Policy Position

Revised, January 2020

IFPMA Position on Convergence of Good Manufacturing Practice (GMP) standards and Related Inspections

This position paper reiterates the global industry position on GMP convergence (June 2017 position paper and addresses the ICDRA WHO recommendations[1] to industry with regard to the sharing of inspections information amongst regulators and procurement agencies under the Reliance approach – see level 3 overleaf.

Key messages

- Good Manufacturing Practice (GMP)[2], Good Distribution Practice (GDP) standards and associated inspections are important components of strong regulatory systems, and contribute to ensuring that pharmaceutical products are manufactured to high quality standards to supply patients worldwide.

- IFPMA recognizes and supports the efforts undertaken by National Regulatory Authorities (NRAs) to advance convergence and cooperation at regional and international level; achievements to date are described in the ICMRA mapping[3]

- IFPMA further encourages processes to strengthen the overall regulatory system, optimize regulatory oversight by authorities, avoid duplication and redundancy and contribute to facilitating reliable global supply chains.

- Thus, IFPMA proposes approaches on GMP/GDP standard convergence, aligned inspection processes and NRA cooperation, as follows.

A. GMP/GDP standards convergence

IFPMA supports international efforts to develop common standards, including through International Council for Harmonisation (ICH) and the World Health Organization (WHO), with adoption into local regulations.

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[1] 18th ICDRA recommendations, WHO Drug information Vol 32, No.4, pp 516, 2018

[2] *For the purposes of this paper, manufacturing is defined as "All operations of purchase of materials and products, Production, Quality Control, release, storage, distribution of medicinal products and the related controls".*

[3] ICMRA Mapping of GMP Inspection Activities, EMA/219981/2014, 2016

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IFPMA also recognizes the role that the Pharmaceutical Inspection Co-operation Scheme (PIC/S) takes in developing guidance for its member inspectorates in harmonizing the interpretation and inspection of GMP/GDP standards.

Industry supports these programs and encourages the opportunities they provide for open scientific discussions on emerging regulations or interpretations.

B. Aligned inspection processes and harmonized GMP/GDP compliance documents

IFPMA recommends alignment of processes and documents to facilitate communication and common understanding amongst NRAs, and between manufacturers and authorities.

Alignment should be sought for the following:

- Inspection report and observation/deficiency classification;
- Certification of GMP compliance;
- Risk-based approaches to inspection programs; and
- Access to manufacturing site information at inspection, e.g. Site Master file.

C. National Regulatory Authorities cooperation on GMP/GDP Inspection Programs

IFPMA advocates for a number of levels of increased cooperation that can ultimately lead to a mutually recognized, fully integrated international GMP inspection scheme which is important to supervise global medicinal products supply chains. IFPMA recognizes that achieving the highest level of cooperation requires consistent approaches and confidence building over time.

Level 1: Acceptance of GMP inspection/GMP Status certificates

IFPMA encourages the recognition of GMP certificates/GMP inspection reports issued by another NRA, or the acceptance of GMP status based on a WHO CPP.

Level 2: Cooperation approach between Authorities

IFPMA welcomes recent cooperation and supports the following approaches:

a. PIC/S reliance program, which can increase inspection capacities and global coverage by relying on inspections previously conducted by other authorities. This further prevents duplication of inspections;
b. Joint and/or observed inspections which reduce workload for regulator and industry. and generate capacity and capabilities building opportunities between inspectors;
c. The Prequalification Program of the WHO or the Certificate of Suitability Program of the European Directorate for the Quality of Medicines (EDQM), validated by inspections using international inspectors.

Level 3: Reliance approach[4]

IFPMA advocates for reliance whereby NRAs can share GMP compliance information and GMP and GDP inspection reports in redacted form with other agencies to support their decision-making related to GMP compliance[1]. Information may be shared by the reference

[4] Considerations for effective regulatory reliance – an Industry perspective, IFPMA, 2019

authority through direct communication with NRAs as established under PIC/S statutes, or under a confidentiality agreement with appropriate safeguards to protect personal data and commercial confidential information, while ensuring Intellectual Property is preserved[5]. For additional information, refer to annex 1.

The use of standardized inspection and GMP documents will further facilitate regulatory review and decision making. In certain regions, a regional unified system is recommended to maximize regulatory mechanisms and access to medicines in the region. This approach further builds on recent PIC/S guidance, namely:

- Classification of Deficiencies https://www.picscheme.org/layout/document.php?id=1609
- Reliance, June 2018 https://www.picscheme.org/layout/document.php?id=1400

Level 4: Mutual recognition

IFPMA encourages and supports GMP Mutual Recognition Agreements as the optimal mechanism to increase GMP convergence and consistency in an efficient and resource effective manner. A series of global mutual recognition agreements would ultimately lead to a single unified system of GMP standards and associated inspections.

Desired results and conclusion

In conclusion**,** high quality, effective and safe medicines for patients remain the primary focus of the research-based pharmaceutical industry. Convergence on GMP/GDP standards and related inspection processes is important to achieve a reliable global supply of quality medicines.

IFPMA applauds the efforts by NRAs toward convergence and encourages on-going activities in the areas of GMP/GDP standards determination and inspection programs. This includes leveraging PIC/S available tools, and implementing PIC/S guidance, irrespective of a membership, IFPMA further encourages inspectorates of NRAs to become members of PIC/S, which will facilitate the exchange of information, training and open communication among the regulatory agencies, and ultimately agree on MRA, where appropriate.

IFPMA is supportive of the exchange of information between authorities as a primary way of collaboration and recommends considering reliance, in accordance with IFPMA practical recommendations for successful Regulatory Reliance – see Annex to this paper also.

[5] Annual Regulatory GMP/GDP Inspection Survey 2018 Data, EFPIA, 2019

<u>Annex 1</u>: IFPMA additional information on effective exchange of GMP/GDP compliance information between NRAs

As a general principle, NRAs are encouraged to always inform the company what inspection information has been shared with the receiving NRA.

Furthermore, the below set of recommendations should always be followed:

1. Preserving Confidentiality and Security of the Information

GMP/GDP compliance information and reports contain company confidential information, and the following should apply:

- Documents must only be shared under a confidentiality agreement with appropriate safeguards to protect personal data and commercial confidential information; intellectual property must also be preserved;
- Documents must be redacted appropriately;
- Only GMP/GDP Inspection reports that cover products and proprietary processes in the receiving NRA should be shared;
- Secure information pathways must be used to protect information in transit.

2. Providing Context

Observations in a GMP/GDP inspection report are short and do not necessarily contain the context or background of the discussions that took place during the inspection at the site. Furthermore, translations may fail to capture context of the observations cited in the inspection report.

Therefore, the follow-up response to the observations by the inspected site, and which provide additional clarification and allow a better assessment of the GMP/GDP conformance at the site, may be useful.

In addition, the NRAs should seek additional contextual information directly from the company, when needed.

3. Ensuring Timeliness

GMP/GDP compliance information and reports represent a summary snapshot in time of specific aspects of a site's compliance. Thus, only reports and company responses from latest inspections should be exchanged.

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