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IN THIS SECTION: International Arrangements	

□ International Arrangements

## **Mutual Recognition Agreements (MRA)**

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Mutual Recognition Agreements (MRAs) between FDA and foreign regulatory authorities allow drug inspectors to rely upon information from drug inspections conducted within each other's borders. Under the Food and Drug Administration Safety and Innovation Act, enacted in 2012, FDA has the authority to enter into agreements to recognize drug inspections conducted by foreign regulatory authorities if FDA determined those authorities are capable of conducting inspections that met U.S. requirements.

## MRAs:

- Yield greater efficiencies for U.S. and foreign regulatory systems by avoiding duplication of inspections; and,
- Enable reallocation of resources towards inspection of drug manufacturing facilities with potentially higher public health risks across the globe.

FDA has MRAs in force with the European Union, Switzerland, and the United Kingdom.

## Resources

- Frequently Asked Questions Mutual Recognition Agreement
- FDA Expands Mutual Recognition Agreement with European Union, OGPS Statement, May 31, 2023
- Ensuring Patient Safety and Drug Manufacturing Quality Through Partnership with European Union Regulators
- U.S.-EU Mutual Recognition Agreement Sectoral Annex for GMPs

- Press Release FDA takes unprecedented step toward more efficient global pharmaceutical manufacturing inspections
- <u>Press Release- Mutual Recognition promises new framework for pharmaceutical inspections for United States and European Union</u>
- Four more EU Member States benefit from EU-US mutual recognition agreement for inspections
- FDA Mutual Recognition Agreement with Swissmedic Enters Into Force, OGPS Statement, July 27, 2023
- Agreement on Mutual Recognition between the Swiss Confederation and the United States of America Relating to Pharmaceutical Good Manufacturing Practice, OGPS Statement, January 12, 2023
- FDA and United Kingdom Announce Mutual Recognition Agreement for Pharmaceutical Good Manufacturing Practice Inspections of Animal Drugs
- U.S.-UK Mutual Recognition Agreement

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