# Auditor and Technical Expert Competency Summary

Use as many forms as necessary to include all auditors and technical experts involved in MDSAP auditing activities. Alternatively, provide an Auditing Organization’s internal record or set of records providing the same set of information.

*Instructions to duplicate the Auditor or Technical Expert name on each page:*

*Double click gray box in Auditor/Technical Expert header. Type the Auditor or Technical Expert name in the default text box then hit OK.*

Date of completion of the form (YYYY-MM-DD):

|  | | |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Auditor?** (Y/N) | | |  |  |  |
| **Technical Expert?** (Y/N) | | |  |  |  |
| **Employee** (E) **vs. External Resource** (ER)**?** | | |  |  |  |
| **Academic Qualification** (highest level of education relevant to the position) | | |  |  |  |
| **Auditor Grade** (such as lead auditor, senior lead auditor, auditor, etc.) | | |  |  |  |
| **MDSAP online Auditor Training Completion Date** (if applicable) | | |  |  |  |
|  | | |  |  |  |
| ***Medical Device Knowledge*** | | |  |  |  |
| ***Non-active Medical Devices*** | | | | | |
| *General  non-active, non-implantable medical devices* | *Non-active devices for anesthesia, emergency and intensive care* | |  |  |  |
| *Non-active devices for injection, infusion, transfusion and dialysis* | |  |  |  |
| *Non-active orthopedic and rehabilitation devices* | |  |  |  |
| *Non-active medical devices with measuring function* | |  |  |  |
| *Non-active ophthalmologic devices* | |  |  |  |
| *Non-active instruments* | |  |  |  |
| *Contraceptive medical devices* | |  |  |  |
| *Non-active medical devices for disinfecting, cleaning, rinsing* | |  |  |  |
| *Non-active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART)* | |  |  |  |
| *Non-active implants* | *Non-active cardiovascular implants* | |  |  |  |
| *Non-active orthopedic implants* | |  |  |  |
| *Non-active functional implants* | |  |  |  |
| *Non-active soft tissue implants* | |  |  |  |
| *Devices for wound care* | *Bandages and wound dressings* | |  |  |  |
| *Suture material and clamps* | |  |  |  |
| *Other medical devices for wound care* | |  |  |  |
| *Non-active dental devices and accessories* | *Non-active dental devices/equipment and instruments* | |  |  |  |
| *Dental materials* | |  |  |  |
| *Dental implants* | |  |  |  |
| *Non-active medical devices other than specified above* | | |  |  |  |
| **Active Medical Devices (Non-Implantable)** | | | | | |
| General active medical devices | Devices for extra-corporal circulation, infusion and haemapheresis |  | |  |  |
| Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anesthesia |  | |  |  |
| Devices for stimulation or inhibition |  | |  |  |
| Active surgical devices |  | |  |  |
| Active ophthalmologic devices |  | |  |  |
| Active dental devices |  | |  |  |
| Active devices for disinfection and sterilization |  | |  |  |
| Active rehabilitation devices and active prostheses |  | |  |  |
| Active devices for patient positioning and transport |  | |  |  |
| Active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART) |  | |  |  |
| Software |  | |  |  |
| Devices for imaging | Devices utilizing ionizing rays |  | |  |  |
| Devices utilizing non-ionizing rays |  | |  |  |
| Monitoring devices | Monitoring devices of non-vital physiological parameters |  | |  |  |
| Monitoring devices of vital physiological parameters |  | |  |  |
| Devices for radiation therapy and thermo therapy | Devices utilizing ionizing radiation |  | |  |  |
| Devices utilizing non-ionizing radiation |  | |  |  |
| Devices for hyperthermia / hypothermia |  | |  |  |
| Devices for (extracorporeal) shockwave therapy (lithotripsy) |  | |  |  |
| Active (non-implantable) medical devices other than specified above | |  | |  |  |
| **Active Implantable Medical Devices** | | | | | |
| Active implantable medical devices for stimulation / inhibition | |  | |  |  |
| Active implantable medical devices delivering drugs or other substances | |  | |  |  |
| Active implantable medical devices substituting or replacing organ functions | |  | |  |  |
| Radioactive seeds for interstitial radiotherapy | |  | |  |  |
| Implantable medical devices other than specified above | |  | |  |  |
| **In Vitro Diagnostic Medical Devices (IVD)** | |  | |  |  |
| Reagents and reagent products, calibrators and control materials for IVD medical devices: | Clinical Chemistry |  | |  |  |
| Immunochemistry (Immunology) |  | |  |  |
| Hematology / Hemostasis / Immunohematology |  | |  |  |
| Microbiology |  | |  |  |
| Infectious Immunology |  | |  |  |
| Histology/Cytology |  | |  |  |
| Genetic Testing |  | |  |  |
| IVD Instruments and Software | |  | |  |  |
| IVD medical devices for near patient use | Devices for home use |  | |  |  |
| Near patient use other than home use |  | |  |  |
| IVD medical devices other than specified above | |  | |  |  |
| **Sterilization Method for Medical Devices** | | | | | |
| Ethylene oxide gas sterilization (EOG) | |  | |  |  |
| Moist heat | |  | |  |  |
| Aseptic processing | |  | |  |  |
| Radiation sterilization (e.g. gamma, x-ray, electron beam) | |  | |  |  |
| Sterilization method other than specified above | |  | |  |  |
| **Medical Devices Incorporating / Utilizing Specific Substances / Technologies** | | | | | |
| Medical devices incorporating medicinal or biologically active substances | |  | |  |  |
| Medical devices containing or manufactured using tissues of animal origin | |  | |  |  |
| Medical devices incorporating derivatives of human blood | |  | |  |  |
| Medical Devices incorporating other human cells/tissues | |  | |  |  |
| Medical devices utilizing micromechanics | |  | |  |  |
| Medical devices utilizing nanomaterial | |  | |  |  |
| Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed | |  | |  |  |

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| **Other areas of expertise** |  |  |  |

Note: Auditing Organizations may use different marks in table to differentiate between practical experience, internal training, and external training.