EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

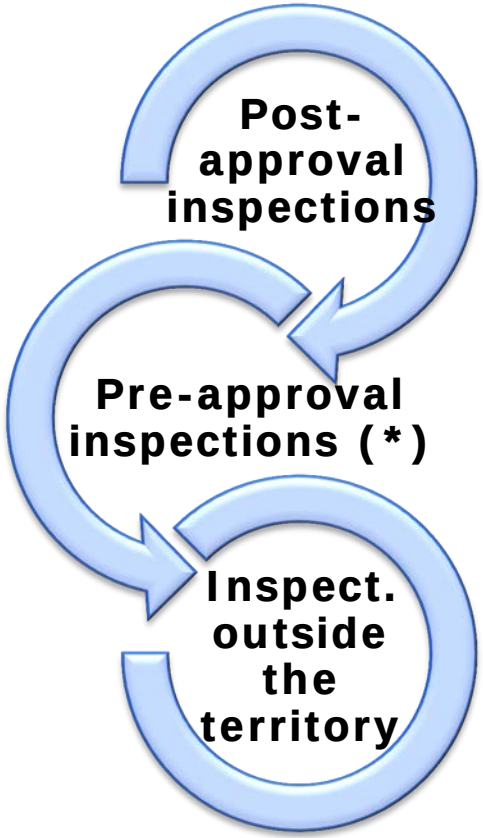
EU US MUTUAL RECOGNITION AGREEMENT

First annual EMA-EuropaBio bilateral meeting
9th June 2017

Presented by Brendan Cuddy
Head of Manufacturing and Quality Compliance
European Medicines Agency

US EU MRA

Scope


Post-approval inspections
Pre-approval inspections (*)
Inspect. outside the territory

Products coverage

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- Marketed FP for
  - Human use
  - Animal use
- Intermediates
- Certain biological products
- Active pharmaceutical ingredients

- Human blood
- Human plasma
- Human tissues
- Organs
- Veterinary immunologicals
- ATMP’s

Products coverage

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Marketed finished pharmaceuticals for human use:

- Medical gases
- Radiopharmaceuticals / radioactive biological products
- Herbal products (*)
- Homeopathic products

Marketed biological products for human use:

- Therapeutic biotechnology - derived biological products
- Allergenic products

Intermediates.
Active pharmaceutical ingredients
IMPs (**)

Veterinary products:

- Veterinary Pharmaceuticals
- Pre-mixes for the preparation of vet medicated feeds

15th July 2019

Vaccines for human use

Plasma derived pharmaceuticals

15th July 2022

Process

Assessment of each Party:
- **EU assessment of FDA: 1st July 2017**
- **FDA assessment of EU Inspectorates: 15th July 2019 (*)**

JOINT AUDIT PROGRAMME:

- **HMA voluntary programme.**
- **Objective: to achieve, maintain and verify equivalence and practical application of GMP standards by national inspectorates Agencies across the EEA.**
- **Tool for international collaboration: to preserve confidence in the equivalence of EEA GMP systems to all MS and to EU MRA partners.**
- **National inspectorates are audited by qualified auditors (evaluation checklist and observed inspections).**
- **FDA observed / will observe the EU JAP audits (2014-2017)**

CAPABILITY ASSESSMENT PACKAGE

Timelines and milestones

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Signature

1st July 2017:
EU assessment
of FDA (human)

Transition phase

1st November 2017
- **Entry into force**
- **8 MSs recognized**

15th July 2019
- **All EU MS recognized**
- **Batch testing**
- **Decision on Vets**

15th July 2022
- **Broaden scope (products)**

Inspections

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Inspections / GMP documents

Manufacturing facilities located in the territory of the issuing Authority (products included in the scope).

Manufacturing facilities located outside the territory of the issuing Authority.

Products not covered.

Products to be covered: to notify in advance. Possibility of joint inspection.

Request of inspections

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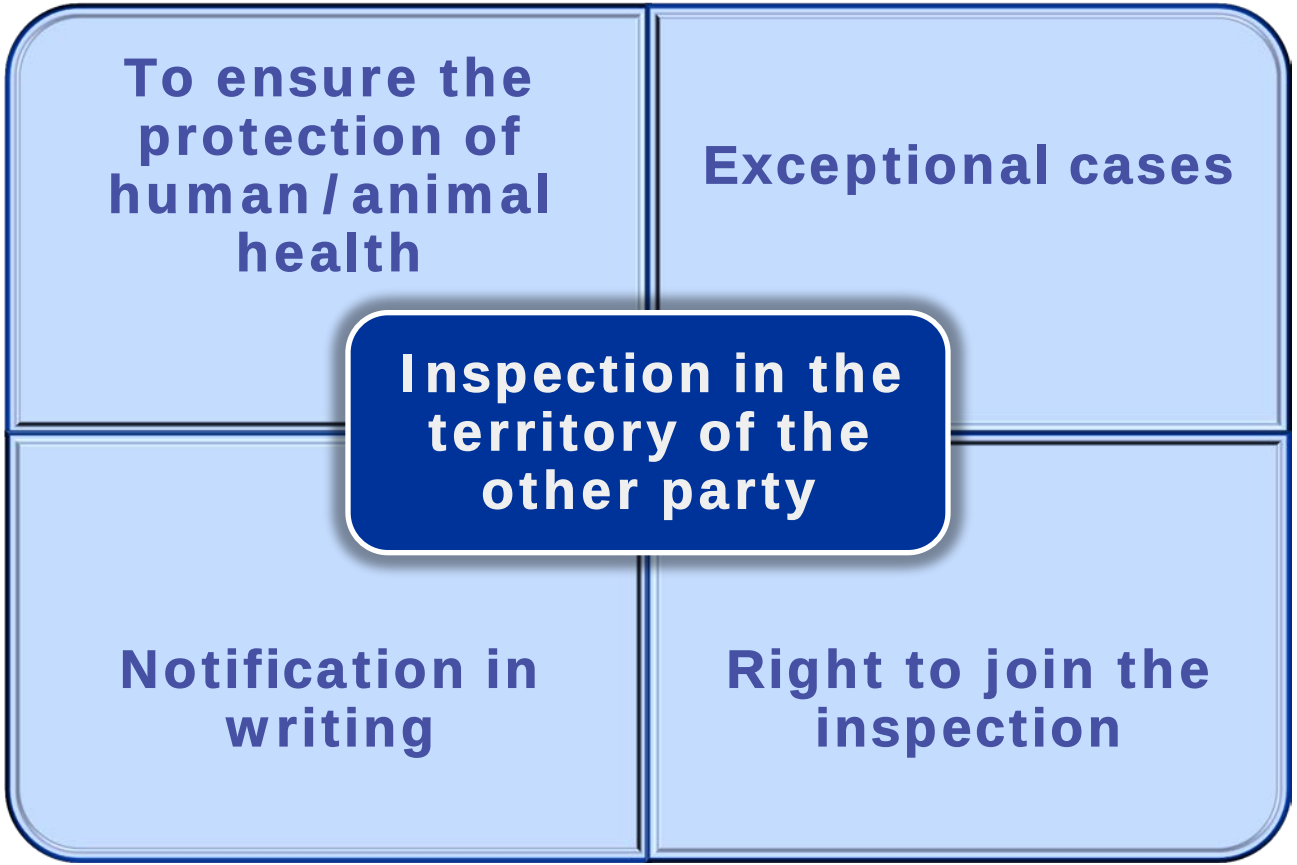
- Reason for the request
- Issues to be addressed in the inspection
- Timeline

Documents already available / pending

Inspection by the requested Authority (where the site is located)

Inspection by the Requesting Authority (joint inspection)

Safeguard clause



Ongoing topics

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Exchange of information

Official GMP documents

Impact on variations

Roadmap for veterinary products

Any Questions?

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