Do GMP inspectors have to be granted access to the management review?

What about the medical device segment? Should auditors from a Notified Body be able to access both internal audit reports and the management review?

Your question – our answer – Part 2

5 min. reading time

by Dr. Sabine Paris

Four weeks ago, we answered an important and quite controversial question from a reader about whether or not GMP inspectors must be granted access to the self-inspection reports of pharmaceutical manufacturers (see LOGFILE 08/2017).

There was a great response to our article, and we received further interesting questions on the issue, for example whether GMP inspectors should also have access to the management review and what rules apply to auditors from Notified Bodies in the medical device segment.

We have now put together the answers from the GMP Compliance Adviser and information from representatives of the authorities.

Your question:
Do GMP inspectors have to be granted access to the management review?

Our source in the GMP Compliance Adviser:

Our author Dr. Stephanie Blum writes in the GMP Compliance Adviser as follows on the question of management reviews (Chapter 19.L.2.1):

> "When selecting key performance indicators, the company should be aware that the management review may be subject to official inspection and that information from the management review may have to the provided during customer audits. This applies in particular to KPIs from sensitive areas (e.g. company takeovers and sales, purchase/sale of co-selling rights/authorisations, portfolio changes, innovation)."

Interestingly enough, the standard procedures for the inspectorates do not contain any indications on this aspect that are comparable to those for internal audit reports. The internal audit reports are only viewed in exceptional cases (cf. LOGFILE 08/2017).

When questioned by us, GMP inspectors responded that management reviews can indeed be viewed as part of an inspection.

Our answer:
The purpose of the management review is the regular assessment of the suitability and effectiveness of the Pharmaceutical Quality System (PQS). Chapter 1.6 of the EU GMP Guide requires European pharmaceutical manufacturers to conduct a management review.

The management review can be part of official inspections, and access may also be requested as part of customer audits.

Your question:
Do auditors from a Notified Body have to be granted access to internal audit reports and the management review?

Our sources in the GMP Compliance Adviser:

Dr. Volker Lücker, Katherine M. Wortley and Claudia Pachl write on this issue as follows in chapter 23.B.5.6 "Records of management reviews" and 23.B.6.1 "Internal audits":

> "Management review records should contain or reference all material reviewed, identify attendees and contain descriptions of any corrective or preventive actions to be taken (including responsibilities, resources necessary, and target dates for completion).
>
> Various regulators and independent third-party auditors may request to see the results or reports from internal audits.
>
> U.S. FDA has indicated in the preamble to 21 CFR 820 that they will neither request management review documentation for review nor internal audit documentation although they retain the right to review the records if desired.
>
> On the European level according to legal regulations in Annex II to Annex VII of Directive 93/42/EEC the national regulatory authorities are authorized to review the entire quality system of the responsible manufacturer in response to specific situations. This also includes the documentation of internal efficiency control and internal management processes and such protocols are accordingly subject to the right to inspection by the authorities. If an element of the quality system has to be separately certified by a notified body due to the risk associated with the medical device and the provisions for the conformity assessment procedure the entire documentation of this feature will be subject to an audit by the notified body."
>
> "At a minimum, there should be documentation or certification that internal audits have been conducted that includes audit date(s), auditors' names and a high level summary of results. This certification may then be provided to external auditors and inspectors in lieu of the full audit report assuming the external auditor is in agreement."

We asked **the body responsible for recognising, designating and monitoring Notified Bodies in Germany, the ZLG** (Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices), and it supports the information in the GMP Compliance Adviser:

> "The auditors should also have access to internal audit reports to allow them to assess whether the internal auditing system is working. (Usually, the specified process is assessed on the basis of spot checks on the audit plan, the audits conducted (compared to the plan), the basis for each audit (checklists), the audit documentation, subsequent communication including CAPAs etc. The recommendation is that this should where possible not be done until the end of the audit so that the system can be audited "with an open mind" and the picture obtained then compared with the picture that the manufacturer itself has established through internal audits.
>
> A clear response on this point can also be found in the current standard for management system certification bodies (EN ISO/IEC 17021-1). Section 9.6.2.2 of this standard requires a surveillance audit.
>
> "… Each surveillance for the relevant management system must include: a) internal audits and management review; …"
>
> This means that the audit documentation and management review are subject to audits."

Our answer:
Both Directive 93/42/EEC and the current standard for management system certification bodies (EN ISO/IEC 17021-1) authorise Notified Bodies to view the documentation of internal efficiency control and the internal management processes.

In an audit by the Notified Body, there should at least be documentation or certification that internal audits have been conducted that includes audit date(s), auditors' names and a high level summary of results. This certification may then be provided to external auditors and inspectors in lieu of the full audit report assuming the external auditor is in agreement.

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