efpia
European Federation of Pharmaceutical Industries and Associations

Proposed process to flag inspection inconsistencies

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Manufacturing and distribution sites have reported receiving conflicting interpretations of EU GMDP guidelines from different regulatory inspectors. We are interested in a mechanism to submit such information and receive feedback on areas where misalignments are observed. This would also allow collection of data to support consistent interpretation when updating a specific guideline or developing Q&As. We are also asking GMDP Inspectors Working Group (IWG) to consider continuing working with PIC/S to support harmonisation among participating inspectorates when enforcing guidelines issued by different jurisdictions driven due to e.g., misconceptions by translation or local legal terminologies, while the scientific basis is equivalent.

1. Background

Companies have reported receiving conflicting interpretations of GMP guidelines from different inspectors.[1] We understand and agreed with EMA IWG that this is the forum to align interpretation between NCAs. However, GMDP IWG made the point that '*companies which see misinterpretation in implementation should raise this with their Supervisory Authority and this authority will raise a problem statement to the IWG should it be necessary*'.[2]

2. Reason why industry sees a problem

Companies are concerned that this suggested process i.e., sharing potential conflicting interpretations with the NCA, might not always get to the attention of the GMPD IWG. Moreover, this might even be misunderstood by the inspectorate of the NCA as criticism and potentially resulting in a delay of the regulatory compliance decision after an inspection.

3. Benefit

By letting EMA-IWG systematically know where interpretations of EU-GMDP guidelines, regulations and legislation in regulatory inspections can lead to uncertainties with both industry and inspectorates, we see the following benefits e.g.,

- Continuous improvement of guidelines,
- Trigger additional Q&As and/or
- Support training of inspectors

4. Proposal

We suggest the following steps based on exiting communication channels:

[1] Letter to EMA-IWG by the Interested Parties 02. Nov 2023.
[2] GMP/GDP IWG meeting with Interested Parties Draft meeting summary, 7th March 2024.

1. Collect: Industry considers having the opportunity to submit a prioritised list of inconsistencies observed in regulatory inspections between different inspectorates. This selection could be performed by one or several of the GMDP IWG Interested Parties.

2. Submit: Industry would submit this prioritised list through established communication channels e.g., the currently established annual letter for the EMA IWG Interested Parties Meeting and/or sending these about a month before a scheduled GMDP IWG meetings to the GMDP IWG working group address.

3. Conclude: It would be greatly beneficial to receive feedback by GMDP IWG on the submitted inconsistencies observed. Doing so, it would be ensured that all parties are aligned and working towards the same goals and support harmonisation of interpretation across the EU-MS and beyond e.g., by working with PIC/S participating authorities.