U.S. Food and Drug Administration
Office of International Programs

FDA

Towards Excellence in Quality

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Disclaimer

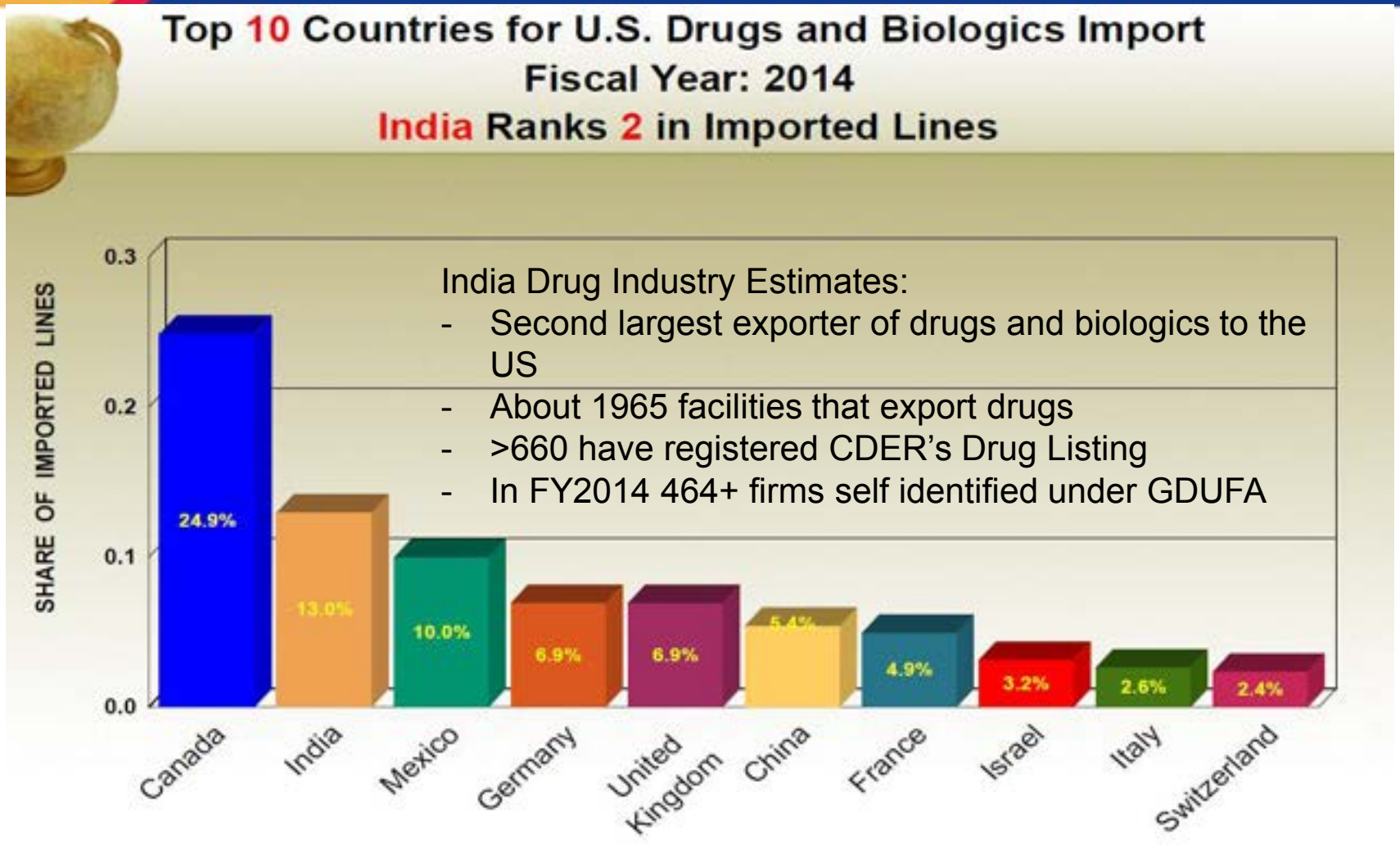
- *Views expressed in this presentation are those of the speaker and not, necessarily, of the U.S. Food and Drug Administration.*

The Indian Pharmaceutical Industry*

- The 8th largest globally and continues to have one of the highest growth rates
- Projected to grow to be the 3rd largest by 2030
- Driving accessibility and affordability of drugs in India and globally

* As per IPA Secretary General Dilip Shah's presentation on January 1, 2016

Fiscal Year:2014 - Import Lines



U.S. FDA India Office - Priorities

- Conduct inspections – upon which regulatory decisions are made
  - Drug and medical product facilities that export such products from India to the U.S., to determine quality, safety, and efficacy
  - Clinical trials to determine data integrity

- Enhance relationships and collaborations with the Government of India (GOI) for strengthening regulatory systems in the area of drugs and medical products and food areas – for building confidence and quality standards

- Enhance relationships and collaborations with Industry and Stakeholders – for developing and maintaining quality standards, enhancing cGMP compliance, and thereby enhance public health

Current Good Manufacturing Practices

cGMP Standards are minimal:

- The cGMP requirements are **basic requirements**
- The “c" in cGMP stands for "**current**." Companies can use up to date validated technologies and innovative systems to comply with the regulations and to enhance quality through **continuous improvement**.
- cGMP allows each manufacturer to decide how to best implement the necessary controls by using scientifically sound design, processing methods, and testing procedures.

Data Integrity

Data Integrity is just that – data integrity:

- Involves the accurate collection, recording, processing, analyzing, reporting, storage and retrieval of data.
- Must involve a life cycle approach from the beginning to the end – to facilitate mapping the entire process and enable detection of steps where problems occur.
- Must not be subjected to bias.

Factors that contribute to Quality

- Rules must be known and as clear and simple as possible
- Improve coordination and promote instant sharing of information
- Employ smarter controls - it is not about more or fewer controls
- Develop strategies and tools for rewarding quality and compliance

Recurring issues affecting Quality

- Written procedures – lacking; inadequate; not-followed
- Records – lacking, inadequate, inaccurate, fabricated
- cGMPs – lacking, inadequate, not followed
- Product contamination
- Sterile products lacking assurance of sterility

Data integrity issues

How does this serve patients and/or the public?

Can't we do better?

Unique Challenges to Quality

- Disparities between big and small firms
- Supply chain complexities
- Disparities in manufacturing products for domestic use versus those for exports
- Lack of robust regulatory systems

Some Common Quality Pitfalls

- Inadequate infrastructure
- Inadequately trained staff
- Lack of adequate supervision
- Restrictive timelines
- Reprisals for negative results or outcomes

How to Overcome Challenges

- Develop a sustainable culture of quality and compliance
- Enhance training for all staff
- Reward compliance
- Encourage open communication
- Trust but verify

Evolving Pharmaceutical Landscape

- Use of electronic systems to monitor compliance
- Use of IT tools for sharing information
- Meaningful and customer-friendly regulatory systems
- Competition from other sources

Evolving Pharmaceutical Landscape

- Global markets demand alignment of standards
- Use of newer technology and treatment tools including the development of innovative new molecular entities, nanotechnology based therapies, biosimilar products, pharmacogenomics treatments, etc.
- Addressing emerging public health needs as per the known risk/benefit ratio

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THANK YOU

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