



FREQUENTLY ASKED QUESTIONS

QUAL-MED YEMEN Good Pharmacovigilance Practices (GVP) Audit

What is a GVP audit?

A GVP audit is an independent audit that has as objective to verify whether a local pharmaceutical distributor's pharmacovigilance system complies with the international Good Pharmacovigilance Practices guidelines (GVP-EMA)¹, relevant local (PV regulations)², and with contractual agreements (SDEAs).

Who Can Request a GVP Audit from Qual-Med Yemen?

GVP audits can be requested by:

Global Pharmaceutical Companies: verifying their local distributors' PV readiness in Yemen.

This helps them to:

- Mitigate risks associated with inadequate pharmacovigilance practices, ensuring patient safety and the integrity of safety data.
- Gain confidence in their local distributors' ability to fulfill their pharmacovigilance responsibilities effectively.
- Support global pharmacovigilance obligations and ensure consistent safety monitoring across their supply chain.

Local pharmaceutical suppliers: who want to benchmark and enhance their PV systems.

What is in a GVP audit report?

We produce a report for each audit. This report contains:

- An overview and analysis of the local distributor's pharmacovigilance system, detailing the level of compliance with GVP-EMA, local regulatory requirements, and contractual agreements.
- Critical, major, and minor observations.
- A Corrective Action and Preventive Action (CAPA) plan.
- The results of an internal rating system that QUA-MED YEMEN has developed, over standardized PV activities.

¹ <https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/good-pharmacovigilance-practices-gvp>

² <https://sbdma.gov.ye/index.php/regulations-laws/decisions-regulations/228>

GVP Q.A. CRITERIA		GVP ACTIVITIES		Level Obtained
Pillar A	Quality Management System	1	Written procedural documents (SOPs, working instructions, forms)	4
		2	Subcontracting activities	2
		3	Internal Audits (Quality Assurance Assessments and Outcomes)	2
		4	Deviations and Corrective and Preventive Action (CAPA) management	2
		5	Computerized systems & Business Continuity Plan (BCP)/Disaster Recovery Plan (DRP), Facilities	2
		6	Archiving & Record Retention	2
Pillar B	Company Overview & Personnel, and Training	7	Organizational structure and resource management	3
		8	Training and Resource Management	2
		9	Qualifications, Job Descriptions, Curriculum Vitae	2
		10	Oversight of the pharmacovigilance system and responsibilities	3
		11	Local Pharmacovigilance System Master Files (PSMF) / Detailed Description of Pharmacovigilance System (DDPS)	2
		12	Notification to Local Competent Authorities	2
Pillar C	Individual Case Safety Report (ICSR) Management	13	Collection of adverse events, including product quality complaints and medical inquiries, and Follow-up processes.	4
		14	Reporting and Reconciliation	4
		15	Local Literature, Website & Social Media Screening	3
		16	Recording and Quality check	3
Pillar D	Periodic Reports, Management & Signal Management/Risk Management	17	Submission to regulatory authorities (as applicable) and tracking	3
		18	Responding to regulatory authority requests for information	4
		19	Reporting of Emerging Safety Issues/signals	4
		20	Implementation of and compliance with Risk Minimization Measures (RMMs) (if applicable)	3
Pillar E	Regulatory Affairs & Regulatory Intelligence	21	Submission and tracking of variation changes to the Regulatory Authority, if applicable	3
		22	Monitoring and management of local regulatory requirements	2
		23	Handling of local authority requests	4

How long does a GVP audit take?

Our GVP audits take 4 days: 1.0 day preparation, 1.0 day on-site visit, and 2.0 days analysis and reporting. However, these days are not consecutive. The GVP audit process includes preparation, the on-site visit, analysis/reporting, and integrating the CAPA (Corrective and Preventive Action) plan, followed by writing the final report.

What are the costs of a GVP audit?

That depends on the specifics of the audit: audit scope, size and complexity of the PV system. Qual-Med Yemen will provide a detailed quotation based on the specific audit requirements.

What resources are required for a GVP audit?

Typically, a GVP audit takes 4 days (1.0 day of preparation, 1.0 day for the site visit, and 2.0 days of analysis and reporting). Qual-Med Yemen GVP audits are performed by qualified auditors with extensive experience in pharmacovigilance regulations and practices, validated according to Qual-Med Yemen's internal Quality Management System. The report is verified and approved by the Technical Coordinator (0.5 days).

How is a GVP audit organized?

Our GVP audit process follows a structured four-phase approach, ensuring thoroughness and efficiency:

A. Preparation

1. Upon receiving a GVP audit request from global pharmaceutical companies or local pharmaceutical suppliers, QUAL-MED YEMEN initiates the process by developing draft Terms of Reference (TOR) outlining the audit scope and objectives, along with a detailed draft budget.
2. Qual-Med Yemen shares the draft TOR and budget with the client for review and input.
3. If required, an introductory meeting is organized between QUALMED YEMEN, the client to ensure mutual understanding and address any initial questions.
4. Once the TOR and budget are mutually agreed upon, QUAL-MED YEMEN issues formal service agreements to the client for signature.
5. To facilitate the assessment, Qual-Med Yemen may request the auditee to provide key documents and complete a pre-audit questionnaire, gathering essential information about their pharmacovigilance system.
6. The assigned lead auditor contacts the auditee to schedule the assessment dates, propose a draft agenda, and request specific documents required for the audit.

B. On-site visit.

10. Qual-Med Yemen auditors conduct comprehensive GVP audits by evaluating the auditee's pharmacovigilance system and activities through facility tours, document and system reviews, and interviews with key PV personnel, ensuring alignment with agreed-upon GVP requirements and Qual-Med Yemen's Quality Management System.
11. The expert uses the standardized GVP audit report template to record findings.

C. Analysis and writing of draft report

12. The auditor uses the QUAL-MED YEMEN GVP audit methodology and format to record findings and produce a draft audit report within 20 days of the onsite visit.
13. The draft report is verified by the QUAL-MED YEMEN Technical Coordinator for quality assurance purposes.
14. QUAL-MED YEMEN sends the draft report to the auditee for comments and with the request to produce a Corrective Action and Preventive Action (CAPA) plan.
15. The auditee is requested to provide a response within 30 days.

D. Integrating the CAPA plan and writing of the final report

16. Upon receipt, the auditee's response and proposed CAPA plan are carefully reviewed, verified, and integrated into the draft audit report by the QUAL-MED YEMEN auditor.
17. The final, comprehensive audit report is then formally shared with both the auditee and the client that commissioned the audit, providing a clear and actionable assessment of their GVP compliance status.