



STATEMENT ON STATUS OF REVISION OF CHAPTER 5 OF THE GMP GUIDE CONCERNING "DEDICATED FACILITIES"

The current text of Chapter 3 section 6 of the GMP guide reads as follows:

"In order to minimise the risk of a serious medical hazard due to cross-contamination, dedicated and self contained facilities must be available for the production of particular medicinal products, such as highly sensitizing materials (e.g. penicillins) or biological preparations (e.g. from live micro-organisms). The production of *certain* additional products, such as *certain* antibiotics, *certain* hormones, *certain* cytotoxics, *certain* highly active drugs and non-medicinal products should not be conducted in the same facilities. For those products, in exceptional cases, the principle of campaign working in the same facilities can be accepted provided that..."

No guidance is given to clarify what is meant by "certain" and "exceptional cases" in this context.

Following a survey of Member States it was agreed that this section of the Guide, together with the corresponding section 19 of Chapter 5, should be clarified and a Concept Paper was published in February 2005. The concept paper recommended that any guidance in this field should take into account principles and guidance being developed at that time through the ICH Q9 process (Quality Risk Management).

The topic has been the subject of a significant amount of debate within the drafting group and the GMP/GDP Inspectors Working Group, including discussions with interested parties at various fora. Discussions have also particularly focussed on whether the Guide should identify those products that present such a high risk to patients through cross contamination that the only acceptable risk mitigating measure is the use of dedicated facilities, or how and to what extent alternative Quality Risk Management processes could be applied. As a consequence the timeframes envisaged in the Concept Paper for the various steps in the revision of the guidance have not been met. In view of the extensive public interest in this topic it has been decided to publish this update on progress.

At present the GMP/GDP Inspectors Working Group agrees that the Guide should indeed identify those products in which the use of dedicated facilities is mandatory. It is acknowledged that the drafting group needs input from toxicological/pharmacological experts in order to develop this part of the guidance so that it is based on well grounded scientific principles and this expertise has now been made available. EMEA's Safety Working Party will be asked to endorse the outcome of this expert input before the new guidance is released for public consultation.

For other products, it is envisaged that those which combine relatively high-risk pharmacological/toxicological characteristics with high risk physico-chemical properties and process design, should not be manufactured using shared facilities unless justified after following a rigorous Quality Risk Management process and taking any appropriate risk mitigating measures for part or all of the process. In this regard the drafting group is currently developing a table to identify those high risk physico-chemical and process characteristics and is working on definitions of some of the terms used in connection with this topic.

At present it is anticipated that a text will be submitted to the European Commission at the end of 2008 / beginning of 2009 for public consultation.