

REGULATORY NEWS

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EU NEWS

Annex 1: European Commission Publishes Revised Document

The European Commission have agreed to engage with stakeholders a second targeted consultation on the revised draft guidance Annex 1: Manufacturing of Sterile Medicinal Products. The first targeted consultation was conducted from 20 December 2017 to 20 March 2018.

The European Commission published the draft guidance on 20 February 2020 on their website. The draft guidance enters a period of consultation from 20 February 2020 to 20 May 2020. This revision is intended to add clarity, introduce the principles of Quality Risk Management to allow for the inclusion of new technologies and innovative processes and to change the structure to a more logical flow.

Reflection Paper on Good Manufacturing Practice and Marketing Authorisation Holders

On 14 January 2020, the EMA published a Reflection Paper on Good Manufacturing Practice and Marketing Authorisation Holders (MAH). The Reflection Paper is focussed on the GMP-related responsibilities that apply to MAH companies.

The current European Commission (EC) Guide to GMP, refers in several places to MAHs and their responsibilities in relation to GMP. In general, these responsibilities relate to outsourcing and technical agreements, that require the MAH to perform certain specific tasks. These responsibilities are spread over the various chapters and annexes of the GMP guide and are quite numerous. This Reflection Paper seeks to provide clarity as to what the various responsibilities are and what they mean for MAHs at a practical level.

In addition to the MAH responsibilities in the GMP guide, this paper also addresses the various legislative provisions (i.e. in European Directives and in other guidelines) which relate to GMP and which concern MAHs. Some of the responsibilities stated in the legislation and in applicable guidelines are written in a way that they apply to marketing authorisation applicants, and they are included in this Reflection Paper because those provisions also convey responsibilities upon MAHs in the post authorisation phase.

In this Reflection Paper, the MAH-related responsibilities are grouped together under a number of different themes. The themes are:

- Outsourcing and technical agreements
- Audits and qualification activities
- Communication with manufacturing sites (e.g. MA dossier information, variations, regulatory commitments, etc.)
- Product Quality Reviews
- Quality defects, complaints and product recalls
- Maintenance of supply of medicinal products
- Continual improvement activities.