



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Update on revision of Chapters 3 and 5 of the GMP Guide: "Dedicated facilities"

A Concept Paper was published in February 2005 highlighting a lack of clarity in the existing GMP guide (section 6 chapter 3, sections 18, 19 chapter 5) with respect to when a medicinal product should be manufactured in dedicated, self-contained facilities. The concept paper proposed that any guidance in this field should take into consideration the principles and concepts of Quality Risk Management described in the ICH Q9 document (see also Annex 20 of the GMP Guide). An update on progress was published in January 2008.

The drafting group has continued to look into the different aspects of this issue; it has been researching and evaluating all the scientific information related to this topic including input from toxicological/pharmacological experts.

The topic of dedicated facilities continues to be the subject of a significant amount of debate but the GMP/GDP Inspectors Working Group has agreed that the use of dedicated facilities should normally be required when beta-lactam antibiotics are produced. In addition dedicated facilities should be used when live pathogenic organisms are handled. Further guidance on the use of dedicated facilities for certain product categories may also be found in the GMP Annexes (e.g. veterinary products in Annex 4, biologicals in the new draft of Annex 2, which should be available for further public comment in the first quarter of 2010). In the meantime, for other products, manufacturers introducing a product into shared facilities should carry out an assessment of all relevant product and process characteristics to evaluate whether it is suitable for production in shared facilities. This assessment should include input from a toxicologist. Where the product has known sensitizing potential, or is highly potent or toxic, the Supervisory Authority should be consulted to discuss the manufacturer's risk management measures.

