveillance for manufacturers

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Abstract: This Technical Report provides a common understanding of post-market surveillance, or PMS facilitating international cooperation in this area. The Technical Report is intended for use by manufacturers of medical devices. With PMS, the manufacturers can collect, evaluate, and analyze experience gained with their devices after placing on the market. The resulting information can be used for, among others, improvement of the devices. The Technical Report aims to describe a comprehensive data collection process and activities that allow characterization of the behavior of the devices as used in practice, and identify necessary and/or possible actions. PMS information may include material that requires reporting to Regulatory Authorities. The Technical Report does not provide information for such reporting, nor for achieving compliance with any other (PMS) requirement by Regulatory Authorities. Market surveillance by national authorities, as well as actions legally required to be performed by manufacturers as part of PMS or vigilance are outside the scope of the Technical Report. The document is not intended to replace or change national or regional legislation on PMS.

Keywords: post market surveillance, medical device, safety

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Contents

Page

Committee representation v
Background of AAMI adoption of ISO TR 20416 Ed.1. vi
Foreword vii
Introduction viii
1 Scope 1
2 Normative references 1
3 Terms and definitions 1
4 Purpose of post-market surveillance process 2
5 Planning of post-market surveillance 4
6 Review of the post-market surveillance plan 12
Annex A (informative) Examples of data sources 14
Annex B (informative) Examples of data analysis methods 24
Annex C (informative) Examples of post-market surveillance plans 31
Bibliography 43

Committee representation

Association for the Advancement of Medical Instrumentation

Application of post market surveillance systems to medical devices Working Group

The adoption of AAMI/ISO TIR 20416/Ed.1, *Medical devices - Post-market surveillance for manufacturers* as an AAMI Technical Information Report was initiated by the AAMI QM/WG06 Application of post market surveillance systems to medical devices Working Group. AAMI QM/WG06 provides input to the Quality management and corresponding general aspects for medical devices Committee which is the responsible group for providing the U.S. input to the relevant group in the International Organization for Standardization (ISO). U.S. representatives from the Application of post market surveillance systems to medical devices Working Group and the TAG played an active part in developing the ISO document.

At the time this document was published, the **AAMI Application of post market surveillance systems to medical devices Working Group** had the following members:

Cochairs:
Mark Swanson
Marc-Henri Winter

Members:
Jahan Azizi, Healthmark Industries Company Inc
Tim Croft, Hill-Rom Holdings
John DeFoggi, Business Process & Technology Management LLC (BPTM)
Hugo Felix, Owlet Baby Care
Christine Krenc, KTA Compliance Consulting
Brian Markey, Baxter Healthcare Corporation
Estee Orani, Becton Dickinson & Company
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B Park, Christine Park & Associates
Donald Powers, Powers Consulting Services
Karen Rittle Leigh, 3M Health Care
Jacob Severns, Amgen Inc
Mark Swanson, H&M Consulting Group LLC
Rachael Tienhaara, Baxter Healthcare Corporation
Marc-Henri Winter, FDA/CDRH
Johannah Zalomski, WL Gore & Associates Inc
Nicole Zuk, Siemens Healthineers

Alternates:
Gennevieve Douglas, Amgen Inc
Todd Gatto, Northgate Technologies
Susumu Nozawa, Siemens Healthineers
Kevin Randall, ComplianceAcuity Inc

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