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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: February 13, 2018

Chairperson: Maria Angela da Paz, ANVISA
Vice Chairperson: To be appointed
Secretariat: To be appointed

Australia: Therapeutic Goods Administration (TGA)

- Adriana Platona, First Assistant Secretary, Medical Device and Product Quality Division
- Tracey Duffy, Assistant Secretary, Medical Device Branch, Medical Device and Product Quality Division

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

- Andre Paes de Almeida, Health Regulation Specialist – Medical Device Inspection Office
- Maria Angela da Paz, Health Regulation Specialist – Medical Device Inspection Office

Canada: Health Canada (HC)

- To be appointed
- Nancy Shadeed, Special Advisor, International Programs Division, Therapeutic Products Directorate

Japan: Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA)

- Yumiko Aoyagi, Deputy Director, Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare
- Mari Shirotani, Division Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency

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

- Melissa Torres, Associate Director International Affairs, Office of the Center Director, CDRH
- Jan B. Welch, Director, Medical Device/RH Program, Office of Regulatory Affairs

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
006	2015/01/23	Page 2: Section 5- Canada: *Heath Canada* Removed name "Mike Ward", Manager, International Programs Division, Therapeutic Products Directorate and replaced with "Nancy Shadeed", Special Advisor, International Programs Division, Therapeutic Product Directorate	Liliane Brown
007	2015/07/13	Page 2: Section 5 – Membership; added Japan as RAC members.	Liliane Brown
008	2015/09/17	Page 2: Section 5 – Membership; ANVISA removed name "Ana Paula Teles Ferreira Barreto, and Luciana Shimizu Takara" to replace with "Andre Paes de Almeida and Fábio Pereira Quintino". Additionally the Vice Chairperson position was updated by removing the name of "Ana Paula Teles Ferreira Barreto" and to replace with the name of "Fábio Pereira Quintino, ANVISA". Additionally, on same page "Membership" Section 5, the names of Japanese delegates have been added due to its participation to MDSAP Pilot.	Liliane Brown
009	2016/01/11	Page 2 Section 5 – Membership: Chairperson – removed KAT FDA and replaced with Fábio Pereira Quintino, ANVISA. Vice Chairperson - removed Fábio Pereira Quintino, ANVISA and will be replaced with	Liliane Brown

		name March 2016. Listing under USA remove KAT name and replaced with Melissa Torres name which is the acting associate director international affairs for 2016 and until further notice.	
010	2016/03/04	Page 2 Section 5 – Membership - Australia: Therapeutic Goods Administration (TGA) Dr. Harry Rothenfluh, Head of Office, Office of Manufacturing Quality was replaced with Dr. Cheryl McRae, Head, Medical Device Branch.	Liliane Brown
011	2016/03/22	Page 2 Section 5 – Membership – Japan: Hideyuki Kondo, Deputy Director, Medical Device and Regenerative Medicine Product Evaluation Division, Pharmaceutical and Food Safety Bureau was replaced by Dr. Kentaro Azuma, Deputy Director, Medical Device and Regenerative Medicine Product Evaluation Division, Pharmaceutical and Environmental Safety Bureau and Daisuke Koga, Deputy Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency was replaced by Jun Kitahara, Division Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency ANVISA Andre Paes de Almeida, Deputy Head Office – Regulatory Management and Sanitary Control in Health Care Services Office was updated with Regulation and Health Surveillance Specialist – Medical device Inspection Office and Fábio Pereira Quintino, Head Office – Company Operation Authorization Office, Sanitary Inspection Superintendence was updated with Manager Medical Device, Cosmetics and Sanitizing Products Inspection Office.	Liliane Brown
012		Page 2 Section 5 – Membership – Australia: Larry Kelly, Ph.D., Chief Regulatory Officer (Acting) was excluded. Membership - Canada: John Patrick Stewart, MD, Acting Senior Executive Director, Therapeutic Products was replaced by Marion Law, Director General, Therapeutic Products Directorate	Liliane Brown
013	2016-07-12	Page 2 Section 5 –Membership: Secretariat: Michelle Jones USFDA was replaced with Lorena Tozetto, ANVISA. Page 2 Section 5 – Membership – Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA) – Dr. Kentaro Azuma, Deputy Director, Medical Device and Regenerative Medicine Product Evaluation Division, Pharmaceutical and Environmental Safety Bureau was replaced with Ms. Yumiko Aoyagi, Deputy Director, Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare. Additionally, PMDA sub-title was changed from, Medical Device and Regenerative Medicine Product Evaluation	Liliane Brown

		Division, Pharmaceutical and Environmental Safety Bureau to Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare. Page 3 Section 5 - United States of America: Food and Drug Administration (FDA) – Melissa Torres, Associate Director International Programs, Office of the Center Director, CDRH – word acting was removed.	
014	2017-04-04	Page 2 Section 5 – Membership: 1) added Vice President info "Ms. Kimby N. Barton, HC" which had been open since 2016. 2) Secretariat: Ms. Lorena Tozetto was removed – to be appointed at a later date. Page 3 Section 5 – Membership USA/FDA replaced "Mr. Steven M. Solomon, Assistant Commissioner for Field Operations, ORA" was replace with "Ms. Jan B. Welch, Director Medical Device/RH Program, ORA.	Liliane Brown
015	2017-9-18	Made the following updates: • Version date and number • Changed owner to Neil Mafnas • Page 2 section 5, "Kimby N. Barton, Interim Senior Executive Director, Interim Director Medical Devices Bureau, Therapeutic Products Directorate" was replaced with "To be appointed" • Page 2 section 5 replaced,"*Brazil: Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency – ANVISA)* − Andre Paes de Almeida, Regulation and Health Surveillance Specialist – Medical Device Inspection Office − Fábio Pereira Quintino, Manager – Medical Device, Cosmetics and Sanitizing Products Inspection Office" with, "*Brazil: Agência Nacional de Vigilância Sanitária (Brazilian Health Regulatory Agency – ANVISA)* − Andre Paes de Almeida, Health Regulation Specialist – Medical Device Inspection Office − Maria Angela da Paz, Health Regulation Specialist – Medical Device Inspection Office" • Page 2 section 5 replaced, "Appointment Date: March 13, 2017 **Chairperson**: Fábio Pereira Quintino, ANVISA **Vice Chairperson**: Kimby N. Barton, HC" with, "Appointment Date: September 4, 2017 **Chairperson**: Maria Angela da Paz, ANVISA" **Vice Chairperson**: To be apointed	Andrew Durfor
016	2018-02-16	Page 2 Section 5 – Membership Appointment date was replaced with February 13, 2018 - Australia*:* Therapeutic Goods Administration (TGA) - Dr. Cheryl McRae, Head, Medical Device Branch was replaced with Adriana Platona, First Assistant	Hiromi Kumada

		Secretary, Medical Device and Product Quality Division - Tracey Duffy, Assistant Secretary, Medical Device Branch, Medical Device and Product Quality Division - Japan: Japan's Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA) - Jun Kitahara, Division Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency was replaced with Mari Shirotani, Division Director, Office of International Programs, Pharmaceuticals and Medical Devices Agency	

Version 016
Approval

Approved: Signature on File ___ Date: 21 February 2018
CHAIR MDSAP RAC