**Auditing Organization** **Click here to enter text.**

Date of receipt of the application Click here to enter a date.

**Application Screening Checklist**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Criteria | Review by RAC Secretariat | | Review by Assessment Program Manager | | |
| Yes | No | Yes | No | Needs Clarification |
| 1. Eligibility in accordance with clause 5.1 of IMDRF/MDSAP WG/N3 2nd edition |  |  |  |  |  |
| 2. Demonstrated financial stability over past 3 years |  |  |  |  |  |
| 3. Available auditing resources ≥ 150% of current demand |  |  |  |  |  |

**Note: The application should not be reviewed any further unless all three mandatory criteria above are met.**

**Application Review Check List**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Application Section | Review by RAC Secretariat | | | Review by Assessment Program Manager | | | |
| Complete | Incomplete | Not Applicable | Acceptable | Not Acceptable | Needs Clarification | Not Applicable |
| 1. AO information |  |  |  |  |  |  |  |
| Address of AO Head Office  (if different) |  |  |  |  |  |  |  |
| 2. Contact information |  |  |  |  |  |  |  |
| Proof of legal status as a legal entity and date obtained | Attached | Not Attached |  |  |  |  |  |
| Proof of adequate com-mercial liability insurance | Attached | Not Attached |  |  |  |  |  |
| Annual report | Attached | Not Attached |  |  |  |  |  |
| List and date of accredita-tions or other recognitions for medical device audits | Attached | Not Attached |  |  |  |  |  |
| 3. Corporate information |  |  |  |  |  |  |  |
| 4. Critical location information |  |  |  |  |  |  |  |
| Separate critical location information form |  |  |  |  |  |  |  |
| 5. Organization information |  |  |  |  |  |  |  |
| 6. Medical device technical areas |  |  |  |  |  |  |  |
| 7. Contractual arrangements with external organizations |  |  |  |  |  |  |  |
| Signature |  |  |  |  |  |  |  |
| Auditing Organization (AO) application matrix |  |  |  |  |  |  |  |
| Management system documentation | Attached | Not Attached  (not Blocking) | |  |  | Select if documentation was not provided | |
| Statement on letterhead paper and signed by senior management agreeing to conduct regulatory audits in conformance with MDSAP requirements | Attached | Not Attached |  |  |  |  |  |
| Identification of branches, regional and/or national offices and any related bodies authorized to conduct regulatory audits and issue MDSAP certification documents | Attached | Not Attached |  |  |  |  |  |
| List identifying the AO personnel or committee members making decisions under the MDSAP | Attached | Not Attached |  |  |  |  |  |
| Auditor and technical expert competency summary | Attached | Not Attached |  |  |  |  |  |
| Draft contract between the AO and the manufacturer | Attached | Not Attached |  |  |  |  |  |
| Sample of certification document | Attached | Not Attached |  |  |  |  |  |
| Template of contractual agreement with external organizations | Attached | Not Attached |  |  |  |  |  |
| Procedures for information exchange between the AO and the RAs under MDSAP | Attached | Not Attached |  |  |  |  |  |

**Conclusion of the Review on the Acceptability of the Application**

Acceptable 🡪 proceed with the assessment program processes

Not Acceptable

Needs Clarifications:

Specifically:

Click here to enter text.

Decision on whether to proceed with the assessment program process considering the need for clarifications:

Click here to enter text.

|  |  |  |  |
| --- | --- | --- | --- |
| Signature |  |  |  |
| Date | Click here to enter a date. | Click here to enter a date. | Click here to enter a date. |
| Function | RAC Secretariat  Check of completeness of the application | Assessment Program Manager  Endorsement of the conclusion | Lead Project Manager  Endorsement of the conclusion if either:   * not acceptable, or * proceed with the assessment program despite the need for clarification |