Your Trusted Knowledge Partner

Välkommen till
5 Ways to Optimize Your Internal Audits

Vi startar inom kort. Bekanta dig gärna med verktyget Zoom under tiden.

- Q&A använder du för frågor till dagens tema som besvaras i så stor utsträckning som möjligt efter presentationen.
- Chat använder du för att komma i kontakt med vår kursadministratör.
- Alla deltagares kameror och ljud är avstängda.
- Webinariet spelas in

QAdvis

QAdvis – Key competence areas

QMS In-the-cloud

Turn Key QMS
Digital Signatures
Efficient and Lean

System Development

Product Software Validation
Computer Systems Validation
Risk Management
Verification and Validation
Process Validation

Legal representation

European Authorized Representative
and UK Responsible Person

Training/Courses

CE-Marking, MDR, IVDR
ISO 13485 & QSR & MDSAP
IEC 62304 & IEC 82304-1
IEC 60601-1
IEC 62366-1
Risk Management

Agile, Lean and Six Sigma

Training and consulting
in cooperation with US partner

QA&RA/Clinical Consulting

Interim Management, Expert Advise
Audits/Mock audit/Due Diligence
Warning Letters, Compliance Projects
PMA, 510k, CE-Marking, Tech Doc
Global Regulatory Support, Clinical Evidence
Vigilance, Recalls, Post market

5 Ways to Optimize Your Internal Audits

Hosted by
Camilla Drott & Emma Jansson
www.qadvis.com

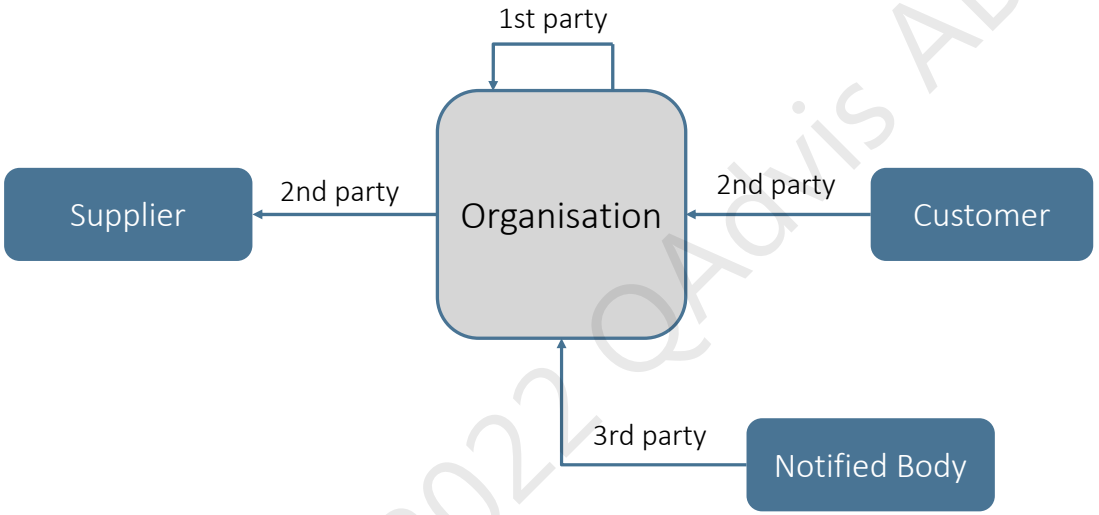
Q&A

Webinar goal

Disclaimer

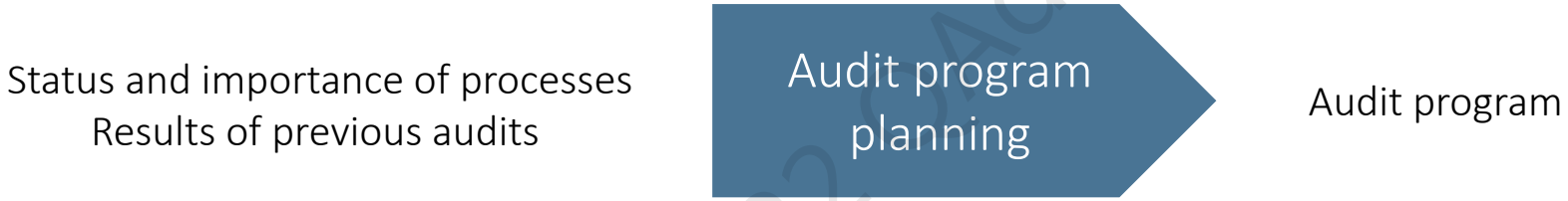
Please note that, any views given by us on the interpretation of the legislation represent our best judgement at the time, based on the information available. Such views are not meant to be a definitive statement of law, which may only be given by the courts.

Understand the various audit types



Implement an efficient internal audit program

An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.



Process map

Process metrics

Status and importance of processes

Results of previous audits

Process issues and changes

Audit results

Audit program planning

Audit program

Process	2022	2023	2024
Management	X Auditor A		X
Design	X Auditor B	X	
Manufacturing		X	X
PMS	X Auditor A	X	
Incident Rep	X Auditor A	X	
Purchasing	X Auditor B		
...			

Save audit time with clear audit criteria

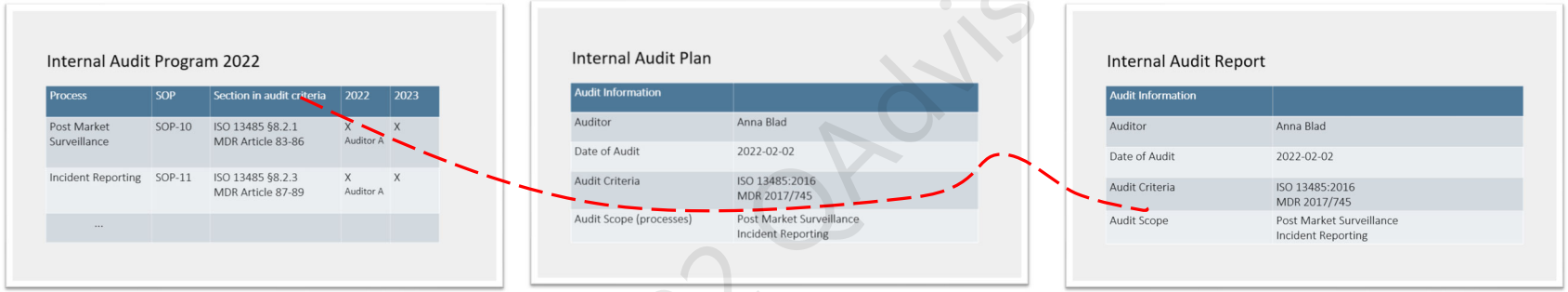
8.2.4 Internal audit

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

a) conforms to planned and documented arrangements (1), requirements of this International Standard (2), quality management system requirements established by the organization (3), and applicable regulatory requirements (4);

1. Contracts
2. ISO 13485
3. SOP/Policies
4. MDR/IVDR, QSR

Type		Nonconformity
Major NC	Minor NC	
☐	☒	Requirement: ISO 13485:2016 clause 7.1 Planning of product realization Description of Nonconformity: The Risk Management process is not fully effective. Supporting Objective Evidence: **A Risk Management Plan has not been established.** *This is required by own procedure SOP-XXX and by ISO 14971.*



Internal Audit Program 2022

Process	SOP	Section in audit criteria	2022	2023
Post Market Surveillance	SOP-10	ISO 13485 §8.2.1 MDR Article 83-86	X Auditor A	X
Incident Reporting	SOP-11	ISO 13485 §8.2.3 MDR Article 87-89	X Auditor A	X
...				

Internal Audit Plan

Audit Information	
Auditor	Anna Blad
Date of Audit	2022-02-02
Audit Criteria	ISO 13485:2016 MDR 2017/745
Audit Scope (processes)	Post Market Surveillance Incident Reporting

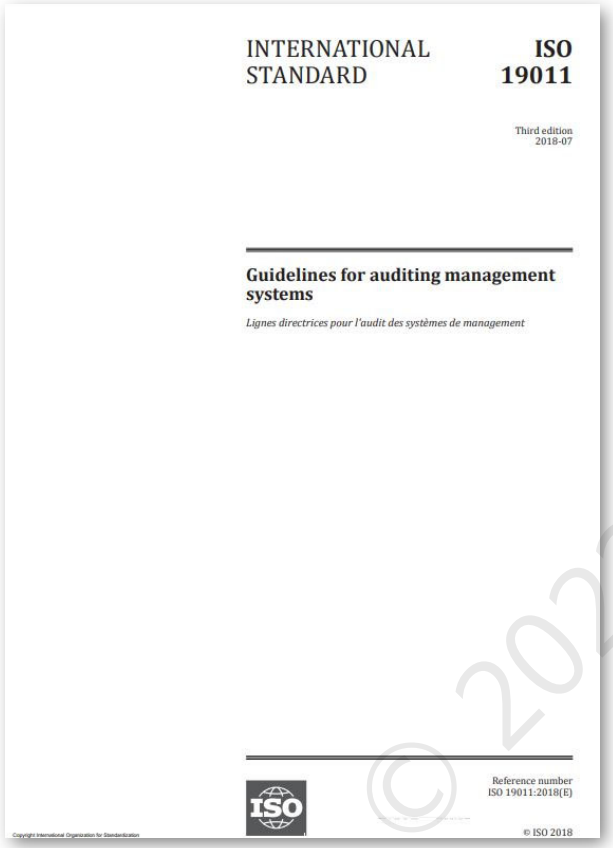
Internal Audit Report

Audit Information	
Auditor	Anna Blad
Date of Audit	2022-02-02
Audit Criteria	ISO 13485:2016 MDR 2017/745
Audit Scope	Post Market Surveillance Incident Reporting

Prepare the audit by reviewing key documents

- Quality manual and process map
- Process description(s) / SOP(s)
- Organizational chart and role descriptions
- Previous audit reports
- Logged deviations and corrective actions within the area
- Process metrics
- Management review protocol

Use the available support



INTERNATIONAL STANDARD

ISO 19011

Third edition
2018-07

Guidelines for auditing management systems

Lignes directrices pour l'audit des systèmes de management

Reference number
ISO 19011:2018(E)

- Managing an audit program
- Performing an audit
- Competence of auditor

- Audit scope
- Audit findings vs Nonconformity, opportunities for improvement
- Audit programme vs audit plan
- Audit methods
- Format for reporting
- Competences required in audit situations

- QSIT - Quality System Inspection Technique
- ISO/IEC 17021-1:2015 - Requirements for bodies providing audit and certification of management systems

5 ways to Optimize Your Internal Audits

camilla.drott@qadvis.com
emma.jansson@qadvis.com

Your
Trusted
Knowledge
Partner

QAdvis