APIC-CEFIC Audit Programme – An Experience Report

by GENZYME Pharmaceuticals, Liestal (Switzerland)

GENZYME Pharmaceuticals, Liestal (Switzerland), a branch of the US-American, Boston-based biotechnology company Genzyme, is a manufacturer of pharmaceutical excipients and APIs and a contract manufacturer for the pharmaceutical industry.

Notwithstanding the fact that companies in this field are audited regularly by the competent registration authorities (in the case of GENZYME: RHI (Switzerland) and FDA), their customers and partners conduct an increasing number of audits, which causes the audited enterprise a not insignificant amount of additional work. In 2004, GENZYME Pharmaceuticals, a firm with 100 employees, spent 50 days on customer audits.

With the aim of counteracting this tendency, APIC-CEFIC initiated an independent Audit Programme in co-operation with CONCEPT HEIDELBERG. By means of having a standardised audit conducted by qualified and certified auditors and giving the customer insight into the audit report, the customer's confidence in the quality assurance system and in the compliance with the ICH Q7A requirements is intended to be reinforced and thus the number of customer audits, minimised.

Preparing the Audit

After applying for an APIC-CEFIC Audit in March 2003, GENZYME Pharmaceuticals first had to fill in a questionnaire that formed the basis for the selection of the two auditors and at the same time helped the auditors to prepare the imminent audit. The auditors hold an APIC certificate, can look back on sufficient professional experience and have attended training courses both on ICH Q7A and on the conduct of audits. In May 2004, the auditors were nominated, and their names, announced to GENZYME Pharmaceuticals.

The auditors and GENZYME Pharmaceuticals agreed on the date for the audit and planned it together - the content of the audit, however, is standardised.

Conduct of the Audit

The audit took place on 25 and 26 September 2003. After an introduction of both sides and a presentation of GENZYME Pharmaceuticals, the auditors were showed around the plant. Then the auditors had a close look at typical quality assurance tasks, like e.g. document control, change control and product release. The second half of the first audit day was dedicated to the production areas, where the focus was among others on production documentation, cleaning and deviations.

The second audit day dealt above all with quality control, qualification and validation as well as with supplier evaluation and -qualification.

The Audit Report

In order to clarify misunderstandings during the audit, the audited company is given the opportunity to correct the draft of the audit report.

The report includes the following sections:

- General information on the APIC-CEFIC Audit Programme
- General information on the audit report in hand
- General information on the audited company
- Management summary

The report contains a list of observations with a table assigning them to the corresponding chapters of ICH Q7A as well as a separate list of the deficiencies with comments by the auditors and evaluations according to the categories mentioned below. The audited company can comment on these deficiencies and define corrective measures including the responsible person and a deadline.

Following a habit common in the pharmaceutical industry, the observations are divided into 3 categories:

- **3 Points** signify that the deficiency has a serious influence on the quality of a product or on the compliance with the regulatory requirements and that it violates basic GMP rules. Immediate action is required.
- **2 Points** denote a deviation that may have a negative influence on the quality of a product or the compliance with the regulatory requirements and that it violates GMP rules. It is recommended to take corrective measures.
- **1 Point** means that the deficiency does not influence the quality of a product or the compliance with regulatory requirements, but that it violates GMP rules.

The audit report is valid for 3 years. Before the end of this period, the audited company is informed about this fact so that it can react accordingly. In case of a prolongation, a new audit has to be conducted and, therefore, it has to be applied for.

Conclusion

According to our experience, the audit conducted at GENZYME Pharmaceuticals was carried out in a thorough and well-structured way. It was confirmed that GENZYME Pharmaceuticals is in compliance with the requirements laid down in ICH Q7A. None of the 11 observations was classified as critical (3 points).

In order to be able to get more benefit from the independent APIC-CEFIC Audit Programme, it should be given a higher profile.

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