U.S. FOOD & DRUG ADMINISTRATION

FDA India Office

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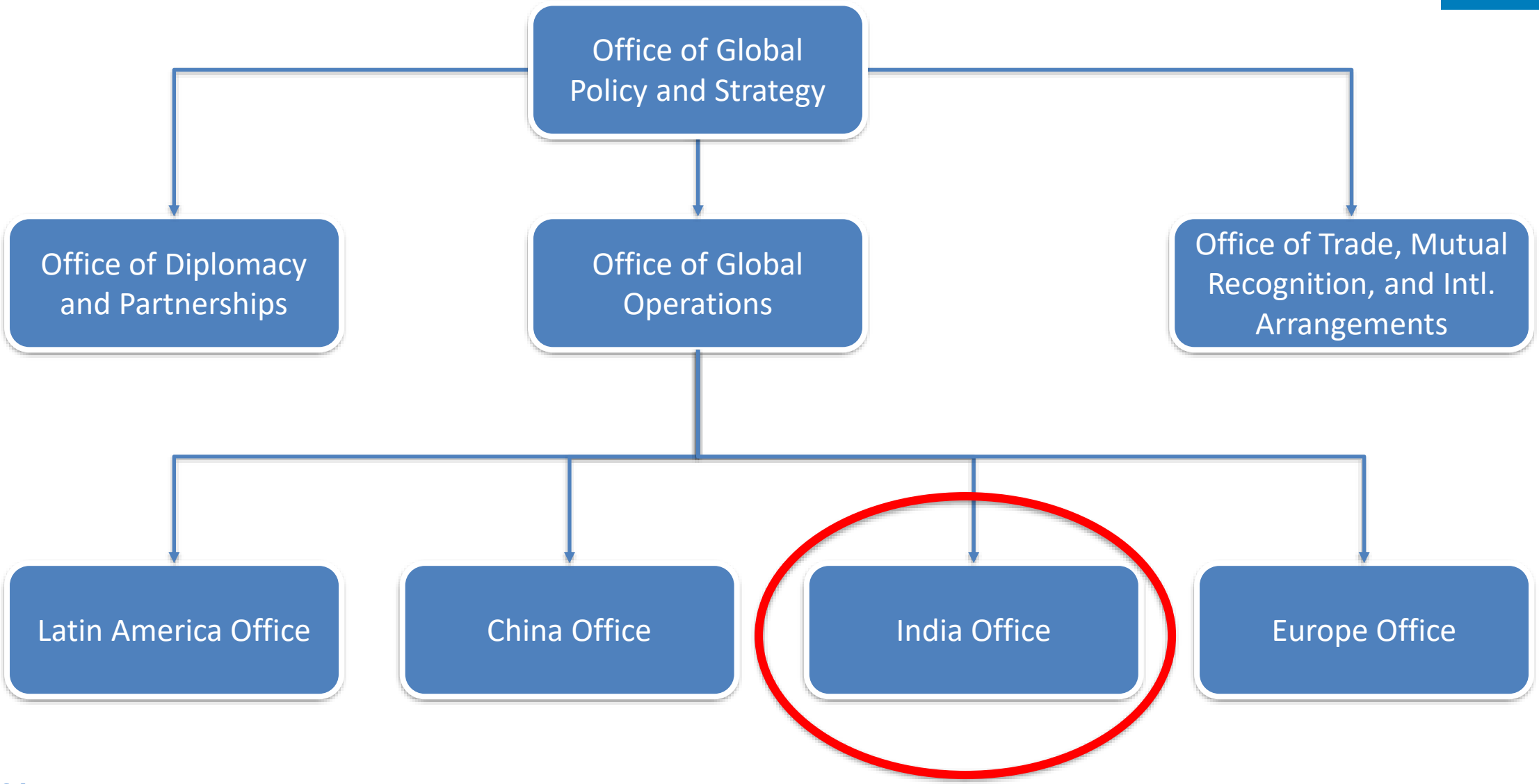
Office of Global Policy and Strategy

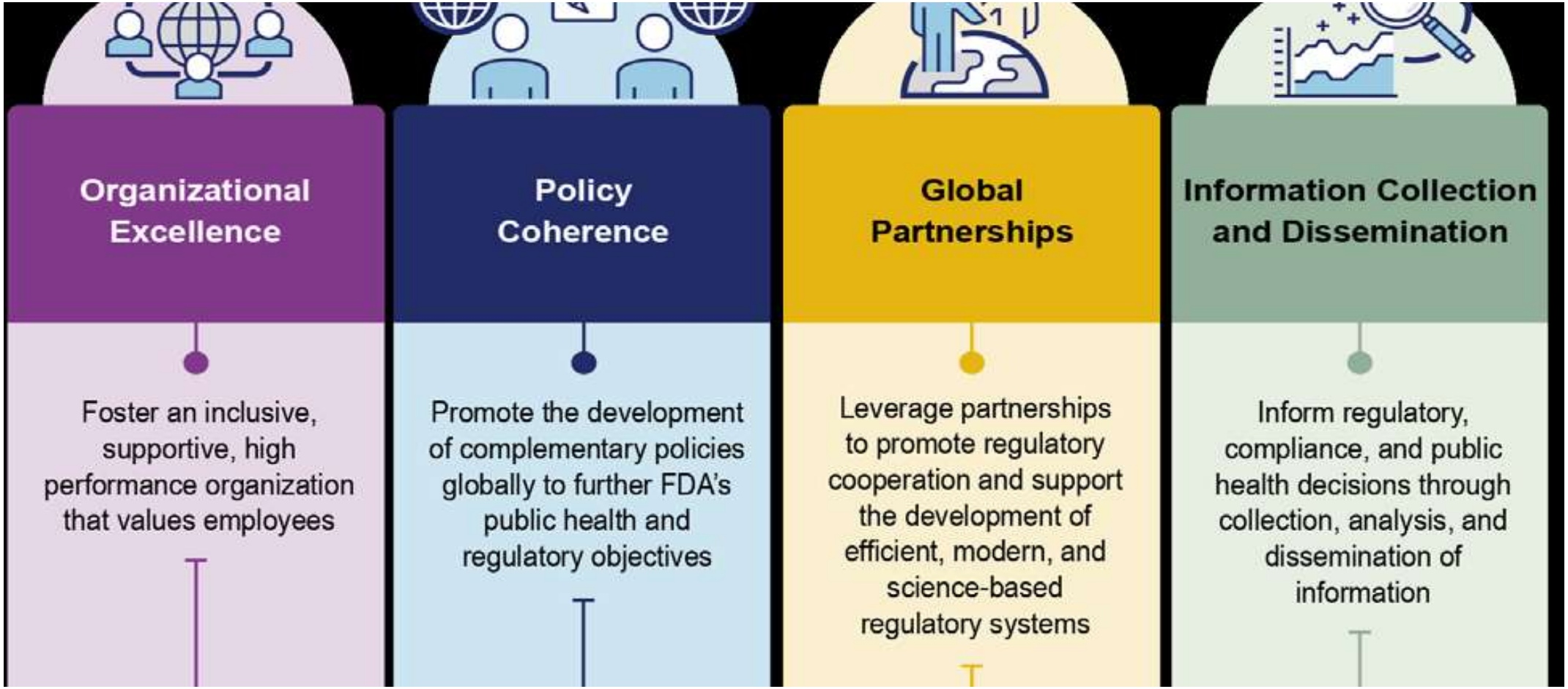


Office of Global Policy and Strategy

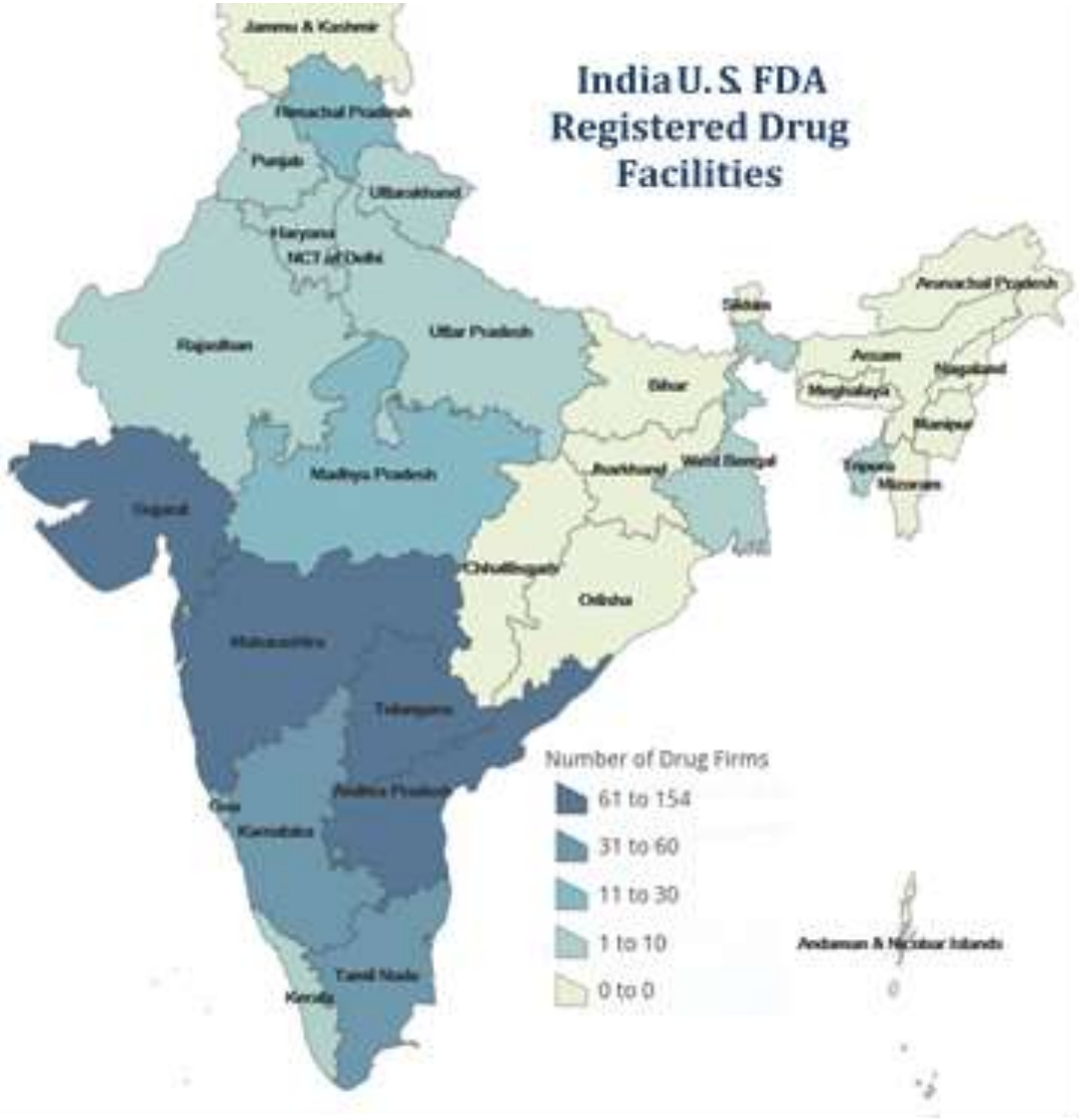
OGPS Mission:

OGPS Mission	*OGPS effectively advances globally the FDA's mission of protecting and promoting the public health of Americans*

Office of Global Policy and Strategy: Strategic Priorities



India



- Largest number of FDA-registered drug manufacturing facilities outside of the U.S.
- India is one of the largest exporters of drug products to the U.S.

U.S. FOOD & DRUG ADMINISTRATION

FDA India Office

Working to ensure a safe and reliable supply chain

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FDA India Office

Working with Government of India

FDA India: Working with GOI

- Statement of Intent to Memorandum of Understanding (MOU)
  - U.S. and India Agreement signed Feb 24, 2020
  - Areas of Cooperation:
    - Information sharing
    - Observed inspections
    - Collaborations with other entities
    - Meetings and other engagements

FDA and GOI MOU: Early results

- COVID-19
  - FDA and the Federal Trade Commission (FTC) worked together in identifying firms promoting unapproved drugs or false and/or misleading claims
  - FDA sends Warning letter to firms
  - Close working relationship and communication with GOI AYUSH
- FDA coordinates with AYUSH to share FDA regulatory actions
  - AYUSH orders firms to cease advertisement
  - AYUSH issues order to all States to stop and prevent publicity and advertisement of AYUSH-related claims for COVID-19 treatment

FDA & GOI: Information sharing

- COVID-19:
  - FDA issues several guidances related to COVID-19
  - FDA India Office maintains an electronic mailing list of industry and gov't professionals (opt in by sending an email to: US-FDA-INO@fda.hhs.gov)
  - FDA India Office distributes select guidances as appropriate to mailing list
  - FDA India Offices shares FDA COVID-19 website with stakeholders FDA India Office future functionality: Listserv management to facilitate information sharing with stakeholders

FDA India Office (INO): Communication on emerging issues

- Communication not limited to GOI
- Information sharing and capacity building with industry
  - Nitrosamine issues
  - FDA collaborates with GOI and other regulatory authorities and facilitated a GMP workshop in November 2019
  - INO office participated in 2019 International Society for Pharmaceutical Engineering (ISPE) South Asia Pharmaceutical Manufacturing Conference at Bangalore on 26th and 27th September 2019.
  - INO office participated in the 5th India Pharmaceutical Forum (IPF) 2020 at Mumbai held on 27-28 February 2020.

FDA India Office: We want to hear from you!

- We maintain a electronic mailbox to assist stakeholders in navigating FDA's regulations
- Assist with questions you may have:
  - Recent pharmaceutical-related inquiries include: hand sanitizers, how to register, COVID-19 and "in-person" inspections
  - Ask us, we are here for you
  - Our mailbox: US-FDA-INO@fda.hhs.gov

Our next speakers

- Thank you for your time
- I would like to introduce the topics for the following session
  - **The State of Pharmaceutical Quality: Surveillance Findings – Raphael Brykman**
  - **Successfully Implementing Advanced Manufacturing – Sau (Larry) Lee**

Thank you for your time!

- **Chris Middendorf**
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