WHY ARE GMP KEY PLAYERS?

- The International Council for Harmonization (ICH) whose mission is to achieve greater harmonization worldwide through the development of ICH Technical Guidelines.
- The Pharmaceutical Inspection Co-operation Scheme that leads the international development, implementation, training, and maintenance of harmonized GMP standards and quality systems of inspectorates.
- The World Health Organization (WHO) who acts as regulatory norms-setting body.

WHAT IS GMP?

GMP is a set of control measures & procedures that are:

- Mutually recognized
- Collaborative approach between authorities
- Reliance-based approach
- Acceptance of GMP inspections
- Utilization of existing information from manufacturing site and product
- Utilization of risk-based approaches
- Certification, communication, and feedback
- Real-time sharing of information
- Mutual recognition

HOW TO ACHIEVE CONVERGENCE?

- A comprehensive inspection should be conducted by the regulatory body to ensure consistency.
- The implementation of risk management practices should be conducted by the regulatory body to ensure consistency.
- The utilization of existing information from the manufacturing site and product.
- The implementation of risk-based approaches.
- The facilitation of communication and common understanding between manufacturers, marketing authorization holders, and competent national regulatory authorities.

HOW CAN COLLECTIVE EFFORTS BENEFIT PATIENTS?

- Promote convergence of GMP standards & inspection processes.
- Collaborate with trusted regulatory authorities to solve GMP & inspection process challenges.
- Enhance regional cooperation to leverage complementary expertise.
- Patient safety first.
- Risk management practices should be conducted by the regulatory body to ensure consistency.
- The utilization of existing information from the manufacturing site and product.
- Utilization of risk-based approaches.
- Facilitate communication and common understanding between manufacturers, marketing authorization holders, and competent national regulatory authorities.

IPMA represents the research-based pharmaceutical companies and associations in Europe. The mandate of the Pharmaceutical Inspectors’ Mutual Assistance Network (PIMAN), a pan-European platform that supports the harmonization of inspection practices, including the development of toolkits, best practices, and information sharing.