

# GOOD

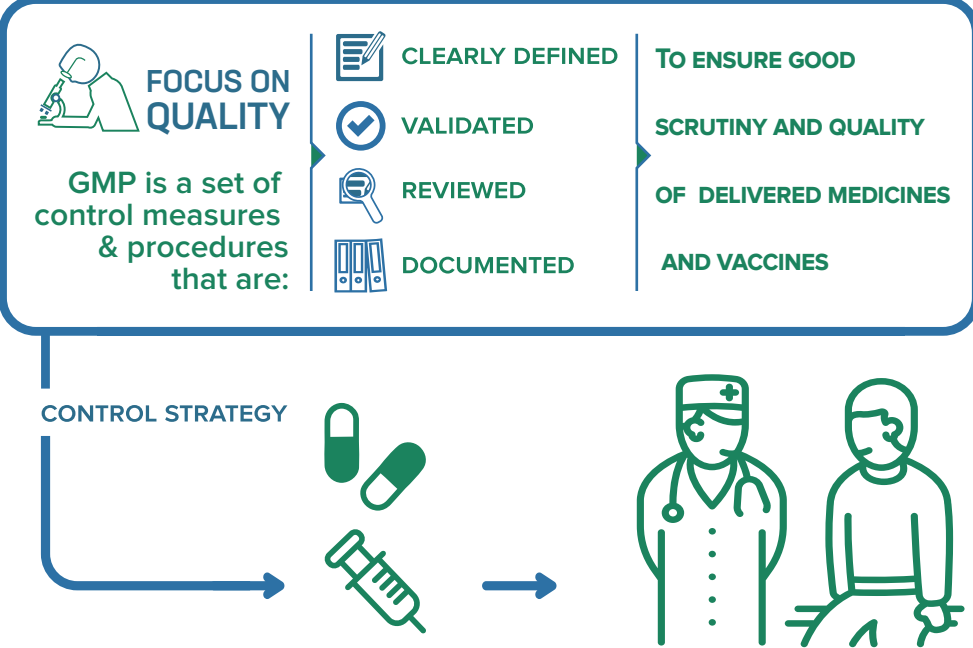
## MANUFACTURING PRACTICES CONVERGENCE

TO SUSTAIN A RELIABLE GLOBAL SUPPLY OF QUALITY MEDICINE



### 1. STANDARDS CONVERGENCE

#### GOAL



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

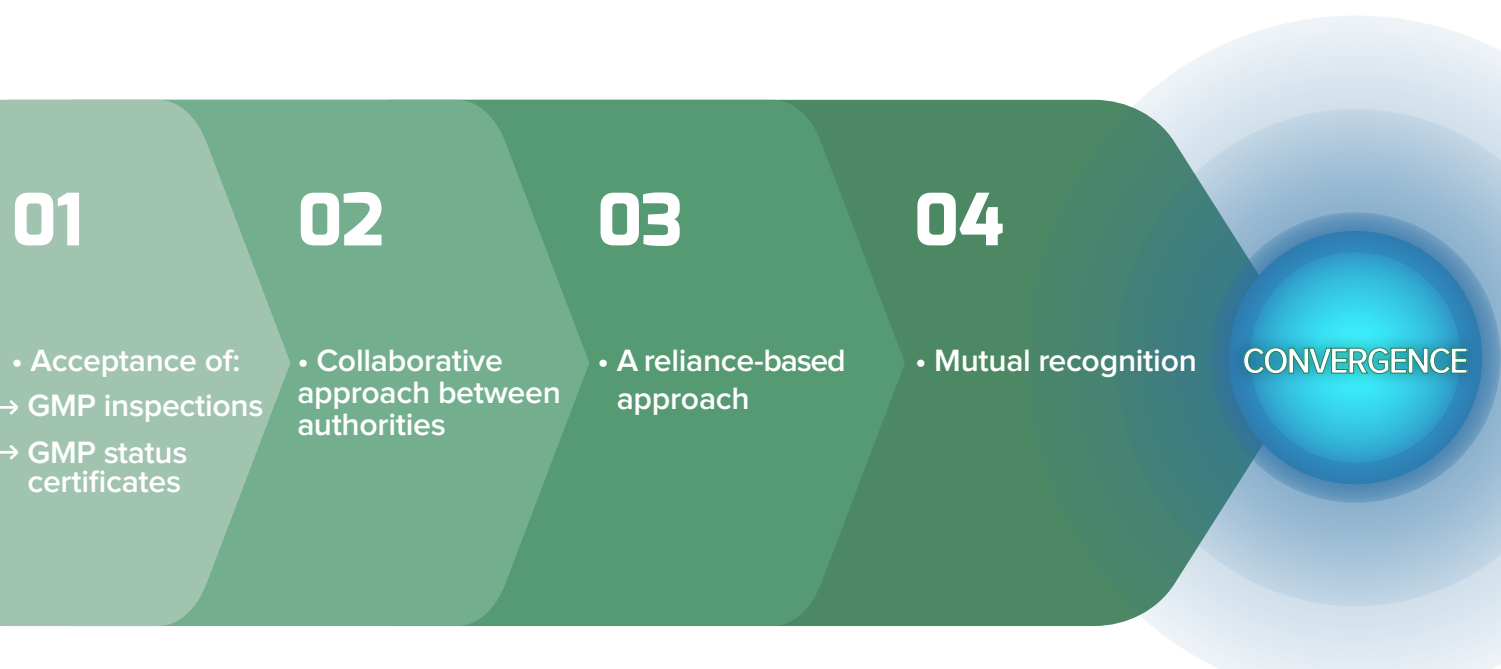
#### STRENGTH

- 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.

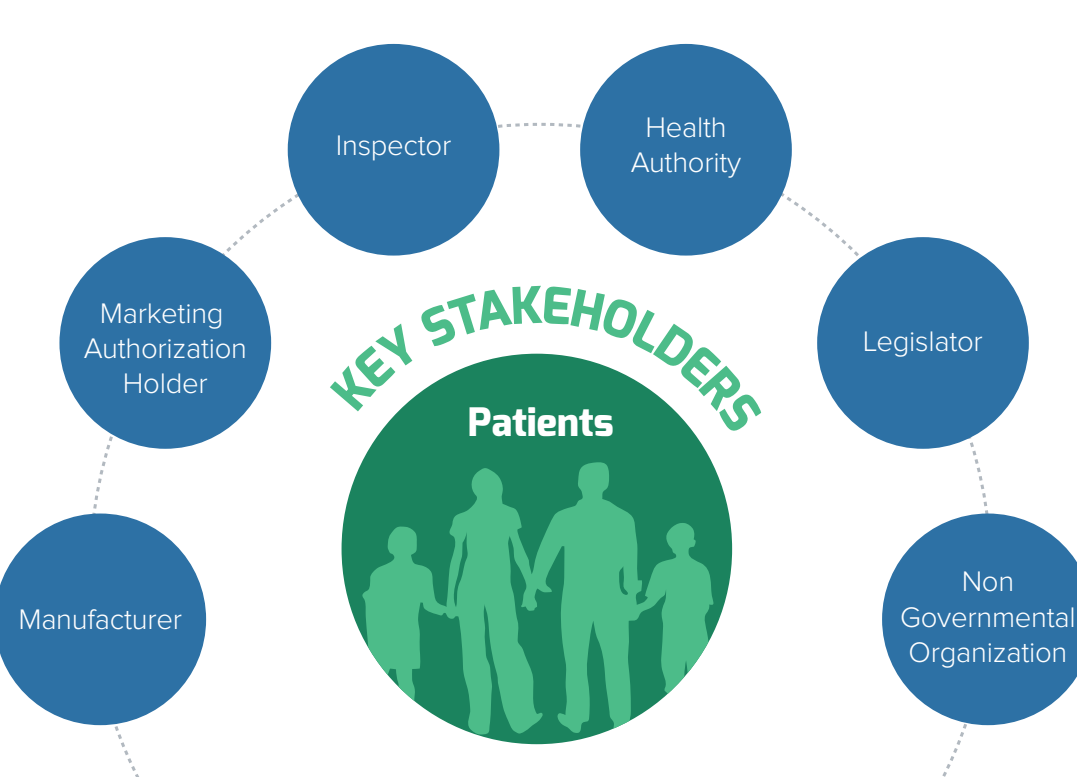
### 3. TOWARDS CONVERGENCE



### 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.