**Auditing Organization Key Activities Matrix**

*Identification of personnel and locations involved in the planning and performance of audit and certification services under MDSAP and supporting functions. Indicate which locations perform (“P”) activities and which locations manage (“M”) or have responsibility for activities. Note that although 17021-1:2015 allows a certification decision to be taken by an individual under a legally enforceable arrangement, (9.5.1.2), those arrangements must be between the individual performing the activity and the legal entity that is the Auditing Organisation for MDSAP (N3(ed2) – 9.5). Also indicate which locations use individual external auditors or technical experts (“E”) (see ISO/IEC 17021-1:2015 7.3) and which locations have outsourced (“O”) activities to another entity (ISO/IEC 17021-1:2015 7.5).*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Activity** | **Head Office** | **Location 1***(specify)* | **Location 2***(specify)* | **Location 3***(specify)* |
| **Name/Address** |  |  |  |  |
| **Operating Language** |  |  |  |  |
| **Management System Development and Maintenance** |
| Formulation of operational policy and objectives  |  |  |  |  |
| Process development |  |  |  |  |
| Procedure development |  |  |  |  |
| **Medical Device Manufacturer Quality Management System (QMS) Certification Process** |
| Sales/Marketing |  |  |  |  |
| Customer contact/Receiving applications |  |  |  |  |
| Application/Contract review |  |  |  |  |
| Assignment of Auditors |  |  |  |  |
| Assignment of Reviewers |  |  |  |  |
| Development/Maintenance of audit programmes |  |  |  |  |
| Planning audits |  |  |  |  |
| Technical review/approval |  |  |  |  |
| Registration decision |  |  |  |  |
| Issuance of certificates |  |  |  |  |
| Oversight of certification/ Surveillance activities |  |  |  |  |
| **Human Resources** |
| Competence management of non-audit personnel |  |  |  |  |
| Competence management of auditors and technical reviewers/certifiers |  |  |  |  |
| Witness/Monitoring Audits |  |  |  |  |
| **Records location (Tick relevant locations)** |
| Human Resources (HR) records | ☐ | ☐ |[ ]  ☐ |
| Auditor records |[ ]  ☐ |[ ]  ☐ |
| Client records (see ISO/IEC 17021-1:2015 9.9) |[ ] [ ] [ ]  ☐ |
| **Monitoring of AO’s QMS / Accountability**  |
| Supervision of implementation of policies and procedures |  |  |  |  |
| Provision of adequate resources for management, audit, and certification activities |  |  |  |  |
| Liability (insurance or reserves) and Financial responsibility/accountability |  |  |  |  |
| **Use of External Resources** |
| Qualification and approval of external organizations/resources |  |  |  |  |
| Oversight of external organizations/resources  |  |  |  |  |
| **Management** |
| Handling of complaints  |  |  |  |  |
| Handling of Appeals |  |  |  |  |
| Corrective Action and Preventive Action |  |  |  |  |
| Internal Quality Audits |  |  |  |  |
| Management Review |  |  |  |  |
| Management System |  |  |  |  |
| Impartiality Management(including the risk management process related to conflict of interest (ISO/IEC 17021-1:2015 5.2.3) and the MDSAP Code of Conduct (N3(ed2) 7.1.6)) |  |  |  |  |