**Information**

1. **Auditing Organization**

AO:

AO HEAD OFFICE ADDRESS:

1. **Assessment Program Manager (APM)**

Name:

Agency:

1. **Reason for Technical Review and Decision**

Initial recognition

Re-recognition

Extension or restriction of scope requested by the AO

Escalation of AO nonconformity report

Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Changes that may affect the recognition**

Description:

APM impact evaluation:

1. **Attached Documents**

|  |  |  |
| --- | --- | --- |
| **Assessment Activity** | **Assessment Reports** | **Nonconformity Reports** |
| Application Review |  |  |
| Stage 1 Assessment |  |  |
| On-Site Assessment (Head-Office) |  |  |
| On-Site Assessment (Critical Location) |  |  |
| Witnessed Audit  WA1 |  |  |
| WA2 |  |  |
| WA3 |  |  |
| Special On-Site Assessment |  |  |
| Special Remote Assessment |  |  |

Other documents:

|  |
| --- |
|  |
|  |

**Recommendation by Assessment Program Manager**

**Check list for the analysis of the assessment and nonconformity reports**

**Please indicate “Not applicable” in the comments section when appropriate**

1. All written nonconformities comply with the requirements in clause 6.2 of IMDRF/MDSAP WG/N11FINAL:2014;

Comments:

1. The grading of nonconformity(s) complies with the requirements in clause 6.3 of IMDRF/MDSAP WG/N11FINAL:2014;

Comments:

1. The remediation plans for Grade 1 or Grade 2 nonconformity(s) has been deemed acceptable and complies with the requirements of clause 6.5 and 6.6 of IMDRF/MDSAP WG/N11FINAL:2014;

Comments:

1. The remediation plans for Grade 3 or Grade 4 (result of recurrence) nonconformity(s) comply with the requirements of clause 6.5 and 6.6 of IMDRF/MDSAP WG/N11FINAL:2014 and has been deemed acceptable. The evidence that the actions have been implemented as planned was verified.

Comments:

1. Inform if there is evidence of possible fraud, misrepresentation or falsification of evidence resulting in a Grade 4 nonconformity;

Comments:

1. Verification and evaluation of the Assessment Report(s), according to *MDSAP AS F0017 .5 Technical Review Form*;

Comments:

1. Inform if there is any complaint or appeal from the Auditing Organization on a particular nonconformity and its outcomes;

Comments:

1. Verify decisions on closure of any nonconformity and any appropriate follow-up which may include Special Remote Assessment or Special On-site Assessment.

Comments:

1. Verify other information relating to a recognition decision.

Comments:

1. Confirm or review of the assessment program.

Comments:

**Recommended type of Decision:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Initial Assessment** | **Re-recognition** | **AO Request** | **NC escalation/Other** |
| Recognition | Re-recognition | Extension of Scope | Maintenance of recognition |
| Refusal | Cease Recognition | Restriction of Scope | Cease Recognition |
|  | Re-recognition with Extension of Scope | Refusal to change the Scope | Restriction of Scope |
|  | Re-recognition with Restriction of Scope |  |  |

**Recommended Statement of Decision:**

**Conditions included/removed in the Recognition:**

**Timeline for the AO to provide the Conditions:**

**Comments included in the Recognition** (to be followed in the next assessment)**:**

**Recommended Decision Rationale:**

**Additional Comments:**

|  |  |
| --- | --- |
| xxx  Assessment Program Manager | Signature: |

**Individual recommendation by the TRRC members**

1. **TGA**

**Rationale/ Comments:**

**Recommended Decision:**

|  |
| --- |
| Reviewer Name and Signature: |

1. **Anvisa**

**Rationale/ Comments:**

**Recommended Decision:**

|  |
| --- |
| Reviewer Name and Signature: |

1. **Health Canada**

**Rationale/ Comments:**

**Recommended Decision:**

|  |
| --- |
| Reviewer Name and Signature: |

1. **PMDA**

**Rationale/ Comments:**

**Recommended Decision:**

|  |
| --- |
| Reviewer Name and Signature: |

1. **FDA**

**Rationale/ Comments:**

**Recommended Decision:**

|  |
| --- |
| Reviewer Name and Signature: |

**Decision by TRRC (representative of a qualified majority):**

|  |  |  |  |
| --- | --- | --- | --- |
| **Initial Assessment** | **Re-recognition** | **AO Request** | **NC escalation/Other** |
| Recognition | Re-recognition | Extension of Scope | Maintenance of recognition |
| Refusal | Cease Recognition | Restriction of Scope | Cease Recognition |
|  | Re-recognition with Extension of Scope | Refusal to change the Scope | Restriction of Scope |
|  | Re-recognition with Restriction of Scope |  |  |

**Recommended Statement of Decision:**

**Conditions included/removed in the Recognition:**

**Additional Comments:**

**Timeline for the AO to provide the Conditions:**

**Comments included in the Recognition** (to be followed in the next assessment)**:**

**Rationale:**

**Comments on Difference of Opinion between the Members of the TRRC:**

|  |  |
| --- | --- |
| xxx  TRRC Chair | Signature: |

**Consideration from Regulatory Authority Council**

|  |
| --- |
| Concordance with TRRC recommended Decision |
| Request to review TRRC Decision |

**Comments:**

|  |  |
| --- | --- |
| xxx  RAC Chair | Signature: |