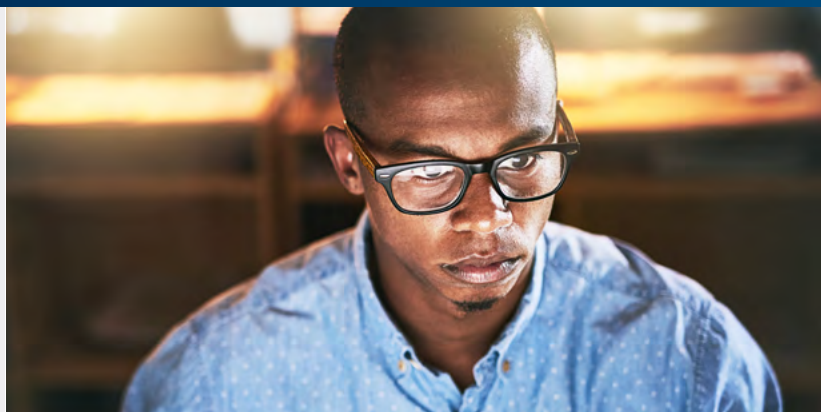
FACT SHEET

Robust Audit Programs

A key to better business decisions

Establishing an effective quality management system is an essential requirement for any manufacturer that designs, produces or distributes pharmaceutical or medical device products.



Good internal audit programs and auditing practices enable an organization to evaluate the effectiveness of its quality management system, and promote continuous improvement by uncovering opportunities for quality and product improvement. **Great** internal audit programs and practices do this, but also deliver an additional return on investment to the organization, by providing insight into business decisions that influence manufacturing, supplier and contractor selection as well as product innovation.

Unfortunately, many internal audit programs fall short of delivering recommendations for continuous improvement, let alone provide insights into better business decision-making. Global regulatory agencies now expect manufacturers to be more risk-focused and "self-regulated" by implementing robust internal audit programs. By identifying any deficiencies now, before the regulators do, you reduce the risk of enforcement actions/license suspensions.

COMMON AUDIT PROGRAM DEFICIENCIES

There are several reasons for audit program deficiencies. In addition to not having the resources to support the internal audit function, the following reasons also explain why audit programs suffer:

- Ineffective risk-based approach to prioritizing and scheduling audits: Resources (e.g., people, time) are not allocated to the facilities, suppliers and contractors that pose the most risk; audit focus is not dedicated to the quality/compliance areas that pose the most risk.
- Non-optimized, non-standardized procedures, forms and work instructions: A harmonized audit program does not exist that would facilitate a continuous improvement environment.
- Auditor inconsistency: Variation exists in the way auditors approach and perform audits.
- Auditor expertise is not always aligned to audit requirements: Skills and competencies for auditing resources are not consistently taken into account when assigning audits and audit-related tasks.
- Auditor resource allocation is not always optimized: Auditors are not geographically located in strategic markets.
- Expectations for audit team roles (e.g., audit lead) are not well defined: Auditing workload is not appropriately shared among auditing resources.
- Inadequate use of technology for support: An audit system — where all audit records are created,

maintained, stored and shared — either does not exist, or is not integrated with ancillary systems.

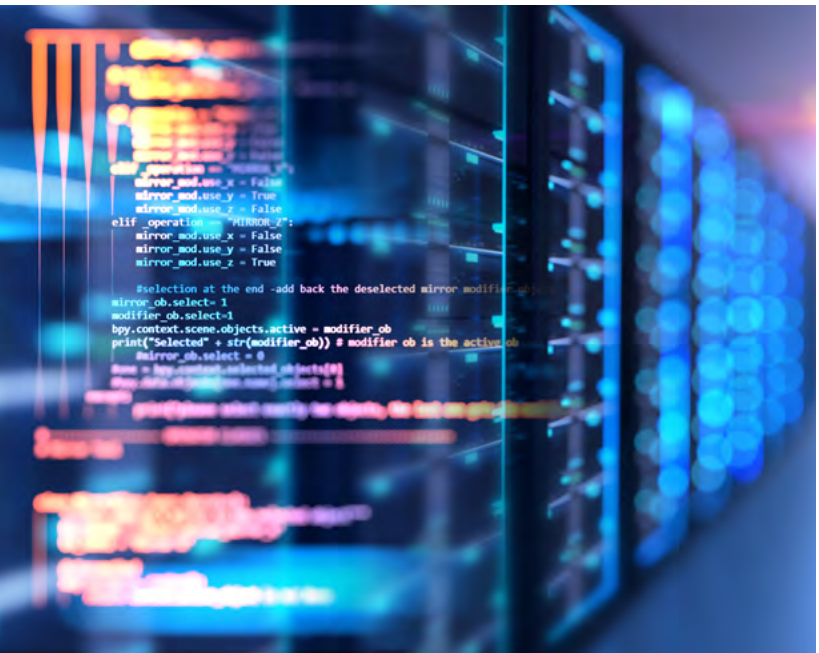
- Inconsistent or nonexistent means to report and assess trends in audit findings and actions.
- Lack of a collaborative relationship between auditors and auditees: Audits are considered a “policing” exercise, as opposed to an opportunity for continuous improvement.
- Lack of harmonization across the different regulatory requirements toward one internal audit program to cover all needs.

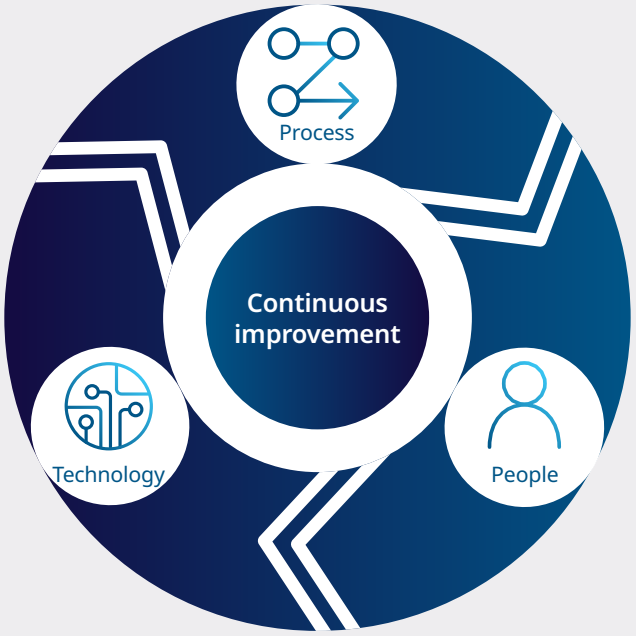
IQVIA SUPPORT FOR YOUR AUDIT PROGRAM

Supplementing manufacturers’ full-time resources, IQVIA consultants regularly provide support for your audit programs, including internal, external (supplier) and mock regulatory agency audits. Our auditors bring key industry experience and impartiality to the processes they audit. Their expertise is further supported by EQMS technology that improves audit program efficiency and effectiveness.

OPTIMIZED AUDIT PROGRAM

An optimized audit program is one in which people, process and technology are connected to facilitate continuous improvement. Optimized audit programs deliver a return on investment to the supply chain and product development by enhancing manufacturing, supplier and contractor operational compliance, effectiveness and efficiency.

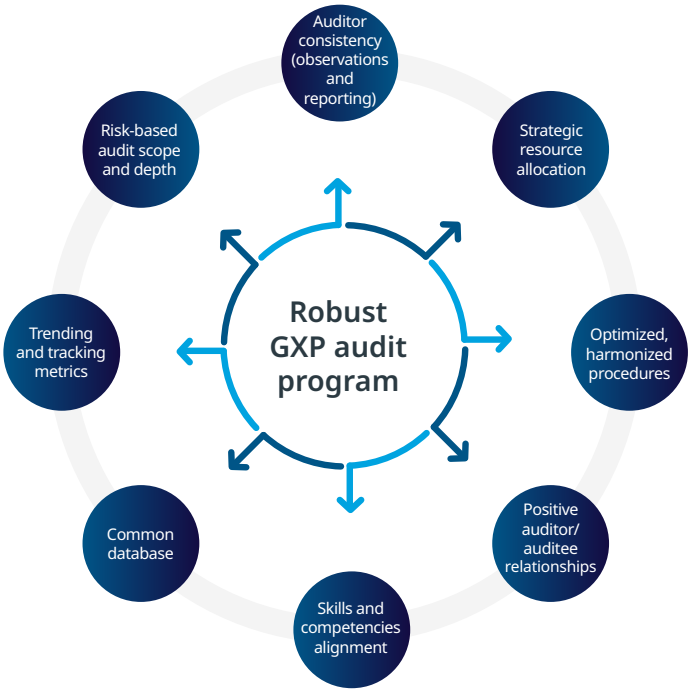




PROCESS	• Risk-based approach. • Standardized procedures. • Consistent observation, identification, categorization and follow-up.
PEOPLE	• Optimized audit assignments. • Professional development opportunities. • Aligned audit expectations.
TECHNOLOGY	Automated audit planning, performance and follow-up, powered by SmartSolve® eQMS: • Streamlined audit, finding and follow-up management. • Automated email notifications and calendar integration. • Consistent policies to ensure CAPA escalation for high-risk findings. • Built-in audit summary reports and trend analysis.

ELEMENTS OF A ROBUST AUDIT PROGRAM

Robust audit programs contain common elements that, when linked together, build a solid foundation for a scalable auditing function globally.



In order to achieve an optimized and harmonized auditing program that promotes continuous improvement and delivers a return on investment, it is important to evaluate the current audit program and practices against these elements. The IQVIA approach includes activities to:

1. Identify the gaps between current practices and the robust audit program elements.
2. Document recommendations for addressing each gap.
3. Prioritize the recommendations, considering expected return to the organization and ensure full compliance with the latest regulatory and technology requirements.

Conclusion

Well-run audit programs can be a valuable asset to an organization, particularly when they reveal insights that enable companies to make better business decisions.

Contact IQVIA to leverage our approach to design and implement your audit program with supporting auditors who are fully conversant with the latest regulations and industry best practices.

CONTACT US

4820 Emperor Boulevard | Durham | NC 27703 | United States

regulatory_quality_compliance@iqvia.com

iqvia.com/smartsolve