European Diagnostic Manufacturers Association

EDMA position paper

QUALITY MANAGEMENT SYSTEM INSPECTIONS

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Background

With the development of more detailed regulatory systems across the globe, manufacturers are facing a growing number of requests for inspections of facilities to audit quality management systems from regulatory authorities across the globe.

As the principles of quality management are universal, the core requirements of all of these inspections are the same, as has been captured in the work of GHTF SG4. However different regulators may and often do add a number of particular requirements on quality management systems which lead to minor discrepancies in the various systems.

Issues

Having the quality management system of a facility audited is important to ensure the overall quality of the production. However the multiplication of audits from various sources causes a number of issues:

- Multiplication of the time needed for auditing the plant itself
- Different emphasis in audits can lead to assessments which are not aligned

These activities could in principle lead to persisting contradictory requirements being requested by different authorities, however in practice this has not been documented to date.

However equally important to the issues raised by the multiple audits themselves are the problems caused by the way authorities use the audits, most notably:

- Blocking of market access to a product before an audit can be completed – a particular issue with authorities which are under a resource strain
- Lack of feedback from authorities after the audit (delays of more than six months have been reported)
- At the international level, the language of the auditors may not be the language in which a manufacturer keeps the technical documentation. This can lead to misunderstandings due to possibly different nomenclatures.

All of these facts together mean that the multiple audit system being put in place by authorities today is far from optimal.

ISO 13485 recognition

Ideally the best solution for the authorities would be to involve them in the standards development process and to recognize ISO 13485 as the standard for quality management systems (is optimal for IVD manufacturers and manufacturers of other medical devices). This does in fact happen in practice for a large number of regulatory authorities (e.g. across the entire EFTA area).

Coupled with the recognition of harmonized requirements there is then the need for the recognition of a single audit: in order for this to happen, regulators need to have confidence that a conformity assessment body (CAB[1]) will be able to audit a facility on behalf of the regulators. This is the system which is in place within the EU where Notified Bodies are under the supervision of authorities:

[1] Notified Bodies within the EU system are typical conformity assessment bodies.

and they in turn build up the expertise to audit manufacturers across Europe.

The US FDA has initiated a voluntary audit report submission program. This program is offering device manufacturers, with a facility audited under the regulatory system implemented by one of the GHTF founding members using ISO 13485, to submit the resulting audit report. FDA will use the report to determine whether that facility can be removed from the FDA's routine inspection plan for one year.

Single audit by a recognized Conformity Assessment Body

In a number of situations however, the recognition of ISO 13485 is not an option, as certain local requirements may not be covered to an accepted level of detail from the viewpoint of a local authority.

In such situations, however, it is possible for a single conformity assessment body to be accountable to multiple authorities and thus to be able to perform a single audit against multiple requirements.

This is a system which is already functional, for instance Canada recognises a series of conformity assessment bodies (registrars in the Canadian system). The key to this system is to have authorities recognizing a series of CABs to perform audits on their behalf, similar systems are being implemented in Japan, Taiwan and Australia.

This system has a number of advantages both for manufacturers and for authorities.

Authorities benefit from the following:

- Less resources need to be allocated to conformity assessment (very close to being resource neutral)
- Focus on the evaluation of the CABs and of their audit reports
- Can include specific requirements (e.g. reporting or regulatory requirements) for the CAB to evaluate
- Will receive documentary evidence (audit reports) from the CAB
- Patients access to essential devices and to state of the art technologies is more easily ensured

The use by a given regulator of internationally recognized conformity assessment bodies will result in a simplification both for the export and the import of devices from that country, thus facilitating trade.

Manufacturers benefit from the following:

- A single consolidated audit to ensure that all requirements are met
- Certainty with regards to evaluations, reports etc.
- Simpler to implement changes coming from one source and maintain a strong QM system as compared to the piecemeal approach.

As such, this is therefore an approach which is in principle applicable by any regulatory body worldwide and which can be implemented to the benefit of all the parties concerned.

When multiple authorities request the same specific requirements additional to the present text of ISO 13485, the standardization process allows the proposal for potential inclusion in the next revision of ISO 13485.

Conformity Assessment Bodies

The competence of Conformity Assessment Bodies needs to be demonstrated to authorities in order they can have a confidence in the work of the CAB.

Competence is both a technical and a regulatory competence which can be demonstrated through the accreditation of the CAB resulting in an international recognition of this accreditation.

Technical competence is the ability to assess the manufacturer's implementation of individual aspects of a quality management system and the documentation of this assessment.

Regulatory competence is the understanding of applicable regulatory requirements and their implementation within a manufacturer's quality management system, e.g. reporting etc.

This is analogous to the framework used in other sectors, e.g. accreditation of laboratories which test food products prior to exportation.

Audits of subcontractors

The recognition of multiple CAB by authorities would simplify the mechanisms of audits of subcontractors provided that subcontractors have all been audited by a recognized CAB. Thus, the work of such CABs would not need to be repeated.

EDMA Recommendations

EDMA strongly encourages the recognition of ISO 13485 as a means of international harmonization. The standard has been shown along the time to provide a solid basis for QMS assessment and should then be sufficient to provide compliance with quality management system requirements. EDMA is not in favour of additional national requirements.

However, in those cases where full ISO 13485 recognition is demonstrated not to be sufficient, additional requirements should be clearly documented by authorities to permit compliance.

EDMA believes in the use of recognized third party Conformity Assessment Bodies, as a means of demonstrating compliance, where the assessment of compliance will be based on ISO 13485 and any relevant additional requirements defined by national health authorities.

The use of such Conformity Assessment Bodies has been demonstrated to guarantee that the quality management systems within the IVD field are in compliance with regulatory requirements from multiple regulators, ensuring both demonstrated product safety and effectiveness with the least burden for authorities and manufacturers.

References:

Draft Guidance for Industry, Third Parties and FDA Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program

EDMA QM Inspections Task Force