

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

Key messages

- Good Manufacturing Practice (GMP)¹ standards and associated inspections are important components of strong regulatory systems, and contribute to ensuring that pharmaceutical products are manufactured to high quality standards.
- IFPMA supports the strengthening of regulatory systems and oversight while facilitating reliable global supply of quality medicines to protect patient safety.
- 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.²
- 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.
- IFPMA proposes approaches on GMP standard convergence, aligned inspection processes and NRA cooperation, as follows.

A. GMP 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.

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

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

B. Aligned inspection processes and harmonised GMP compliance documents

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

Alignment should be sought for the following:

¹ 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”.

² [ICMRA mapping GMP Inspection Initiatives](#)

- Inspection report and observation/deficiency classification;
- Certification of GMP compliance;
- Risk-based approaches for inspection programs; and
- Manufacturing site information available as part of inspection, e.g. Site Master file.

C. National Regulatory Authority cooperation on GMP Inspection Programs

IFPMA advocates 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 product 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 recognition of GMP certificates/GMP inspection reports issued by another NRA or acceptance of GMP status based on a WHO CPP, be adopted to facilitate GMP compliance determination.

Level 2: Cooperation approach between Authorities

IFPMA welcomes recent cooperation and supports the following approaches:

- a) PIC/S reliance which can lead to opportunities for increased inspection capacity and global coverage by relying on inspections previously conducted by other authorities. It will avoid inefficient duplication and redundancies.
- b) Joint and/or observed inspections which reduce workload for regulator and industry. and provide the opportunity of building new capacity and capabilities between inspectors.
- c) the Prequalification Programme of the WHO or the Certificate of Suitability Programme of the European Directorate for the Quality of Medicines (EDQM), validated by inspections using international inspectors.

Level 3: Reliance approach

IFPMA advocates reliance where NRAs can share GMP compliance information and assessment reports with other agencies to support decision-making related to GMP of a manufacturer. The use of standardized inspection and GMP documents would facilitate regulatory review and decision making. In certain region, a regional unified system is recommended to maximize regulatory mechanisms and access to medicines in the region.

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 good manufacturing practice 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 standards determination and inspection programs.