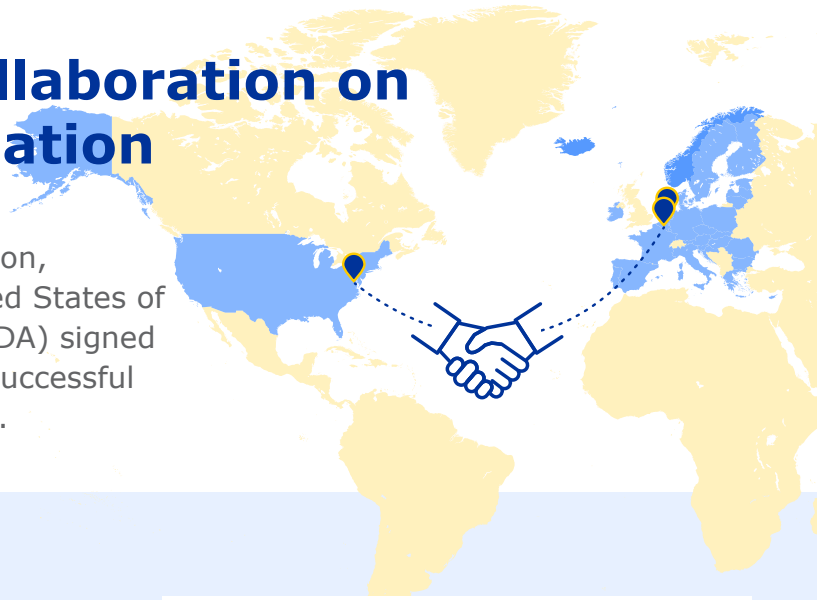
20 years EU/US collaboration on medicines regulation



On 12 September 2003, the European Commission, European Medicines Agency (EMA) and the United States of America (USA) Food and Drug Administration (FDA) signed a **confidentiality arrangement** starting their successful collaboration in tackling public health challenges.

Milestones

12 September 2003 — European Commission, EMA and FDA sign Confidentiality Arrangement

2004 — First Cluster established in oncology

2005 — First request from a company for Parallel Scientific Advice (PSA)

2009
- EMA-FDA Good Clinical Practice (GCP) initiative starts
- First FDA Liaison arrives at EMA

2010
- First EMA Liaison arrives at FDA
- Start of fellowship programme

2012 — First Common Commentary on a paediatric development

2017 — EU-USA Mutual Recognition Agreement (MRA) for human medicines is signed

2021 — Latest two clusters established: Pregnancy and Lactation and Generic Drugs

2023 — EU-USA MRA extended to veterinary medicines

Confidentiality arrangement

Permits the exchange of unredacted, commercially confidential information relating to regulatory and scientific processes, and thus facilitates collaboration between regulatory agencies.

Cluster

Regular and intensive exchange of information and collaboration between experts on a special topic or therapeutic area. Currently there are 31 established clusters. See Cluster activities

Parallel scientific advice (PSA)

Concurrent scientific advice from EMA and FDA on scientific issues during the development of human and veterinary medicines. See General principles EMA-FDA scientific-advice

Liaison officials

Posted to the respective partner agency to facilitate collaboration and identify areas for further regulatory and scientific collaboration.

Fellowship programme

Short-term staff exchanges between EMA and FDA. See Fellowships

Common Commentary

Informal, non-binding comments on paediatric development plans submitted to both agencies. See: Cluster activities

EU/US mutual recognition agreement (MRA)

Allows EU and US authorities to rely on each other's good manufacturing practice (GMP) inspections for some types of medicines. See Mutual recognition agreements

EMA EUROPEAN MEDICINES AGENCY

FDA U.S. FOOD & DRUG ADMINISTRATION