EMA
EUROPEAN MEDICINES AGENCY

International collaboration GMP inspections of API manufacturers

CEP Conference, Budapest, 23 September 2025

Presented by Phillip Arntz, Inspection Office

EU Medicines Regulatory Network

- 27 **EU** member states + 3 **EEA** members states (~500 million citizens)
- **European Commission** & Decentralised Agency (**EMA**)
  - ≈ **50 National Regulatory Authorities**
  - 4,500 European experts
- EMA is a technical, scientific and administrative secretariat
- **EMA role** for GMP:
  - GMDP Inspectors Working Group (IWG)
  - Co-ordination of verification of GMP Compliance and Market Surveillance
  - Experience with training of assessors, inspectors, coordination of inspections and evaluation processes

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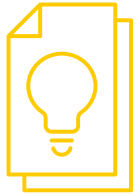
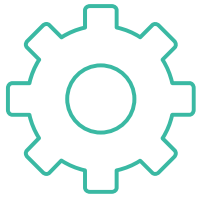
International collaboration
GMP inspections of API manufacturers

Agenda



Background

International API Inspection Programme



The pilot

Current programme

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Strategic priorities

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Alternative ways of working catalysed by the pandemic

Extension of GMP certificates

- A pragmatic approach that has helped address issues with travel restrictions
- In 2020 and 2021 - 385 inspections in third countries were deferred due to the extension of GMP certificates

Reliance on GMP inspections conducted by other authorities (FDA, MHRA, KR)

- 8 GMP inspections were deferred by the Member States due to the reliance of GMP compliance information received from third country Authorities (2020, 2021, 2022)
- 12 EMA Inspection reports were sent in 2020, 2021, 2022 to third country authorities

Distant assessments

- 59 EMA co-ordinated and 433 national distant assessment conducted from 2020 – 2022

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GMDP IWG Pilot on Reliance

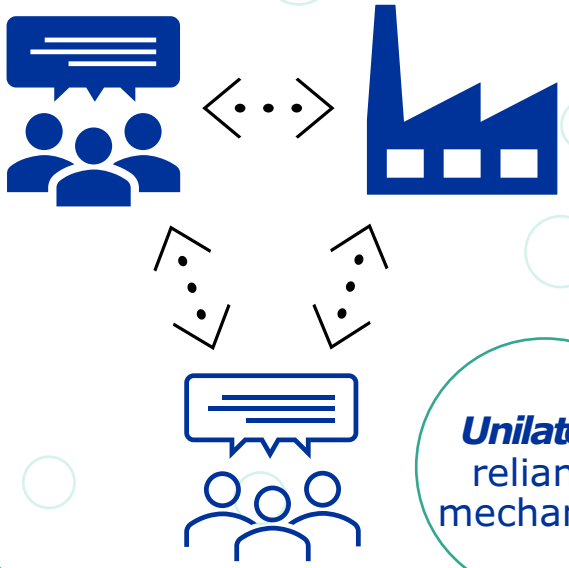
13 sites included (in 7 PIC/s countries) – positive outcome for 10 sites → EU GMP certificate extended

Reference to **PIC/s Reliance Procedure** to be added to **CoUP**

Applies to ***re-inspections*** of API or FP manufacturing sites

A GMPc can be issued indicating this is based on a remote assessment

EU authorities apply the remote (desktop) review procedure outlined in **PIC/s Reliance Procedure**



Unilateral reliance mechanism

October 2022 - December 2024 EU Inspectorates pilot evaluate impact of reliance on PIC/s Authorities for GMP verification

Reliance: *take into account inspections performed by another regulatory authority, or to any other authoritative information, in reaching its own decision*

Inspections of sites located in the territory of **PIC/s authorities**

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Inspection reliance link to other global initiatives

Pharmaceutical Quality Knowledge Management *(PQKMS)*

International collaboration for global regulators to share and use information on the same facilities, products, marketing authorization applications and marketing application holders

Enable mutual reliance among regulators

(*assessment and inspections*)

comparability of the assessments and conclusions

Harmonize data expectations for the dossier and **electronic formats** (e.g. unique facility identifiers)

Secure sharing of information on manufacturing facilities

More streamlined regulatory assessment of post-approval CMC changes, and promote effective PQS

Pilot on **collaborative assessments**

Pilot on **hybrid inspections**

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International API Inspection Programme

How it started

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How it started

- Globalisation of Active Pharmaceutical Ingredients manufacturing
- Increased need for international inspections to ensure adequate oversight
- Limited regulatory resources
- Harmonisation of regulatory standards

making best use of inspection resources worldwide through increased cooperation

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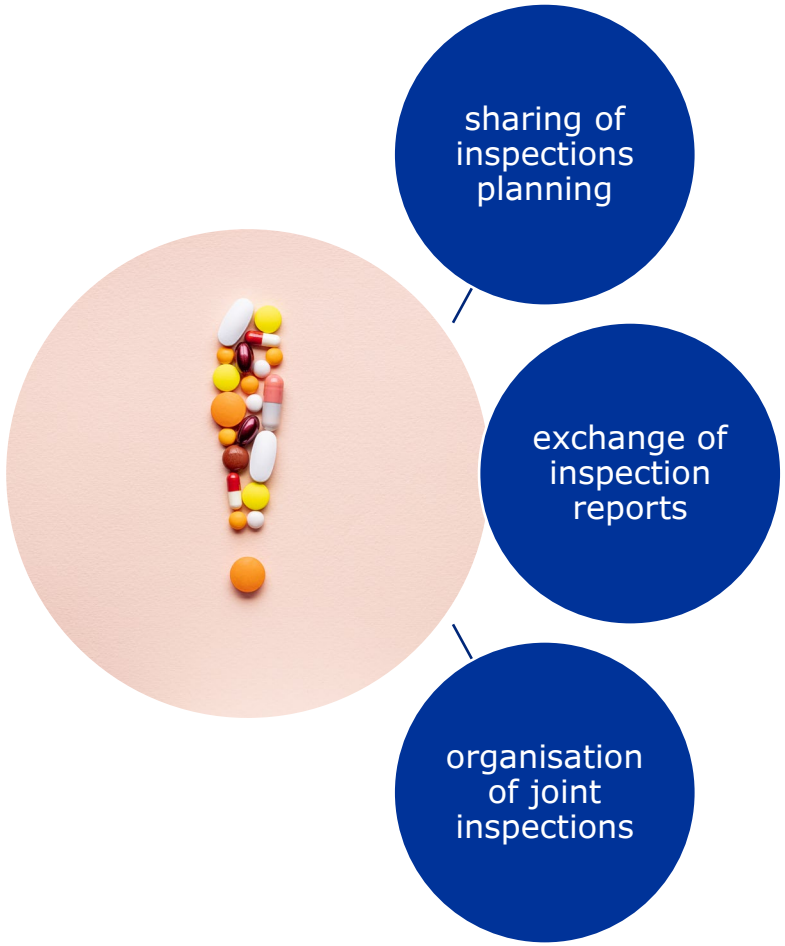
Pilot Programme



- Increased transparency and visibility of inspections
- Decrease in “duplicate inspections”
- Increase in the number of inspections performed of value to more than one authority
- Overall increase in the number of API sites inspected
- Positive assessment of the deliverables by the participating authorities

Between December 2008 and December 2010

Australia, Europe and the United States of America

[Final report on the International API Inspection Pilot]

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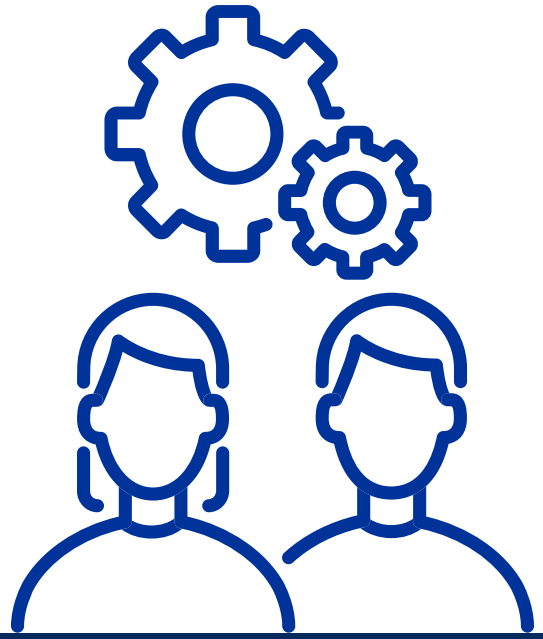
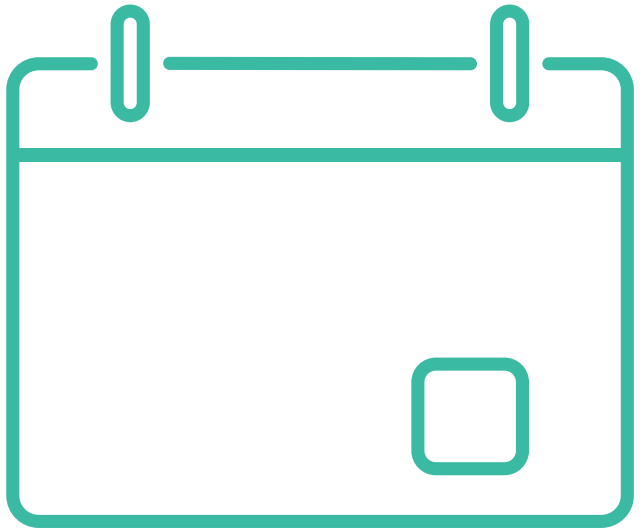


Increase in identified sites of common interest

458 sites (49%) located in 18 countries: primarily India with 226 sites and China with 165 sites

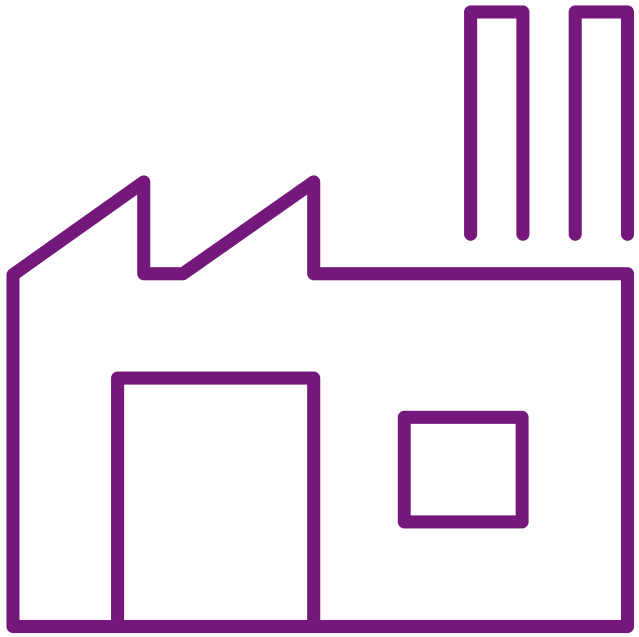
47 joint inspections at 43 sites



Increase in members

EMA, AIFA, ANSM, DKMA, MHRA, EDQM, FDA, TGA, WHO (2012)

Additional observers
HC (2015) and PMDA (2016)



Grown inspection coverage

Increased number of API sites inspected

[Report on the international API inspection programme 2011-2016]

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Challenges

- GMP non-compliant outcomes could lead to multiple inspections due to participants' policies regarding non-compliance information – these were not considered duplicate

- Multiple inspections of a site might cover different scopes so that classification as duplicate might not be appropriate

- No clear view on how often the programme led to a decision to not inspect a site

- Legal requirements leading to duplicate inspections may not be avoided by means of the programme

Number of inspections per site between 2011-2016

non-compliant sites 2.3

compliant sites 1.7

Report on the international API inspection programme 2011-2016

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International API Inspection Programme

How it’s going

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Programme to rationalise international GMP inspections of API/AS manufacturers

Objective:

- foster greater international collaboration and information sharing to help better distribute inspection capacity, allowing more sites to be monitored and reducing duplication
- Voluntary agreement building on equivalent GMP standards to
  - coordinate inspection planning taking into account risk-based approaches
  - share information on inspection outcomes

Scope:

national and international regulatory authorities responsible for the coordination and conduct of GMP inspections of manufacturers of non-sterile and sterile APIs, of chemical and biological origin, for human and veterinary medicinal products, located outside the territories of the participating authorities

Terms of reference for participating authorities

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Participating authorities and organisations

- the European Directorate of the Quality of Medicines and Healthcare (EDQM)
- EU Member States (France, Denmark, Ireland and Italy), the European Commission and EMA
- the United Kingdom's Medicines and Healthcare products Regulatory Authority (MHRA)
- the United States Food and Drug Administration (US FDA)
- the Australian Therapeutic Goods Administration (TGA)
- Health Canada (HC)
- the Japanese Pharmaceuticals and Medical Devices Agency (PMDA)
- the World Health Organization (WHO)
- Brazilian Health Regulatory Agency (ANVISA) from October 2021

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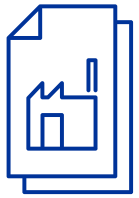
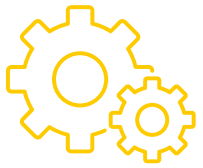
Mode of action

- regular meetings and monthly exchange of information
  - ✓ To share and coordinate planned inspections
  - ✓ To share information on inspection outcomes
- Building of a shared Master List
- Additional bi- or multilateral exchange
  - ✓ To organise joint inspections
  - ✓ To share inspection reports
- Reporting of activities





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Conclusion

- Better GMP oversight for participating authorities
- More transparency and efficiency for planning and realisation of GMP inspections
- reduced number of duplicate inspections not only allows more strategic use of inspectional resources but reduces the burden to all participants, including on the API industry

The international API Programme is subject to ongoing refinement.

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Thank you

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