**Appeal Request**

1. **Auditing Organization Section**

**Auditing Organization**:

**AOID#**:

**Scope of Recognition:**

**Contested decision**:

**Decision date**:

**Aspect of the decision being contested**:

🞏 Inconsistency with prior decisions

🞏 Substantial irregularities in the assessment process

🞏 Substantial irregularities in the decision-making process

🞏 Partiality of the decision: the decision does not take fully into account the information available at the time of the decision

🞏 New information not available at the time of the decision but with potential for changing the decision

**Detailed rationale for contesting the decision**:

**Evidence supporting the rationale (reference of provided information)**:

**Request the opportunity to be heard**: 🞏Yes 🞏No

1. **MDSAP Quality Management System Manager (QMS Manager) Section:**

**Is the appeal admissible?** 🞏Yes 🞏 No

**Information relevant to the case in addition to the information provided by the AO**:

🞏 AO Assessment Program Management File

🞏 Assessment Reports:

🞏 Technical Review and Recognition Decision Records

🞏 Notification letter of the Recognition Decision

🞏 Other, specify:

**Additional information requested to the AO, if applicable**:

1. **Regulatory Authority Council (RAC) Section**

**Designation of the Technical Review and Recommendation Committee for the examination of the appeal**:

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| --- | --- | --- |
| **Regulatory Authority** | **RAC Member designating the TRRC members** | **Appointed TRRC members acting as RA representative to the committee** |
| Australia: TGA | Name:  Date |  |
| Brazil: ANVISA | Name:  Date |  |
| Canada: Health Canada | Name:  Date |  |
| Japan: MHLW/PMDA | Name:  Date |  |
| USA: FDA | Name:  Date |  |

1. **Technical Review and Recommendation Committee (TRRC) Section**

**Hearing session**: 🞏 Yes 🞏 No

Hearing session date:

Minutes of the hearing session: see attached record reference \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Analysis of the appeal request and the supporting information**:

**Recommendation**:

The Appeal is: 🞏 DENIED 🞏 ACCEPTED, see below:

Proposed amended Recognition Decision:

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Proposed recognition status of the AO:

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Proposed changes to the AO Assessment Program (AOAP):

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Rationale for the recommended appeal decision:

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In case of divergence of opinion between the TRRC members, the options and rationales where the following:

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**Review of the proposal** (indicate name, signature and date):

TRRC Chairperson:

TRRC TGA Representatives:

TRRC ANVISA Representatives:

TRRC Health Canada Representatives:

TRRC MHLW/PMDA Representatives:

TRRC FDA Representatives:

1. **Regulatory Authority Council (RAC) Section**

**Final Appeal Decision:**

🞏 As proposed by the TRRC (See endorsement below)

🞏 Amended by the RAC as follows:

The Appeal is: 🞏 DENIED 🞏 ACCEPTED, see below:

Final Recognition Decision:

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Proposed recognition status of the AO:

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Proposed changes to the AO Assessment Program (AOAP):

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Rationale for the recommended appeal decision:

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**Endorsement** (indicate name, signature and date):

RAC Chairperson:

RAC TGA Representatives:

RAC ANVISA Representatives:

RAC Health Canada Representatives:

RAC MHLW/PMDA Representatives:

RAC FDA Representatives: