Inspections in a COVID-19 World

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Perspectives

- Common mission and goals that U.S. patients have access to a secure and consistent supply of pharmaceuticals
- Our nation needs a diverse and resilient pharmaceutical supply chain
- Industry has the primary responsibility to reliably produce safe quality products

Pandemic

- Onset of the COVID-19 pandemic and travel restrictions
- On March 10 and 18, respectively, FDA postponed conducting routine foreign and domestic inspections
- ORA continued mission-critical on-site work, such as for-cause inspections on a case-by-case basis, import review, laboratory analysis of samples
- On July 10, FDA announced plans to resume prioritized domestic inspections
- Resumed prioritized surveillance inspections

Pandemic, cont.

- On July 10, FDA announced a plan to resume prioritized domestic inspections
- ORA stands ready to resume any postponed inspections as soon as feasible, applying a strategic benefit versus risk calculus to our inspectional work

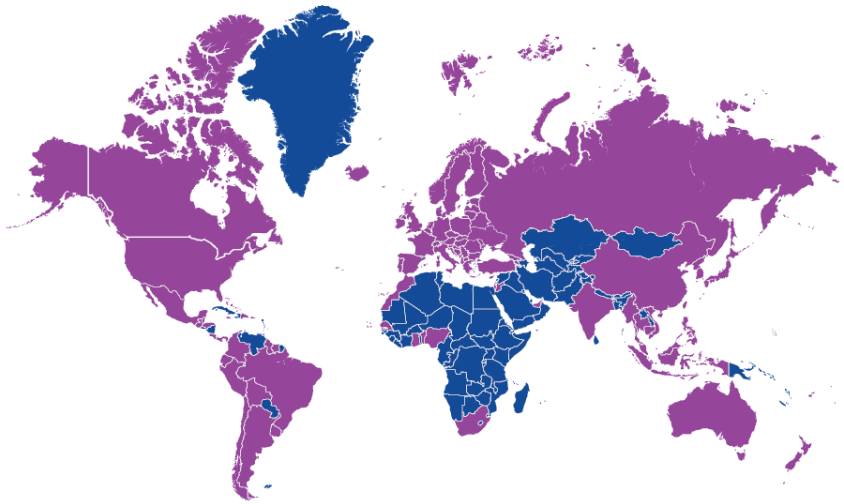
Foreign Pharmaceutical Inspection

Inspections: ORA's Global Reach

ORA's Global Inspections:

United States	Czech Republic	Japan	Singapore
Albania	Denmark	Jordan	Slovakia
Argentina	Dominican Republic (the)	Korea (the Republic of)	Slovenia
Armenia	Ecuador	Latvia	South Africa
Australia	Estonia	Lithuania	Spain
Austria	Faroe Islands	Macedonia	Suriname
Bahamas	Fiji	Malaysia	Sweden
Barbados	Finland	Malta	Switzerland
Belarus	France	Marshall Islands	Taiwan
Belgium	Georgia	Mauritius	Thailand
Belize	Germany	Mexico	Tonga
Benin	Ghana	Moldova	Trinidad & Tobago
Bolivia	Greece	Morocco	Turkey
Bosnia-Hercegovina	Grenada	Netherlands	Ukraine
Brazil	Guatemala	New Zealand	United Arab Emirates
Bulgaria	Guyana	Nigeria	United Kingdom
Burma (Myanmar)	Honduras	Norway	Uruguay
Cambodia	Hong Kong SAR	Panama	Vietnam
Canada	Hungary	Peru	Western Samoa
Cape Verde	Iceland	Philippines	
Chile	India	Poland	
China	Indonesia	Portugal	
Colombia	Ireland	Romania	
Costa Rica	Israel	Russia	
Croatia	Italy	Senegal	
Cyprus	Jamaica	Serbia	

Countries Where ORA Conducts Inspections



FY19 Statistics

	Biologics	BIMO	Devices (MQSA)	Pharma	Tobacco	Human & Animal Food	Total
FDA Domestic	1,641	1,016	2,144 (785)*	**941**	131	8,522	14,395
State Domestic	N/A	N/A	7,449 (7,402)*	**N/A**	N/A	9,613	17,062
FDA Foreign	57	315	581 (12)*	**1,045**	0	1,784	3,782
Total FDA and State Domestic Inspections	1,641	1,016	9,593	**941**	131	18,135	31,457
Total FDA Domestic, State Domestic, and Foreign Inspections	1,698	1,331	10,174	**1,986**	131	19,919	35,239

* MQSA count are in parenthesis. The MQSA counts re a sub-set of the Devices count.

Lessons from Crisis: A Changed World

- Ability to conduct on-site facility inspections is important to carrying out our mission
- Implemented alternative ways to conduct inspectional work that do not jeopardize public safety and that protect firms as well as FDA staff.

Innovation and Alternative Approaches

- Using our authority to request records and other information in advance of or in lieu of inspections
- Relying on global partnerships in requesting establishment inspection reports from capable foreign regulatory authorities under the MRA
- Looking critically at ways to innovate and optimize use of these tools to better serve the American public in the future

Facilitating New Approaches

- To create efficiencies and regulatory predictability we will need to engage on new approaches and new tools
- Leveraging technologies, such as secure data platforms to share, assess and exchange records
- Further enhancing relationships with capable regulatory partners to reduce redundant and duplicative work and disperse critical resources more effectively

Facilitating New Approaches, cont.

- Benchmarking operations against other inspectorates to identify new and improved strategies
- An open and honest dialogue about a true partnership to advance medical product quality and accessibility
- Expanded cooperation with industry, working collaboratively to evaluate facility processes and ways to achieve inspectional operations in innovative and creative ways

Future Opportunities

- Understand how the pandemic has changed pharmaceutical industry
- Identify how we work together toward achieving outcomes in the best interest of patients
- Engaging on ideas for strengthening partnerships particularly in the area of inspection operations

Thank You - Questions?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