Warsaw, November 5, 2013

European Commission

Directorate General for Health and Consumers, Unit SANCO/D/6

Brussels, Belgium

and

European Medicines Agency

London, United Kingdom

Ref. Revision of EU Commission guidelines on Good Manufacturing Practice for Medicinal Products – Annex 16 "Certification by a Qualified Person and Batch Release"

Dear Sir or Madam,

SciencePharma welcomes the Commission's initiative to consult with stakeholders drafts of the revised chapters of the GMP guidelines and appreciates the possibility to provide its comments.

SciencePharma is a Polish consultancy company offering comprehensive regulatory services to the pharmaceutical industry. SciencePharma falls within the EU definition of a small and medium-sized enterprise.

- **A clarification of section 3 is needed.**

In section 3.5.5 it is stated that the entire supply chain of the medicinal product should be documented and available for the QP. It is further required that the supply chain includes i.a. manufacturing sites of components used for the manufacture of the finished products. Although one example is given ("components and equipment for aseptic processing"), it is not entirely clear which other components are expected to be comprised in the supply chain documentation. It is therefore suggested providing clear provisions. It should be noted here that other GMP requirements do not exactly specify such requirements in respect to supply chains for finished products.

- **A change of section 5 is proposed.**

Point 5.1 is proposed to focus on deviations relating to the manufacturing process and/or the analytical control of a finished product batch and therefore compliance of active substances and excipients with respective specifications is proposed not to be discussed here. It is noted that for these materials out-of-specifications may be acceptable in justified cases.

Moreover, it is proposed to discuss deviations in general, i.e. not only unplanned and unexpected ones.

5.1. As long as registered specifications for ~~active substances, excipients and~~ finished products are met, a QP may, taking the following guidance into account, consider confirming compliance / certifying a batch where a~~n~~ ~~unplanned and unexpected~~ deviation from details contained within the Marketing Authorisation and/or GMP has occurred.

Points 5.2 and 5.2.1 are proposed to be changed accordingly.

5.2. Where a deviation has occurred during manufacture or testing of a batch of finished product it may be considered to conclude that ~~meet~~ the requirements of the marketing authorisation and GMP are met when the details described below have been taken into account:

5.2.1 The deviation ~~is unexpected, unplanned and~~ relates to the manufacturing process and/or the analytical control methods as described in the Marketing Authorisation.

We hope that you will find our comments constructive. We remain at your disposal, should you need further clarification.

Yours faithfully,

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