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PDA Europe gGmbH

Adalbertstr. 9 16548 Glienicke/ Germany Tel: +49 (0)33056 2377-0 Fax: +49 (0)33056 2377-77 Senior Vice President Dr. Georg L. Roessling Info-europe@pda.org https://europe.pda.org/index.php

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European Commission
Pharmaceuticals Unit, Brussels
SANCO-gmp@ec.europa.eu

European Medicines Agency Compliance and Inspection, London ADM-GMP@ema.europa.eu

EudraLex, Volume 4
Good Manufacturing Practice
Medicinal Products for Human and Veterinary Use
Revised EU GMP Chapter 5: Production

Dear Colleagues:

PDA is pleased to provide comments on the proposed revision of *Chapter 5 of the EU GMP Guide*, released for consultation in November 2010. Our comments were prepared by an international group of expert volunteers with experience in GMP and regulatory affairs. We have three general comments, mentioned below, and specific technical comments in the attached EMA matrix format.

Comment 1, Risk Management: PDA appreciates and supports the need for supply chain transparency. However we have a concern that, as proposed, the revised chapter does not recognize and allow for the adoption of risk-based approaches consistent with the recent revisions to EU GMP Chapter 1, GMP Annex 20 (ICH Q9, Pharmaceutical Quality Risk Management), and the ICH Q10 guidance on Pharmaceutical Quality Systems.

Recommendation: We recommend revision of the draft to allow a company to assess the specific risks that each starting material (active and inactive) potentially poses when used in their process. The company would then develop an appropriate and justified control strategy to mitigate those risks. PDA is willing to support the EC and EMA in hosting a public meeting to discuss and better understand the concerns associated with the proposed revisions of the chapter.

Comment 2, Purchased Materials: ICH Q10 adopts the terminology "purchased materials" rather than starting materials, raw materials, actives or inactives. In the interests of harmonisation, PDA suggests adoption of the ICH terminology throughout the revised chapter.

Recommendation: Replace the term "starting" material with "purchased" material throughout the revised chapter.

Comment 3, Traceability of Active Substance: The proposed revision to this chapter includes a footnote (see p.5) requiring a record of where each active substance, including its critical starting materials, is manufactured, propagated, processed and handled prior to its use in the manufacture of a medicinal product. PDA believes that in some cases this information may be proprietary and therefore unavailable to the drug product manufacturer (Marketing Authorisation Holder). As such, compliance with the requirement would have the potential to result in shortages of critical active substances. Further, this requirement appears to conflict with the concept / requirement for filing a Drug Master File (DMF).

Recommendation: A specific recommendation has been proposed in the body of comments below. PDA believes this issue to be of great concern to the stakeholders and regulators alike and, as mentioned earlier, is willing to assist in hosting a public forum to discuss and mutually resolve potential issues.

If you have any questions please contact me, or James Lyda of the PDA staff (lyda@pda.org) who coordinated this project.

Georg Roessling, Ph.D. Senior VP, PDA Europe

Georg Hothing

Roessling@pda.org

cc: S. Rönninger, S. Schniepp, K. Ginsbury, J. Lyda, R. Levy, R. Dana