EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Towards Excellence in Quality

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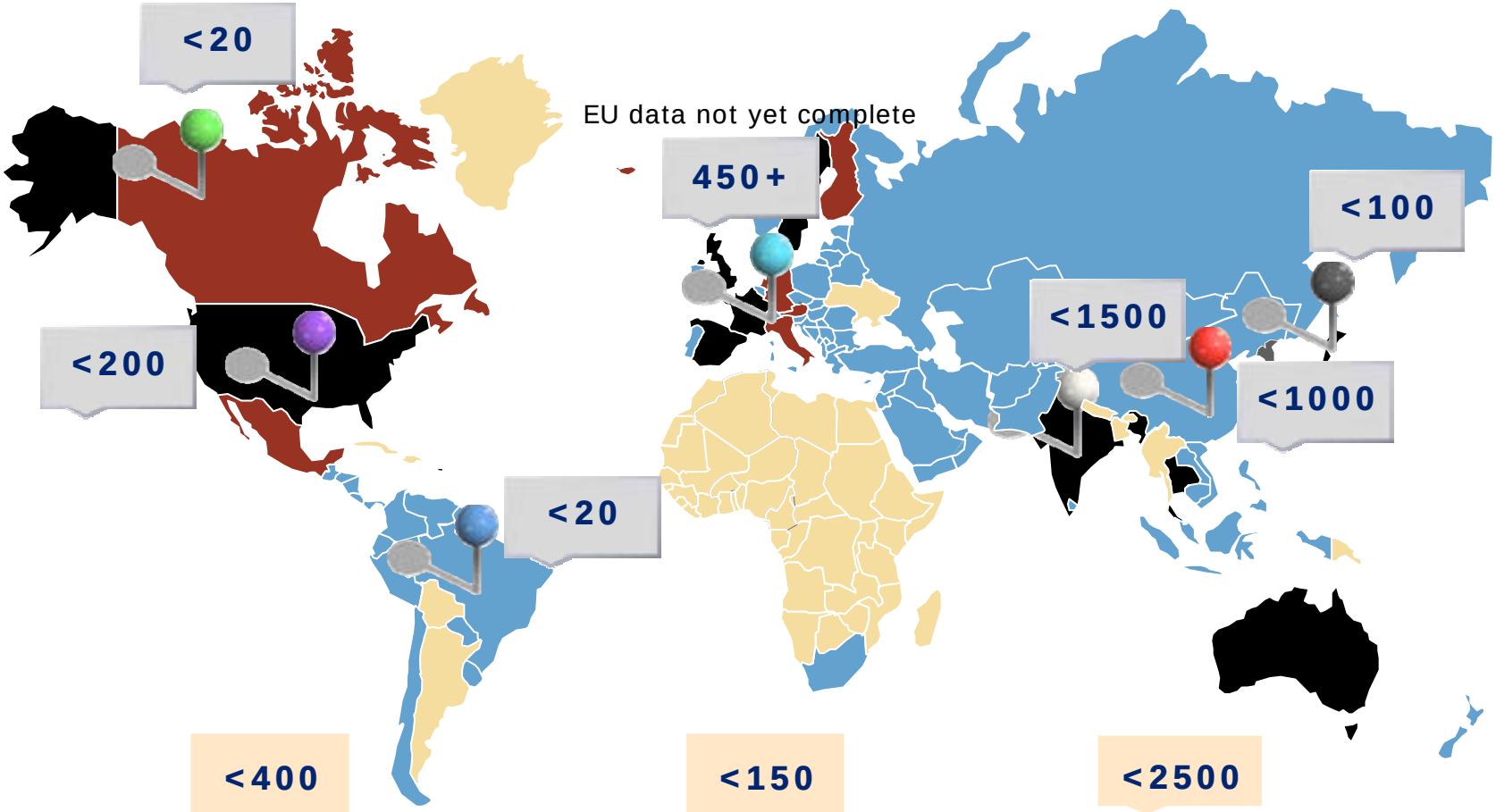
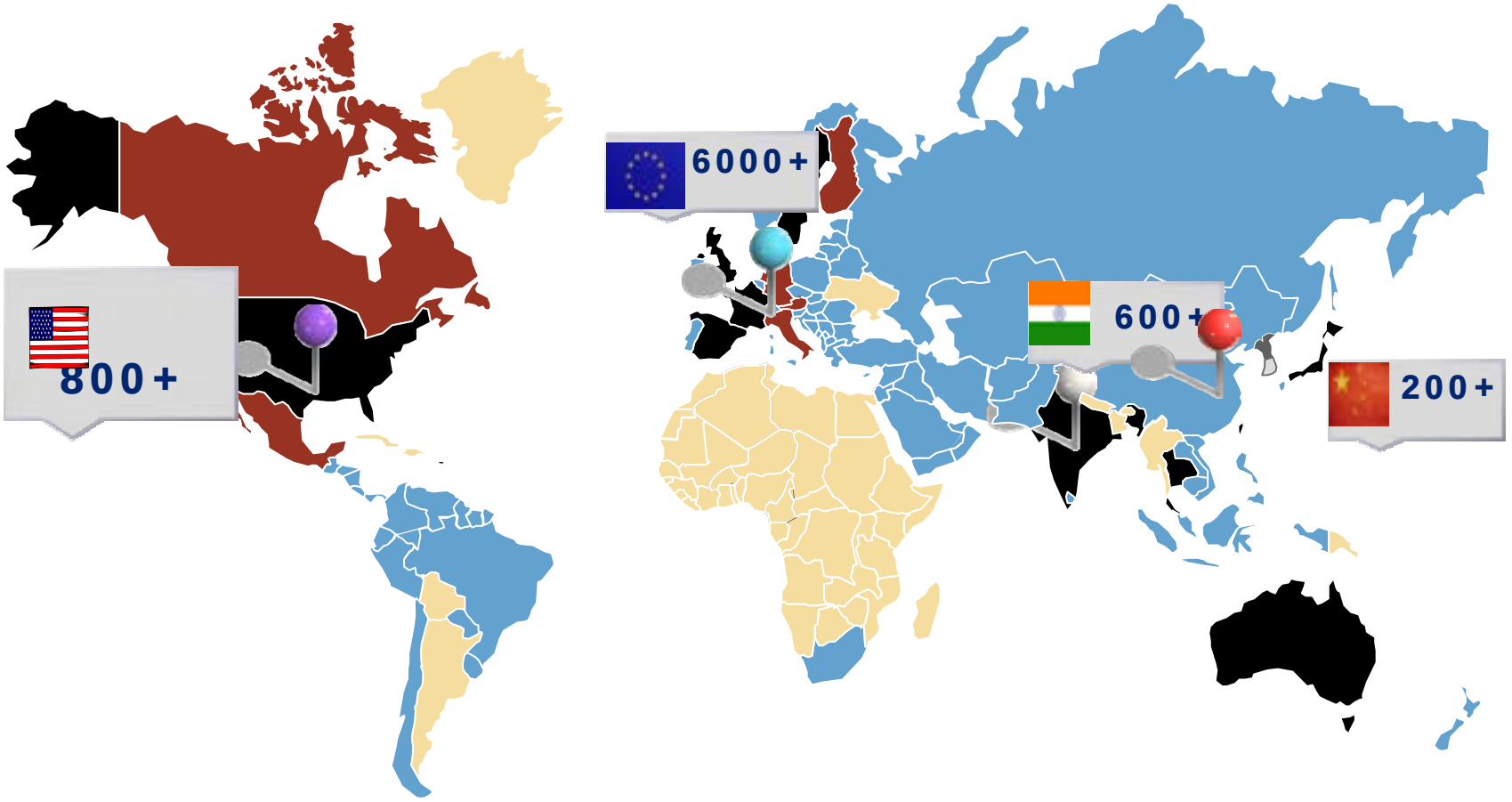
EUROPEAN MEDICINES AGENCY

Locations of Supply Chain Operators - APIs



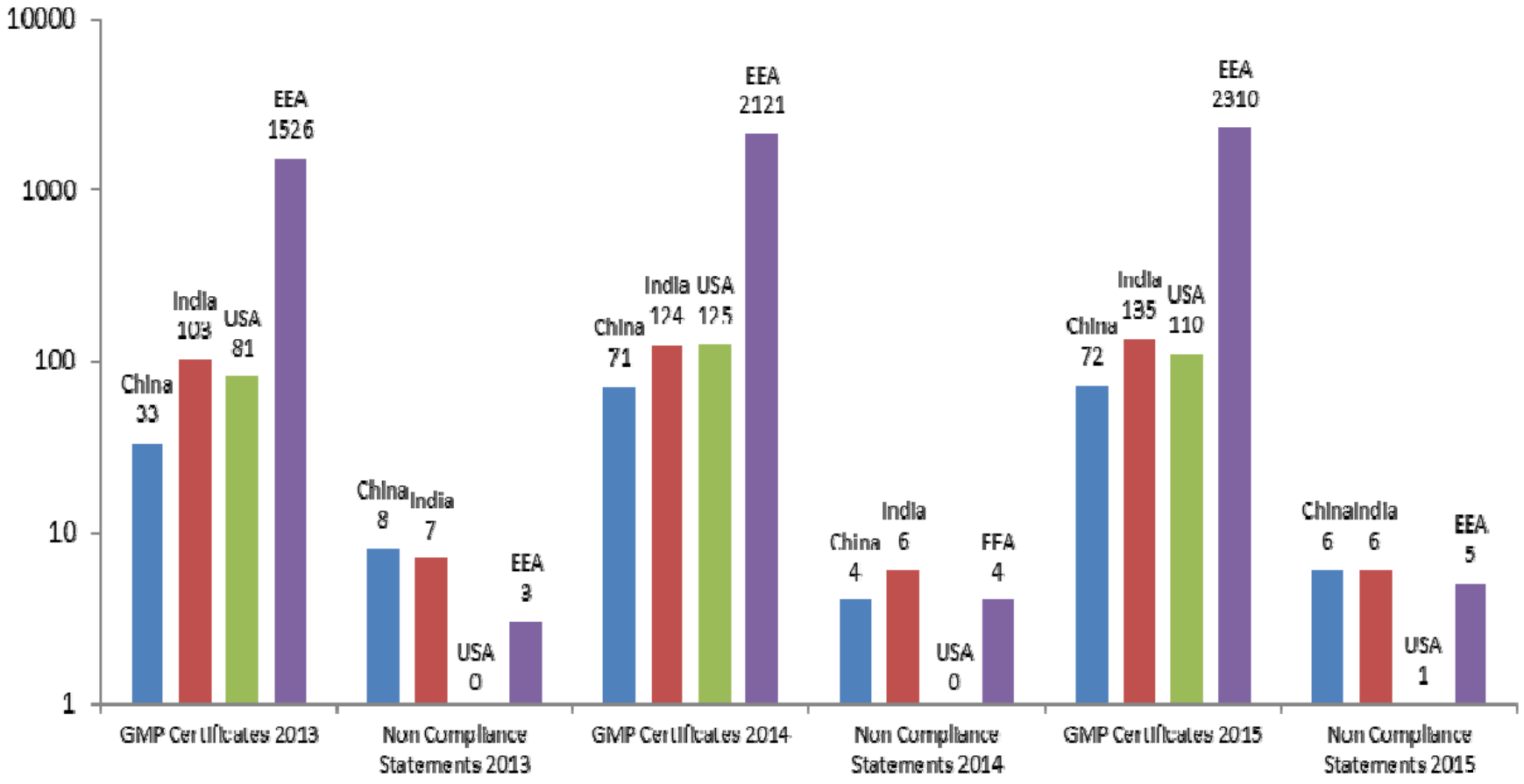
Locations of Supply Chain Operators - medicinal products



Global Supervision of the supply chain - EMA Long term vision

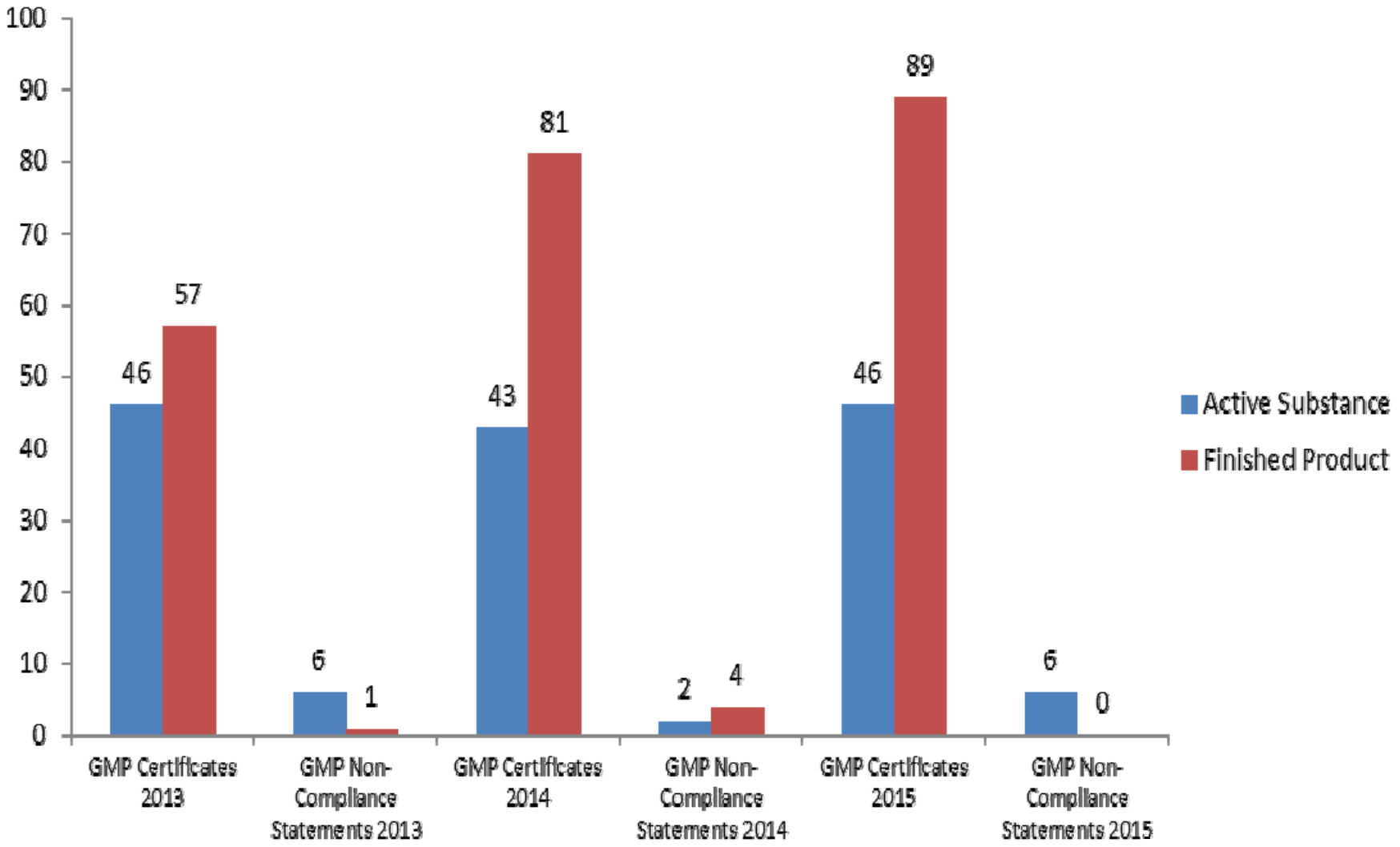
- Creating synergies through communication, collaboration and cooperation with international partners
- Supporting a global approach to authorisation and supervision of medicines
- Initial focus on inspection cooperation and best use of inspection resources
  - Standards based on ICH and WHO requirements
  - Using existing partnerships (bilateral/multilateral) and tools (guidelines, mechanisms for information sharing, unique facility identifiers)/inspection schedules.
  - E.g Mechanism for information sharing with CDSCO on GMP non-compliance
  - Broaden Inspection Coverage and maximize Inspectional resources by focusing on sites of highest risk
  - Take a more proactive approach to compliance management.

2013-2015 GMP Certificates & Non Compliance Statements Issued by EU Authorities

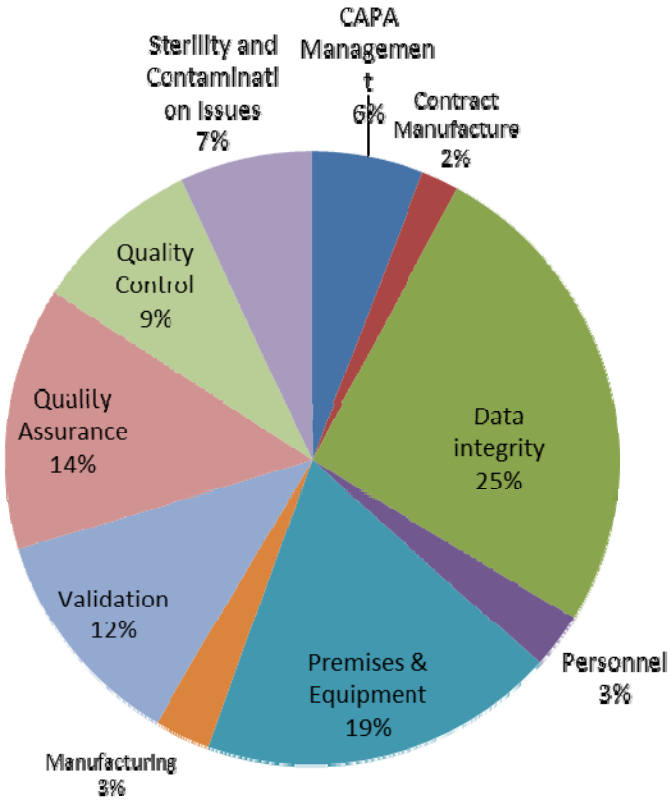


Majority of GMP inspections have an overall positive outcome

2013-2015 Outcome of Inspections in India by Manufacturing Operations

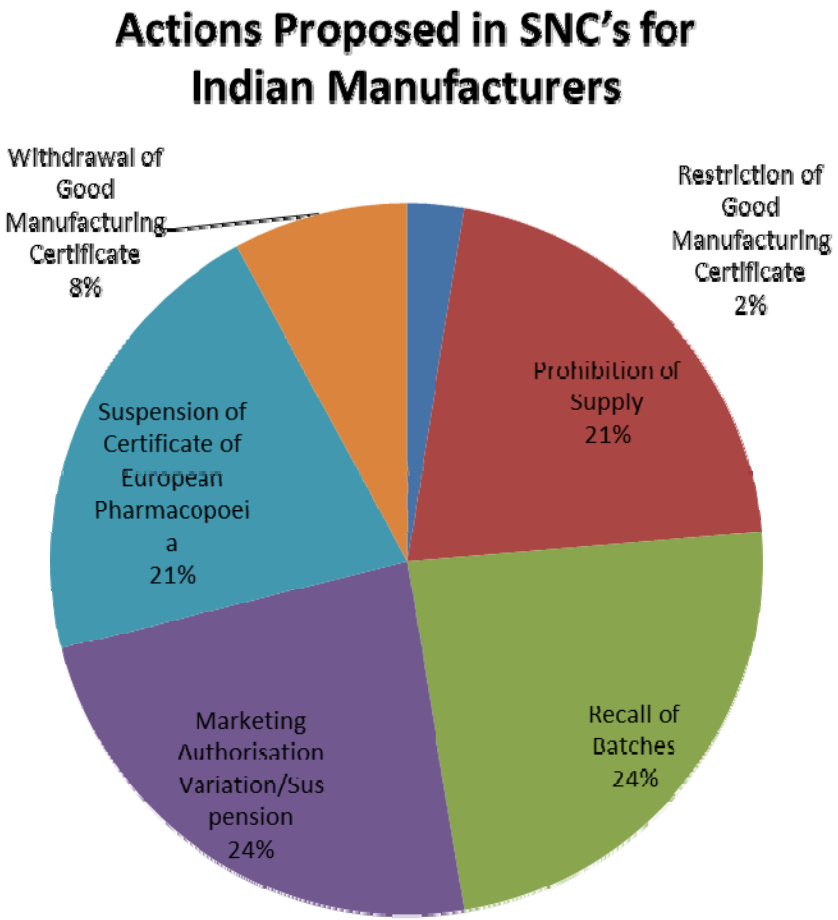


Analysis of Critical / Major Deficiencies (SNC's for Indian Manufacturers 2013 - 2015



- Record keeping: data integrity.
- Contamination and Cross contamination issues (sterility assurance)
- Quality Assurance and Control Systems
- Equipment qualification & process validation
- Loss of traceability for raw materials
- Facility Maintenance

Actions as a result of GMP Non-Compliance



- In case of serious deficiencies/critical findings actions may need to be taken by Inspectorate and EU authorities. These actions may include:
  - Prohibition of supply
  - Batches withdrawn from the EU market
  - Refusal of the granting of a Marketing Authorisation
  - Variation of Marketing Authorisation(s)
  - Suspension of Marketing Authorisation(s)
  - Revocation of Marketing Authorisation(s)
  - Action v CEP (API's)

Manufacturing and Quality – global issues we are seeing?

- Potential or actual shortages due to manufacturing and quality problems;
- Lack of supply chain resilience
- Lack of proactivity in risk assessment and risk mitigation measures
- Non-compliant sites; including due to data integrity issues.
- Reduction in manufacturing capacity ; alternatives not filed in MA
- Known problems in development getting through to market – failures in technology transfer;
- Lack of continuous improvement;
- Lack of investment
- Poor quality interactions between the industry and the regulator
- **All of the above have been linked to Quality Culture…..**

What makes a company excellent?

- **Prepared**
- Are you **proactive** in picking up on evidence of a developing problem or only reacting after the problem has become significant?
- Can you **detect** signs of increasing risk especially if production pressure is increasing?
- How do you get top management to **engage**?
- How do you **encourage** staff to take ownership for quality and good behaviour

- **Transparent - How do you increase transparency?**
- Do you identify and monitor vulnerabilities?
- To what extent is information about quality / compliance problems shared within your organisation?
  - Shared within your supply network?
  - Shared with regulators?
- How do you encourage staff dealing with suppliers to focus on the aspects that really matter, as opposed to price?

- **Flexible – adapting to change?**
- How do you adapt to change, disruptions and opportunities?
- Is your supply chain resilient and robust?
- Can you invest in quality at those times when it appears to be unaffordable?

Thank you for your attention

Further information

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EU procedures for marketing authorisation

Centralised Procedure (via EMA)

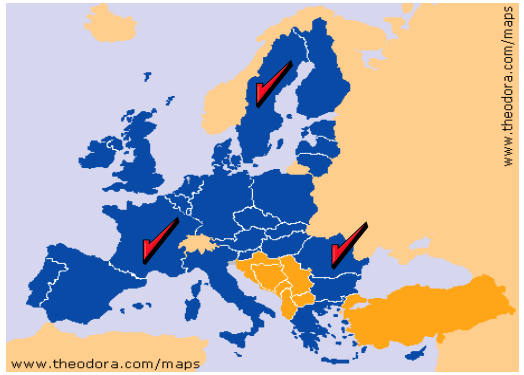
Mutual Recognition procedure

Decentralised Procedure

National Procedure

EMA

National Authorities



EMA – EU Network

- 28 member states
- European Commission & Decentralised Agency (EMA)
- ≈ 50 National Regulatory Authorities
- 4,500 European experts
- EMA are co-ordinating Agency;
  - Co-ordination of verification of GxP Compliance
  - Co-ordination of Market Surveillance
  - Experience with training of assessors, inspectors, coordination of inspections and evaluation processes
  - GMDP Inspectors Working Group