



GMPs & GDP Auditor Competence Framework

Common requirements for Certification & Assessment Bodies and Auditors

ONE FRAMEWORK. CONSISTENT RULES. RECOGNIZED COMPETENCE.

Framework scope: WHO GMP | ICH Q7 | IPEC-PQG GMP | EFfCI GMP | FDA cGMP | ISO 22716 | ISO 15378 | EU GDP | WHO GDP

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Recognition principle	Scope-specific recognition based on demonstrated competence
Public transparency	Recognized scope and status may be published in the WEO Life Sciences Public Registry

Important: This framework does not create regulatory approval, product authorization or accreditation. WEO Recognition is an independent competence-recognition and public-registration framework intended to complement applicable regulatory, accreditation and scheme-owner requirements.

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1. Purpose and Rationale

The WEO Life Sciences Oversight Framework establishes a common and transparent competence baseline for organizations and auditors performing audits and conformity evaluations across GMPs and GDP programs. The framework is designed for a market in which oversight arrangements differ by jurisdiction, program and activity. Some programs operate within mature regulatory, accreditation or scheme-owner structures, while other GMPs and particularly certain GDP assessment activities may have limited, fragmented or no dedicated third-party competence-oversight mechanism for the bodies and auditors performing the work.

WEO therefore provides a cross-program recognition framework focused on the competence, integrity, consistency and public transparency of the organizations and auditors conducting these activities. Where an established regulatory, accreditation or scheme-owner mechanism already applies, WEO Recognition is complementary and does not replace that mechanism.

Different programs. Different oversight structures. One consistent competence framework.

The framework is particularly relevant because deficiencies in pharmaceutical, cosmetic, ingredient, packaging and distribution controls may affect product quality, consumer health and, for medicinal products, patient safety. Auditor competence is therefore treated as a core control rather than an administrative qualification.

2. Scope and Applicability

This framework applies only to two recognition populations:

- **Certification & Assessment Bodies** that conduct third-party or independent GMPs/GDP audits, assessments, certification or conformity evaluation activities within a defined WEO-recognized scope.
- **Auditors**, including Lead Auditors where applicable, who personally conduct GMPs/GDP audits within a defined technical and program scope.

No separate WEO Life Sciences recognition category is established in this framework for assessors, trainers, internal assessors, technical experts, consultants or other professional roles.

Recognition is scope-specific. Recognition for one GMP or GDP program does not automatically confer competence for another program, product category or technical sector.

3. Framework Principles

Principle	WEO requirement
Competence before title	Recognition is based on demonstrated competence and objective evidence, not job title alone.
Scope specificity	Programs and technical scopes are explicitly identified and separately authorized.
Evidence-based decisions	Training certificates alone are insufficient without relevant experience and demonstrated audit capability.
Impartiality	Conflicts of interest are identified, evaluated and controlled.
Consistency	Common minimum rules apply across all included GMPs and GDP programs.
Transparency	Recognition number, status and approved scope may be publicly verifiable.

Principle	WEO requirement
Proportionality	Depth of evidence and witnessing reflects risk, complexity and requested scope.
Complementarity	Existing regulatory approvals, accreditations and scheme-owner approvals may be accepted as evidence where relevant, but do not automatically create WEO Recognition.

4. Terminology and Role Boundaries

Auditor: A person who conducts a systematic, independent and documented audit to obtain and evaluate objective evidence against defined GMPs or GDP requirements.

Lead Auditor: An auditor authorized to lead an audit team and take responsibility for audit planning, team coordination, audit conclusions and final reporting.

Certification & Assessment Body: An organization that manages and delivers third-party or independent conformity evaluation activities and is responsible for auditor authorization, assignment, process control, technical review and integrity of outputs.

Recognition Scope: The specific GMP/GDP program(s), technical sector(s), product categories and role level for which WEO has accepted demonstrated competence.

5. Recognition Architecture

Level	Recognition object	Typical public entry
Organization	Certification & Assessment Body	Organization name, WEO number, recognized GMPs/GDP programs, technical scope, status
Individual	Auditor / Lead Auditor	Name, WEO number, role, recognized GMPs/GDP programs, technical scope, status

WEO Recognition shall not be expressed as unrestricted recognition for “all GMPs” unless the body or auditor has demonstrated competence for each program and technical scope included in the public claim.

6. Common Requirements for Certification & Assessment Bodies

6.1 Legal identity and accountability

The body shall have verifiable legal identity, defined ownership, accountable management and documented responsibility for the integrity of its GMPs/GDP activities.

6.2 Defined recognition scope

The body shall define each program, product/technical sector and activity for which recognition is sought. Marketing claims shall not exceed the approved scope.

6.3 Competence management system

Documented criteria shall exist for selection, qualification, authorization, assignment, monitoring, reauthorization and removal of auditors.

6.4 Auditor competence records

For every authorized auditor, the body shall maintain evidence of education, technical experience, program knowledge, audit training, audit experience, witnessing/observation where applicable, scope authorization and continued competence.

6.5 Audit process control

The body shall control application/contract review, scope determination, audit planning, duration, sampling, audit execution, findings, reporting, technical review and final output.

6.6 Auditor assignment

Auditors shall be assigned only where their approved competence scope matches the program, product category, processes and risk profile of the audit.

6.7 Impartiality and conflicts

The body shall identify and control financial, employment, consulting, commercial and personal conflicts that could affect audit independence.

6.8 Technical review

Completed audit files and reports shall undergo an appropriate independent review before a certification, recognition or formal conformity statement is issued, where such a decision is part of the body's service.

6.9 Complaints and appeals

Documented, accessible and impartial processes shall exist for complaints and appeals, with records of investigation, decision and corrective action.

6.10 Information control

Confidential information, audit evidence, client records and personal data shall be protected against unauthorized access, alteration, loss or disclosure.

6.11 Public claims and marks

Claims, certificates, statements and marks shall be accurate, traceable and limited to the approved scope and status.

6.12 Corrective action

The body shall investigate significant process failures, auditor performance concerns and substantiated complaints, determine causes and implement effective corrective action.

7. Common Requirements for Auditors

7.1 Identity and professional history

Verified identity and a complete professional history sufficient to establish relevant education, employment and technical experience.

7.2 Education and technical foundation

Education or equivalent technical development appropriate to the requested scope, supported by relevant industry experience.

7.3 Program knowledge

Demonstrated understanding of the applicable GMPs/GDP requirements, terminology, intent, regulatory context and expected objective evidence.

7.4 Audit-method competence

Recognized audit training or equivalent demonstrated competence in audit planning, interviewing, sampling, evidence evaluation, findings, conclusions and reporting.

7.5 Sector and process competence

Practical understanding of the products, processes, technologies, contamination/control risks, quality systems and distribution conditions relevant to the requested scope.

7.6 Audit experience

Documented audit experience appropriate to the requested role and scope. Experience shall demonstrate active participation in audit planning, execution, evidence evaluation and reporting.

7.7 Lead Auditor competence

Where Lead Auditor status is requested, evidence shall demonstrate team leadership, audit coordination, management of audit conclusions and responsibility for final reporting.

7.8 Evidence evaluation

Ability to distinguish objective evidence from opinion, assess sufficiency and relevance of evidence, evaluate systemic significance and avoid unsupported conclusions.

7.9 Findings and reporting

Ability to write clear, factual and traceable findings linked to applicable requirements and supported by objective evidence.

7.10 Professional conduct

Commitment to integrity, impartiality, confidentiality, respectful conduct and avoidance of conflicts of interest.

7.11 Scope limitations

The auditor shall not accept or represent competence outside the WEO-recognized scope.

7.12 Continued competence

The auditor shall maintain current knowledge and sufficient audit activity to remain competent for each recognized program and technical scope.

8. Auditor Qualification and Authorization Process

Stage	Required evidence / control
1. Application	Requested role, GMPs/GDP program, technical scope, CV/professional history and declarations.
2. Authentication	Identity, qualifications, employment history and key evidence are verified.
3. Technical screening	Education, sector experience and program-specific knowledge are evaluated against the requested scope.
4. Audit-method review	Audit training and demonstrated audit-method capability are reviewed.
5. Experience review	Audit log is evaluated for relevance, recency, role and complexity.
6. Witness / observation where required	Practical performance is observed when documentary evidence alone is insufficient or risk warrants direct verification.
7. Recognition decision	Approved role and scope are documented. Any limitations are explicitly stated.
8. Public registration	Recognition number, approved scope and status may be published in the WEO registry.
9. Continued monitoring	Status is maintained through activity, competence evidence, complaint information and reassessment when necessary.

9. Program-Specific Competence Requirements

The following program matrix defines the minimum subject-matter areas that should be evidenced for recognition. It is not a substitute for the underlying standard, regulation or scheme requirements.

Program	Minimum competence focus
WHO GMP	Pharmaceutical quality system; personnel/hygiene; premises and equipment; documentation; production; QC; validation/qualification; complaints/recalls; self-inspection; contamination and cross-contamination controls.
ICH Q7	API quality management; personnel; buildings/facilities; process equipment; documentation; materials; production/in-process controls; packaging/labeling; storage/distribution; laboratory controls; validation; change control; rejection/reuse; complaints/recalls; contract manufacturers/labs.
IPEC-PQG GMP	Pharmaceutical excipient GMP; quality management; personnel; buildings/facilities; equipment; documentation; materials; production; packaging/labeling; laboratory controls; change management; supply chain and excipient-specific risks.
EFfCI GMP	Cosmetic ingredient GMP; quality management; personnel; hygiene; premises/equipment; operations; QC; subcontracting; deviations; change control; complaints/recalls; traceability and ingredient-specific contamination risks.
FDA cGMP	Applicable US cGMP regulatory framework for the requested product category; quality unit responsibilities; facilities/equipment; components/materials; production/process controls; packaging/labeling; laboratory controls; records; deviations/investigations and data integrity.
ISO 22716	Cosmetics GMP: personnel; premises; equipment; raw materials/packaging; production; finished products; QC laboratory; out-of-specification; waste; subcontracting; deviations; complaints/recalls; change control; internal audit; documentation.
ISO 15378	Primary packaging materials for medicinal products: ISO 9001-based QMS plus GMP requirements; contamination control; clean environments where applicable; traceability; validation; change control; risk management; defect prevention and product-contact considerations.

Program	Minimum competence focus
EU GDP	Medicinal product distribution quality system; personnel; premises/equipment; documentation; operations; complaints/returns/recalls; outsourced activities; self-inspections; transportation; temperature control; falsified medicines and supply-chain integrity.
WHO GDP	Storage and distribution practices; quality system; personnel; premises; stock control; transport; temperature/environmental controls; documentation; complaints/recalls/returns; outsourced activities; traceability and supply-chain integrity.

10. Audit Conduct and Evidence Requirements

10.1 Audit planning

The audit plan shall reflect scope, applicable requirements, sites/activities, product/process risks, prior performance and time needed to obtain sufficient evidence.

10.2 Sampling

Sampling shall be risk-based and sufficient to support conclusions. The auditor shall document what was sampled and avoid presenting sampled evidence as proof of universal conformity.

10.3 Objective evidence

Evidence may include records, observations, interviews, data, electronic systems, traceability exercises and direct examination of facilities/processes. Evidence shall be relevant, verifiable and traceable.

10.4 Data integrity awareness

Auditors shall evaluate controls affecting the reliability, completeness, contemporaneity and traceability of data relevant to the applicable program.

10.5 Risk focus

Greater audit attention shall be given to controls that can affect product identity, strength, purity, quality, contamination, mix-up, traceability, storage conditions, distribution integrity or patient/consumer safety.

10.6 Remote techniques

Remote methods may be used only where appropriate to the audit objective and risk. Limitations shall be identified and shall not be used to claim evidence that could not reasonably be verified remotely.

11. Findings, Reporting and Technical Review

Findings shall be written so that an independent reader can understand the requirement, the evidence and the nature of the conformity or nonconformity. Unsupported adjectives, assumptions and conclusions shall be avoided.

- Each nonconformity shall identify the applicable requirement or defined criterion.
- Objective evidence shall be specific enough to be traceable.
- The finding shall explain the observed failure without prescribing consultancy-style solutions.
- Where grading is used, grading criteria shall be defined and consistently applied.
- The final report shall identify audit scope, dates, locations, audit team, criteria, sampled activities, findings, limitations and conclusions.

Where the Certification & Assessment Body issues a formal certification or conformity decision, technical review shall be performed by a competent person independent from the audit activity to the extent required by the applicable program or body procedure.

12. Impartiality, Ethics and Confidentiality

- Auditors shall disclose actual, potential or perceived conflicts before assignment.
- Auditors shall not audit work for which recent consulting, design or direct operational responsibility creates unacceptable self-review risk.
- Commercial pressure, audit-fee arrangements or client relationships shall not influence findings or conclusions.
- Confidential and proprietary information shall be used only for authorized audit purposes.
- Auditors shall not falsify, omit or materially distort evidence, findings, experience records or recognition claims.
- The Certification & Assessment Body shall maintain a mechanism to investigate integrity concerns and take proportionate action.

13. Witnessing and Competence Verification

Witnessing is a direct method for verifying whether an auditor can apply knowledge in practice. WEO or the recognized body may require witnessing when a new role or high-risk scope is requested, documentary evidence is insufficient, performance concerns exist, or a significant scope extension is sought.

Witness evaluation should consider audit preparation, opening activities, interviewing, process understanding, sampling, evidence evaluation, handling of difficult situations, formulation of findings, communication, time management, conclusions and reporting.

A witness outcome shall identify strengths, limitations, required corrective actions and the scope for which competence has been demonstrated.

14. Continued Competence and Monitoring

Recognition is not permanent evidence of competence. Continued status depends on maintaining current knowledge and practical audit capability.

Monitoring element	Expected evidence
Audit activity	Recent audit log showing continued participation in the recognized scope.
Program updates	Evidence of review/training when relevant GMPs/GDP requirements materially change.
Technical currency	Ongoing exposure to the relevant sector, processes, risks and regulatory expectations.
Performance	Acceptable witness results, report quality, technical-review feedback and absence of unresolved serious concerns.
Integrity	Continued compliance with ethics, impartiality and confidentiality requirements.
Scope review	Reassessment when adding materially different programs, product categories or technologies.

15. Recognition Decision and Public Registry

Recognition decisions shall identify the exact approved scope. Public registry entries should enable users to verify whether an organization or auditor is currently recognized for the program relevant to the intended activity.

A public entry may include: recognition number; legal/person name; role; recognized GMPs/GDP programs; technical/product scope; country; recognition status; effective/renewal information; and any defined limitation.

Recognition shall be specific enough that a user can distinguish competence for ISO 22716 Cosmetics GMP from ICH Q7 API GMP or EU GDP.

16. Suspension, Reduction and Withdrawal

WEO Recognition may be suspended, reduced or withdrawn when evidence indicates that continued recognition is no longer justified.

- material misrepresentation of recognition status or scope;
- serious or repeated auditor competence failures;
- substantiated integrity or impartiality violations;
- failure to maintain required competence evidence;
- failure to address significant corrective actions;
- loss of a prerequisite regulatory, accreditation or scheme approval where that approval was essential to the recognized scope;
- use of WEO recognition in a misleading manner.

Scope reduction should be used where competence remains demonstrated for some, but not all, recognized programs or technical areas.

17. Records and Retention

Certification & Assessment Bodies shall maintain controlled records sufficient to demonstrate the basis of auditor authorization and continued competence. Records should include qualification evidence, audit logs, witness results, scope approvals, monitoring, complaints, corrective actions and reauthorization decisions. Retention periods shall reflect applicable legal, regulatory, contractual and scheme requirements.

18. Annex A - Competence Evidence Matrix

Competence area	Examples of acceptable evidence	Decision focus
Identity / history	Verified ID, CV, employment records, references	Authenticity and traceability
Education	Degree, diploma, recognized technical qualification	Relevance to requested scope
Program knowledge	Program-specific course, examination, structured interview, technical review	Depth and currency of knowledge
Industry experience	Employment records, role descriptions, project evidence	Hands-on understanding of relevant processes
Audit-method competence	Lead auditor/auditor course, witnessed performance, audit records	Ability to conduct an effective audit
Audit experience	Audit log with dates, days, role, standard/program, sector and organization	Volume, relevance, recency and role
Lead Auditor capability	Lead audit log, witness record, team-management evidence	Ability to lead and conclude audits
Reporting	Sample reports/findings, technical-review feedback	Clarity, evidence linkage and accuracy
Continued competence	Recent audits, update training, program change review	Ongoing capability

19. Annex B - Program Scope Matrix

Program	Example technical scope descriptors
WHO GMP	Finished pharmaceuticals; sterile/non-sterile; selected dosage forms; manufacturing/packaging/QC
ICH Q7	APIs; chemical synthesis; fermentation; purification; packaging; storage
IPEC-PQG GMP	Pharmaceutical excipients; manufacturing; packaging; storage/distribution
EFICI GMP	Cosmetic ingredients; manufacturing; processing; packaging; storage
FDA cGMP	Applicable regulated product category and manufacturing scope
ISO 22716	Cosmetics manufacturing, filling, packaging, storage and related operations
ISO 15378	Primary packaging materials for medicinal products; relevant material/process categories
EU GDP	Wholesale/distribution; warehousing; transportation; temperature-controlled distribution
WHO GDP	Storage and distribution activities; transportation and supply-chain controls

20. Annex C - Sample Auditor Authorization Record

Field	Example controlled entry
Auditor name	[Name]
WEO recognition number	[WEO-LS-XXXXX]
Role	Auditor / Lead Auditor

Field	Example controlled entry
Authorized program(s)	e.g., ICH Q7; EFfCI GMP; EU GDP
Technical scope	e.g., APIs - chemical synthesis; cosmetic ingredients; pharmaceutical distribution
Geographic/regulatory limitations	[If applicable]
Evidence reviewed	Education; technical experience; training; audit log; witness record
Authorization decision	Approved / Limited / Not approved
Effective date	[Date]
Review / renewal date	[Date]
Decision authority	[Authorized WEO recognition decision function]
Restrictions	[Any explicit limitations]

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WEO Life Sciences Oversight

Independent competence recognition across GMPs & GDP programs.