The Mutual Reliance Initiative: A New World for Pharmaceutical Inspections

Dara A. Corrigan
Acting Deputy Commissioner for Global Regulatory Operations and Policy

Food and Drug Law Institute’s Annual Conference
May 5, 2017
FDA Registered Drug Facilities
2011

United States
6,877 FACILITIES

European Union
957 FACILITIES

India
435 FACILITIES

China
453 FACILITIES
FDA Inspections Throughout the World

European Union
China
India
Rest of the World
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

KEY
- □ = ~ 25 Drug Facilities
- ◼️ = Facilities inspected in 2016
• 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
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

Michael B. Froman
Signed in Washington DC, on
January 19, 2017

On behalf of the European Union

Carol J. Muzny
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 US and EU
Major Deliverables

Mar 2017: Letters exchanged
Jul 2017: EU completes FDA assessment
Nov 2017: FDA completes & assessments
Nov 2017: Recognize inspections
July 2019: FDA completes all assessments
Determine inclusion of other products
Potential FDA Inspection Coverage

KEY

- Red circle = Facilities inspected in 2016
- Blue circle = Theoretical coverage post-MRA

CHINA

INDIA
A New World for Pharmaceutical Inspections

The Mutual Recognition Agreement

http://www.fda.gov/go

Questions? FDA-MRA@fda.hhs.gov