AO NAME

AO HEAD OFFICE ADDRESS

Attn: AO REPRESENTATIVE’S NAME

AO REPRESENTATIVE’S TITLE

**RE: Recognition as Auditing Organization under the Medical Device Single Audit Program (MDSAP)**

Dear Mr./Ms. AO REPRESENTATIVE’S NAME

Considering:

1. The Statement of Cooperation among the United States Food and Drug Administration (US FDA), the Australian Therapeutic Goods Administration (TGA), the Brazilian Health Surveillance Agency (ANVISA), and the Canadian Health Products and Food Branch (Health-Canada) regarding cooperation in the Medical Device Single Audit Program (MDSAP), signed in Manaus, Brazil on November 27th, 2012;
2. The MDSAP Functional Statement (Document #: MDSAP P0001) among US FDA, TGA, ANVISA, Health-Canada, and Japan’s Ministry of Health, Labour and Welfare and the Japanese Pharmaceuticals and Medical Devices Agency (MHLW/PMDA);
3. The assessments of the compliance of AUDITING ORGANIZATION to the requirements set in the IMDRF MDSAP WG documents N3[[1]](#footnote-1) and N4[[2]](#footnote-2), performed between DATE and DATE, as listed in schedule 1;
4. The recommendation from the assessment team leaders; and
5. The review of the assessment file by the Technical Review and Recommendation Committee and the endorsement of their decision by the MDSAP Regulatory Authority Council.

TGA, ANVISA, Health-Canada, MHLW/PMDA and the US FDA, as listed on the Schedule 2, decided to recognize AUDITING ORGANIZATION as an auditing organization under the MDSAP.

This decision by the signatories of the Statement of Cooperation and the MDSAP Functional Statement, on START DATE, takes effect the same day.

The recognition is conditional upon continued compliance with MDSAP requirements, and the additional conditions documented in the Schedule 3 (if any), and is valid for a period of four (4) years starting on the date of decision and expiring on EXPIRY DATE.

-Signature-\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

CHAIRPERSON NAME:

Chair of the Regulatory Authority Council

Date:

Assessment Program Manager: APM NAME & TITLE

Postal Address: APM Address

Tel.: APM Phone #

Email.: APM Email address

**Schedule 1: List of assessment activities supporting the recognition decision**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Assessment Report** | **Assessment Starting Date** | **Assessment Ending Date** | **Assessment Activity Type** | **Visited Location** |
|  |  |  | Stage 1 Assessment | NA |
|  |  |  | Stage 2 Assessment | Head Office |
|  |  |  | Assessment of Critical Location | Critical Location’s Address |
|  |  |  | Witnessed Audit 1 | NA\* |
|  |  |  | Witnessed Audit 2 | NA\* |
|  |  |  | Witnessed Audit 3 | NA\* |

\* Witnessed audits take place at a medical device manufacturer, not part of the auditing organization

**Schedule 2: Contact information at the recognizing regulatory authorities, by country**

|  |  |
| --- | --- |
| **Country** | **Contact Information at the Recognizing Regulatory Authority** |
| **Australia** | Australian Government Department of Health  Therapeutic Goods Administration (TGA)  Office of Manufacturing Quality  PO Box 100  Woden ACT 2606  Australia |
| **Brazil** | ANVISA – Brazilian Health Regulatory Agency  Setor de Indústria e Abastecimento (SIA)  Trecho 5, Área Especial 57 / Lote 200  Brasília (DF) CEP 71205-050  Brazil |
| **Canada** | Health Canada  Medical Devices Directorate  Health Products and Food Branch  5th Floor – Holland Cross – Tower A  11 Holland Avenue  Address Locator: 3002A  Ottawa, Ontario K1A 0K9  Canada |
| **Japan** | Japan’s Ministry of Health, Labour and Welfare  Ministry of Health, Labour and Welfare  Medical Device Evaluation Division,  Pharmaceutical Safety and Environmental Health Bureau  1-2-2, Kasumigaseki, Chiyoda-ku, Tokyo 1008616 Japan  Pharmaceuticals and Medical Devices Agency  Office of Standards and Compliance for Medical Devices- Division of Registered Certification Body Assessment  Shin-kasumigaseki Bldg. 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan |
| **United states of America** | Food and Drug Administration (FDA)  Center of Device and Radiological Health  Office of Compliance  Division of International Compliance Operations  Medical Device Single Audit Program  10903 New Hampshire Avenue  Silver Spring, MD 20993  USA |

**Schedule 3: Conditions**

|  |  |
| --- | --- |
| **Condition** | **Due date to present the fulfilment of the requirements identified in the condition** |
| 1. | YYYY-MM-DD |
| 2. | YYYY-MM-DD |
| 3. | YYYY-MM-DD |
| 4. | YYYY-MM-DD |

1. IMDRF MDSAP WG N3 - Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition [↑](#footnote-ref-1)
2. IMDRF MDSAP WG N4 - Competence and Training Requirements for Auditing Organizations [↑](#footnote-ref-2)