

Regulations/MDSAP Mapping Task Force



13 May 2024 MDCG Meeting
Agenda item 3.1.2

Outline

Benefits of MDSAP:

- General considerations
- NB/AOs performing combined audits
- NBs currently not participating in the program

Patient safety and scrutiny

- **Issues of concern addressed in design and production within one audit**
Standardized audit sequence (management -> TD/pre-market -> CAPA -> vigilance -> design -> production) with prioritised selection of samples to review in audit based on outputs from earlier parts of the same audit
- **Deeper scrutiny – more holistic perspective**
Overall audit task amplified with view angles of different regulations on the same topic
- **Objective grading of nonconformities**
Algorithmic grading fixed to the related ISO 13485 requirement clause and binary escalation factors
- **Swift response to issues**
14-day CAPA plan and **30-day CAPA actions** on grade 4 and 5 nonconformities
90-day audit report for all audits or **45-day audit report** in case of severe problems
- **Immediate transparency of severe problems**
5-day notice to regulators of severe nonconformity situations / public health threat / fraud / counterfeit

General considerations



Transparency to regulators

- **Audit report in a uniform format** – comparable level of detail across different AOs
- **Transparent audit reports and nonconformities** – provided to authorities through REPs database
- **Data analysis of audit reports and nonconformities** – data is extracted by REPs from XML-based forms
- **Informed decision on regulatory action in case of issues** – can be based on audit records available in REPs

General considerations



Lower barriers for industry

- **Certificates recognised** by multiple jurisdictions – 5 members, 6 affiliates and other countries
Could this even further **raise acceptance of MDR/IVDR** in the world and lower trade barriers for our industry, like it was the case at the time of GHTF?
- **Transparent, consistent, predictable process** – detailed audit process requirements accessible to public
- **Objective through uniformity** – audits performed in similar way across different AOs
(Lack of process harmonisation between NBs seems to be a prominent concern)
- **Audit leveraging resources** – by avoiding multiple/redundant audits, reduce inspections

Notified bodies who are also AOs



NB/AOs

Harmonised, streamlined, enhanced and predictable process under MDR/IVDR

- Uniform audit checklist (P0002), planning (P0008), reports and NC (P0019), terminology, roles, codes... - consolidated audit expectation, **no need for NB to invent its own way**
- Thorough **planning of audit programme** (P0008 aligned to Annex VII) - aligned audit duration, increased scrutiny
- **Reduced administrative burden** – no need for filling multiple reports, parallel processes, parallel resolution of NCs...
estimated saving **1-2 auditor-days per audit** on admin work by removing repetitive items, **potentially more** through clear content guide

What would specifically exceed the benefit of combined audits as performed today

- **Free up auditor resources** – combining audits is not mandatory today, therefore not utilized uniformly across NB/AOs
- **Free up internal resources** - managing overlapping schemes cost a lot of effort for scheme owners and project managers

Notified bodies who are not AOs



NB who are not AOs

Same benefits as for NB/AOs (previous slide), plus:

Lower-barrier access to MDSAP

- More so than for NB/AOs: **mature recipe** for a uniform audit, removal of need to establish own ways
- It is already easy for a designated NB to comply with MDSAP recognition requirements – were initially widely aligned to common NB requirements at the time of their establishment (apart from auditing process requirements, some specific training requirements)

EU joining MDSAP can massively contribute to efforts made when the scheme was initially created



“...a global approach to auditing and monitoring the manufacturing of medical devices could improve their safety and oversight on an international scale...” [from [MDSAP webpage](#)]

However, no rush as there are still steps to take

To do:

- **Guidance for NBs** to use AO audit approach (at least audit reporting and NC writing) in MDR/IVDR audits
Abbreviated training for NBs on the method from existing NB/AOs or regulators to lower entry barrier (normally a 2-week full-time training for every auditor)
Voluntary pilot use of AO methods by NBs as option
- **Clarification** of AO-NB interaction as to how the AO uses input from, and provides output to, the NB process, to allow effective coverage of MDR/IVDR in its audit, for example:
 - Does NB need to perform an “extra” QMS assessment in addition to AO audit?
 - What constitutes the AO “general” portion of the audit report and NCs and what is NB “extra” content on top of that?

Need some more time as official observer, but must become significantly more engaged to create a legal and technical roadmap to join as full member, which should be our clear objective and priority for our industry

Thank you for your attention

Questions & Answers



Regulations/MDSAP task force

