US-EU Mutual Recognition Agreement

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121st AFDO Educational Conference
June 20, 2017
Benefits of Mutual Recognition

The EU and member state authorities and FDA relying upon each other’s data and information from Good Manufacturing Practice (GMP) inspections.

**GOAL:** To reallocate scarce resources to areas of higher risk by recognizing inspections performed by capable foreign regulatory authorities.
FDA Registered Drug Facilities 2016

- United States: 2%
- European Union: 28%
- India: 66%
- China: 66%
FDA Inspections In The European Union

- In 2016, there were 1224 drug facilities in EU
- FDA inspected 32% of the drug facilities in EU
- 5% of inspected facilities in EU led to an Official Action Indicated classification

**KEY**

- ⚖️ = ~ 25 Drug Facilities
- 🔴 = Facilities inspected in 2016
FDA Inspections In China

- In 2016, there were 754 drug facilities in China
- FDA inspected 21% of the drug facilities in China
- 22% of inspected facilities in China led to an Official Action Indicated classification
FDA Inspections In India

- In 2016, there were 722 drug facilities in India
- FDA inspected 23% of the drug facilities in India
- 14% of inspected facilities in India led to an Official Action Indicated classification
FDA’s Inspection Outcomes: Import Alerts Issued

- China: 36%
- India: 28%
- Other Countries: 24%
- European Union: 12%
Negotiation of the U.S. – EU Mutual Recognition Agreement

• Exchanged and analyzed ideas
In the beginning...

EU’s legal and regulatory framework for GMP oversight
EU’s Conflict of Interest policy for drug investigators
Jobs EU’s management of its inventory

28 member states
Competence and Comparison of Inspectorates
Fear Change

Global Risk Resources
Negotiation of the U.S. – EU Mutual Recognition Agreement

- Exchanged and analyzed ideas
- Developed Capability Assessment Process
Joint Audit Programme (JAP)

**Purpose**
- Ensure consistency of GMP standards and a harmonized approach throughout.

**Process**
- EU auditors from two different EU countries go into a third EU country.

**Tools**
- PIC/S Evaluation Guide
- EU auditor’s inspectional expertise and experience
Capability Assessments
Negotiation of the U.S. – EU Mutual Recognition Agreement

• Exchanged and analyzed ideas

• Developed Capability Assessment Process

• Amended 1998 Agreement
Decision No 1/2017
of the Joint Committee established under Article 14 of the Agreement on Mutual Recognition between the European Community and the United States of America, amending the Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs)

THE JOINT COMMITTEE,

Having regard to the Agreement on Mutual Recognition between the European Community and the United States of America (the "Agreement") done in 1998, and in particular its Article 14 and Article 21; and

Whereas the Joint Committee is to take a decision to amend the Sectoral Annex on GMPs pursuant to Article 21(2) of the Agreement;

HAS DECIDED AS FOLLOWS:

1. Attachment A to this Decision is the United States – European Union Amended Sectoral Annex for Pharmaceutical Good Manufacturing Practices ("Amended Sectoral Annex") which amends the Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs) done in 1998 and replaces it with a consolidated version.

2. Attachment A has been agreed by the Parties.

This Decision, done in duplicate, shall be signed by representatives of the Joint Committee who, pursuant to Article 21(2) of the Agreement are authorized to act on behalf of the Parties for purposes of amending the Annexes. This Decision shall be effective from the date of the later of these signatures.

On behalf of the United States of America

On behalf of the European Union

Signed in Washington DC, on

January 19, 2017

Signed in Brussels, on

March 1st, 2017
Scope

- Includes a vast majority of drugs
- Certain products will be reevaluated in the future, such as vaccines and veterinary products
- Surveillance and, under certain conditions, pre-approval inspections of marketed human drug facilities located within the U.S. and EU
Major Deliverables

**May 2014**
- Negotiations to amend MRA

**March 2017**
- U.S.-EU exchange letters finalizing amended MRA

**June 2017**
- FDA completes observations of all scheduled internal EU audits (started in Sept 2014)

**July 2017**
- EU completes FDA capability assessment

**November 2017**
- FDA completes capability assessments of 8 EU regulatory authorities
- Provisions operationalizing amended MRA enter into force

**July 2019**
- FDA completes all capability assessments

**2019 and beyond**
- Continued collaboration to include other products

**2019 and beyond**
- Provisions operationalizing amended MRA enter into force

**2019 and beyond**
- Continued collaboration to include other products

**MAY 2014**
- Start... FDA and EU exchange and analyze ideas

**May 20 2017**
- Negotiations to amend MRA
Potential FDA Inspection Coverage

CHINA

INDIA

KEY

- Facilities inspected in 2016
- Theoretical coverage post-MRA
Pharmaceutical Annex to the 1998 U.S.-EU MRA

MRA

Cements the FDA and EU’s collaboration by taking concrete steps to rely upon each other to benefit public health.

Enables the FDA and EU to avoid the duplication of drug inspections and devote those resources to other parts of the world, where there may be greater risk.
http://www.fda.gov/go
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