Chapter 7: Outsourced Activities

EIPG (European Industrial Pharmacists Group) observations on the proposed revision of "Chapter 7: Outsourced Activities" of Volume 4 of the Rules Governing Medicinal Products in the European Union

Paragraph 7.3

It is suggested to add a reference to Annex 20: Quality Risk Management.

Paragraph 7.6

The following sentence is proposed to be added, in order to ensure consistency with other Chapters of Volume 4 where outsourced activities and/or suppliers of starting materials are involved, particularly in Par. 5.26 of the proposed Chapter 5: Production, currently under public consultation:

"*The results and the frequency of these activities are to be documented*"

Paragraph 7.7

Taking into account the presence of different situation regarding specifications compliance and products release, as amply indicated in Sections 4 – 6 of Annex 16: Certification by a Qualified Person and Batch Release, in the second sentence it is proposed to replace the word *or* with *and/or*

Paragraph 7.12

It is suggested to specify that the contract drawn up between the Contract Giver and the Contract Acceptor is also to be signed by the two respective QPs. This is particularly relevant in view of the responsibilities of the Qualified Persons vis-à-vis batch release, as outlined in Annex 16.

Paragraph 7.16

In the climate of the pharmaceutical industry expansion to developing countries, albeit that the obligation for ensuring compliance of third country manufacturing contract activities with Good Manufacturing Practice principles lies with the holder of the manufacturing licence within the European Union, one cannot omit the possibility of inspection of these international sites by the competent authorities. It is therefore suggested to replace the term "*contract analysis*" with the term "*contract manufacturing/analysis*", as this seems more appropriate to the scope of this paragraph.