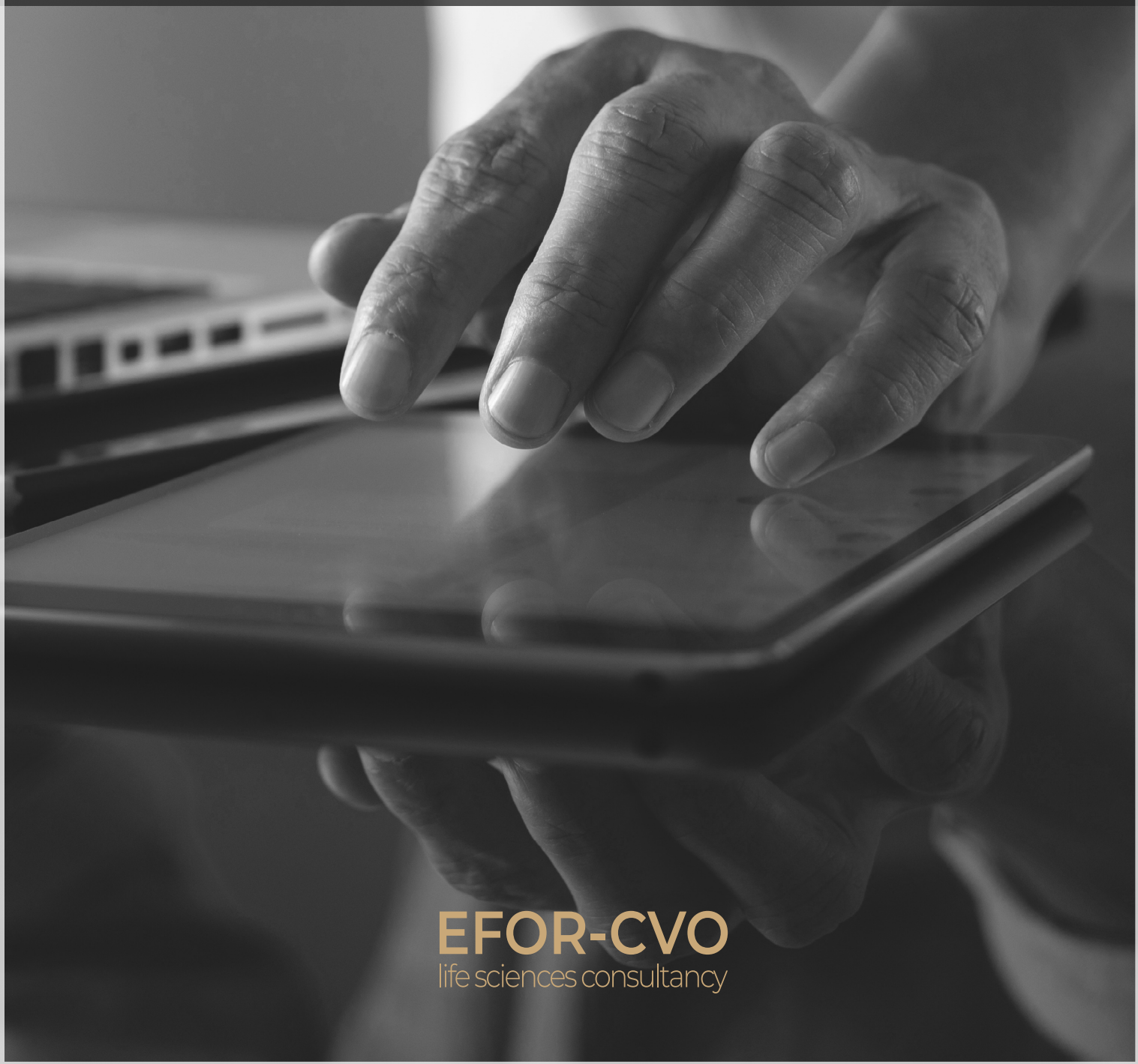
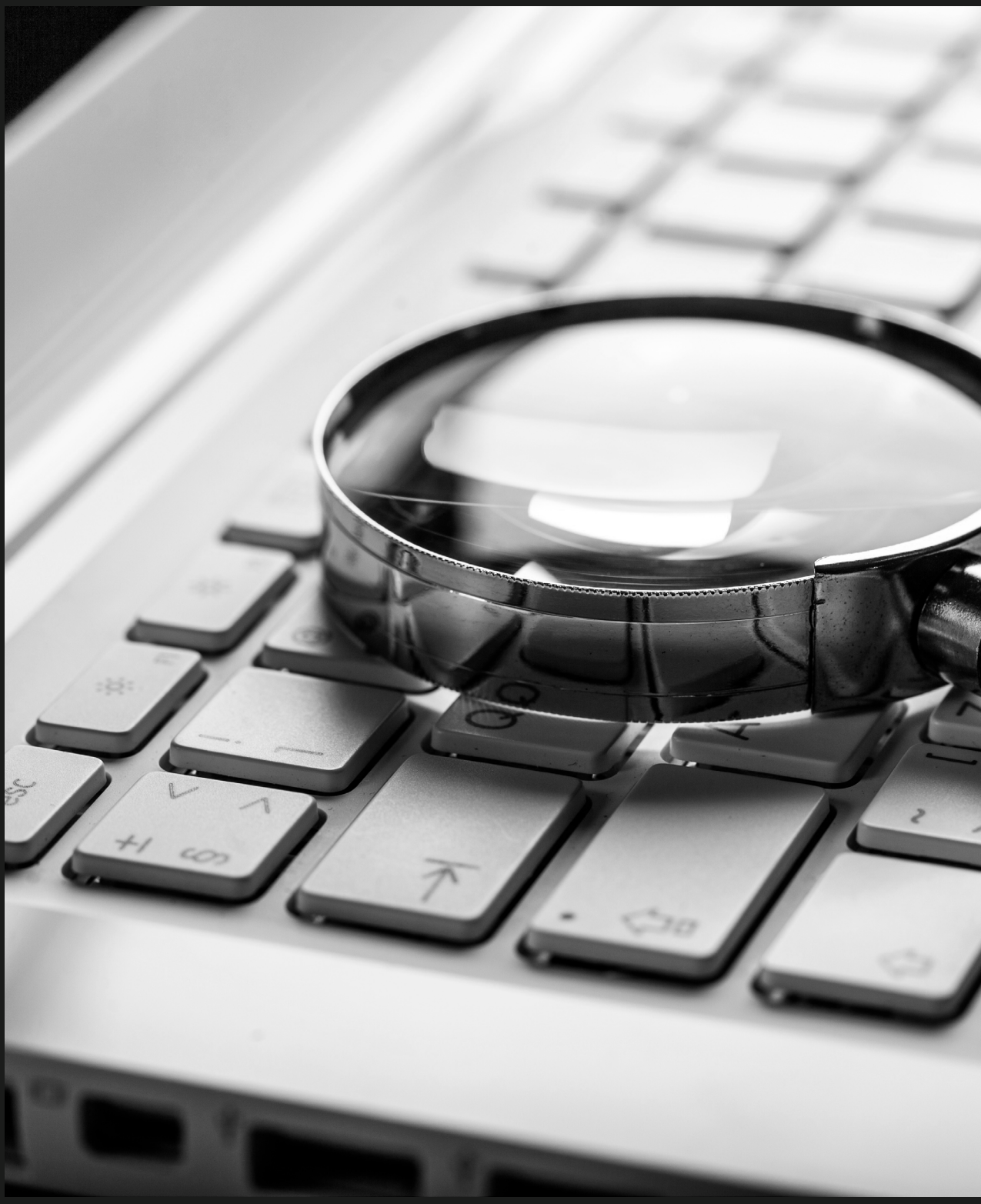
AUDIT CENTRE

MEDICAL DEVICES - PHARMACEUTICALS - COSMETICS



EFOR-CVO
life sciences consultancy



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CONTENTS

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OUR AUDITING SERVICES

Drawing on our life science and regulatory compliance expertise, our Audit Centre provides auditing and evaluation services that assess the compliance and performance of your organisation and system and those of your upstream and downstream partners.

We carry out audits for the life sciences industry:

PHARMACEUTICALS

Medicinal products, Veterinary, Combination products

MEDICAL DEVICES

MDs, IVDMDs

COSMETICS

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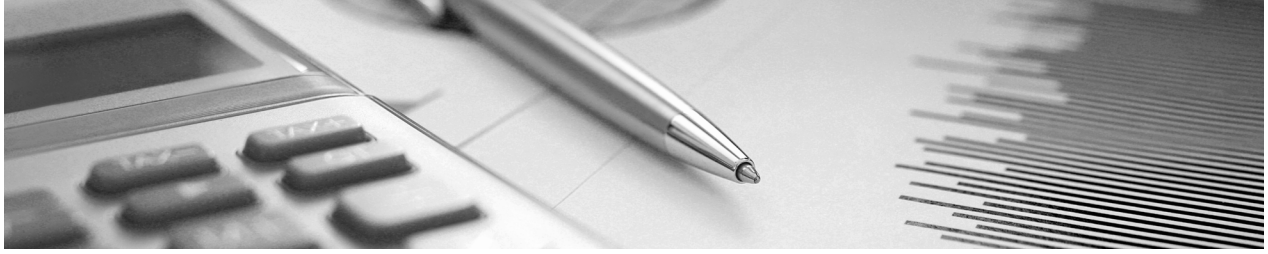

OUR AUDITING AND EVALUATION SERVICES

AUDITING

To gain external perspective

An audit analyses gaps in your system according to the new regulations and includes an audit and observation report.

EVALUATION

To improve on what already exists

An evaluation is not a regulatory requirement; rather, it is a detailed survey of an existing system (data integrity, risk management, infrastructure qualification/validation, document management system, etc.) conducted with the aim of improving it. It is accompanied by an action/remediation plan.

SHARED/GROUPED AUDITS

To reduce your costs

A shared/grouped audit is an audit of the same 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 working, 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:

- CSV audit
- Inspection assistance (front or war room)
- Organisational audit (simulation)
- Documentation audit (common technical document / technical dossier / qualification / validation protocol and report)
- For-cause audit

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* 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

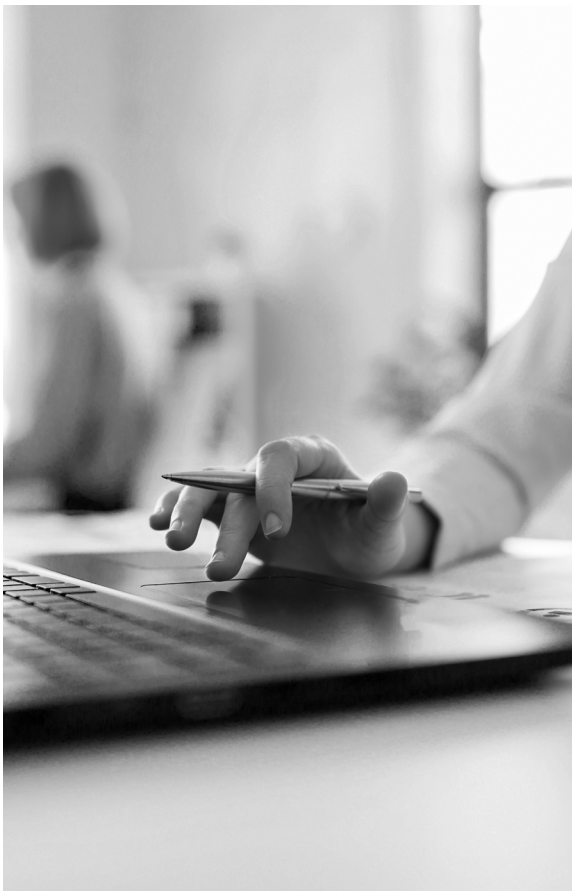
The auditing subcontractor ensures that the sponsors remain confidential. The sponsors do not know one another; they know how many sponsors there are but are not informed of the other sponsors' identities. The auditing subcontractor produces as many reports as there are sponsors. Each sponsor's report 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 shared audits.
2. The sponsor asks its supplier if it 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 REMOTE AUDITING SOLUTION

CONTEXT

With the spread of remote working, and with potential restrictions on access (especially in the context of the health crisis) it can become increasingly difficult for outside personnel to access industrial sites.

In order to respect your constraints without compromising your audit and evaluation schedule and while maintaining your regulatory compliance, we can provide you with an alternative solution: remote auditing.

We regularly implement remote audits, which are recognised by the regulatory authorities, depending on the context and the criticality of the process to be audited.

THE ADVANTAGES OF A REMOTE AUDIT

Remote follow-up and support, subject to your availability.

The same service quality as with an on-site audit.

Saves you and your teams time.

You do not fall behind when it comes to your audit schedule.

A team of auditors with expertise in the areas of life sciences and regulatory compliance.

HOW DOES A REMOTE AUDIT WORK?

We use a web conferencing system at your convenience.

We first send you an audit plan and a list of key documents to be returned to the auditor to save time by carrying out a preliminary documentation audit.

We conduct the audit in a web meeting, sharing screens to view SOPs, protocols, plans and records between you and our auditor.

Our auditor interacts with you, answers your questions, and identifies any gaps.

The audit is finalised with a wrap-up.

A complete audit report is then sent to you with details concerning the audit procedures.

Note that in some cases, based on a risk analysis and when deemed appropriate, an additional “field” audit is carried out to supplement the remote audit.

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OUR ADDED VALUE

THE EPC CONCEPT

Guaranteeing the effectiveness of our audits

Our goal is to provide audit services tailored to the needs of sponsors and auditees alike, in order to set the standard for health audits.

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

THE ADVANTAGES PROVIDED BY OUR AUDIT CENTRE

- Specific, dedicated audits for the life sciences industry
- A team of expert auditors
- Audits in line with our changing businesses and with regulatory developments
- Services with high added value
- “A la carte” service provision

EXCELLENCE

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

PERFORMANCE

We adapt our audits in light of the 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.

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A SERVICE CENTRE

Comprehensive management of your audit activity

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

- Audit planning
- Management of auditor training and authorisations
- Selection of normative and regulatory guidelines
- Preparation of standard audit questionnaires
- Analysis of response compliance
- Management of observations
- Management of CAPAs
- Publication of reports
- Email alerts
- Multi-site audits
- Management of rights

OUR SYSTEM

An effective system

We have our own QMS.

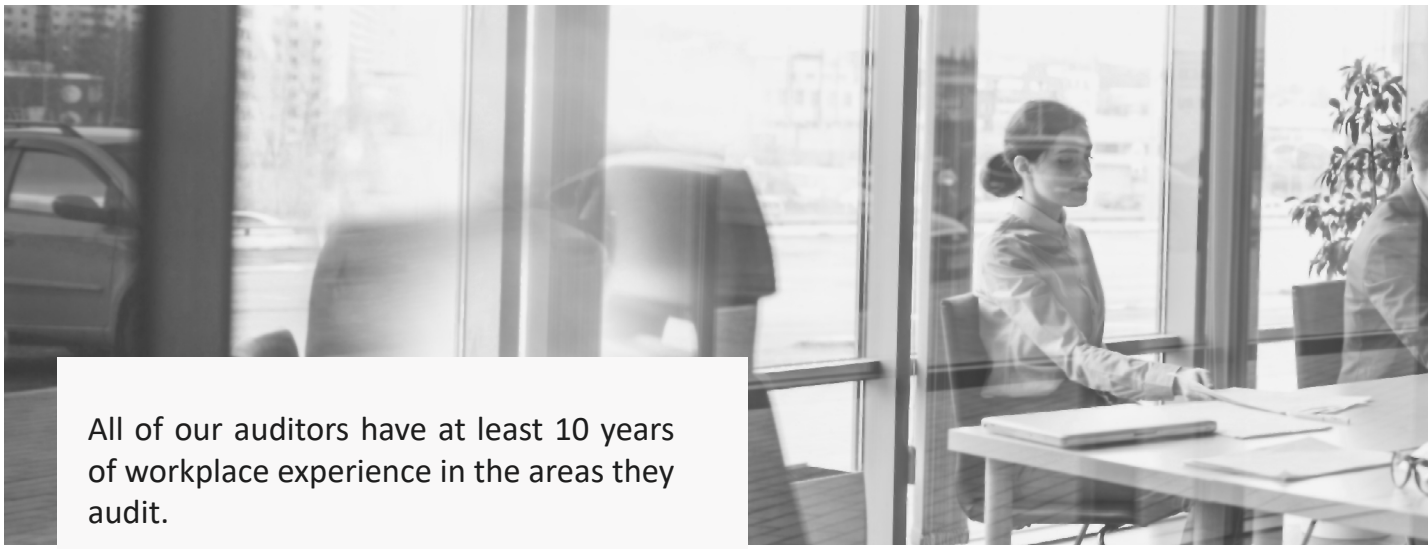
We have an electronic audit database.

We have procedures and records.

We can provide you with our own formats (audit programme, audit plan, audit reports, CAPA monitoring).

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 auditors are EFOR-CVO internally certified by a strict programme that is based on the ISO 19011 recommendations and is formalised in our CVO_FACPR001 procedure, which has been approved by the Audit Director and technical department.

This programme includes several certification options depending on the future auditors' experience. All of these options start with theoretical training validated by assessing the auditor's knowledge and degree of understanding of auditing principles and concepts. A pass rate of at least 70% is required to move up to the next level.

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A NETWORK OF MOBILE EXPERTS

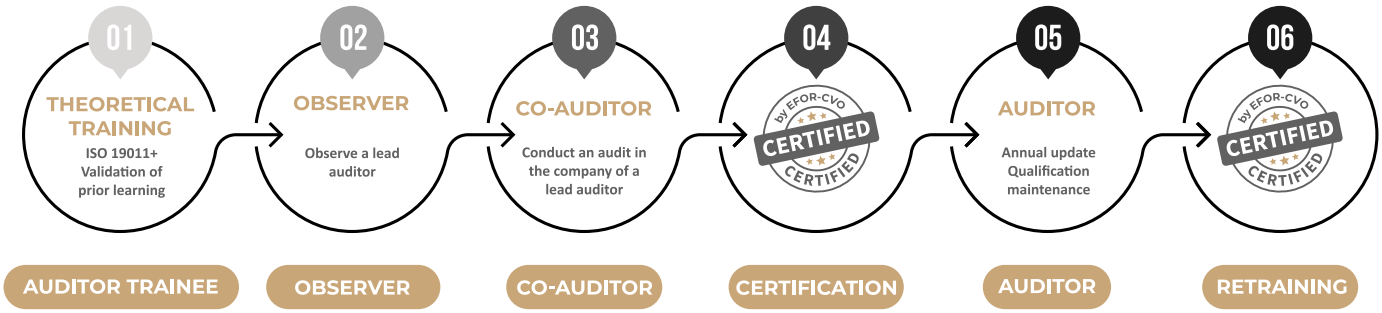
Worldwide presence

We have carried out over 2,000 audits in Europe, North Africa, South America, Asia, the United States, and India.

Auditors working in close proximity to companies

Our auditors are spread across most of our agencies in France, Belgium and Switzerland in order to provide local services and minimise travel time and costs.

THE QUALIFICATION SCHEME FOR OUR AUDITORS



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OUR CATALOGUE

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CLINICAL AUDITS

ICH E6 (R2) reinforces the notions of the risks to and safety of subjects in a quality assurance system. 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-CVO can help you select your suppliers/vendors/third parties and carry out independent audits of investigation sites.

AC01 CRO / INVESTIGATION CENTRE / SPONSOR CLINICAL AUDIT

- 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
- Internal audit: evaluation of the sponsor's QMS

AC02 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

AC03 IT/IP MANUFACTURER CLINICAL AUDIT

- Supplier audit according to IT or GMP guidelines for the investigational product

AC04 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 programme
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. Mailing 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 centre
- Monitoring centre

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

- Directive on “clinical trials on medicinal products”
- EU Volume 10 Clinical Trials guidelines
- ICH E6 (GCP)
- ICH E9
- Personal protection
- ISO 14155-1 and 2, 9001
- ISO 9001
- Bioresearch directive
- GDPR (CNIL, PIA, etc.)
- PI 011-3 (IS validation); GCDMP (CDISC)
- French data protection act
- GCP
- GCP + IT guidelines
- GMP
- Good hospital pharmacy practice
- WHO GCLP
- EMA clinical lab GCP inspections

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PRE-CLINICAL AUDITS

Any non-clinical laboratory that carries out GLP trials must comply with GLP requirements and may be subject to an inspection by the competent authorities or other certification bodies.
EFOR-CVO can support you by carrying out independent audits of the facilities and studies of sponsors and subcontractors, providing you with additional assurance that the laboratory complies with the regulations (e.g. 21 CFR Part 58, OECD GLP), SOPs or study protocol.

APC01 PRE-CLINICAL AUDIT - STUDY CONDUCT

- Single- or multi-site study
- Management of sponsor communication
- Management of amendments/deviations

APC02 PRE-CLINICAL AUDIT - RAW DATA PROCESSING

- Audit trail for raw data: electronic, paper, laboratory logbook management, environmental monitoring

APC03 PRE-CLINICAL AUDIT - TEST ITEM

- Characterisation
- Storage, receipt, management of references and standards

APC04 PRE-CLINICAL AUDIT - TEST SYSTEM

- Veterinary, cell cultures, validation of analytical methods

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 programme
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. Mailing 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

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.

MAIN APPLICABLE GUIDELINES/AUDIT CRITERIA

- OECD GLP
- 21 CFR Part 58
- 21 CFR Part 11
- ISO 9001

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REGULATORY AFFAIRS 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.

AAR01 REGULATORY AFFAIRS AUDIT - MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE

AAR02 REGULATORY AFFAIRS AUDIT - RADIOPHARMACEUTICALS

AAR03 REGULATORY AFFAIRS AUDIT - FOODSTUFFS AND NUTRIENTS

AAR04 REGULATORY AFFAIRS AUDIT - COSMETIC PRODUCTS

AAR05 REGULATORY AFFAIRS AUDIT - BIOLOGICAL PRODUCTS

AAR06 REGULATORY AFFAIRS AUDIT - MEDICAL DEVICES

AAR07 REGULATORY AFFAIRS AUDIT - COMBINATION PRODUCTS

OBJECTIVES

- Audit a submission dossier for a medicinal product – MA, NDA
- Audit a dossier to carry out clinical trials – IND application
- Audit a notification dossier following a variation or modification
- Audit a submission dossier for one or more given countries
- Audit a registered dossier with a view to updating it

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

** During the audit, advice is provided to make it easier to understand the gaps observed and to set up appropriate corrective actions.*

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: EP, USP, JP, etc.
- Medical device directives
- ISO 9001
- ISO 13485
- Other applicable regulatory texts from the EMA, the FDA, MHLW, PMDA, etc.

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REGULATORY AUDITS OF SUBCONTRACTORS AND ECONOMIC OPERATORS

The European GMP requirements state that suppliers of raw materials (RMs) and packaging items (PIs) must be evaluated. This evaluation is not possible without conducting a regulatory on-site audit of the supplier. As manufacturing authorisation holder responsible for traceability and vigilance before the regulatory authorities, or for subcontracted processes, you must also audit these subcontractors in order to ensure compliance with the regulatory requirements. When you use service providers, one of the challenges you are faced with is guaranteeing the expected level of service as well as compliance with the regulatory and normative requirements relating to the type of service being requested. An audit will help ensure service quality and the capabilities of suppliers and will provide the regulatory authorities with proof that the service is being properly managed. Determining the level of control over operations and therefore building trust are key components of a good relationship.

ARF01 REGULATORY AUDIT OF RM AND PI SUPPLIERS

ARF02 REGULATORY AUDIT OF DISTRIBUTORS – VIGILANCE

ARF03 REGULATORY AUDIT, PROCESS SUBCONTRACTING

ARF04 REGULATORY AUDIT OF SERVICE PROVIDERS (METROLOGY/ INSTRUMENTATION/CALIBRATION)

ARF05 AUDIT OF CONTROL LABORATORIES/ ANALYTICAL TESTS

OBJECTIVES

- Select a supplier/subcontractor from several options: Selection audit
- Qualify a supplier/subcontractor: Qualification audit Re-qualify a qualified supplier/subcontractor: Re-qualification audit or follow-up audit

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 supplier
2. Reviewing the supplier's main procedures, the contract between the sponsor and supplier, the supplier's history, and the most recent audit report where applicable
3. Preparing the audit plan and audit materials
4. Sending the audit plan to the supplier
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 supplier'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

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MAIN APPLICABLE GUIDELINES/AUDIT CRITERIA

- 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
- GMP Europe Annex 11, Computerised systems and Annex 15, Qualification and Validation
- GMP Europe Annexes depending on the type of activity or service
- ISO 15378 - Primary packaging materials for medicinal products
- The Joint IPEC – PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients
- GDP Europe – Good distribution practice
- GVP Europe – Good vigilance practice
- ISO 9001 (Quality management systems)
- ISO 17025 (Metrology)
- ISO 22716, GMP Europe, Good manufacturing practice for cosmetic products
- MDR 2017/745
- MDR 2017/746

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AUDITS OF SYSTEMS SUPPLIERS AND SOFTWARE VENDORS

How can you be sure that the equipment you are going to purchase meets the regulatory requirements and, most importantly, that it will truly meet the user's needs? Certifications seldom guarantee that the equipment in question is or has been designed and developed according to good practice as part of a quality management system. A software program or computerised and/or automated system cannot be fully verified with only end-of-development tests. Auditing is the only solution that can ensure that the designer/developer/integrator will meet the user's needs and comply with good design and development practices as well as good integration practices. Similarly, using external control laboratories does not clear you of your responsibilities in terms of checks. Auditing these facilities is essential to guarantee the validity of the analyses performed and their results.

AFS11 AUDITS OF PRODUCTION OR LABORATORY EQUIPMENT SUPPLIERS

AFS12 AUDITS OF COMPUTERISED AND/OR AUTOMATED SYSTEMS SUPPLIERS

AFS13 AUDITS OF DESIGNERS/DEVELOPERS/INTEGRATORS OF COMPUTERISED/AUTOMATED SYSTEMS AND SOFTWARE

AFS14 AUDITS OF SAAS/IAAS/PAAS SERVICE PROVIDERS, IS HOSTS, PROVIDERS OF DATA CENTRES, IT/INDUSTRIAL INFRASTRUCTURE, ETC.

AFS15 AUDITS OF SOFTWARE VENDORS (INCLUDING SOFTWARE CONSIDERED AS MDS OR IVDMDS AND SOFTWARE RELATED TO CONNECTED HEALTH OBJECTS, MHEALTH, IOT)

OBJECTIVES

- Select a designer/developer/integrator/supplier/subcontractor from several options: Selection audit
- Qualify a designer/developer/integrator/supplier/subcontractor in relation to a need: Qualification audit
- Re-qualify a qualified subcontractor: Re-qualification audit or follow-up audit

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 supplier
2. Reviewing the supplier's main procedures, the contract between the sponsor and supplier, the supplier's history, and the most recent audit report where applicable
3. Preparing the audit plan and audit materials
4. Sending the audit plan to the supplier
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 supplier's responses
9. Audit follow-up - Optional

DURATION

Half-day to 1 day for preparation
1 to 2 days for the audit depending on the type of supplier and the type of equipment or system
Half-day to 1 day to generate the report

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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

MAIN APPLICABLE GUIDELINES/AUDIT CRITERIA

- ISO 9001 (Quality management systems)
- ISO 90003 (Quality management systems applied to software)
- GAMP 5 (Computerised and/or automated systems)
- IEEE Software Engineering (software and programs)
- Lab GAMP (laboratory equipment)
- PIC/S PI011-3
- 21 CFR Part 11, GMP Annex 11
- ISO 17025, ISO 15189 (medical laboratories)
- IEC 62304
- IEC 82304
- ISO 14971
- IEC 80001
- ISO 80002-1
- ITIL (hosts, data centres)
- GAMP 5 (SAAS, hosts, data centres)
- IT GAMP (hosts, data centres)
- IEEE Software Engineering (SAAS)
- eSCM-SP (outsourcer's audit)

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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 turnover. It should therefore be pragmatic and tailored to the type of manufactured product. Our quality management professionals can help you conduct an accurate assessment of your system.

ASQ41 INTERNAL QUALITY AUDIT OF A COMPANY'S PROCESSES

ASQ42 AUDIT OF A COMPANY'S QUALITY MANAGEMENT SYSTEM

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

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

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 10xxx series

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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.

ADI143 DATA INTEGRITY EVALUATION

ADI144 MOCK INSPECTION FOCUSING ON DATA INTEGRITY

ADI145 DATA INTEGRITY AUDIT OF THIRD PARTIES

ADI146 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

- ISO 9001– Quality management systems
- EU GLP/GMP / cGMP
- ICH Guidelines
- ISO 13485 – Quality management systems for medical devices
- FDA 21 CFR Part 820, Quality System Regulation
- GMP Europe Annex 11, Computerised systems
- FDA 21 CFR Part 11, Electronic Records, Electronic Signatures
- FDA, General Principles of Software Validation
- CLUSIF (France, computer security)
- ISO 14971 – Risk management applied to medical devices
- Guidelines for the application of ISO 9001 to computer software
- ISPE guides
- PIC/S PI 011-3 and PI 041-1
- Data integrity guidance: MHRA, FDA, WHO, EMA

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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.

MIS21 MOCK INSPECTION OF A MEDICINAL PRODUCT PRODUCTION SITE

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

MIS22 MOCK INSPECTION OF A COSMETIC PRODUCTION SITE

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

MIS23 MOCK INSPECTION OF A VETERINARY PRODUCTION SITE

(To prepare for a European or American inspection)

MIS24 MOCK INSPECTION OF A FOOD PRODUCTION SITE

(To prepare for a European inspection)

MIS25 MOCK INSPECTION OF A MEDICAL DEVICE PRODUCTION SITE

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

MIS26 MOCK INSPECTION OF A BIOTECHNOLOGICAL PRODUCTION SITE

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

MIS27 GLP SITE MOCK INSPECTION

(To prepare for a European, American, 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

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.

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MAIN APPLICABLE GUIDELINES/AUDIT CRITERIA

- 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
- GMP Europe Annex 11, Computerised systems
- ISO 22716, GMP Europe, Good manufacturing practice for cosmetic products
- PIC/S PI 011-3, Computerised systems
- OECD GLP (as revised in 1997)
- European medical device directives, 90/385/EEC – Active implantable medical devices
- European medical device directives, 93/42/EEC – "Other" medical devices
- European medical device directives, 98/79/EC – IVD medical devices
- MDR 2017/745
- MDR 2017/746
- MDSAP Audit Model
- MDSAP Audit Companion
- GHTF guidance
- IMDRF guidance
- MEDDEV guidance
- 80002
- 82304
- ISO 13485 – Quality management systems for medical devices
- ISO 14971 – Risk management applied to medical devices
- 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
- IEC 62304 – Software life cycle processes
- GAMP 5
- ANSES
- HACCP
- Health Canada guidance document 10-109087-604
- Standards Council of Canada CAN-P-1583

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EVALUATIONS

Having a company evaluate your quality management or computer system practices and procedures, or having a third party conduct a technical evaluation of your systems, gives you an objective view and makes it easier for you to take a step back from the situation. If they are carried out by professionals with expertise in the audited field, as is the case for the EFOR-CVO auditors, these evaluations let you benefit from the feedback of the auditors and capitalise on best practices to eliminate losses and be more efficient and more profitable.

EV31 EVALUATION OF QMS PRACTICES AND PROCEDURES

EV32 EVALUATION OF IT PRACTICES AND PROCEDURES

EV33 EVALUATION OF PRACTICES AND PROCEDURES FOR QUALIFICATION/VALIDATION (CSV, ASV), METROLOGY, ETC.

EV34 LEAN 6 SIGMA EVALUATION

All companies have the goal of eliminating losses and being more efficient and profitable. A Lean 6 Sigma approach led by Lead 6 Sigma Black Belts can help you achieve this goal. To do so, an initial Lean 6 Sigma evaluation is necessary in order to conduct an assessment that will then allow you to build a future through a culture of continuous improvement.
Various Lean 6 Sigma tools can be used:
Gemba Walk, PDCA, MUDA Elimination (loss/waste), A3, Voice of Customer – VoC, Transfo Lean, DMAIC, Kaizen, DFLSS, Project Charter, SIPOC, VSM, Benefit/Feasibility Matrix, PUGH Matrix, Statistics (linear regression, ANOVA, research design, etc.)

EV35 EVALUATION OF AN ENGINEERING OR IT PROJECT

EV36 TECHNICAL EVALUATION OF SYSTEMS AND EQUIPMENT (UTILITIES, ETC.)

OBJECTIVES

- Conduct an objective assessment of procedures/processes and/or practices in relation to a specific field and regulatory, normative or international guidelines (corporate standard)
- Determine action plans to resolve potential gaps
- Carry out an analysis in order to simplify and streamline the QMS
- Conduct an objective assessment of IT production/processing procedures and/or practices
- Conduct an assessment of IT project practices
- Conduct a review of IT infrastructure management procedures and practices
- Conduct a review of software design and development
- Optimise processing practices
- Conduct a review using the Lean 6 Sigma approach to identify areas for improvement to increase profits
- Reduce waste, defects and stock
- Reduce cycle and lead times: R&D, production, distribution, QC, services, etc.
- Better control processes by reducing variations for critical process parameters
- Conduct an objective technical assessment of systems and equipment in relation to a specific field and regulatory or normative guidelines

DESCRIPTION

Evaluation 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 5 days with 1 or 2 auditors for the evaluation depending on the size of the company and the scope of the evaluation
1 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: 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, strengths, weaknesses, conclusion, audit findings/observations, and related action plan.

MAIN APPLICABLE GUIDELINES/AUDIT CRITERIA

- ICH Q10 – Pharmaceutical Quality System
- ICH Q9 – Quality Risk Management
- ISO 13485 – Quality management systems for medical devices
- ISO 14971 – Risk management applied to medical devices
- ISO 17025 (Metrology)
- ISO 12207 – Systems and Software Engineering – Software Life Cycle Processes
- ISO 9001– Quality management systems
- ISO 90003 (Quality management systems applied to software)
- NF EN 62304 Systems and Software Engineering – Software Life Cycle Processes for Medical Devices
- NF EN 62366 Medical Devices – Application of usability engineering
- GMP Europe Annex 11, Computerised systems
- PIC/S PI 011-3, Computerised systems
- FDA 21 CFR Part 11, Electronic Records, Electronic Signatures
- FDA 21 CFR Part 820, Quality System Regulation
- FDA, Process Validation: General Principles and Practices
- FDA, General Principles of Software Validation
- Lab GAMP (laboratory equipment)
- GAMP 5 (Computerised and/or automated systems)
- IT GAMP (IT infrastructure)
- IEEE Software Engineering (software and programs)
- ITIL (IT infrastructure)
- CMMI (IT processes)
- SPICE (software design and development)
- COBIT
- CLUSIF (France, computer security)
- Lean 6 Sigma tools
- PDA TR32
- ISO/IEC 90003 – Software Engineering – Guidelines for the application of ISO 9001 to computer software
- Project Management Body of Knowledge (PMBOK)
- PRINCE 2
- ISPE guides
- Public procurement guidelines
- All technical guidelines and guidance documents

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SPECIFIC CLINICAL EVALUATIONS

Implementing clinical research activities is currently a core concern for laboratories and manufacturers, which have to combine their ambitions with the need to comply with strict regulatory frameworks and international standards. Boasting over 30 years of clinical experience, the EFOR-CVO and Soladis teams help you evaluate your clinical strategy, standardise your research processes and related documents, and verify the compliance of your products.

EPC01 EVALUATION AND GAP ANALYSIS OF A CLINICAL STRATEGY

EPC02 EVALUATION OF CLINICAL PROCESSES

EPC03 EVALUATION AND GAP ANALYSIS OF CLINICAL DOCUMENTATION

EPC05 CDISC COMPLIANCE EVALUATION

EPC06 EVALUATION OF A STATISTICAL ANALYSIS OF CLINICAL DATA

OBJECTIVES

- Evaluate strategic choices in light of the company's objectives and determine action plans to resolve potential gaps
- Conduct an objective assessment of procedures and processes in relation to clinical research and standardise approaches with regard to regulatory externalities
- Evaluate ad hoc deliverables and their compliance with regulatory, normative or internal guidelines (corporate standard)

DESCRIPTION

Evaluation audits are conducted by technical and scientific audit consultants and include the following steps:

1. Determining the need (kick-off meeting)
2. Collecting customer documents required for the evaluation
3. Evaluating the current situation
4. Drafting the audit report with a corrective or rolling action plan, standardised procedures, document annotation, etc.
5. Delivering the report

DURATION

1 to 5 days with 1 or 2 auditors 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
1 feedback meeting with advice about implementing the 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

- Current regulatory and normative texts depending on the scope and issues:
- ICH Efficacy Guidelines (including GCP)
- CDISC
- Competent authorities and ethics committee (France: CPP, ANSM, etc.)
- GDPR (CNIL, PIA, etc.)

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OPERATIONAL EXCELLENCE

Operational excellence is a systematic and methodological approach implemented in a company with the aims of maximising productivity and product quality, reducing costs, and improving performance.

All ambitions – change of business model, central point of the value chain, identification of new services/products, knowledge of the customer, forecasts – can be studied.

EO10 ORGANISATIONAL ASSESSMENT

Map the steps of your processes and propose improvements to ensure the success of your transformation projects

EO11 ASSESSMENT OF PROBLEMS

Analyse the situation, identify areas to be worked on, and propose a remediation plan

EO12 CORPORATE STRATEGY APPRAISAL

Carry out an internal and external assessment and help define your company's strategy

EO13 DIGITAL ASSESSMENT

Internet of Things (IoT) and Artificial Intelligence (AI):Use data to benefit your transformation projects

OBJECTIVES

- Conduct a customised, individual assessment of the state of the art and organisation with regard to your ambitions, or identify potential for innovative topics
- Identify new areas of growth
- Define an approach and an action plan
- Use data to benefit your transformation projects with an operational action plan

DESCRIPTION

Evaluation assessments are conducted by highly experienced auditors/evaluators who provide their advanced knowledge of and extensive experience with organisations; they include the following steps:

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

DURATION

1 to 5 days with 1 or 2 auditors for the evaluation depending on the size of the company and the scope of the evaluation
1 to 3 days to generate the report and the related action plan
1 day for feedback and for advice concerning the implementation of the action plan

DELIVERABLES

- Assessment plan
- Assessment report: audit summary, people interviewed, documents reviewed, strengths, weaknesses, areas for improvement, conclusion
- List of solutions to highlight
- Project plan and recommendations

MAIN APPLICABLE GUIDELINES/AUDIT CRITERIA

- Regulatory and normative texts depending on the scope and issues:
- ICH Efficacy Guidelines (including GCP)
- State of the art of the industry (SOTA)
- Lean tools (SWOT, PESTLE, VSM, etc.)

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ABOUT EFOR-CVO

EFOR-CVO is EFOR Group's life sciences consultancy. It is the result of the merger of **3 major consulting firms – EFOR Healthcare**, a leader in the medical devices sector, **CVO-EUROPE**, providing valuable support to pharmaceutical industries, and **Soladis**, an expert in digital technology and data processing.

Pooling our expertise has enabled us to **strengthen our position as European leader in life science consulting** and build a **comprehensive range of innovative services** benefiting the entire product life cycle.

Our Technical Department made up of over 150 experts aims to **provide customised responses to our customers' requests** and offer them **premium support addressing each and every one of their challenges.**

United around common values and aspirations, we are determined to **rally our engaged, passionate and truly unique employees in an effort to enhance our customers' performance.**

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