

Vendor Audit Services from SAFC



The FDA is becoming more aggressive in tracking quality issues, which reflects an increasing need for more traceability in the drug manufacturing supply chain.

No single company can physically audit every supplier but, because SAFC routinely audits numerous companies in the course of its business, we can expand your compliance reach by offering a complete package of audit services.

Using our professional team of global auditors, SAFC can help its customers ensure proven quality in their own supply chain by facilitating the vendor audit process, for key intermediates and starting raw materials.

Why Outsource Your Audits?

Expand your audit reach: SAFC can help you increase the number of audits you can perform without expanding your regulatory compliance staff.

Reduce your audit costs:

- SAFC's audit services provides an economical approach that is more competitive than many internal and external audit programs.
- For greater economies of scale, our customers have the option of sharing vendor audit results.

Rely on SAFC's Experienced Resources – SAFC has professional auditors in place around the globe, experienced in US /EU quality standards and the FDA audit process. Our team includes in-house professionals and specifically-qualified audit experts located in many countries.

Why SAFC?

Confidence and convenience – As a financially stable, global company with operations in over 36 countries, SAFC can remove traveling, translation and reliability issues from the vendor auditing process and provide you with timely dependable results.

With a network of over 10,000 suppliers, 34 manufacturing facilities (including 9 cGMP sites), SAFC has a **deep understanding of audit requirements** from experience at our own facilities or our vendors' sites.

Annually, we host more than 100 audits within our own manufacturing facilities and perform over 100 audits per year with our vendors. By extending our audit expertise to our customers, SAFC aims to build a shared resource where audit reports and vendor quality information can be easily attainable.

Vendor Audit Services from SAFC



Audit Deliverables

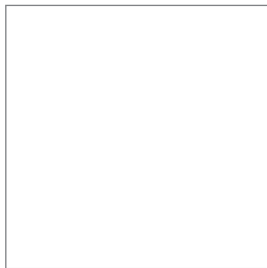
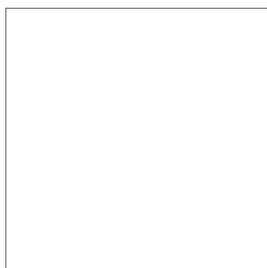
SAFC audits are performed by a team of compliance professionals and all audits are followed by a preliminary report, delivered in a timely fashion, using a report format that has been adapted to the customer requirements.

Initial audit findings are typically available within seven business days, with a final report provided within 30 days.

Timelines for actual standard audits can vary from one to five days, depending on whether they are based on Good Laboratory Practices (GLP) or Good Manufacturing Practices (GMP).

Standard audits available include:

- ISO 9001:2008 (previously ISO 9001:2000)
- ISO 13485:2003
- 21 CFR 211
- 21 CFR 820
- ICH Q7A
- GAMP 5
- GLP
- 21CFR58



SAFC can also perform audits to customer specifications upon request.

Typical list of audits include reviews for:

- Quality systems
- Process quality
- Product quality

Pricing

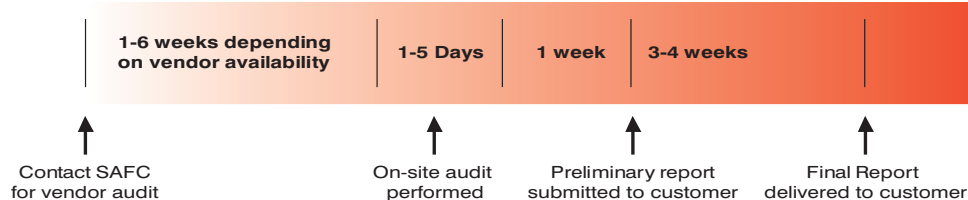
- Competitively priced standard audits usually require one to three business days for GLP audits, and up to five business days for GMP audits including report composition.
- Special pricing options will be discussed with customers willing to allow SAFC to reuse audit information for other customers. In these agreements, full confidentiality of customer-specific information will be preserved.

Contact details

For more information or inquiries please contact our team of quality experts at Qualityauditrequests@sial.com

SAFC continues to grow its quality services offer and has become a trusted adviser to its customers. Our Audit services allow us to be the extension of your supply chain and your quality department.

SAFC's Typical Audit Services Timeline



Inspiring Science™

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