European Industrial Pharmacists Group
Groupement des Pharmaciens de l'Industrie en Europe

30th December 2016

Comments on:

"Concept paper on Good Manufacturing Practice and Marketing Authorisation Holders"

EMA/582064/2016
GMP/GDP Inspectors Working Group
1 September 2016

Comments from: European Industrial Pharmacists Group (EIPG)

General comment

The initiative of a concept paper on Good Manufacturing Practice and Marketing Authorisation Holders is appreciated as there is a need for clarity of responsibilities, taking into account regulatory compliance and the complexity of the supply chain.

The production of a reflection paper, intended for Part III of the EU GMP Guide and providing a degree of flexibility in relation to the management of future GMP Guide changes, should provide better interaction and mutual understanding between MAHs and manufacturers.
The document should be brought to the attention of the signatories of the MAHs.

Observations and suggestions

1. When the manufacturer is outside the EU or EEA, clarification is needed as to whether or not the QP can be in place directly at the MAH site or whether a third party releasing batches for the EU market is mandatory.

2. The responsibilities of the MAH as far as the supply chain management and the prevention of counterfeiting are also to be considered.

3. In the final document, we propose that an index with references and explanations be included to prevent sections of the document becoming obsolete as a result of amended regulations.

4. We suggest the responsibilities of MAHs and manufacturers, as defined in the Delegated Regulation of the Commission 2016/161, be included in this document.

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