



CONVERGENCE

TO SUSTAIN A RELIABLE GLOBAL SUPPLY OF QUALITY MEDICINE



1. STANDARDS CONVERGENCE

GOAL





CLEARLY DEFINED

VALIDATED

REVIEWED

TO ENSURE GOOD **SCRUTINY AND QUALITY** OF DELIVERED MEDICINES

CONTROL STRATEGY

that are:

GMP is a set of

control measures & procedures





DOCUMENTED





IFPMA encourages key players to continue working towards harmonization of GMP standards

WHO 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.

2. PROCESSES ALIGNMENT **OPPORTUNITIES**



Share inspection reports



Recognize certificates



Implement risk-based approaches



Utilize existing information from manufacturing site and product

STRENGTH



Consistency



Efficiency



Effectiveness

WHAT COULD BE DONE?

- Share inspections reports, recognize certificates, and implement risk-based approaches. • Utilize existing information form manufacturing site and product.
- Utilize resources for both regulators and industry by implementing efficient risk-based approaches.
- Facilitate communication and common understanding between manufacturers, marketing authorization holders, and competent national regulatory authorities.

3. TOWARDS CONVERGENCE

01

03

04

Mutual recognition

CONVERGENCE

- **GMP** inspections **GMP** status
- certificates
- Collaborative approach between authorities

approach

A reliance-based

• There is a number of levels of increased cooperation that can ultimately lead to a mutually recognized, fully integrated international GMP inspection scheme to supervise global medicinal product supply chains. • Collaboration, communication, and trust building are key.

HOW TO ACHIEVE CONVERGENCE?

4. KEY STAKEHOLDERS

Health Inspector Authority STAKEHOLDERS Marketing Legislator Authorization Holder **Patients** Non Manufacturer Governmental Organization

community find solutions that improve global health.

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.
- Put patient safety first.



IFPMA represents the research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry's 2 million employees discover, develop, and deliver medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health