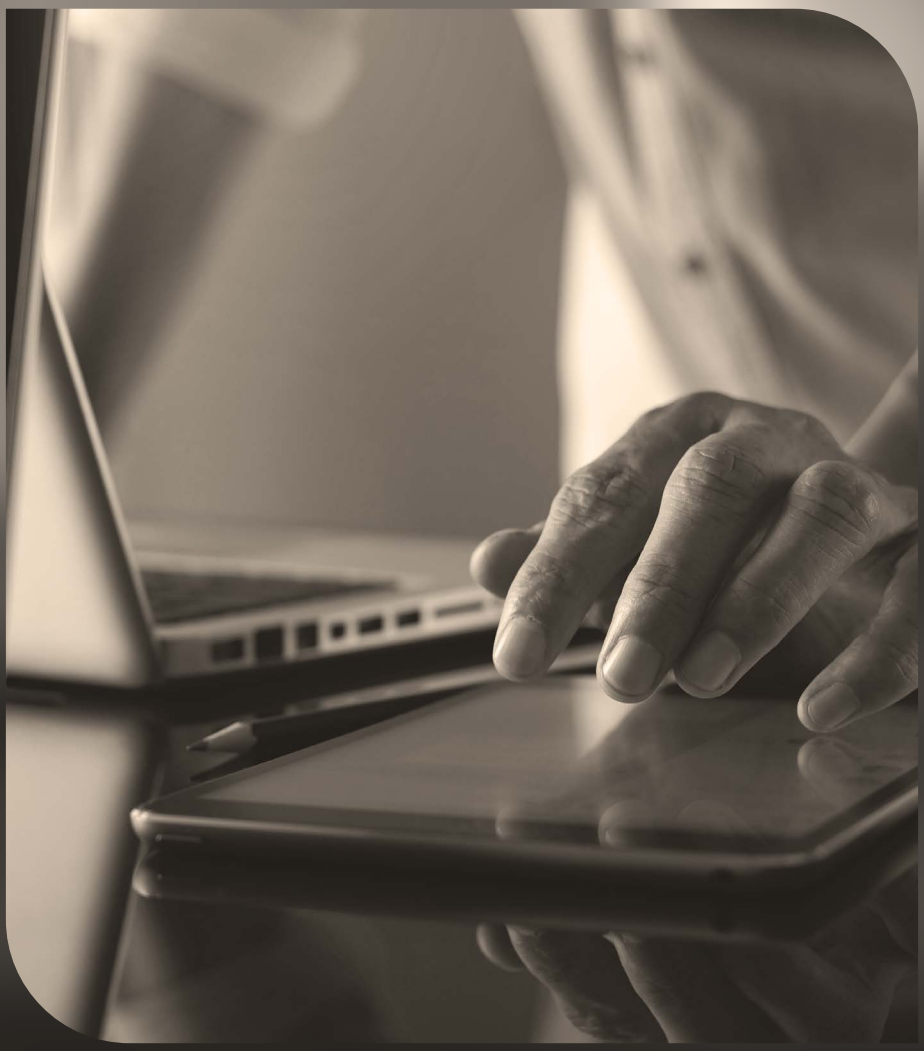
Audit Center



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CONTENTS

OUR AUDITING SERVICES

Driven by our life science and regulatory compliance expertise, our Audit Center provides auditing and evaluation services that assess the compliance and performance of your organisation, your systems and your upstream and downstream partners.

We carry out audits for the life sciences industry:

BIO-TECHNOLOGY

PHARMACEUTICALS

Medicinal products,
Veterinary,
Combination products

MEDICAL DEVICES

MDs, IVDs and Software
(SaMD)

COSMETICS

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OUR AUDITING AND EVALUATION SERVICES

AUDITING

To gain external perspective

A gap assessment of your quality system according to the current regulation, including an audit report with observations.

EVALUATION

To improve existing processes

A detailed survey of an existing system (data integrity, risk management, infrastructure qualification/validation, manufacturing process, etc.) conducted with the aim of improving it. It is accompanied by an action/remediation plan.

SHARED/GROUPED AUDITS*

To reduce costs

A shared/grouped audit is an audit of the single supplier performed by an auditing subcontractor for several sponsors/customers.

REMOTE AUDITS

To maintain the continuity of your audits

A remote audit ensures continuity of your audit and evaluation activities, therefore maintaining your regulatory compliance while adapting to potential constraints (remote sites, restricted access to industrial sites, lockdowns, etc.).

SPECIFIC AUDITS

To provide a custom response to a specific need

A specific audit is conducted to meet a particular need:

- Due Diligence audit
- Pre-submission technical file review
- Computer System Validation (CSV) audit
- Organisational audit (simulation)
- For-cause audit

* SHARED/GROUPED AUDITS

ADDED VALUE

Reduced auditing costs for the sponsor – as these are largely shared with other sponsors – while ensuring a satisfactory audit.

Reduced costs for the auditee, who has to undergo fewer audits, and a single overall report.

MANAGING CONFIDENTIALITY

The auditing subcontractor ensures that the sponsors remain confidential. The sponsors do not know one another; they know how many sponsors there are but are not informed of the other sponsors' identities. The auditing subcontractor produces as many reports as there are sponsors. Each sponsor's report only contains the common elements and the content specific to the sponsor.

HOW DOES A SHARED AUDIT WORK?

In general, it proceeds as follows:

1. A sponsor decides to perform a shared audits.
2. The sponsor asks its supplier if they agrees.
3. The sponsor contacts an auditing subcontractor.
4. The auditing subcontractor contacts the supplier to check if there are other potential sponsors.
5. The auditing subcontractor contacts the potential sponsors to obtain their agreement.
6. The auditing subcontractor submits a final audit proposal to the sponsors that agreed.

We can manage the entire process and contact your suppliers to explain the process and the advantages of shared audits to them. We can perform audits in almost every country across the world, including China and India.

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OUR ADDED VALUE

Our vision of auditing is based on the triad of excellence, performance and compliance

EXCELLENCE

Our auditors are trained on best auditing techniques and have several years of experience in the areas they audit.

PERFORMANCE

We adapt our audits based on associated risks (product, process, context), at the lowest cost, with effective methods and tools.

COMPLIANCE

The services we deliver are fully in line with the applicable regulatory requirements, for perfect auditing of your QMS.

OUR SYSTEM

An effective system

Our own quality system

An electronic audit database

Specific procedures and records

We can provide you with our own sharable templates (audit program audit plan, audit reports, CAPA monitoring)

A SERVICE CENTER

Comprehensive management of your audit activity

Thanks to our digitised tools, our Audit Center can operate as a service center for your audit activity:

- Audit planning
- Auditors qualification and certification
- Selection of normative and regulatory guidelines
- Preparation of standard audit questionnaires
- Review and management of CAPAs
- Publication of reports
- Email alerts
- Multi-site audits

OUR TEAM OF AUDITORS

HIGHLY QUALIFIED PROFESSIONALS

All of our auditors have at least 10 years of workplace experience in the areas they audit.

CERTIFIED AUDITORS

Certification for all our auditors

Our auditing team includes American Society for Quality (ASQ) Certified Quality Auditors with extensive experience in US, Canadian, and international quality and regulatory affairs. All our auditors are internally certified by a strict program that is based on ISO 19011 recommendations and formalised in our internal procedure.

WORLDWIDE PRESENCE

Our auditors are spread all around the North America continent and in the rest of the World in order to provide local services, and minimise travel time and costs. We have the capacity to carry over audits on your behalf on every contient.

THE QUALIFICATION SCHEME FOR OUR AUDITORS

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OUR CATALOGUE

QUALITY SYSTEM AUDITS

A quality management system must be continuously improved. To do so, you must have process performance indicators, and audit them on a regular basis in order to detect potential gaps and identify areas for improvement.

A quality management system should also be in line with the organisation, and its main objective should be to increase efficiency and compliance.

QS01 INTERNAL QUALITY AUDIT ACCORDING TO ISO 13485

QS02 INTERNAL QUALITY AUDIT ACCORDING TO MDSAP

QS03 INTERNAL QUALITY AUDIT ACCORDING TO MDR (EU).

QS04 INTERNAL QUALITY AUDIT - OTHER REFERENTIAL

OBJECTIVES

- Conduct an objective assessment of a process in relation to regulatory guidelines
- Conduct an objective assessment of a quality management system in relation to good quality practices
- Identify areas for improvement
- Comply with the regulatory requirements
- Conduct an objective assessement of the followings: change control, deviation, CAPA, training, stability program, maintenance, validation program, equipment/calibration, material control and customer feedback

DESCRIPTION

The internal quality audit is conducted by a certified auditor in accordance with the ISO 19011 recommendations and includes the following steps:

1. Determining the audit date with the process or QMS manager
2. Reviewing the process's main procedures and the most recent audit report where applicable
3. Preparing the audit plan and audit materials
4. Sending the audit plan to the process or QMS manager
5. Audit: opening meeting, document review and interviews, closing meeting
6. Drafting the audit report
7. Sending the report to the audited individuals for verification
8. Sending the report to the sponsor
9. Reviewing the responses provided by the process or QMS manager if applicable

DURATION

Half-day for preparation
Half-day to 1 day for an audit of an internal process depending on the type of process
1 to 5 days with 1 or 2 people for an audit of a complete QMS
Half-day to 2 days to generate the report and the recommended action plan for an audit of a complete QMS

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DELIVERABLES

- Audit plan
- Audit materials: may consist solely of regulatory and/or normative texts
- Audit report: audit summary, people interviewed, documents reviewed, strengths, weaknesses, conclusion, audit findings/observations
- Action plan for an audit of a complete QMS

MAIN APPLICABLE GUIDELINES/AUDIT CRITERIA

All of the regulatory and normative guidelines applying to each area of health depending on the audited process.

- ISO 19011 - Guidelines for quality audits
- ISO 9000
- ISO 9001
- ISO 13485
- MDR 2017/45 and MDR 2017/46
- MDSAP
- ISO 10xxx series

INSPECTION READINESS AND SITE MOCK INSPECTIONS

Undergoing a European regulatory inspection is not always easy, and when it comes to a Canadian or Japanese inspection or an American investigation, it can be even more complicated, especially if you are not prepared for culture shock or for different and even surprising interpretations. Mock inspections can keep you from falling into traps that can have dramatic consequences when placing a new product on the market.

MI01 MOCK INSPECTION OF A MEDICINAL PRODUCT PRODUCTION SITE

(To prepare for a American, European, Japanese inspection)

MI02 MOCK INSPECTION OF A COSMETIC PRODUCTION SITE

(To prepare for a American, European, Japanese inspection)

MI03 MOCK INSPECTION OF A VETERINARY PRODUCTION SITE

(To prepare for a American or European inspection)

MI04 MOCK INSPECTION OF A FOOD PRODUCTION SITE

(To prepare for a European inspection)

MI05 MOCK INSPECTION OF A MEDICAL DEVICE PRODUCTION SITE

(To prepare for a American, European, Japanese, Brazilian, Canadian, Australian inspection)

MI06 MOCK INSPECTION OF A BIOTECHNOLOGICAL PRODUCTION SITE

(To prepare for a American, European, Japanese inspection)

MI07 GLP SITE MOCK INSPECTION

(To prepare for a American, European, Canadian inspection)

OBJECTIVES

- Have an objective overview of a site in relation to regulatory guidelines
- Determine action plans to resolve potential gaps
- Learn how to describe processes to inspectors, with their way of seeing things
- Prepare to undergo an inspection with a different vision

DESCRIPTION

The mock inspection is conducted by a certified auditor, using the same techniques implemented by inspectors, and includes the following steps:

1. Determining the mock inspection date with the company
2. Preparing the inspection plan
3. Sending the inspection plan to the company
4. Audit*: opening meeting, document review and interviews, closing meeting
5. Writing the audit report with the recommended action plan
6. Delivering the report with advice concerning the action plan to be implemented

** All throughout the mock inspection, advice is given to facilitate the approach and make it easier to understand the process and the inspectors' culture.*

FDA mock audits can be conducted in English in order to place the various participants in situations that are as realistic as possible.

DURATION

3 to 5 days with 1 or 2 auditors for the mock inspection depending on the size of the company and the scope
2 to 3 days to generate the report and the related action plan
1 day for feedback and advice about implementing the action plan

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DELIVERABLES

- Audit plan
- Audit materials: may consist solely of regulatory and/or normative texts
- Audit report: mock inspection summary, people interviewed, documents reviewed, strengths, weaknesses, conclusion, audit findings/observations, and related action plan.

MAIN APPLICABLE GUIDELINES/AUDIT CRITERIA

- FDA 21 CFR Part 58
- FDA 21 CFR Part 110 – cGMP
- FDA 21 CFR Parts 210 & 211, cGMP
- FDA 21 CFR Part 500
- FDA 21 CFR Part 600
- FDA 21 CFR Part 700
- FDA 21 CFR Part 820, Quality System Regulation
- FDA 21 CFR Part 11, Electronic Records, Electronic Signatures
- FDA, Process Validation: General Principles and Practices
- FDA, General Principles of Software Validation
- FDA QSIT – Quality System Inspection Technique
- FDA Guide to Inspections of Foreign MDs
- FDA/CDRH design control report and guidance
- GMP Europe Part I, Good manufacturing practice for finished products
- GMP Europe Part II - ICH Q7, Good manufacturing practice for active pharmaceutical ingredients
- GMP Europe Part III - ICH Q9, Quality Risk Management – ICH Q10, Pharmaceutical Quality System
- MDR 2017/745
- MDR 2017/746
- ISO 13485 – Quality management systems for medical devices
- ISO 14971 – Risk management applied to medical devices
- IEC 62304 – Software life cycle processes
- Health Canada guidance document 10-109087-604
- Standards Council of Canada CAN-P-1583

HEALTH AUTHORITY REMEDIATION AUDITS

Receiving an injunction from the FDA is a serious matter. A proper response and an efficient remediation plan is necessary in order to avoid escalation. This is particularly important as the FDA will often not provide feedback until the action is closed and evidences have been submitted by the manufacturer.

RE01 REVIEW OF A RESPONSE TO FORM 483

RE02 REVIEW OF ACTION PLAN EFFECTIVENESS
- REVIEW OF AN ACTION PLAN IMPLEMENTATION EVIDENCES AND EFFECTIVENESS CHECK

RE03 REVIEW OF WARNING LETTER RESPONSE

RE04 CONSENT DECREE COMPLIANCE AUDIT

RE05 RECALL EVALUATION

OBJECTIVES

• Evaluate the injunction received by the firm (form 483, warning letter, consent decree, recall) to define the perimeters of the deviation.

• Conduct an objective assessment of procedures, processess and records to determine proper action plan. Evaluate the effectiveness of the action plan and determine remaining risks.

DESCRIPTION

Health Authority remediation audits are conducted by technical and scientific audit consultants and include the following steps:

1. Review of the injunction and gap assessment (both holisitc and specific)

2. Review of the firm's response and evaluation of the response pertinence.

3. Review of evidences of action plan implementation

4. Review of the effectiveness check plan and evidencces of effectiveness of the action plan

5. Delivering the report

DURATION

1 to 5 days with 1 for the evaluation, or remotely depending on the scope of the evaluation
1 to 3 days to generate the report and the related action plan

DELIVERABLES

• Audit plan
• Audit materials: check-list with areas to be audited and questions; may consist solely of regulatory and/or normative texts or questionnaires dealing with specific guidelines
• Audit report: audit summary, people interviewed, documents reviewed, annotated databases, strengths, weaknesses, conclusion, audit findings/observations with related action plan.

MAIN APPLICABLE GUIDELINES/AUDIT CRITERIA

• 21 CFR part 820
• 21 CFR parts 210 and 211
• 21 CFR parts 803 and 806

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SUPPLIER AND VENDOR AUDITS

Suppliers, subcontractors and vendors has a big impact on the quality of your products. They also impacting the traceability of your products. An audit will help ensure service quality and capabilities of suppliers and will provide the regulatory authorities with proof that the service is being properly managed.

SVA01 AUDIT OF RAW MATERIALS AND PACKAGING ITEMS SUPPLIERS

SVA02 AUDIT OF DISTRIBUTORS – VIGILANCE

SVA03 AUDIT, PROCESS SUBCONTRACTING

SVA04 REGULATORY AUDIT OF SERVICE PROVIDERS (METROLOGY/ INSTRUMENTATION/CALIBRATION)

SVA05 AUDIT OF CONTROL LABORATORIES/ ANALYTICAL TESTS

SVA06 AUDITS OF COMPUTERISED, AUTOMATED SYSTEMS AND/OR SOFTWARE SUPPLIERS

OBJECTIVES

- Initial qualification of a supplier/vendor.
- Requalification of a supplier/vendor
- Audit for cause of a supplier/vendor

DESCRIPTION

The audit is conducted by a certified auditor in accordance with the ISO 19011 recommendations and includes the following steps:

1. Determining the audit date with the auditee
2. Reviewing the auditee main procedures, the contract between the sponsor and auditee, the auditee history, and the most recent audit report where applicable
3. Preparing the audit plan and audit materials
4. Sending the audit plan to the auditee
5. Audit: opening meeting, document review and interviews, closing meeting
6. Drafting the audit report
7. Sending the report to the sponsor
8. Reviewing the auditee's responses
9. Audit follow-up (optional)

DURATION

Half-day for preparation
1 to 5 days for the audit depending on its scope, the number of sites, the type of subcontracting and the type of supplier (e.g. 1 day for metrology; 5 days for a data centre)
Half-day to 2 days to generate the report and review the supplier's responses

DELIVERABLES

- Audit plan
- Audit materials: may consist solely of regulatory texts
- Audit report: audit summary, people interviewed, documents reviewed, strengths, weaknesses, conclusion, audit findings/observations

MAIN APPLICABLE GUIDELINES/AUDIT CRITERIA

- FDA 21 CFR Parts 210 & 211, cGMP
- FDA 21 CFR Part 820, Quality System Regulation
- FDA 21 CFR Part 11, Electronic Records, Electronic Signatures
- ISO 13485
- MDSAP
- MDR 2017/745
- MDR 2017/746

PRECLINICAL AND CLINICAL AUDIT

The purpose of a sponsor's audit, which is independent of and separate from routine monitoring or quality control functions, should be to evaluate trial conduct and compliance with the protocol, SOPs, GCP, and the applicable regulatory requirements. Efor can help you select your suppliers/vendors/third parties and carry out independent audits of investigation sites.

CA01 CRO / INVESTIGATION SITE / SPONSOR CLINICAL MONITORING

- Selection audit: choice of investigation centres for the study
- QMS audit: audit of the quality system (GCP, ISO, sponsor requirements, etc.)
- Follow-up audit: periodic audit of compliance with GCP and sponsor requirements
- Study protocol audit: audit of compliance with GCP and sponsor requirements for essential documents before study initiation (clinical study design, CRF, consent form, etc.)
- Phase/process audit: audit of the clinical study (volunteer inclusion phase, critical study phase, etc.)
- Study report audit: audit of documents and clinical data, consistency with CRF, data management
- For-cause audit: investigative audit following non-compliance

CA02 DATA MANAGEMENT/BIOSTATISTICS CLINICAL AUDIT

- QMS audit: audit of compliance with good data management practices for clinical data and the statistical processing of these data

CA03 PRECLINICAL AUDIT - TEST ITEM

- Storage, receipt management of references and standards

CA04 LABORATORY CLINICAL AUDIT

- QMS audit: audit of compliance with good practices for clinical laboratories
- Selection audit: choice of clinical laboratories or test benches

OBJECTIVES

Evaluate trial conduct and compliance with the protocol, SOPs, GCP, and the applicable regulatory requirements.

DESCRIPTION

The audit is conducted by a certified auditor in accordance with Good Clinical Practice recommendations and includes the following steps:

PREPARATION

1. Defining the type of audit and its objectives with the applicant
2. Choosing guidelines/check-list
3. Collecting data: study documents, contract, CAPA, etc.
4. Drafting the audit program
5. Contact with the auditee: choice of audit date and sending of audit agenda

ON-SITE AUDIT

6. Performing the audit (with or without sponsor representative): opening meeting, document review and interviews, observations for current study phase, closing meeting

REPORT AND FOLLOW-UP

7. Writing the report
8. Review by sponsor/on-site presentation
9. Sending to auditee
10. Reviewing auditee response
11. Monitoring the corrective plan
12. Classifying providers

DURATION

Half-day to 1 day for preparation
2 to 5 days for the audit depending on its scope
1 to 3 days to generate the report and review the responses

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DELIVERABLES

- Audit plan
- Audit materials: may consist solely of regulatory texts
- Audit report: audit summary, people interviewed, documents reviewed, strengths, weaknesses, conclusion, audit findings/observations, and audit details.

TYPES OF AUDITED SITES

STUDY CONDUCT

- CRO
- Investigation site
- Monitoring site

CLINICAL DATA PROCESSING

- Data management/biostatistics
- Archiver
- IT host, IT support
- Solutions developer (eCRF, IVRS, pharmacovigilance, etc.)

INVESTIGATIONAL PRODUCT

- Investigational product manufacturing
- Pharmacy (receipt/dispatch of the investigational product)

ANALYSIS

- Laboratory

MAIN APPLICABLE GUIDELINES/AUDIT CRITERIA

- 21CFR Part 312
- 21 CFR Part 58
- 21 CFR Part 11
- 21 CFR Part 312, 21CFR Part 11, and SOR/2003-196 Part 4, GUI-0100 - Part C
- ICH E6 (GCP)
- ICH E9
- GCP
- GCP + IT guidelines
- GMP
- Good hospital pharmacy practice
- WHO GCLP

REGULATORY DOSSIER AUDITS

How can you be sure that the regulatory dossier you are going to submit is complete, consistent and compliant with the regulatory requirements of the countries concerned? How can you manage the life cycle of a registered product? The answers to these questions lie in the audits, evaluations and verifications carried out, which enable you to be certain of the good quality (content, compliance, etc.) of the dossier you intend to submit or notify.

RD01 REGULATORY DOSSIER AUDIT - MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE

RD02 REGULATORY DOSSIER AUDIT - RADIOPHARMACEUTICALS

RD03 REGULATORY DOSSIER AUDIT - FOODSTUFFS AND NUTRIENTS

RD04 REGULATORY DOSSIER AUDIT - COSMETIC PRODUCTS

RD05 REGULATORY AFFAIRS - BIOLOGICAL PRODUCTS

RD06 REGULATORY AFFAIRS - MEDICAL DEVICES

RD07 REGULATORY AFFAIRS - COMBINATION PRODUCTS

RD08 DUE DILIGENCE AUDIT - ALL TYPE OF DOSSIERS

OBJECTIVES

- Audit a submission dossier for a medicinal product – NDA, MAA (EU)
- Audit a dossier to carry out clinical trials – IND application
- Audit a notification dossier following a variation or modification
- Audit a submission dossier for medical device - 510(k), PMA, Technical file (CE mark)
- Audit a technical file for CE Mark
- Audit a submission dossier for other countries (Canada, UK, Switzerland, Mexico, Brazil, Japan, China, Australia, MENA region...)
- Due Diligence prior to acquisition and/or for fundraising purpose.

DESCRIPTION

The audit is conducted by a certified auditor in accordance with the ISO 19011 recommendations and good practices for the area in question and includes the following steps:

1. Determining the audit date with the company
2. Preparing the audit plan
3. Sending the audit plan to the company
4. Audit*: opening meeting, document review and interviews, closing meeting
5. Writing the audit report with the recommended action plan
6. Delivering the report with advice concerning the action plan to be implemented

** if necessary*

DURATION

1 to 5 days with 1 or 2 auditors for the audit depending on the number of dossiers and their complexity
1 to 3 days to generate the report and the related action plan
1 day for feedback and advice about implementing the action plan

DELIVERABLES

- Audit plan
- Audit materials: may consist solely of regulatory and/or normative texts
- Audit report: audit summary, people interviewed, documents reviewed, strengths, weaknesses,
- conclusion, audit findings/observations, and related action plan.

MAIN APPLICABLE GUIDELINES/AUDIT CRITERIA

The following guidelines can be used for this audit:

- Electronic Common Technical Document (eCTD)
- Non-eCTD electronic Submission (NeeS)
- Monographs: USP, EP, JP, etc.
- Medical device regulation
- 21 CFR parts 312 and 314
- ISO 13485
- Other applicable regulatory texts from the ANVISA, TGA, MHLW, PMDA, etc.

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DATA INTEGRITY AUDITS

The integrity of GxP data guarantees product compliances, patient and user safety, and the good auditability of the quality system. It is true that requirements on data integrity are not new; however, recent publications by the regulatory authorities (MHRA, FDA, WHO guidance documents) require complete and effective control over all GxP data, governance included. Our experts can help you carry out a comprehensive analysis of all of your data.

DI01 DATA INTEGRITY EVALUATION

DI02 MOCK INSPECTION FOCUSING ON DATA INTEGRITY

DI03 DATA INTEGRITY AUDIT OF THIRD PARTIES

DI04 COMPUTERISED SYSTEM COMPLIANCE AUDIT

OBJECTIVES

- Conduct a comprehensive analysis of processes, the data used/generated, and the records used/generated
- Determine the format for data and records (paper/electronic)
- Determine the type of data and records (static/dynamic)
- Determine metadata
- List data processing operations, decisions made, signatures used
- Analyse means of control and compliance vs ALCOA+
- Determine a ST/MT/LT action plan

DESCRIPTION

Data integrity audits are conducted by certified auditors and include the following steps:

1. Determining the evaluation audit date with the company
2. Preparing the audit plan and audit materials
3. Sending the audit plan to the company
4. Evaluation: opening meeting, document review and interviews, closing meeting
5. Writing the audit report with the recommended action plan
6. Delivering the report

DURATION

1 to 30 days with 1 or 2 auditors for the evaluation depending on the size of the company and the scope of the evaluation
1 to 5 days to generate the report and the related action plan
1 day for feedback and advice about implementing the action plan

DELIVERABLES

- Evaluation plan
- Audit materials: check-list with areas to be audited and questions; may consist solely of regulatory and/or normative texts or questionnaires dealing with specific guidelines
- Audit report: list of gaps and areas for continuous improvement, scoring, audit summary, proposed remediation action plan

MAIN APPLICABLE GUIDELINES/AUDIT CRITERIA

- FDA 21 CFR Part 820, Quality System Regulation
- FDA 21 CFR Part 11, Electronic Records, Electronic Signatures
- EU GLP/GMP / cGMP
- ICH Guidelines
- ISO 13485 – Quality management systems for medical devices
- GMP Europe Annex 11, Computerised systems
- CLUSIF (France, computer security)
- ISO 14971 – Risk management applied to medical devices
- ISPE guides
- PIC/S PI 011-3 and PI 041-1
- Data integrity guidance: FDA, MHRA, WHO, EMA
- FDA, General Principles of Software Validation

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