Agence nationale de sécurité du médicament et des produits de santé

ANSM GMP Inspection Overview

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ANSM inspection division presentation

Inspection Division in few figures

High level process of qualification

125 employees

- 70 inspectors

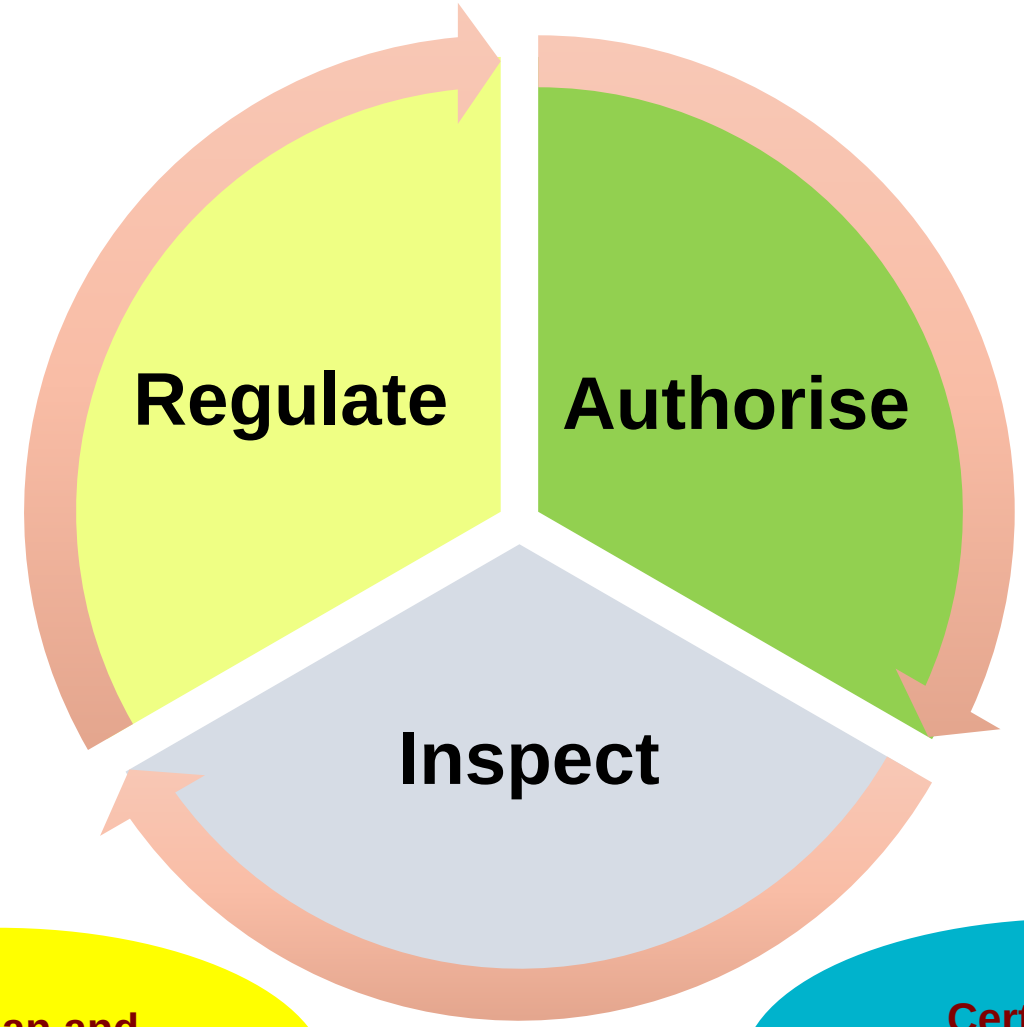
650 inspections per year

- 10 % abroad

Departments covering all health products and all steps of life cycle

• GLP, GCP, pharmaceutical raw materials as active substances (GMP), chemical and biological human medicines (GMP, GDP), pharmacovigilance (GVP), blood products, tissues-cells, milk banks, microorganisms and toxins, medical devices (MD), *in vitro* diagnostic medical devices (IVD), MD/IVD vigilances, cosmetics.

Three major missions



European and international cooperation

TWO PILLARS

Certified and accredited quality management system

Sites overview

950 Pharmaceutical sites

430 Manufacturer & or importer

280 Exploitant/MAH

350 Wholesaler

over 800 Manufacturer, distributor &/or importer of Raw materials

2018 metrics

675 inspections

11% Unannounced inspections

6% International inspection

61 Injunctions 9%

5 Regulatory actions

4 Financial fines

1 Penal citation

INSPECT

Inspection Process

Programming

Risk rating approach

- The Intrinsic risk associated with the site
  - Complexity of the site (size, nb of contractors nb of AS…)
  - Complexity of the processes (non sterile, sterile aseptic)
  - score
- The extrinsic risk associated with the site
  - Deficiencies : nb of majors/critical
  - Implementation of the CAPA since last inspection
  - score

Risk Based Planning for Inspection of Pharmaceutical Manufacturers

Immediately after an inspection of the site Using an internal algorithm	Upon receipt of info (e.g. modification quality defect TC communication	Review by a committee Head unit and referent inspector	Update of the database
• Fill in the worksheet in of the CoCP Model ✓ Assign **risk rating** for the site. ✓ Establish the **recommended inspection frequency**. ✓ Establish the **recommended scope** ✓ Establish the necessary **expenditure of inspection time**	Update the frequency and/or scope of the next routine inspection if needed	1/month Confirmation of the frequency assigned Typically 1 to 5 years	Portfolio by inspector 3rd Quarter

Inspection sizing

- Typical inspection team
  - 2 inspectors in general
  - Assessor or expert if needed
- Typical inspection duration
  - 2 to 3 days for “non sterile” site
  - At min 5 days for “sterile site”
  - Adjustment in case of complexity
    - Following regulatory action
    - (aseptic process, sterile & non sterile processes)
    - Last inspector feedback
    - Quality defect associated

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Inspection process

Mission organisation

- **Inspector involvement**
  - Preparation
  - Execution
  - Restitution
  - Reporting
- **Administrative follow-up**
  - GMP certificate issuance
  - Coercive measures

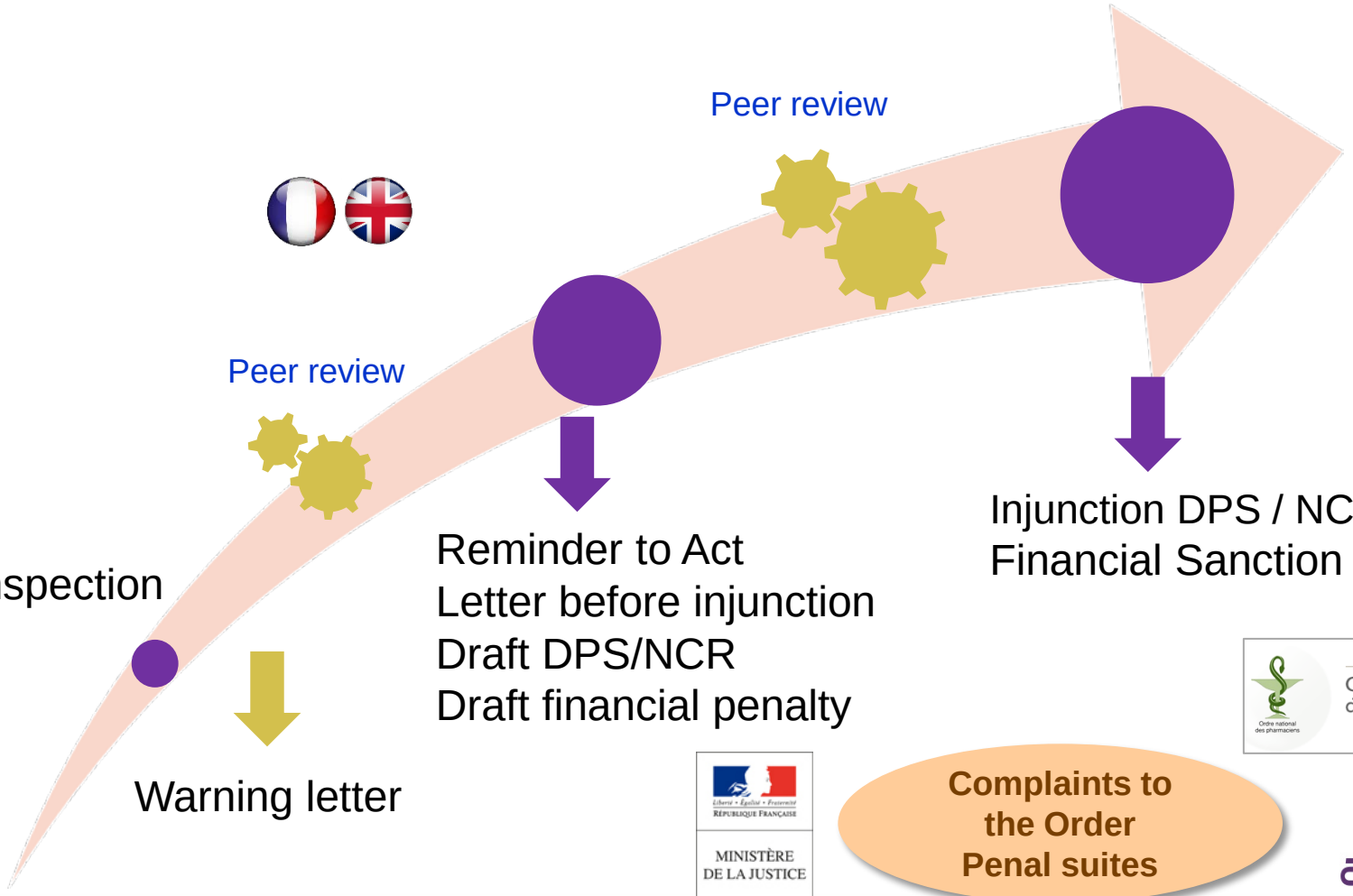
Mission Preparation

- **Assessment of the plant dossier**
  - Authorization
  - Modification
  - Any other information (last risk assessment…)
- **Assessment of the site master file**
  - Quality system description
  - People (figures, organization and training)
  - Lay out and flow
  - Utilities : Water, AHU, Steam, Nitrogen, compressed air…
  - Quality control lab

Mission Preparation

- Consideration of complaints logged within ANSM
  - Description
  - Report provided by the site
  - Decision
- Consideration of recalls logged within ANSM
- Metrics: number of batches of raw material/FP manufactured/rejected

Focus on inspections follow up



Ordre national des pharmaciens

MINISTÈRE DE LA JUSTICE

Complaints to the Order
Penal suites

ansm


Thank you
Any Question ?

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Avertissement

- Lien d'interêt : personnel salarié de l'ANSM (opérateur de l'État).
- La présente intervention s'inscrit dans un strict respect d'indépendance et d'impartialité de l'ANSM vis à vis des autres intervenants.
- Toute utilisation du matériel présenté, doit être soumise à l'approbation préalable de l'ANSM.

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- Any further use of this material must be submitted to ANSM prior approval.