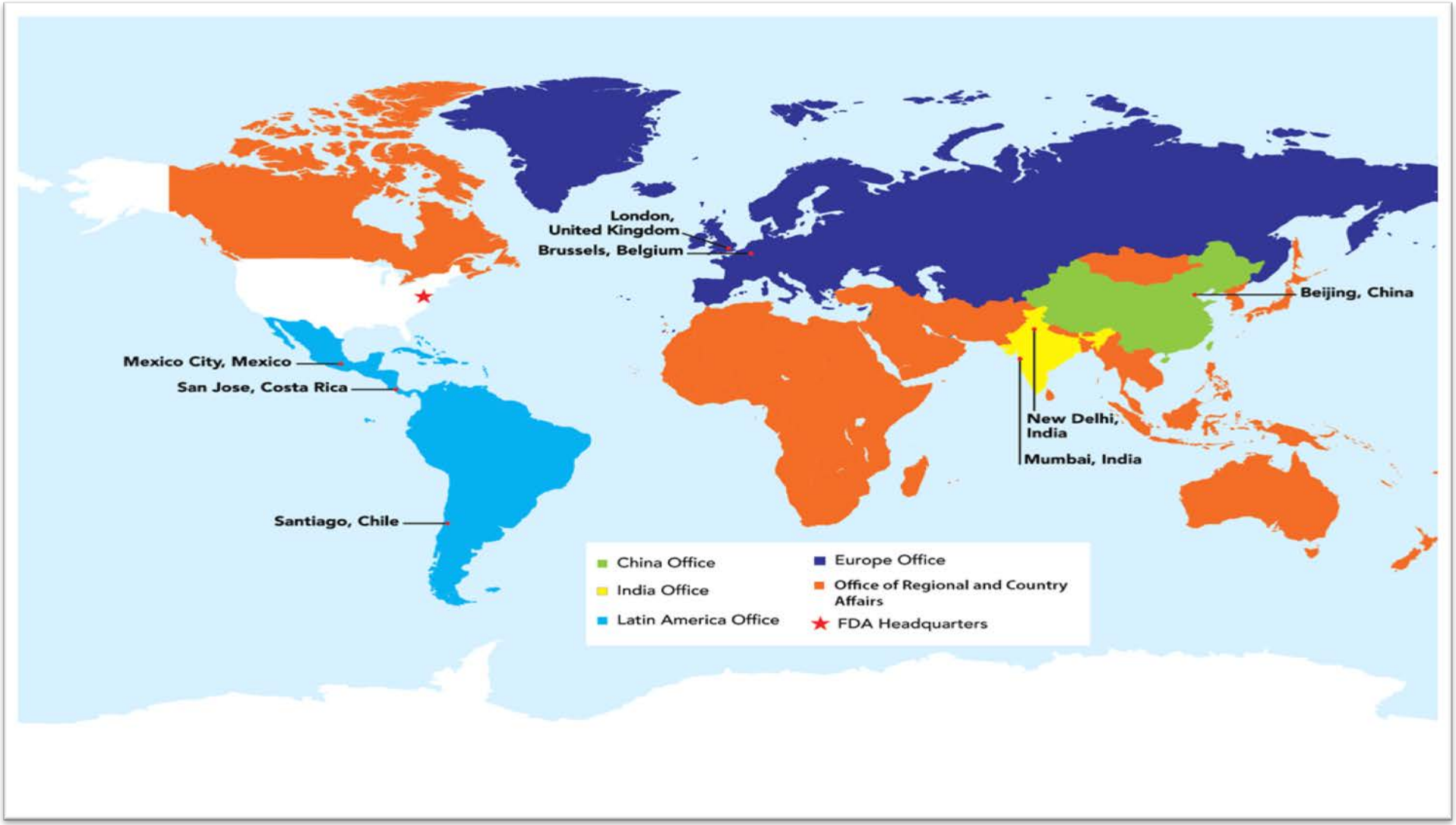
FDA U.S. FOOD & DRUG ADMINISTRATION

Office of International Programs

FDA International, Europe

Navigating present and future

FDA Foreign Posts



Globalization: A Strategic Priority

Globalization – FDA priority for 2014-2018

Cross-cutting Strategic Priorities

- Regulatory Science
- **Globalization**
- Safety and Quality
- Smart Regulation
- Stewardship

FDA's Globalization Strategy:

- Information sharing
- Data-driven risk analytics
- Enhanced intelligence
- Smart allocation of resources through partnerships

International Priorities: Two mechanisms

- Multilateral Organizations
  - Establish technical & policy standards (ICH, PIC/S, IMDRF)
  - Build coalitions, advise and enhance capacity to further public health and efficiency (WHO, PAHO)
  - FDA regional offices engage to some degree in these, but variable
- Bilateral Engagements
  - In depth and high volume activity
  - Forte of the FDA Foreign Offices
  - Scope and specifics vary with location
    - Europe – Broad policy matters at HQ and medical product activities mostly at EMA
    - China, India – manufacturing and inspections

Multilaterals in Context

- Forums for regulators to share information
- Range of approaches to common challenges
  - Regulatory trends reflect society; range of perspectives matter as we ultimately cross paths
  - Multilateral discussions focus on larger matters, not individual products
  - Complexities of regulatory agencies
  - Peer engagement
- FDA priority is ML that will benefit our work and public health

Bilateral: FDA's Eyes and Ears

- With diversity of cultures and regulatory approaches, linkages with institutions are key
- Trust and diplomacy are crucial factors
- Increase our knowledge base around a country's regulatory context
  - Better understand federal/state dynamics
  - Role of industry or multilateral institutions
- Work with other regulators to expand our reach and build strong collaborations

Europe Office

- US trade and investment relationship with Europe
  - Largest and most complex in the world
- Facilitate regulatory dialogue between U.S. and Europe
- Exchange Data, Information and Technical Expertise
  - About 50% of FDA's confidentiality commitments are with organizations in the EU region.
- Headquarters in Brussels
  - Director and Staff: Focus on high level policy, foods, etc.
  - Deputy/EMA Liaison in London

FDA and EMA in Focus

- Embedded Liaison on site in each agency
- Coordination; collaboration; communication
- Technical work through standing working groups and their extensions
- Intensive staff exchanges/fellowships on topic areas
- Working Groups or “Clusters”
  - Meet monthly or quarterly
  - Share information and build collaborations

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What is discussed in a Cluster?

- Information on individual products
  - Reviews and analyses
  - Challenging scientific issues
  - Breadth of perspectives
  - Regional constraints and expectations
- How to facilitate scientific dialogue
  - Workshop planning; draft guidelines
- Potential collaboration to align on a topic

Who participates in Cluster?

- EMA and FDA always
  - often Health Canada and PMDA (Japan) and SwissMedic
- FDA
  - Office/Division Directors, reviewers, experts/ RPMs
- EMA
  - Staff, Rapporteurs and Assessors, Committee of Working Party members

*New in 2016

Current Cluster List

Advanced Medical Therapies
Biosimilars
Blood Products
Non Clinical Oncology
Oncology
Orphan Products
Pediatrics
Pharmacogenomics
Pharmacovigilence
Vaccines
Veterinary Medicines
API Working Group
Rare Diseases*
Patient Engagement*

Evolving Focus: Getting medicines to patients

- Development should be efficient
- Expectations clear up front by regulators to enhance planning
- Regulatory alignment can make a difference
  - Especially for unmet medical need or patient resources are scarce (e.g., rare disease; pediatrics)
  - May continue to be some aspects that differ, but rationale should be clear (e.g., medical care standards; regional ethics)
  - Shared understanding of the science is key

Parallel Scientific Advice

- Process to get simultaneous advice on development from FDA and EMA
- Not an agreement to aligned, but if there are differences all aware up front
- Useful for industry and regulators
  - Early understanding of expectations
  - Allows differences to be addressed and, in some cases, resolved across regulators

What about the future?

- Fast pace science and development demand new ways of thinking and novel trial methods
- Increasingly complex manufacturing
- Growth of markets for production
- Increasing societal demand for rapid access

All of these will converge to drive greater need for strong regulatory collaboration across regions

Thank You!

- **For more information about FDA's International Programs, visit our website at:**

- **http://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/default.htm**

- **FDA Europe Office: OC-OIP-Europe@fda.hhs.gov**

OIP in FDA

Office of the Commissioner

- Office of Foods and Veterinary Medicine
  - 
    Center for **F**ood **S**afety & **A**pplied **N**utrition
  - 
    Center for **V**eterinary **M**edicine
- Office of Medical Products & Tobacco
  - 
    Center for **D**evices & **R**adiological **H**ealth
  - 
    Center for **B**iologics **E**valuation & **R**esearch
  - 
    Center for **D**rug **E**valuation & **R**esearch
  - 
    Center for **T**obacco **P**roducts
- Office of Global Reg. Ops & Policy
  - 
    Office of **R**egulatory **A**ffairs
  - 
    Office of **I**nternational **P**rograms

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