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Agenda item: Session 2, item 2a
GLP requirements in EU legislation and guidance – medical devices

Document title: Thought-starter on GLP and medical devices

Action required: For discussion

THOUGHT-STARTER ON GLP AND MEDICAL DEVICES

This document is a follow-up to the meeting of the EU GLP Working Group on 18 March 2016, during which the Austrian representative gave a presentation on GLP and Medical Devices. It provides some considerations on the applicability of GLP to pre-clinical data for medical devices. It is meant as a basis for discussion and cannot be considered as an official position of the European Commission.

1. LEGAL TEXT

The legislative proposal for the Regulation on Medical Devices (adoption pending) contains the following provision on pre-clinical and clinical data[1] in Annex II ('Technical documentation'):

> *Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances shall be demonstrated.*

2. APPLICABILITY

The scope of applicability of the principles of GLP for non-clinical data on medical devices is not defined in the legislative proposal, but is considered to cover the following two cases:

1. Medical devices that incorporate a substance which, if used separately, would be considered to be a medicinal product, with action ancillary to that of the device. The device is expected to be assessed and authorised in accordance with the Medical Device Regulation. The pre-clinical data on the substance would be subject to GLP.
2. Medical devices that also fall under other EU legislation containing a GLP requirement.

In these cases, the manufacturer shall demonstrate compliance with GLP for preclinical safety tests in the technical documentation. This GLP claim is subject to verification in accordance with Directive 2004/9/EC. In other cases, GLP is not considered to be applicable to the pre-clinical data in the technical documentation.

3. GLP VERIFICATION

Depending on the class of the device, the conformity assessment of the medical device may require the involvement of a notified body, which would have access to the technical documentation. In such cases, and if the technical documentation contains GLP data, the notified body may choose to verify the GLP compliance status of the data by contacting a GLP monitoring authority.

[1] In order to demonstrate conformity with the general safety and performance requirements, the manufacturer of a medical device may use clinical and/or non-clinical safety data (see Article 49 of the legislative proposal).