

ORA – Compliance Activities

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Our Origin Story Program Alignment

...Modernize and strengthen the FDA workforce to improve public health response.

2013 FDA Program Alignment Charge



Con-Ops: The Framework...

Jointly developed operating model to advance the pharmaceutical quality program.

INTEGRATION OF FDA FACILITY EVALUATION AND INSPECTION PROGRAM FOR HUMAN DRUGS: A CONCEPT OF OPERATIONS



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





MRA - 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



Benefits of Mutual Recognition

- 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.
- Expand surveillance and gain intelligence from other authorities
- Focus our inspectional resources to inspect facilities where the regulatory authorities are not as mature.

GOAL: To reallocate scarce resources to areas of higher risk by recognizing inspections performed by capable foreign regulatory authorities.



A New World for Pharmaceutical Inspections The Mutual Recognition Agreement



http://www.fda.gov/go

Questions? FDA-MRA@fda.hhs.gov