

INTERNAL AUDITS IN MEDICAL DEVICE COMPANIES ARE THEY REALLY INTERNAL?

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Abstract

In my experience as a lead auditor for a European Notified Body, I have noticed many cases where internal audits are done by external consultants. This is really an easy solution for the management of the medical devices company and a good business opportunity for consultants. However this approach is missing the main intent of the Internal Audit as required by the Quality Management System standards and regulations.

The requirements for internal audits are detailed in ISO 13585 and in the FDA Quality System Regulation 21 CFR part 820. There is a requirement that the audit needs to be performed by individuals who do not have direct responsibility for the matters being audited.

In many small and medium size medical devices companies (mostly startups), the internal audits are actually done by external consultants. In many cases the audit is conducted as a preparation before an external audit (Notified Body, FDA or customer). In many cases the "Audit Criteria" used in those internal audits are the requirements of the regulation or standard and not the requirements of the company's procedures and instructions.

Therefore essential parts of the real intention of the standards and regulations in regard to internal audit are missed. This paper describes the problematic issues with internal audits as performed by external consultants and suggests ways to improve the quality and effectiveness of the internal audits so that the real intentions are met.

Essentials of Internal Audit

Internal audit is a key element of the Quality Management System (QMS).

ISO 13485 tells us the following:

“The organization shall conduct internal audits at **planned intervals to determine whether the quality management system:**

- a) **Conforms to the planned arrangements** (see 7.1), to **the requirements of this International Standard** and to the **quality management system requirements established by the organization**, and
- b) Is **effectively** implemented and maintained.”

Internal Audit Criteria

As we can see ISO 13485 wants the internal audits to determine whether the Quality Management System conforms to the:

- Planned Arrangements
- Requirements of this international standard (ISO 13485)
- QMS Requirements established by the Organization.

For some reason many medical device companies build their internal audits mostly around the second bullet - Requirements of this international standard (ISO 13485) and add also requirements of additional regulations. A typical audit plan of such company looks like the following example:

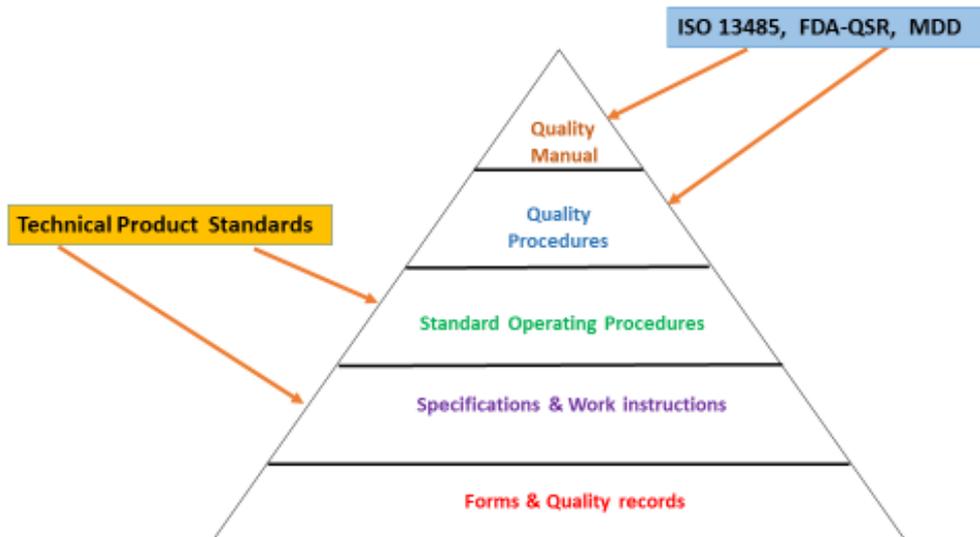
Annual Internal Audit Plan

Year: _____ Issued by: _____ Date: _____

Subject	ISO 13485	MDD 93/42/EEC	Section in FDA QSR	Due (month)	Resp.	Performed on
Documentation control	4.2.1; 4.2.2; 4.2.3		820.40 820.186			
Records Control	4.2.4		820.180 820.184			
Quality Objectives, Quality Policy, Planning	5.3; 5.4.1; 5.4.2; 4.1	Annex II section 3.2	820.20			
Management Responsibility - Responsibility, Authority; Internal Communication, management rep.; Quality Manual	5.5; 4.2.2; 4.1	Annex II section 3.2 (b)	820.20			
Management review	5.6; 8.2; 5.1; 5.2; 8.4; 8.1					
Resource management - training	6.1; 6.2; 6.3; 6.4		820.20			

This is not what the intention of Internal Audit is. This type of plan is more appropriate for a third party certification audit where the criteria is based only on regulatory and standard requirements.

It is important to understand when the Quality Management System is established the intention is to meet all applicable requirements of the relevant regulations and standards as shown in the documentation pyramid below:



When the Quality Management System is initially established it should be verified that all applicable requirements of the relevant regulations and standards are really met. Furthermore this is also verified by the external audit of the regulatory authority who certifies the Quality Management System and issues a formal certificate.

This certification actually means that the planned arrangement and the requirements established by the organization comply with the relevant regulations and standards.

From this point and on the internal audits should be against the internal procedures and instruction and should verify the adherence to the requirements in those internal documents.

When changes are made to the regulations and standards, the internal documentation may need to be revised. This is controlled by the external document control process which is an explicit requirement of ISO 13485 (clause 4.2.3 f).

Internal Audit Plan

The periodic internal audit plan is in most cases an annual plan and it is a good practice to present the plan as part of the annual Management Review.

ISO 13485 tells us that:
 “An audit programme shall be planned, **taking into consideration the status and importance of the processes and areas to be audited**, as well as the **results of previous audits.**”

Do we need to include in the periodic audit plan all of the QMS processes and areas? Some companies think that yes and they actually have a fixed annual plan that includes all the clauses of the standard/regulations. They repeat every year this same plan without any change.

The intention is that the periodic internal audit plan will be dynamic and will prioritize the processes / areas that are have higher importance or known weaknesses. This is why the periodic plan will probably need to be somewhat different each time.

ISO 13485 also tells us that:
Selection of auditors and conduct of audits **shall ensure objectivity and impartiality** of the audit process. **Auditors shall not audit their own work.**

Unfortunately in most cases I cannot see in the audit plans who are the person who are planned to the audit are the persons responsible for each process / area. The objectivity needs to part of the audit plan. Following is a suggestion for the content of an internal audit plan that reflects those requirements:

Annual Internal Audit Plan

Year: 2015 Rev 0 Issued by: _____ Date: _____

#	Subject	Reference SOP / WI	Due (month)	Responsible for Process	Planned Auditor	Date Performed
1	Documentation & Records control					
2	Training & Competence					
3	Design Control					
4	Change Control					
5	Purchasing & Supplier Control					
6	Incoming inspection					
7	Production & Process Control					
8	Clean Room -work environment					
9	Calibration					
10	Non-conforming Product					
11	Corrective and Preventive Action					
12	Technical File					
13	Clinical Trials					
14	Product Line 1					
15	Product Line 2					
16	Process A					
17	Process A					
18	Physical Configuration Audit 1					
19	Physical Configuration Audit 2					

Approved by: _____ Date: _____ Signature: _____

This issue of objectivity may lead small / medium size companies to outsource some of the audited processes to an external consultant.

This outsourcing is allowed by ISO 13485. However some companies take this to an extreme where all the internal audits are outsourced.

This may be a convenient solution for the company and a profitable one for the consultant, but the intention of the whole internal audit can be missed. In some cases the audit by the external auditor is not done against the internal procedures and instructions and a generic audit checklist per regulations / standard is used.

Audit for Effective implementation and maintenance

ISO 13485 clause 8.2.2 b) requires that the audit shall determine whether the QMS is effectively implemented and maintained.

Therefore the verification of the effectivity of implementation needs also to part of the internal audit. For this purpose it is recommended to use the” **process approach**” which is part of ISO 13485 (clause 0.2). If we realize that the output of a process is an input for another process we need as part of the audit to look also into the other processes that are fed by the audited process. For example: When we audit the incoming inspection process we need to look also into the manufacturing and assembly process and see if we can find issues that can be attributed to faulty incoming inspection.

Conclusions

Companies should revisit their internal audit practices and try to make them more “internal” by:

- Using as criteria their own procedures and instructions
- Using as much as possible their own staff as auditors.

This will improve the internal audit outputs so the real, effective and meaningful corrective action can be generated.

Bibliography

1. ISO 13585 :2003 - Medical devices- Quality management systems – Requirements for regulatory Purposes
2. FDA - Quality System Regulations (QSR) – 21 CFR part 820