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1. Purpose

The purpose of this policy is to define the MDSAP Regulatory Authority Council (RAC) including the Chairperson, Vice Chairperson, Secretariat, and individual membership representing all participating regulatory authorities.

2. Scope

This policy applies to all participating regulatory authorities.

3. Definitions/Acronyms

Medical Device Single Audit Program (MDSAP): MDSAP allows a single regulatory audit of a medical device manufacturer's quality management system to satisfy the needs of multiple regulatory jurisdictions. The single audit of a medical device manufacturer's quality management system will include the assessment of the quality management system processes including management responsibility, resource management, product realization, measurement, analysis and improvement, and adverse event reporting; as well as compliance with Good Manufacturing Practices (GMPs) or other applicable requirements specific to a participating regulatory authority.

Medical Device Single Audit Program Regulatory Authority Council (RAC): The RAC consists of representatives from all participating regulatory authorities and provides direction, oversight, and resources to support the MDSAP development, implementation, maintenance, and expansion.

Regulatory Authority (RA): A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements. (IMDRF WG (PD2)/N3R5)

(GHTF/SG1/N78:2012)

4. Authorities/Responsibilities

The RAC authorities, responsibilities, and terms are described in detail in MDSAP P0003 Regulatory Authority Council and Lead Project Manager – Authorities, Responsibilities, Governing Policy and Rules.

5. Membership

Appointment Date: September 1, 2012

Chairperson: Kimberly A. Trautman, USFDA
Vice Chairperson: Ana Paula Teles Ferreira Barreto, ANVISA
Secretariat: Michelle Jones, USFDA

Australia: Therapeutic Goods Administration (TGA)

Larry Kelly, Ph.D., Chief Regulatory Officer (Acting)
Dr. Harry Rothenfluh, Head of Office, Office of Manufacturing Quality

Brazil: Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency – ANVISA)

Ana Paula Teles Ferreira Barreto, Advisor – Office of Director Chairman
Luciana Shimizu Takara, Deputy Director

Canada: Health Canada

John Patrick Stewart, MD, Acting Senior Executive Director, Therapeutic Products Directorate
Mike Ward, Manager, International Programs Division, Therapeutic Products Directorate

United States of America: Food and Drug Administration (FDA)

Kimberly A. Trautman, Associate Director International Affairs, Office of the Center Director, CDRH
Steven M. Solomon, Assistant Commissioner for Field Operations, ORA

6. Reference Documents

MDSAP P0003 Regulatory Authority Council and Lead Project Manager – Authorities, Responsibilities, Governing Policy and Rules

7. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2012/10/19	Initial Release	Robert G. Ruff
002	2013/01/17	Page 2: Section 5-Membership for US FDA: Removed the name "Roberta Wagner" Assistant Commissioner for Field Operations, ORA and replaced with "Steven M. Solomon" DVM, MPH, Associate Director Global Operations and Policy, ORA	Robert G. Ruff
003	2013/06/04	Revised Header: add logo and changed "revision" to "effective". Added new revision and effective date and updated document version	Liliane Brown
004	2013/07/25	Page 2: Section 5- Removed the name "Bill Turner" Branch Head, Office of Manufacturing Quality, and replaced with Doug Fenwick, Head Office of Manufacturing Quality (Acting) Page 1; Section 3-Definitions/Acronyms: Regulatory Authority definition was added as described in document (IMDRF WG (PD2)/N3R5) (GHTF/SG1 /N78:2012)	Michelle Jones and Liliane Brown
005	2013/11/20	Page 2: Section 5- Removed the name "Doug Fenwick" Acting, Office of Manufacturing Quality, and replaced with Dr. Harry Rothenfluh, Head of Office, Office of Manufacturing Quality	Michelle Jones

Version Approval

Kimberly A. Trautman
CHAIR, MDSAP RAC

Approved: Date: 2013/11/20