

Danish Medicines Agency develops guideline for API audits

Muenster (DE), Copenhagen (DK), 19. Juli 2010. The Danish Medicines Agency DMA intends to develop an own guideline for API audit reports, which shall provide guidance to finished medicinal product manufacturers for the documentation of the GMP compliance of their active pharmaceutical ingredient (API) suppliers. This is the result of a survey conducted by the DMW last year concerning the GMP surveillance of pharmaceutical companies¹. "Overall the pharmaceutical manufacturers comply with the relevant GMP obligations concerning the quality of APIs but there seems to be also an obvious lack of minimum standards", comments Dr. Stefan Kettelhoit, of the blue inspection body GmbH (www.blue-inspection.com) the result of the survey. "However, the decision of the Danish Agency to develop a national audit-guideline is not very helpful", according to Kettelhoit.

"A patchwork of national audit standards will certainly weaken the competitiveness of the European drug product industry", adds the general manager of blue as a matter of caution. Instead of that, one single international standard will be important, since the same active pharmaceutical ingredient is usually supplied to several pharmaceutical manufacturers in different European countries. "It is not understandable, that on one hand the GMP rules for manufacturing are harmonized in Europe, but on the other hand the surveillance standards of these rules are handled in a different manner from country to country." Dr. Stefan Kettelhoit

¹ Danish Medicines Agency (2010): "Report on compliance with rules on good manufacturing practice by manufacturers of active pharmaceutical ingredients" http://www.dkma.dk/db/filarkiv/7907/rapport_api_projekt_2009_uk.pdf

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promotes therefore one commonly accepted audit standard in Europe, in line with the "Community Format" of the European Medicines Agency EMA²: "Acting as API auditor, I think this report format is quite suitable. Our reports, which have been created based upon this format, are already accepted throughout Europe." The blue inspection body conducts API audits globally on behalf of pharmaceutical manufacturers as independent, according to ISO 17020 accredited Third-Party auditor in the European community.

The Qualified Person of a pharmaceutical company is personally liable to ensure that the medicinal products manufactured from this company (including the contained excipients and APIs) have been produced according to current GMP standards. The API production from suppliers in e.g. India or China has therefore to be audited regularly. The related audit reports have to be submitted upon request to the health authorities. Deficiencies from GMP compliance may result in sanctions up to the withdrawal of the manufacturing authorization. However, so far it is not regulated how GMP audit reports have to be structured and which contents need to be covered in these reports. *(approx. 2.680 characters)*

Background information: blue inspection body GmbH

The blue inspection body GmbH examines the Good Manufacturing Practice (GMP) of pharmaceutical companies around the globe. Third-party audits by blue efficiently relieve manufacturing authorisation holders, API suppliers and API manufacturers. The blue inspection body GmbH is the first independent and accredited service provider for GMP audits within the European Union.

² *Kettelhoit Stefan (2010): "GMP for APIs: Judging the audit quality from the audit report". Pharm. Ind. 72, Nr. 2, 242-247.*
