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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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Eli Lilly

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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

REF : EudraLex, Volume 4
Good Manufacturing Practice
Medicinal Products for Human and Veterinary Use
Revised EU GMP Chapter 7: Outsourced Activities

Dear Colleagues:

PDA is pleased to provide comments on revised *Chapter 7 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. They consist of two general comments, mentioned below, and specific technical comments attached in the EMA matrix format.

Comment 1, **Scope:** As presently written the chapter appears to apply primarily to contract manufacturing activities with a few references to contract testing. The full scope of the chapter is unclear regarding which outsourcing activities are covered.

Recommendation:
In the EMEA concept paper relating to this revision (October 2009), examples of outsourced activities potentially covered by the chapter were provided in Section 2. The use of such examples would make it clearer which types of activities are intended to be within the scope of the chapter.

Comment 2, **Purchased (starting) materials:** It is not clear whether the purchase of starting materials is covered by this chapter or if the proposed revisions to Chapter 5 are intended to address such materials. ICH Q10, Section 2.7, 'Outsourced Activities and Purchased Materials', appears to distinguish between the two. We suggest it would be appropriate to clarify that Chapter 5 covers GMP aspects for purchased materials, and not Chapter 7.

Recommendation:
Revise the chapter so it is clear that purchased materials are not in the scope of Chapter 7, but are addressed in revised Chapter 5, which is undergoing concurrent revision**.** PDA also recommends adopting the terminology of ICH Q10 and referring to "purchased" rather than "starting" materials in this and other chapters of the EU GMP as they are revised.

PDA believes that the particular issues surrounding purchased/starting materials are so important and nuanced that there should be opportunity for a public discussion of the impact of the revised chapter in these areas. PDA is willing to help the EC and EMA in hosting a public forum to help resolve such issues.

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

With very best regards,

Georg Roessling, Ph.D.
Senior VP, PDA Europe
Roessling@pda.org

Attachment

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