THE TOP 10 THINGS REGULATORS LOOK FOR

by Liz Allanson

There is an increased regulatory focus on audits within the pharmaceutical industry as a result of cases of adulterated materials, eg heparin, and the increasing threat of counterfeit medicines.

SO WHAT ARE THE TOP 10 THINGS THAT REGULATORS ARE LOOKING FOR?

1. ROBUST AUDIT SYSTEMS

Company audit systems (both external and internal) must be part of the written quality management system supported and resourced by the company senior management. Responsibilities should be clearly defined for both external and internal audit systems and performance measures should be in place to confirm that the systems are working correctly and are effective.

2. DECISIONS SUPPORTED BY SUFFICIENT AUDIT EVIDENCE

Decisions made especially by Qualified Persons (QPs), are supported by thorough and reliable audit reports. QPs have been known to sign GMP declarations for active pharmaceutical ingredients, based on minimal information, and in some cases no audit report at all!!

3. COMPETENT AUDITORS

An audit is only as good as the auditor that performed it. Regulators are looking for evidence that auditors are trained in the skills and techniques of auditing and have a good level of GMP knowledge and experience and that they know the standards that must be applied.

4. RELEVANT AUDIT STANDARDS APPLIED

Audit evidence must demonstrate that the correct standards have been applied as audit criteria.

5. SUFFICIENT TIME FOR THE AUDIT

Adequate time must be allowed for each audit and must be appropriate for the scope of the audit. Time allocated must include preparation and follow-up time.

6. RISK-BASED AUDITS

Audits must not be tick-box compliance audits. The auditor should constantly understand and assess the risks posed to the patient by the operations being audited.

7. GOOD SUPPLIER AUDIT REPORTS

The focus and concern associated with global supply chains has resulted in regulators taking a much more robust stance and supplier audit reports are being routinely reviewed by inspectors. The detail should support the final conclusion or recommendation.

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8. GOOD USE OF AUDIT INFORMATION

A good audit system will have formal mechanisms for sharing audit reports and findings with others who can then make informed decisions and use the data to improve other aspects of the business.

9. FOLLOW-UP

There should be a formal procedure for following up on the audit observations. Confirmation that deficiencies have been rectified and CAPA plans implemented should be available.

10. CONTINUAL IMPROVEMENT OF AUDIT SYSTEMS AND OF SYSTEMS AUDITED

All audits should produce improvements and this includes improvements to the processes and systems that the auditor is applying.

ABOUT THE AUTHOR

Liz Allanson is a pharmacist by profession and has a special interest in quality management and leadership skills. She spent almost 19 years as a GMP inspector with the UK MHRA, primarily as one of the senior managers in the MHRA Medicines Inspectorate. Her last position with MHRA was managing the GMP inspection team.

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