



European Directorate for the Quality of Medicines & HealthCare Council of Europe

edqm
European Directorate
for the Quality
of Medicines
& HealthCare | Direction européenne
de la qualité
du médicament
& soins de santé

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

Session 10: The EDQM inspection programme – Risk-based inspections and reliance

IPA 11th Advanced GMP Workshop 2026 (Virtual)

Florence Benoit-Guyod, Head of Site Management Unit

9 October 2026 | 17:40–18:10 hrs IST



Background of the EDQM Inspection Programme



Integral part of the Certification of Suitability (CEP) Procedure



For sites manufacturing APIs involved in CEP applications



Selection of sites eligible to be inspected by EDQM

- In line with EU legislation for GMP compliance of API manufacturers
- According to a risk-based approach



On-site Inspections mostly in Asia (China, India) about 40 sites per year, to verify:

- Compliance with the CEP dossier and Ph. Eur.
- Compliance with EU GMP (Part II & any applicable annex)



Exchange of GMP information with international partners

EDQM Inspection Programme

The 3 pillars
of the EDQM Inspection Programme
for the supervision of the GMP compliance of manufacturers



On-Site
Inspection
Traditional
approach
~40 sites/year



Real Time
Remote
Inspection
Adopted as
permanent tool
in 2022



Inspection reliance
Documentation-
based GMP
assessment
Complementary to
inspections
Since 2010

Selection of sites by
Periodic Site Status Review & Risk Assessment

EDQM Inspection Programme

- ➔ Not all sites need nor can be inspected
- ➔ Select the riskiest sites

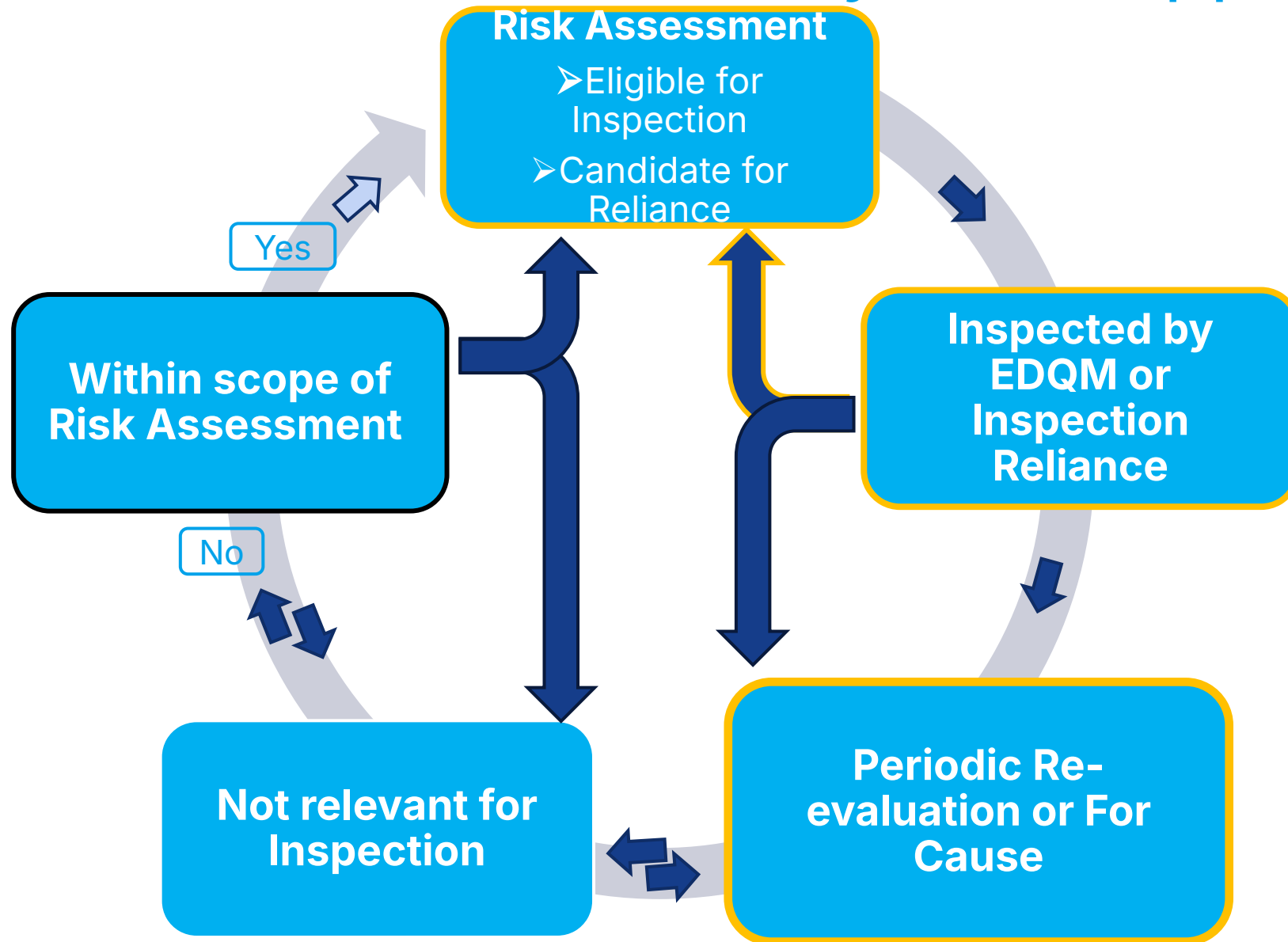
Inspection programme
via SSR/Risk
assessment

▮ Avoid duplication of
inspections worldwide
as much as possible

Inspection
reliance

SSR = Site Status Review

Site Status Review (SSR) – a dynamic approach



Site Status Review (SSR) – risk assessment

- To perform a Risk Assessment data is collected from the API manufacturers involved in CEPs
- Information is requested to the API manufacturers:
 - Systematically when there is a new site associated to a CEP dossier
 - Periodically / routinely to all sites registered
 - Whenever justified ("for cause")
- Substance x Site x CEP = Overall quotation → **Priority High or Medium or Low**

SUBSTANCES



SITE



CEP



Site Status Review (SSR) – risk assessment

Substances	Site	CEPs
▪ Economical aspect ▪ Production route & impurities ▪ Physicochemical characteristics ▪ Structure impact on therapeutic activity/toxicity ▪ Highly active, Sensitizing ▪ Critical therapeutic use ▪ Any other 	▪ Regulatory environment ▪ Inspection history ▪ Cross contamination ▪ Microbial contamination ▪ Any other 	▪ Info from CEP assessment ▪ CEP lifecycle maintenance ▪ Robustness of CEP dossier ▪ Any other 

Site Status Review (SSR) – outcomes

Inspection reliance possible

Candidate
for
reliance

No reliance possible + high RA score

Eligible for
programme

No inspection reliance possible + low RA score

Not
relevant
for
inspection

International collaboration

- EU GMDP Inspectors Working Group at European Medicines Agency (EMA)



- PIC/S Committee of officials



- Working groups for elaboration and revision of GMP guidelines and documents



- PIC/S; EMA; ICH

- Confidentiality agreements
 - Sharing of inspection reports

- International API inspection programme



Optimisation of inspection resources

• **Worldwide** International programme for inspection of Active Pharmaceutical Ingredient (API)

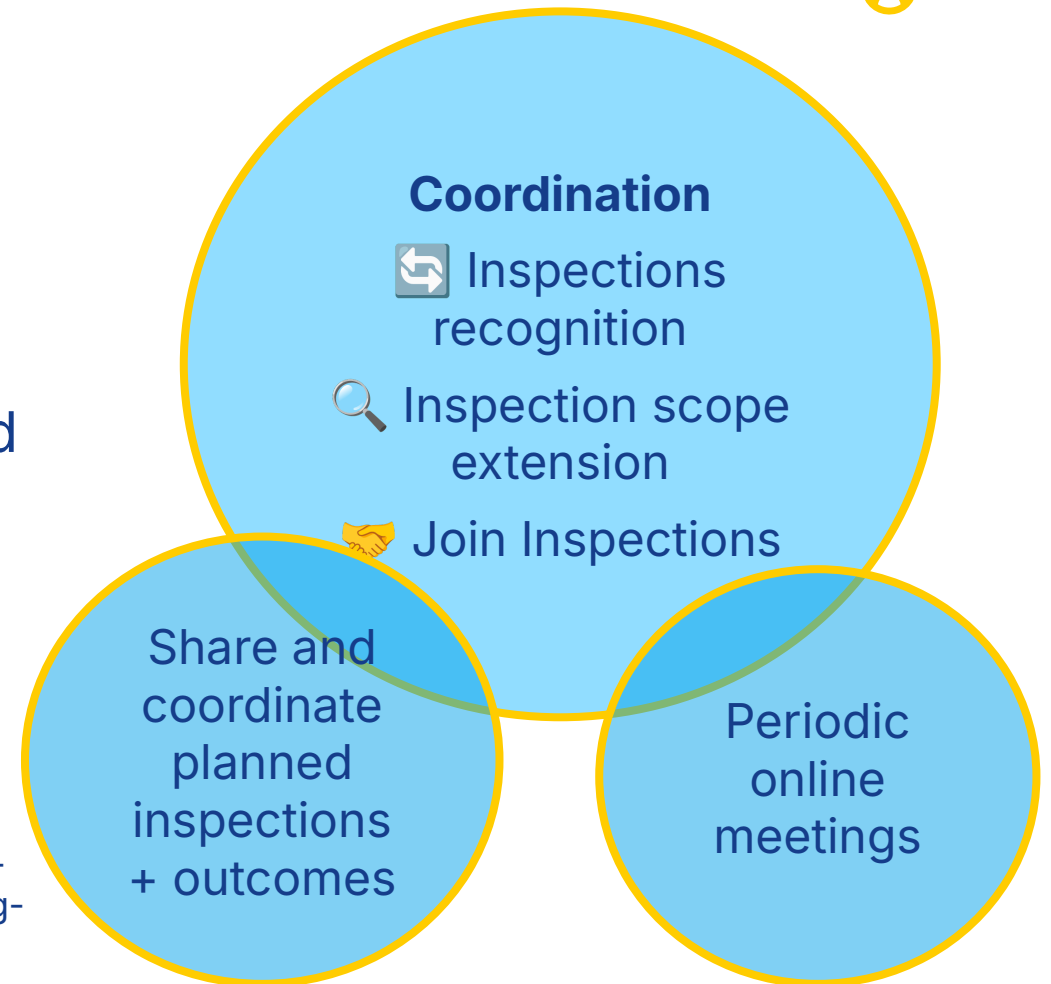
- Voluntary Collaboration built on mutual confidence and enforcement of equivalent GMP

Goals:

- Foster greater international collaboration and information sharing
- Increase inspectional oversight and reduce duplication to allow more sites to be monitored

<https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/compliance-research-and-development/good-manufacturing-practice/international-collaboration-gmp-inspections>

<https://www.ema.europa.eu/en/news/increasing-oversight-api-manufacturing-through-international-collaboration>



Inspection reliance



GMP recognition

Source: EEA/Swiss GMP Certificates

No API inspections on EU/EEA/Swiss territory

Use of GMP Certificates

Direct recognition possible in most of the cases

Use of Statement of GMP Non-Compliance

Distant Assessment

Source: Inspection Reports

Documentation based assessment

Evaluation of inspection reports from "Trusted Authorities" *

Comparison of scope, duration, extent

Result: accept outcome and include in re-inspection framework

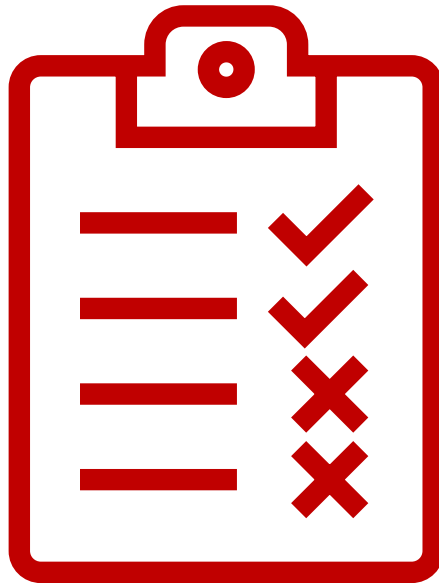
* High degree of similarity between EU and the authority's inspection procedures and GMP standards. Currently equivalent inspections can be considered in connection with an MRA, ACAA and PIC/S.

Inspection reliance – GMP recognition



- Use of EU/EEA **GMP Certificates with compliant outcome**
- Source: EUDRA GMDP public database
<https://eudragmdp.ema.europa.eu/inspections/displayWelcome.do>
- Conditions:
 - ✓ Scope is equivalent (API wise or/and workshop wise)
 - ✓ Absence of non-compliances from available sources

Inspection reliance – GMP recognition



- Use of **Statement of GMP Non-Compliance**
- Source: EUDRA GMDP public database
- Condition:
 - ✓ Scope is equivalent
- Action: suspend the CEPs and close ongoing new applications

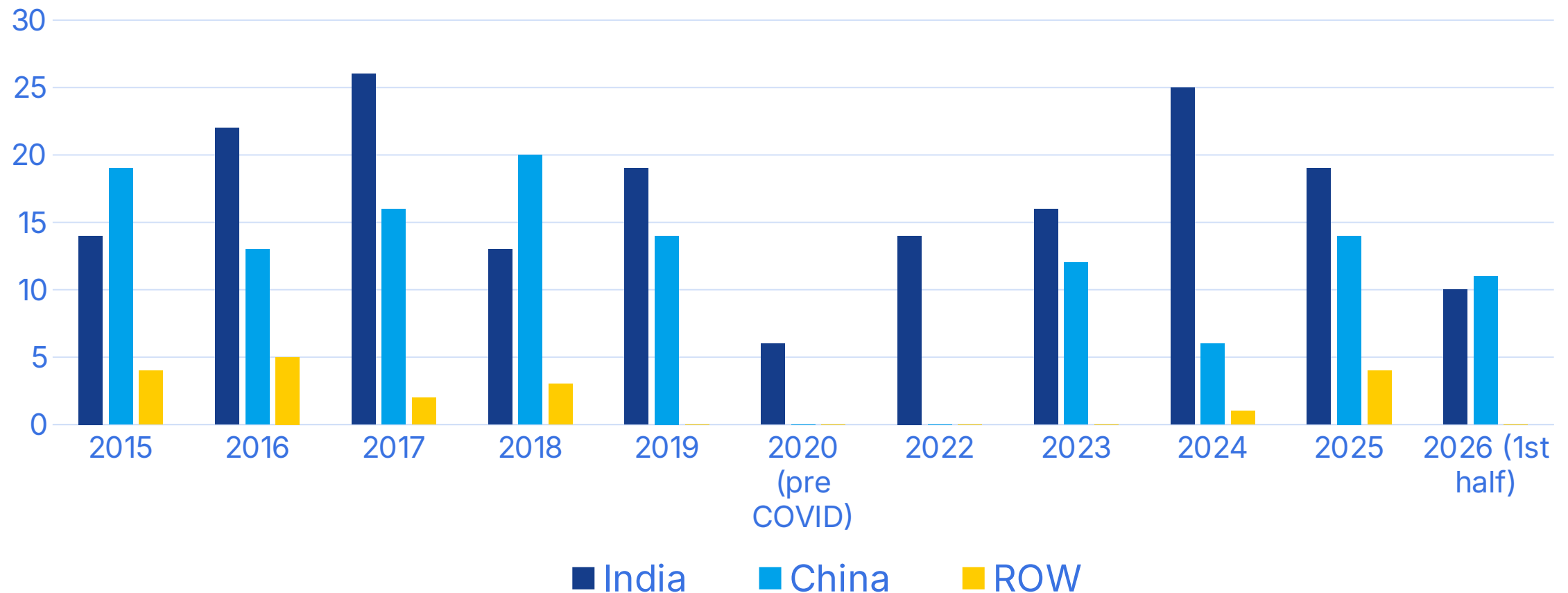
Inspection reliance – Distant assessment

- Use of **inspection reports** from trusted authorities with compliant outcome
- Sources:
 - Initial information on the inspection outcome: companies, or bilateral information exchanges, or public authorities databases (Canada), or restricted authorities databases (COMSTAT USFDA)
 - Report: issuing authorities or companies
- Conditions:
 - ✓ Inspection report is in English
 - ✓ Scope (API wise or/and workshop wise), duration, extent is equivalent
 - ✓ Absence of non-compliances from available sources
- Action:
 - Reliance is possible: no immediate inspection needed, SSR postponed

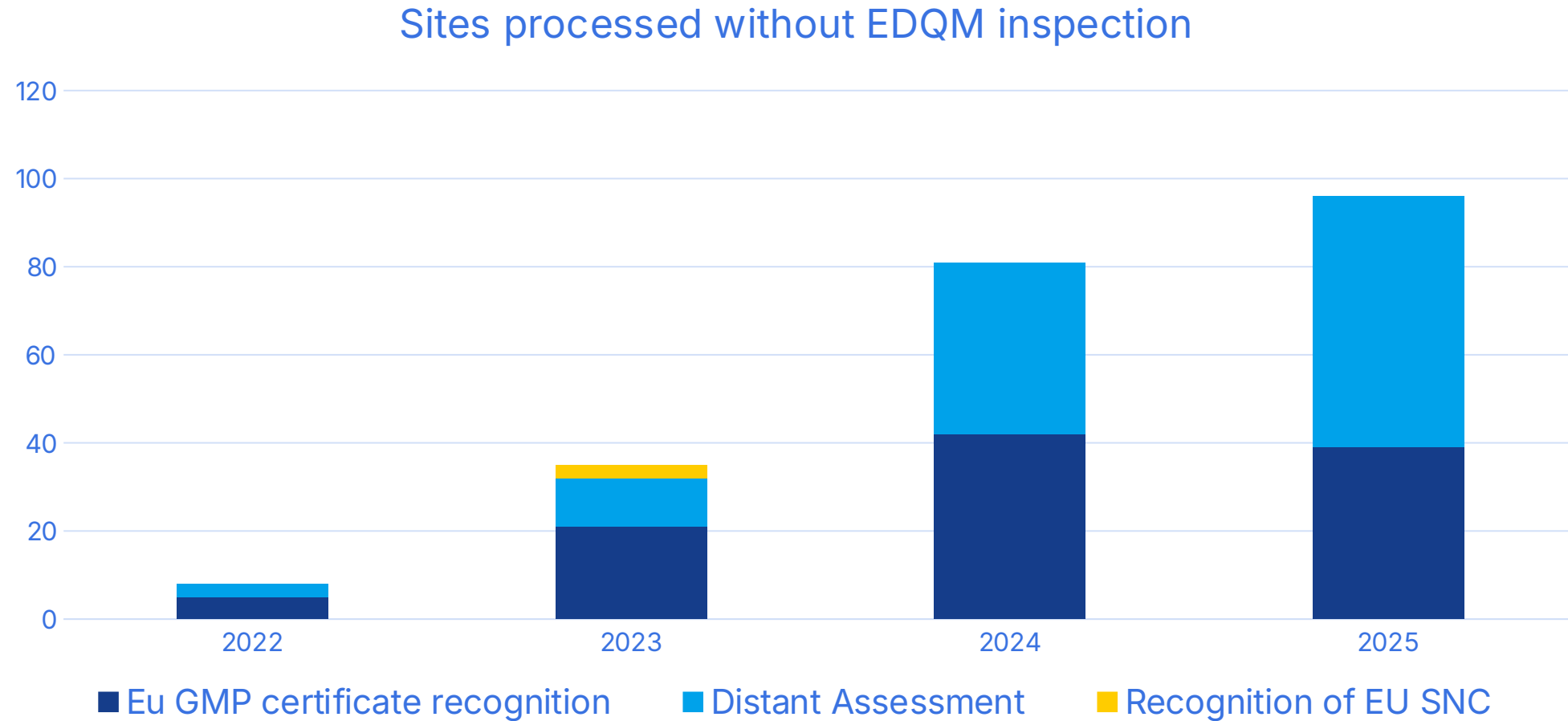


EDQM Inspection Programme – On-site inspections

EDQM on-site inspections
Geographical location 2015-2026

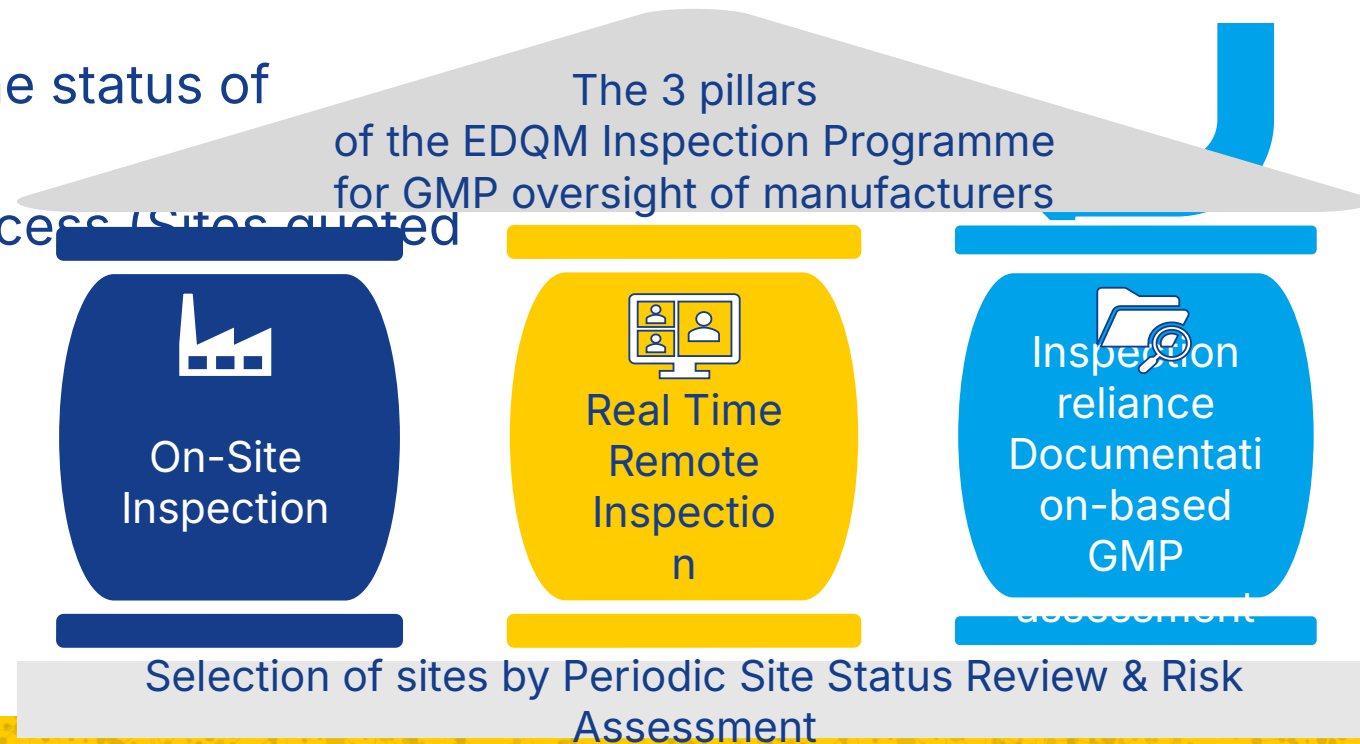


EDQM Inspection Programme – Inspection reliance



Conclusion on the EDQM inspection programme

- Integral part of the Certification procedure
- aims to check compliance with GMP and the CEP
- at the manufacturing/distribution sites covered by CEPs.
- EDQM ensures a good oversight of manufacturers thanks to:
 - Dynamic and systematic review of the status of manufacturers
 - Comprehensive risk assessment process (Sites selected by inspection priority)



Thank You!

Florence Benoit-Guyod, Head of Site Management
Unit

