



[Home](#) > Identifying supplier deficiencies

Identifying supplier deficiencies

Jun 01, 2009

By [Andy McCallum](#) [1], [Brian Alexander](#) [2]

When outsourcing, pharmaceutical companies must conduct thorough audits of service providers to ensure they comply with the required quality standard. This audit is usually straightforward, but only if you are fully aware of the written procedure.

What systems are in place to manage and control quality?

Identifying the systems used to control and manage the quality of a service or product is a key function of the auditing process. One of the principal considerations is what accreditation or compliance (e.g., ISO, GLP or cGMP) the provider claims for the service; for example, service providers that say they comply with cGMP should be in possession of the relevant licences and, if applicable, a letter of inspection and support from the Medicines and Healthcare Products Regulatory Agency.

When selecting a provider, the first stage is usually to establish the existence of a quality system and any third party inspection bodies, such as the UK Accreditation Service, that are useful for calibration services. A quality management system should contain, as a minimum:

- Quality Manual. This is a high-level policy document that describes the management's commitment to quality.
- Standard Operational Procedures. These documents follow on from the Quality Manual and describe how the policies described in the manual are put into practice.
- Test methods (if appropriate). Any tests conducted should be fully described in a written method, which should be validated and approved by management and the quality assurance department.
- Relevant and fully traceable test records and raw data. All test data and records should be traceable to the originator by dated signatures, checked for accuracy, and signed and dated by a second person. Electronic documents and raw data systems must conform to 21 CFR Part 11 for audit trails and electronic signatures.
- Training records. Records must be available for all staff and should be relevant to the duties assigned. They must be kept up to date and include training in the relevant quality management system and regulatory requirements, such as cGMP.
- Regulatory documentation, such as licences, product specifications and regulatory inspection records/certificates. These must be up to date and, where relevant, fully authorized.
- Calibration and maintenance records for all relevant equipment. All equipment used must be fit for purpose and calibrated to a national standard where required. The records should be kept in a dedicated file that is readily retrievable and shows the equipment history.
- Characterization documents for all relevant materials, such as certificates of analysis. Where appropriate, there must be adequate documentation characterizing all test materials, raw materials, starting materials or excipients. This includes test certificates, which must be authorized and authentic.

What are the common deficiencies encountered during the audit of suppliers?

The most common deficiencies encountered during supplier audits are related to documentation; for example, procedures, test methods and the Quality Manual may be out of date or passed review periods, or procedures may not be clear and present ambiguous instructions. The presence of obsolete documentation that has not been removed can also cause problems, as well as test records that may be missing traceability information, such as analyst and check signatures, consumable batch numbers or expiry dates. Sample or product information may also be incomplete.

Other common deficiencies include:

- Training records not in place, not reviewed or not up to date.
- Equipment may not be calibrated or maintained, or the relevant records may not be in place to establish the validated status or maintenance history of equipment.
- Labelling may be ambiguous, such as equipment status, consumable expiry dates and sample/product information.
- No trend information available; for example, water system quality, product quality and environmental data.

This is by no means an exhaustive list, but represents some common deficiencies encountered in quality management systems.

How may these be addressed?

The deficiencies provided at the end of the audit will normally be categorized as critical, major, minor or observation/recommendation, and a corrective/preventative action plan should be established to remedy the deficiency and prevent reoccurrence.

These actions should be identified by the operational area of the supplier, and agreed with the auditor with a fixed completion target date and system to monitor progress. As part of the resolution, a risk analysis should also be conducted by the operational area of the supplier (as they fully understand all the processes) to ensure that the impact and effectiveness of the corrective action is understood.

Critical deficiencies will require the immediate initiation of corrective action, and those classed as major will require an action plan to identify relevant corrective actions and time frames for completion. Minor issues are usually included along with any major non-compliances within the action plan, and recommendations may also be suggested as improvements to existing quality systems, but these do not require a formal action plan.

Having completed the corrective and preventative actions, it is essential to establish whether they have been successful in eliminating the identified deficiencies and preventing reoccurrence. The Quality Assurance department measure the effectiveness of the CAPA by trending non-compliances and feeding the information back to the operational area.

Brian Alexander
Director of Regulatory Compliance, Tepnel Pharmaceutical Services at
Gen-Probe Life Sciences Ltd.
Andy McCallum
QA Manager, Tepnel Pharmaceutical Services at Gen-Probe Life Sciences Ltd.

© 2015 Advanstar Communications, Inc. All rights reserved. Reproduction in whole or in part is prohibited. Please send any technical comments or questions to our webmasters.

Source URL: <http://www.pharmtech.com/identifying-supplier-deficiencies>

Links:

[1] <http://www.pharmtech.com/andy-mccallum-0>
[2] <http://www.pharmtech.com/brian-alexander>