The Impact of Standards on the Global Medical Device Industry

8th Annual AAMI/FDA International Standards Conference on Medical Devices

5-6 March, 1998
McLean Hilton Hotel

Association for the Advancement of Medical Instrumentation
3330 Washington Boulevard, Suite 400
Arlington, Virginia 22201-4598
Phone: 703-525-4890  Fax: 703-276-0793
www.aami.org
Contents

Final Program
Faculty Biographies
Exhibitor Information
List of Registrants

A - International Standards and Regulatory Requirements for Design Control
Moderator: Joseph J. Tsiakals, VP, Quality Management, Baxter Healthcare Corporation  A-1

Kimberly Trautman, GMP Quality Systems Expert, CDRH, FDA  A-2

Design Control (Design Input) requirement Compliance for International Standards – Les Schnoll, Director, Regulated Industries, KPMG Peat Marwick LLP Quality Registrar  A-3


Joseph J. Tsiakals, VP, Quality Management, Baxter Healthcare Corporation  A-57

B - Biomaterials and Biocompatibility Testing
Moderator: Daniel E. McLain, MS PhD, Director, Corporate Medical Affairs, Toxicology & Product Support Services, Becton Dickinson & Co.  B-1

Presentation by Ronald P. Brown, Toxicologist, Office of Science & Technology, CDRH, FDA  B-13

Presentation by Mel E. Stratmeyer, PhD, Supervising Chemist, Office of Science & Technology, CDRH, FDA  B-14

C - Electromagnetic Compatibility
Moderator: Michael D. Willingham, VP, Quality & Regulatory Affairs, Physio-Control Corp.  C-1

Presentation by Roland W. Gubisch, Chief Engineer, EMC, Conformity Assessment Americas, Intertek Testing Services  C-5

Presentation by Donald M. Witters, Jr., Chairman, CDRH EMC Working Group, CDRH, FDA  C-21

D - Luncheon Address: The Strategic Implications of Standards
Michael J. Miller, JD, President, Association for the Advancement of Medical Instrumentation  D-1
E - FDA Use of International Standards in the Premarket Review Process
Moderator: Donald J. Barth, Regulatory Staff Manager, Medical Products Group, Hewlett-Packard Co.

A New 510(k) Paradigm -- Eric J. Rechen, Policy Analyst, Office of Device Evaluation, CDRH, FDA

Donald E. Marlowe, Director, Office of Science & Technology, CDRH, FDA

Use of Standards in Product Reviews: Diagnostic X-Ray Devices -- Larry A. Kroger, PhD, Senior Regulatory Programs Manager, GE Medical Systems

Paul Brooks, Scheme Manager, British Standards Institution

F - Labeling and Nomenclature (Metrication)
Moderator: Charles Sidebottom, Standards Manager, Medtronic, Inc.

Presentation by Leighton Hansel, Director, Division of Surveillance Systems, CDRH, FDA

Presentation by Daniel A. Spyker, PhD MD, Deputy Director, Division of Cardiovascular, Respiratory, and Neurological Devices, CDRH, FDA

Presentation by Marlene K. Tandy, MD JD, Director, Technology & Regulatory Affairs & Associate General Counsel, HIMA

Presentation by Charles Sidebottom, Standards Manager, Medtronic, Inc.

G - Software
Moderator: Richard C. Fries, Manager, Support Engineering, Ohmeda, Inc.

Presentation by Sherman Eagles, Senior Principal Software Engineer, Medtronic, Inc.

Presentation by Verna Fitzsimmons, Convener, IEC WG on Programmable Systems

Presentation by John F. Murray, Jr., Electronics Engineer, Office of Science & Technology, CDRH, FDA

H - Conformity Assessment
Moderator: Robert C. Flink, Director, International Regulatory Affairs and Standards, Medtronic, Inc.

Donald E. Marlowe, Director, Office of Science & Technology, CDRH, FDA

Richard C. Fries, Manager, Support Engineering, Ohmeda, Inc.

Steven M. Anderson, Director, Medical Division, TUV Product Service, Inc.

Linda R. Horton, Director, International Policy, Office of the Commissioner, FDA

I - Risk Management/Risk Assessment
Moderator: Alfred M. Dolan, CCE, Samuel Lunenfeld Professor of Clinical Engineering, Institute of Biomedical Engineering, University of Toronto

Presentation by Paul McDaniel, Product Risk Manager, Hill-Rom, Inc.

Presentation by Harvey R. Rudolph, PhD, Acting Deputy Director, Office of Science Technology, CDRH, FDA
J - Human Factors Engineering
Moderator: Matthew Weinger, MD, Associate Professor, Anesthesiology, University of California
San Diego, and Staff Physician, VA Medical Center
Presentation by Robert J. Cangelosi, PE, Chief, System Analysis and Human Factors Branch, Division
of Device User Programs, CDRH, FDA
Presentation by Peter B. Carstensen, Mechanical Engineer, Office of Health & Industry Programs,
CDRH, FDA
Presentation by Richard P. Avoy, Manager of Global Standards and Compliance, Research &
Development, Johnson & Johnson Medical Inc.
Presentation by Carl A. Pantiskas, Principal CE, Spacelabs Medical, Inc.

K - In vitro Diagnostics
Moderator: David Kelly, Assistant Executive Director for International Programs, NCCLS
Presentation by Edward R. Kimmelman, BME JD, VP, Regulatory Affairs & Compliance, Boehringer
Mannheim Corp.
Presentation by Kimber C. Richter, MD, Deputy Director, Office of Device Evaluation, CDRH, FDA

L - Sterilization Standards
Moderator: Timothy Ulatowski, Director, Division of Dental, Infection Control, and General Hospital
Devices, CDRH, FDA
Presentation by Barry F.J. Page, Consultant, & W. Howard Cyr, PhD, CDRH, FDA
Presentation by Lois Jones, Standards Manager, Becton Dickinson and Company

M - Standards and the Marketplace
Moderator: Edward R. Kimmelman, BME JD, VP, Regulatory Affairs & Compliance, Boehringer
Mannheim Corp.
Lillian Gill, Director, Office of Compliance, CDRH, FDA
Dennis Hughey, President, AQSR

N - Background Documents
Commonly Used Acronyms and Abbreviations
Various Web Sites Related to Standards
AAMI Standards Program of Work
Current Public Review Documents
AAMI Standards New Work Proposals
Committees and TAGs Not Administered by AAMI