Inspection landscape: Good Manufacturing and Distribution Practices (GMP/GDP)

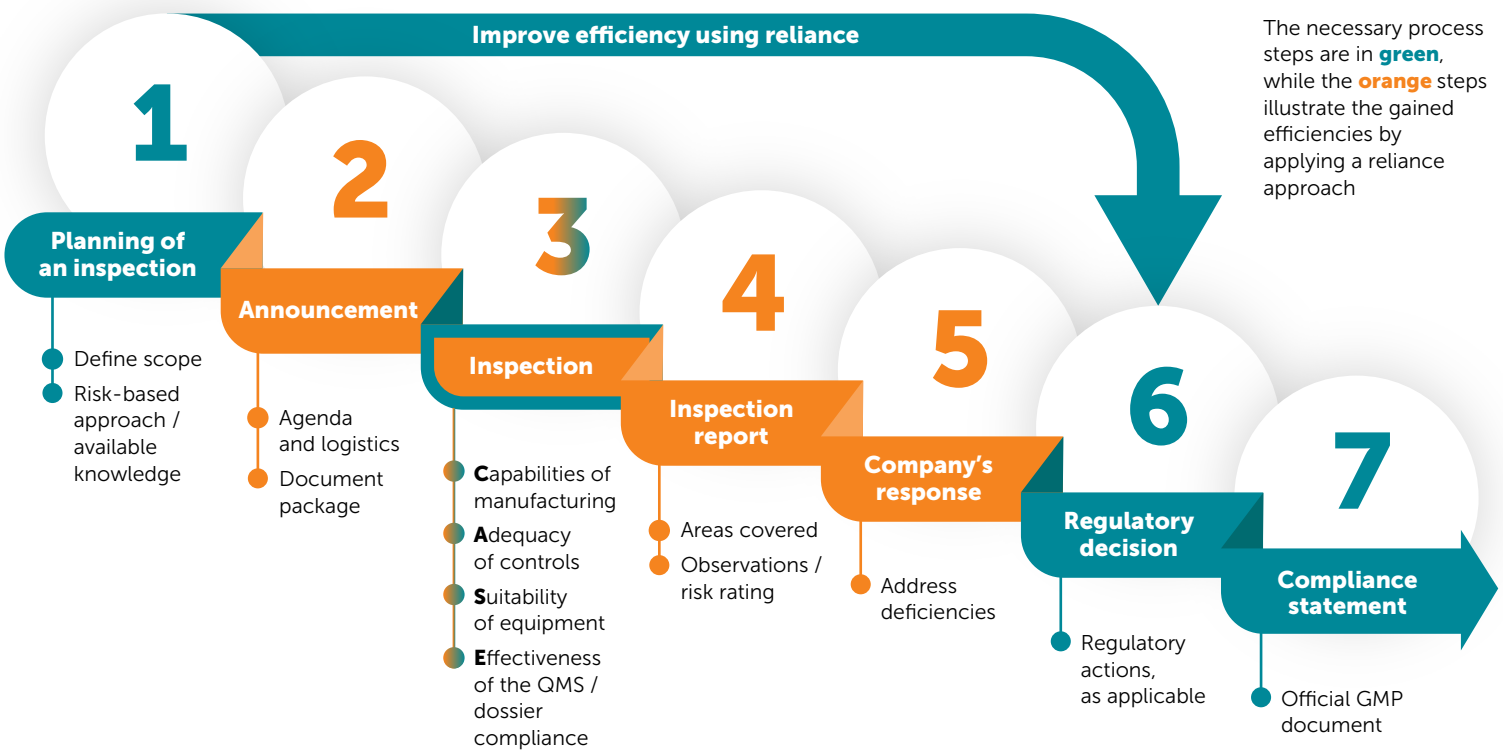
efpia

Why inspections matter

Pharmaceutical manufacturing is strictly regulated, with Good Manufacturing and Distribution Practices (GMP/GDP) following similar principles worldwide. Regulatory inspections assess compliance with regulatory expectations for manufacturing and distribution.

By ensuring the safety and quality of medicines, inspections of manufacturers and distributors play a **crucial role in protecting public health**.

Seven steps of any inspection process



The necessary process steps are in **green**, while the **orange** steps illustrate the gained efficiencies by applying a reliance approach

Our commitment

Continued surveillance of systems and processes along with fulfilling inspection and registration commitments.

Continuously improve QMS by keeping track with innovations and regulatory expectations and regional/local regulatory expectations.

Streamlined communication on inspections from third countries and on timelines for document submissions.

Have a look at EFPIA's website for more information on GMP:

Current challenges in the inspection landscape

Fragmentation of standards
Regulatory requirements vary across countries, creating inefficiencies in inspection preparation and compliance.

Growing burden
A surge in foreign inspections by global health authorities adds pressure on resources, time, and costs for manufacturers and inspectorates.

Operational inefficiencies
Onsite inspections by third-country inspectorates are time-intensive, carbon-intensive, and often fail to utilise advancements in real-time remote technologies or established reliance frameworks.

Increasing redundancy
An EFPIA survey demonstrates that over 80% of foreign inspections at site overlap in topics, leading to repetitive evaluations without significant additional insights compared to inspections by domestic inspectorate.

Towards greater inspection efficiency

The following approaches provide opportunities to further streamline and enhance GMP/GDP inspections:

Global collaboration and trust building

Build on the equivalence of regulatory and enforcement standards through global cooperation among inspectorates. Platforms such as the Pharmaceutical Inspection Co-operation Scheme (PIC/S) help coordinate schedules and facilitate communication on deferred inspections, while pilots and initiatives like ICMRA PQ KMS enhance understanding.

Adoption of innovative methods

Interpret or amend local legislation to permit reliance approaches, or at least consider setting up pilots. Expand the use of document reviews or real-time remote inspections to complement physical inspections, especially for sites in third countries.

Reliance pathways

Regulatory authorities can reduce duplication by relying on inspections conducted by stringent inspectorates on their territory.
This approach includes:

- **Risk-based approaches:** Focus and adjust scope and/or length of inspections based on prior knowledge and risk assessments.
- **Unilateral/multilateral reliance:** Recognise compliance statements from inspections performed by trusted foreign authorities.
- **Mutual Recognition Agreements (MRAs):** Implement formal agreements to accept each other's inspections and release testing.

Call to action

Streamline

Inspect representative products for the entire site, standardise document requests, accept local language and e-files.

Optimise

Apply unilateral reliance or MRAs, waive import testing, and coordinate to defer inspections.

Prioritise

Focus on uninspected sites and topics; adjust schedules, frequency, and agendas.