



IFPMA

GOOD

MANUFACTURING PRACTICES

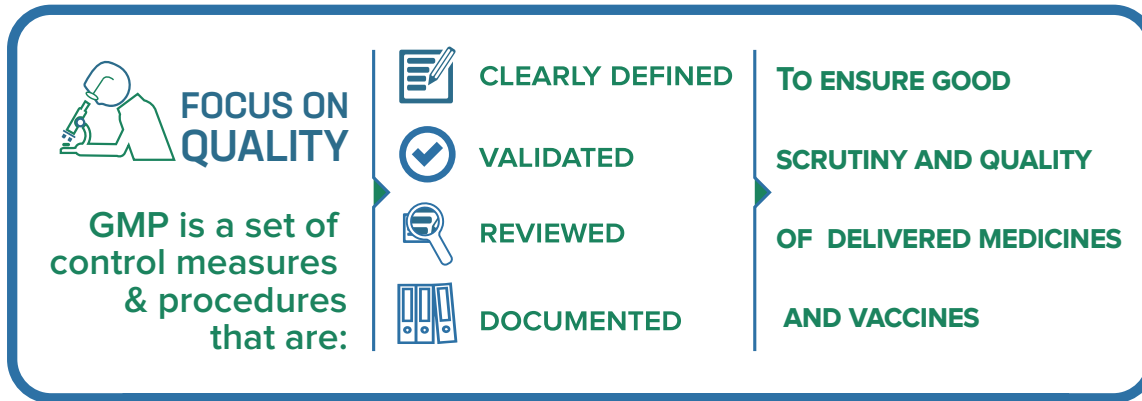
CONVERGENCE

TO SUSTAIN A RELIABLE GLOBAL
SUPPLY OF QUALITY MEDICINE



1. STANDARDS CONVERGENCE

GOAL



CONTROL STRATEGY



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

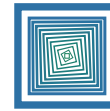


Implement risk-based approaches



Utilize existing information from manufacturing site and product

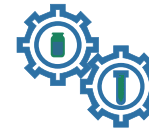
STRENGTH



Consistency



Efficiency

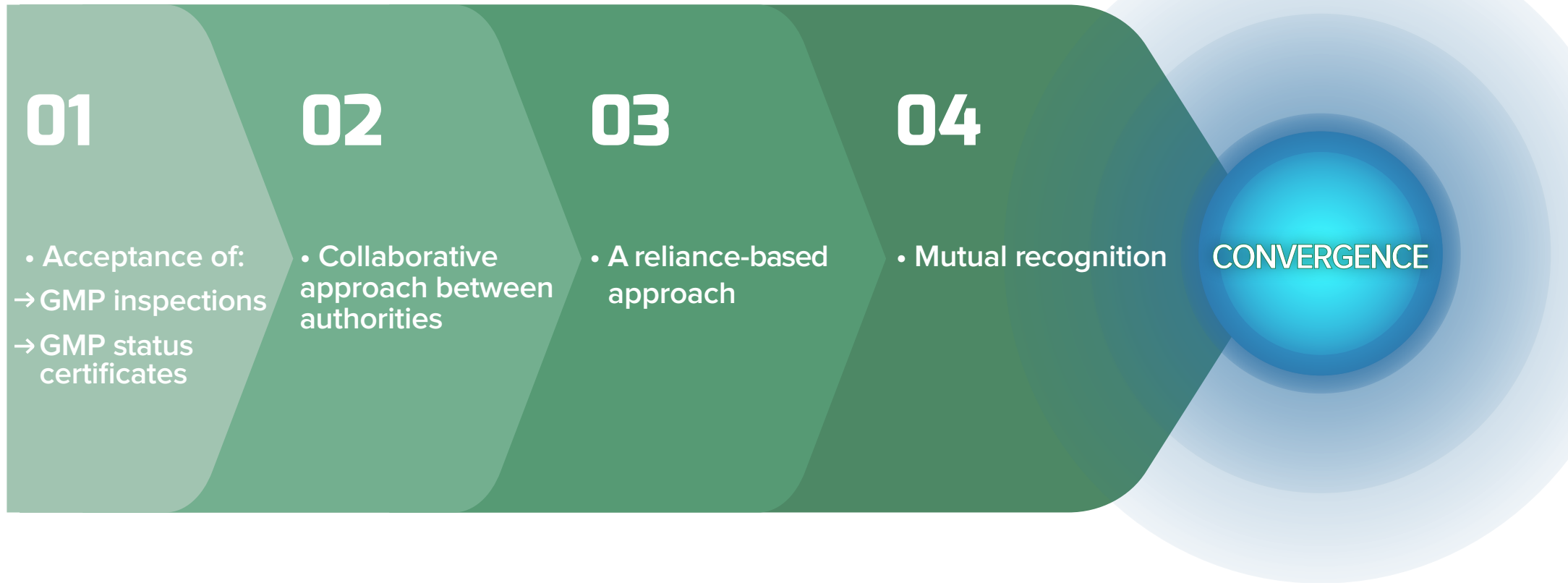


Effectiveness

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



HOW TO ACHIEVE CONVERGENCE ?

- 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.

4. KEY STAKEHOLDERS



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

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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 community find solutions that improve global health.