The Mutual Reliance Initiative: A New World for Pharmaceutical Inspections

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Food and Drug Law Institute's Annual Conference

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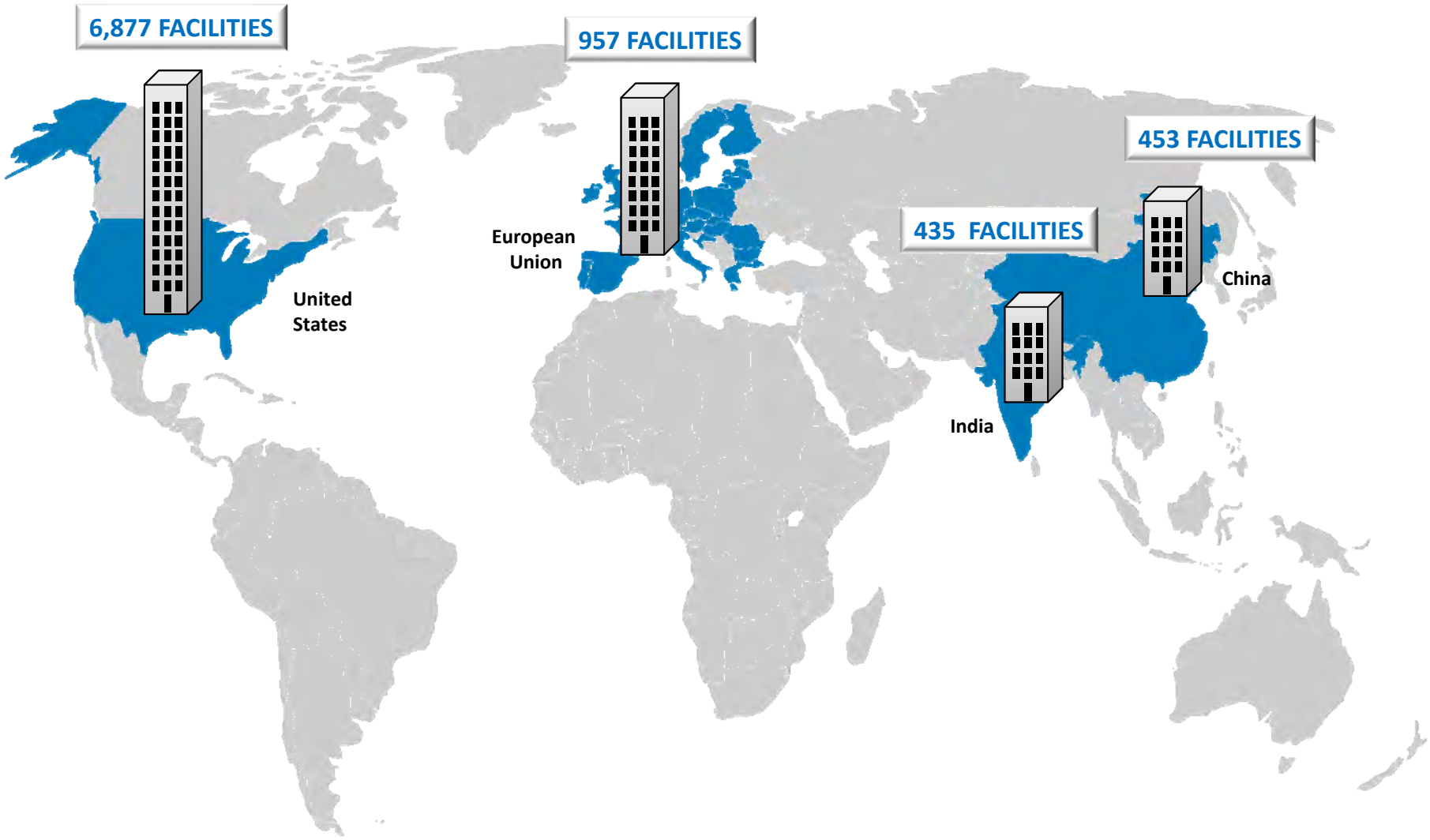
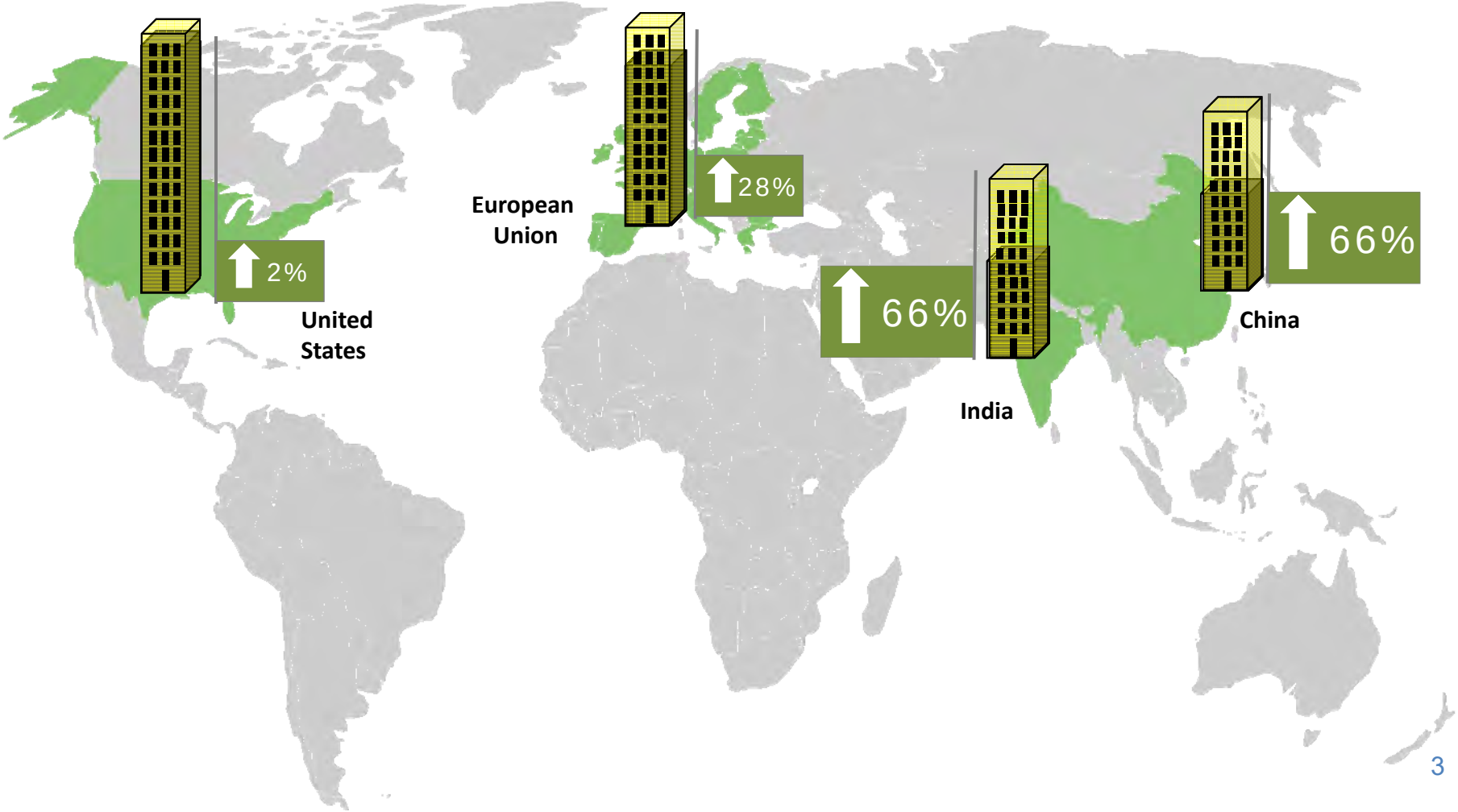
FDA Registered Drug Facilities

2011

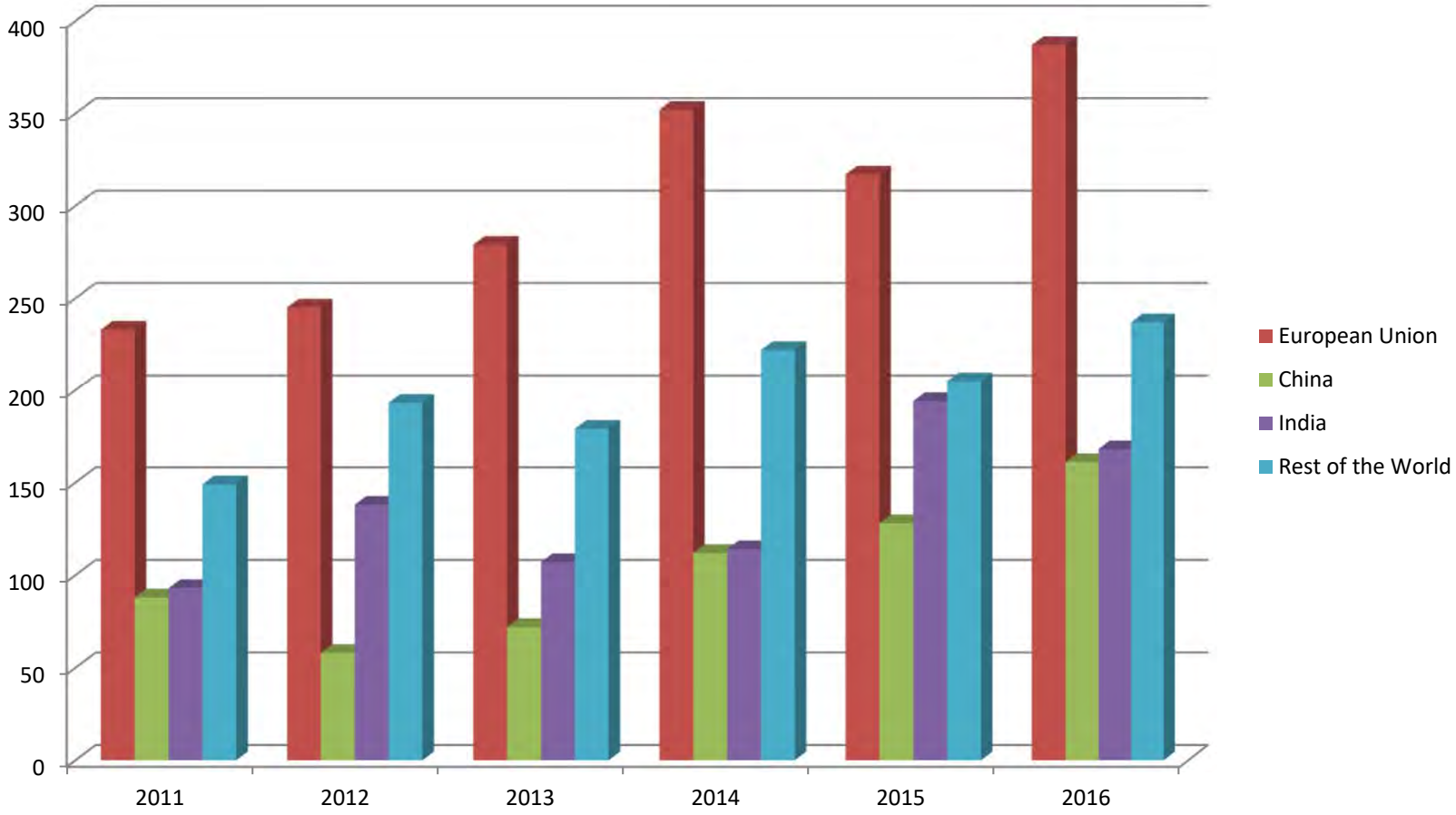


FDA Registered Drug Facilities

2016

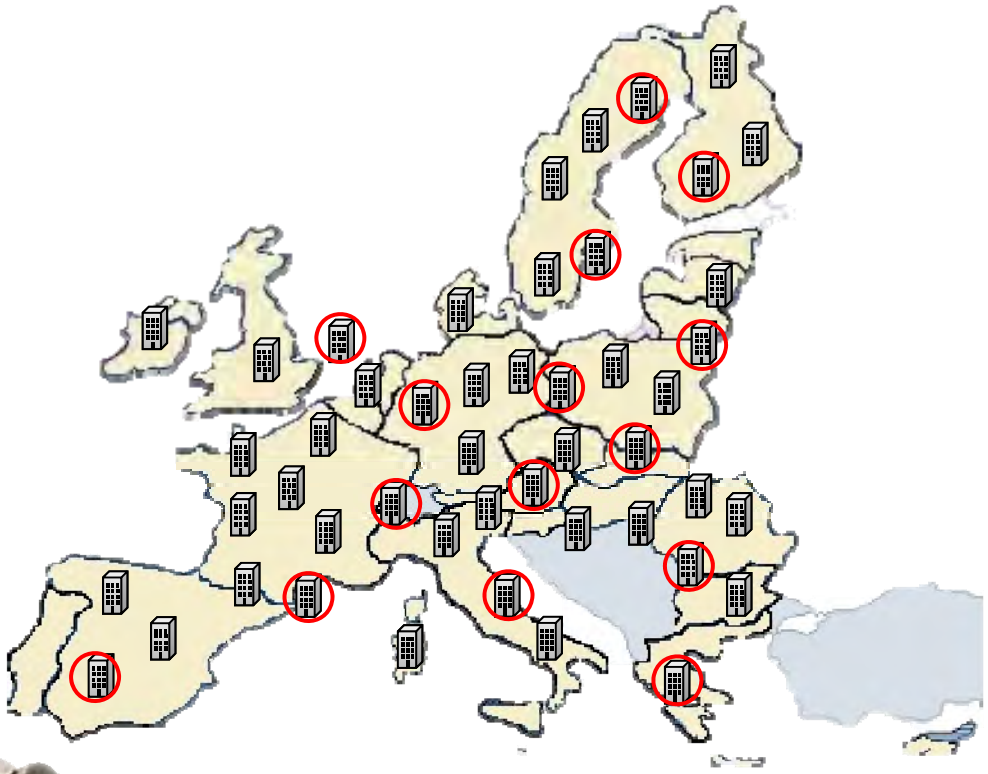


FDA Inspections Throughout the World



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

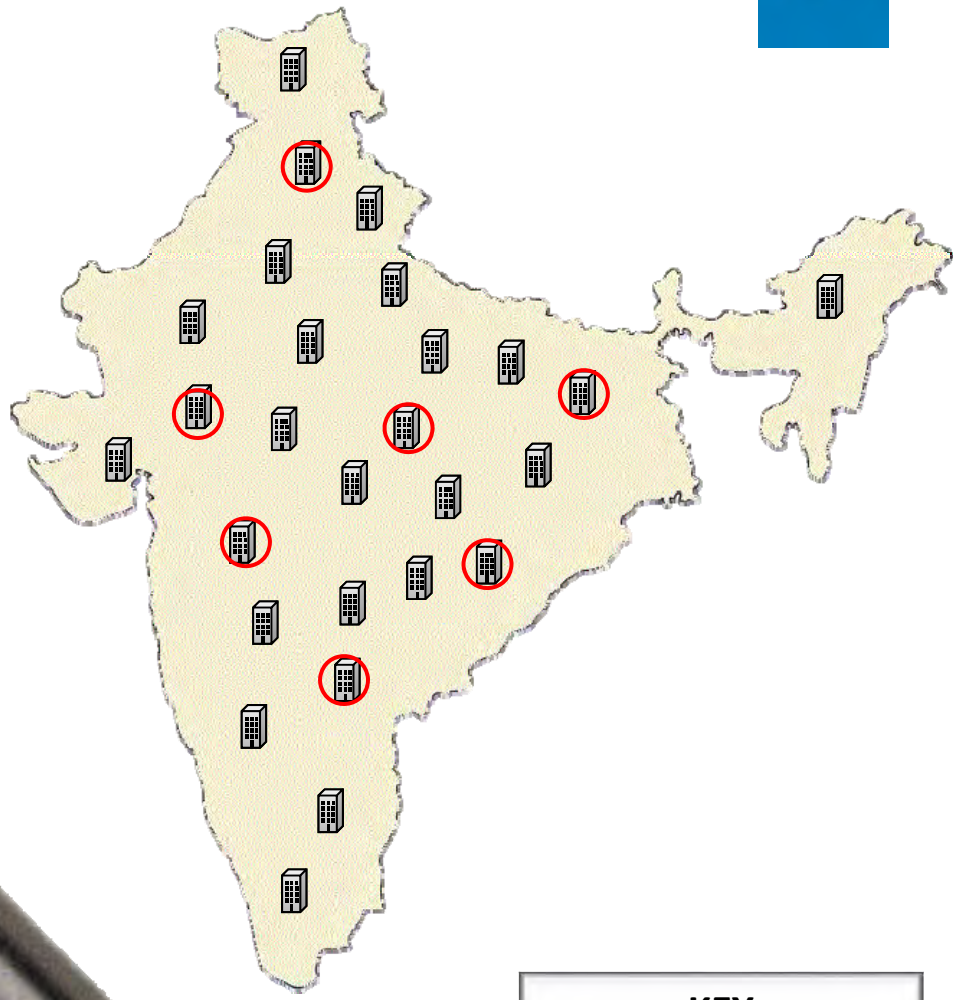
KEY

= ~ 25 Drug Facilities

= Facilities inspected in 2016

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



KEY

= ~ 25 Drug Facilities

= Facilities inspected in 2016

Negotiation of the U.S. – EU Mutual Recognition Agreement

- Exchanged and analyzed ideas
- Developed Capability Assessment Process
- Amended 1998 Agreement

2017 Revision to Pharmaceutical Annex to the 1998 U.S./EU MRA

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.

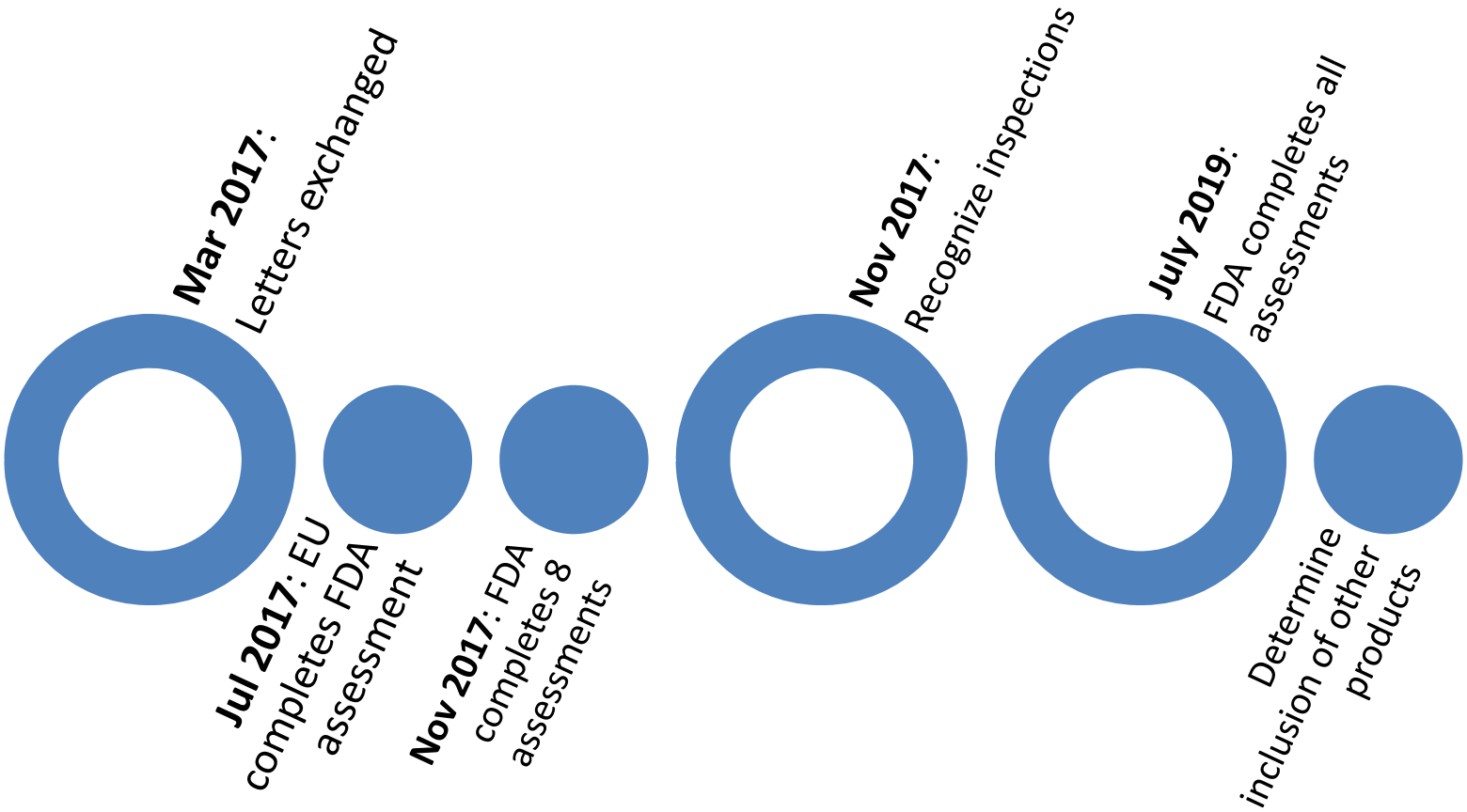
This Decision, done in duplicate, shall be signed by representatives of the Joint Committee who, pursuant to Article 21(2) of the Agreement are authorized to act on behalf of the Parties for purposes of amending the Annexes. This Decision shall be effective from the date of the later of these signatures.

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

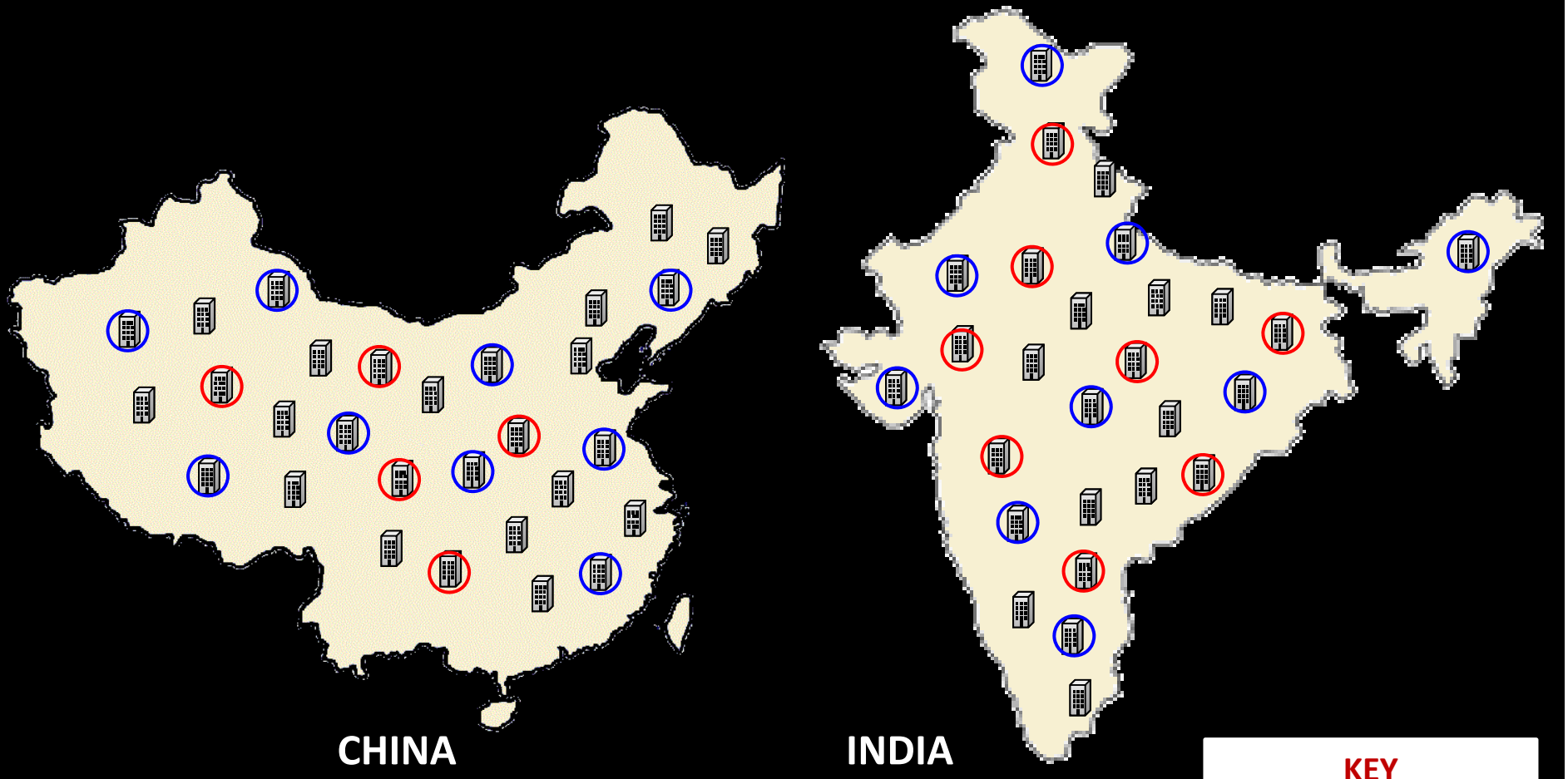
Scope

- 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 US and EU

Major Deliverables



Potential FDA Inspection Coverage



http://www.fda.gov/go

Questions? FDA-MRA@fda.hhs.gov