

# FDA OFFICE OF GLOBAL POLICY AND STRATEGY (OGPS)



## STRATEGIC PLAN OVERVIEW FISCAL YEARS (FY) 2020–2024

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## Message from the Associate Commissioner for Global Policy and Strategy, Mark Abdo



Last year, the United States (U.S.) Food and Drug Administration (FDA) reorganized the Commissioner's Office to increase efficiencies, better meet the demands of our work environment, and enhance collaboration efforts across commodities and policy areas.

Through the reorganization, the Office of Global Policy and Strategy (OGPS) was established under the Office of Policy, Legislation, and International Affairs (OPLIA) to enable the Agency to respond to its global mission to protect and promote the public health of Americans. OGPS was created by assuming the former Office of Global Regulatory Operations and Policy (OGROP) and a part of the Office of International Programs (OIP). This new structure enhances the breadth of the Office's international policy, diplomacy, and compliance work in the United States and abroad.

OGPS is now structured into three sub-offices, based around our key focus areas – partnerships and multilateral diplomacy (Office of Global Diplomacy and Partnerships [OGDP]), operations and maintenance of our foreign posts and any associated policy work (Office of Global Operations [OGO]), and development of formal inter-governmental arrangements and issues related to the trade of FDA-regulated products (Office of Trade, Mutual Recognition and International Arrangements [OTMRIA]).

The OGPS Strategic Plan for Fiscal Years (FY) 2020-2024 outlines our priorities and goals as we continue to leverage our resources and strengthen our programs to achieve our mission. This plan identifies four complementary and connected strategic priority areas for our office: Organizational Excellence, Policy Coherence, Global Partnerships, and Information Collection and Dissemination. These four areas will guide our work and direct how we put our mission into practice.

In developing our strategic plan, we aligned our mission and strategic priorities to the strategic goals of the U.S. Department of Health and Human Services (HHS). We also collected significant input from our leadership and employees, and their contributions helped define the direction of our office. We will continue to consult with our employees and FDA partners to periodically review this strategic plan, as needs evolve and priorities change.

In closing, I would like to thank our employees for their tireless efforts and all our partners for their continued support. I look forward to continuing our work with you in fulfilling our mission.

## Introduction

Many of the FDA-regulated products that Americans consume and use every day originate from outside of the United States. About 15% of foods, 70% of biologics, and 35% of medical devices used and consumed by households are imported to the United States (“FDA Strategy,” 2019; “Fact Sheet,” 2019). Additionally, 80% of active pharmaceutical ingredients manufacturers are located outside of the United States (“Fact Sheet,” 2019). Part of OGPS’s role is to work with our many partners to strengthen and modernize FDA’s global operations, policy, and diplomacy activities to assure that imported products meet FDA’s regulatory standards to maintain the health and safety of the American people.

FDA, including OGPS, rely on strong partnerships with foreign governments, industry, academia, and nongovernmental organizations to achieve our mission and facilitate progress towards our goals. Through these partnerships, we exchange regulatory information, achieve transparency in decision-making, and help our regulatory partners move towards global norms through harmonization and transparency.

This strategic plan provides OGPS with a foundation for carrying out our work over the next five years. This plan is intended to serve as a living document, outlining strategic priorities and supporting goals and objectives to promote OGPS’s ongoing work, while emphasizing continuous improvement and new focus areas as they arise.

The strategic priorities outlined in this plan align with and support the goals established in [HHS’s Strategic Plan FY 2018 - 2022](#) to enhance the health and well-being of all Americans. Please refer to Appendix A for a summary as to how OGPS strategic priorities align to HHS strategic goals.

This document presents our OGPS mission and our four strategic priorities for FY 2020-2024. The following sections further define the goals, objectives, and activities to support these strategic priorities.

## Strategic Priorities, 2020 – 2024

The strategic priorities in this plan support OGPS's continued efforts to foster partnerships and multilateral diplomacy; operate and maintain FDA's foreign offices, including the policy planning and evaluation work associated with the foreign offices; and address issues related to the importation of FDA-regulated products. Each strategic priority includes supporting goals and objectives that will serve as the blueprint for achieving our mission, as shown in Figure 1.



Figure 1: OGPS Mission Statement

We will focus on the following four strategic priorities, as shown in Figure 2:

- Organizational Excellence
- Policy Coherence
- Global Partnerships
- Information Collection and Dissemination

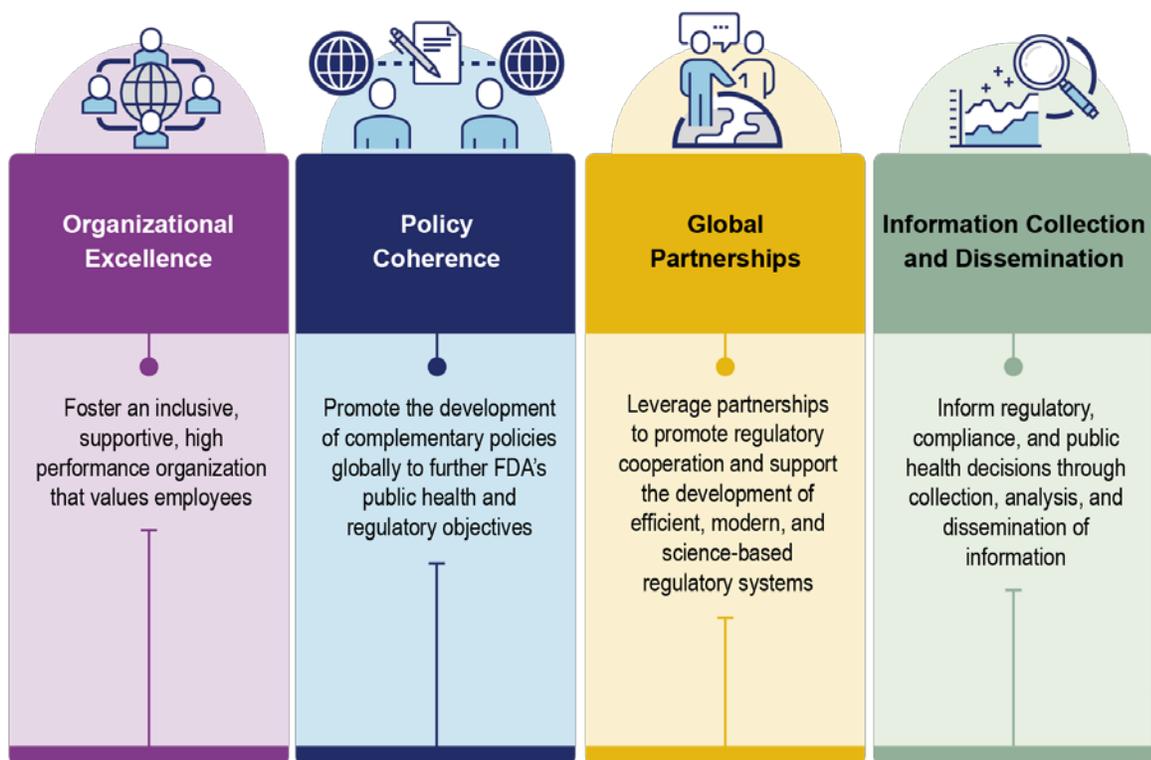


Figure 2: OGPS Strategic Priorities and Associated Descriptions

## Goals Summary

Each goal supports the strategic priorities and sets a specific target for where the organization would like to be in the next five years. It is important to note that these goals are inherently interrelated and successful achievement of one will naturally influence the success of others. Providing a framework, outlined by these goals, will position OGPS to meet our commitments and deliver on our mission.

Figure 3 provides an overview of the goals aligned to the strategic priorities.



Figure 3: OGPS Goals and Alignment to Strategic Priorities

## Goals and Objectives

Tables 1-4 on the following pages show an overview of the goals and objectives linked to each strategic priority. The objectives describe the intended outcomes of each goal and will assist in measuring progress throughout the strategic plan period. Each objective includes a brief description of sample activities OGPS will leverage to operationalize each objective.



**Organizational Excellence:** Foster an inclusive, supportive, high performance organization that values employees.

Table 1: Organizational Excellence Goals and Objectives

Goal	Objectives	Summary of Activities
<b>Cultivate and maintain a successful organization and workforce</b>	<b>Foster and support an inclusive and empowering organizational culture</b>	<ul style="list-style-type: none"> <li>• Implement ongoing initiatives to support employee engagement</li> <li>• Promote and emphasize the importance of trust, empowerment, and accountability as key organizational values</li> <li>• Leverage Employee Viewpoint Survey (EVS) results and feedback from staff to continually assess areas for improvement</li> </ul>
	<b>Attract and recruit highly skilled employees</b>	<ul style="list-style-type: none"> <li>• Develop and implement an integrated workforce plan to recruit employees</li> <li>• Improve the interview process to support identifying and hiring qualified candidates</li> <li>• Improve onboarding and offboarding processes for employees</li> <li>• Focus on the reintegration experiences from foreign offices</li> </ul>
	<b>Develop and retain highly skilled employees</b>	<ul style="list-style-type: none"> <li>• Provide opportunities for enhanced career planning and employee development</li> <li>• Develop additional employee resources and opportunities for continuous learning</li> <li>• Prioritize employee growth through training opportunities on specific job-related topics</li> <li>• Identify and implement additional long-term retention strategies</li> </ul>
	<b>Develop and document efficient processes, policies, and procedures to assure consistent practices</b>	<ul style="list-style-type: none"> <li>• Evaluate Knowledge Management (KM) opportunities to improve records management</li> <li>• Implement a plan to update and maintain the Office's and foreign offices' Information Technology (IT) infrastructures</li> <li>• Improve management, implementation, and archive of required reporting</li> </ul>
	<b>Create opportunities for OGPS employees to increase cross-collaboration</b>	<ul style="list-style-type: none"> <li>• Develop strategies to improve relationships, engagement, and teamwork</li> <li>• Continue to develop and use communication tools to share ongoing activities and achievements</li> </ul>



**Policy Coherence:** Promote the development of complementary policies globally to further FDA's public health and regulatory objectives.

Table 2: Policy Coherence Goals and Objectives

Goal	Objectives	Summary of Activities
<b>Assure policy actions are understood and promoted domestically and globally</b>	<b>Promote policy coherence and mutual understanding across FDA Centers/Offices to advance public health priorities</b>	<ul style="list-style-type: none"> <li>• Plan and engage in various methods of communication with FDA Centers/Offices</li> <li>• Maintain ongoing dialogue and continue joint efforts with FDA Centers/Offices to collaborate on policy initiatives, inspections, and resources</li> <li>• Exchange expert knowledge with FDA Centers/Offices about global priorities and related activities through the Global Activities Council (GAC)</li> </ul>
	<b>Assure alignment of the Agency's strategic direction and policy actions with United States Government (USG) agencies</b>	<ul style="list-style-type: none"> <li>• Enhance FDA's role in the development of U.S. trade policy</li> <li>• Broaden engagement strategies to effectively convey OGPS activities to USG agencies to advance public health priorities</li> </ul>
	<b>Advance the Agency's public health regulatory positions domestically and globally through effective advocacy</b>	<ul style="list-style-type: none"> <li>• Foster similar levels of public health protections globally by streamlining regulatory efforts, sharing of strategies and best practices, and communicating regularly with counterparts, industry, academia, and other public health entities/bodies/organizations</li> <li>• Exchange knowledge on emerging and trending issues through engagement with USG agencies, global counterparts, industry, and other organizations</li> <li>• Collaborate on inspection policies by enhancing relationships with FDA Centers/Offices</li> <li>• Improve industry and foreign counterparts' understanding of regulatory science and Agency requirements</li> </ul>



**Global Partnerships:** Leverage partnerships to promote regulatory cooperation and support the development of efficient, modern, and science-based regulatory systems.

Table 3: Global Partnerships Goals and Objectives

Goal	Objectives	Summary of Activities
<b>Engage international stakeholders to promote FDA policies</b>	<b>Strengthen policy alignment through engagement with stakeholders to support USG and FDA priorities</b>	<ul style="list-style-type: none"> <li>• Identify opportunities to strengthen multilateral and bilateral relationships between FDA and counterpart regulatory agencies</li> <li>• Strengthen diplomatic relationships through high-level meetings and conferences with foreign counterparts and international stakeholders regarding product development and policies</li> <li>• Develop a new mechanism for managing and tracking stakeholder relationships and interactions</li> <li>• Assess the value and frequency of engagement activities with international stakeholders and provide strategic and consistent messaging to stakeholders to advance FDA's public health and regulatory interests globally</li> </ul>
	<b>Foster collaborative relationships with stakeholders to advance Agency priorities</b>	<ul style="list-style-type: none"> <li>• Develop and manage International Arrangements, Cooperative Arrangements, and Confidentiality Commitments to enhance collaboration</li> <li>• Work with USG agencies and U.S. Embassy missions to protect and promote FDA's interests</li> <li>• Continue efforts with multilateral organizations to support FDA priorities</li> <li>• Develop foreign stakeholders' understanding of FDA regulatory requirements, integrity, and regulatory science</li> </ul>



**Information Collection and Dissemination:** Inform regulatory, compliance, and public health decisions through collection, analysis, and dissemination of information.

Table 4: Information Collection and Dissemination Goals and Objectives

Goal	Objectives	Summary of Activities
<p><b>Advance the OGPS mission by collecting, analyzing, and sharing information and data</b></p>	<p><b>Enhance risk-based strategies by gathering information</b></p>	<ul style="list-style-type: none"> <li>• Evaluate regulatory, policy, and industry developments and trends of FDA-regulated products and share with FDA Centers/Offices and USG agencies</li> <li>• Analyze new foreign regulatory legislation and policy developments to advance FDA knowledge of foreign activities and policies</li> <li>• Meet with FDA Centers/Offices to share current events, discuss emerging issues, and support coordination of activities</li> <li>• Obtain information from government counterparts, industry, academia, and nongovernmental organizations</li> <li>• Provide information and expertise to FDA Centers/Offices and USG agencies to enhance risk-based regulatory decision-making</li> </ul>
	<p><b>Exchange information with external stakeholders</b></p>	<ul style="list-style-type: none"> <li>• Assist and train OGPS employees in understanding laws and regulations governing FDA’s abilities to share non-public information with foreign counterparts</li> <li>• Complete the equivalence determination for raw bivalve molluscan shellfish with European Union (EU) Member States</li> <li>• Host periodic meetings with global counterparts to discuss and collect FDA-related information and data</li> <li>• Coordinate with FDA Centers/Offices to disseminate information and data to the public</li> <li>• Continue to report office performance measures and projects via FDA-TRACK<sup>1</sup></li> </ul>

<sup>1</sup> FDA-TRACK is FDA’s agency-wide performance management system that monitors FDA Centers and Offices through key performance measures and projects (“FDA-TRACK,” 2019).

## Conclusion

OGPS employees work tirelessly to make sure imported products regulated by the FDA are safe and of the highest quality. We are meeting the challenges of globalization – continuously seeking to improve global regulatory systems and contributing to FDA’s knowledge of the countries supplying imports to the United States.

This strategic plan establishes our priorities and shapes the Office’s actions for the next five years. Through collective action and partnerships, OGPS is committed to meeting our mission and contributing to the overall success of the FDA.

## References

*Fact Sheet: FDA at a Glance.* (2019, October 18). FDA.gov. Retrieved March 11, 2020, from <https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance>

*FDA Strategy for the Safety of Imported Food.* (2019, May 22). FDA.gov. Retrieved March 11, 2020, from <https://www.fda.gov/food/importing-food-products-united-states/fda-strategy-safety-imported-food>

*FDA-TRACK: Agency-wide Program Performance.* (2019, December 31). FDA.gov. Retrieved March 11, 2020, from <https://www.fda.gov/about-fda/transparency/fda-track-agency-wide-program-performance>

# Appendices

## Appendix A: OGPS Strategic Priorities Alignment to HHS Strategic Goals

The figure below provides more detail as to how OGPS strategic priorities align to the HHS strategic goals.

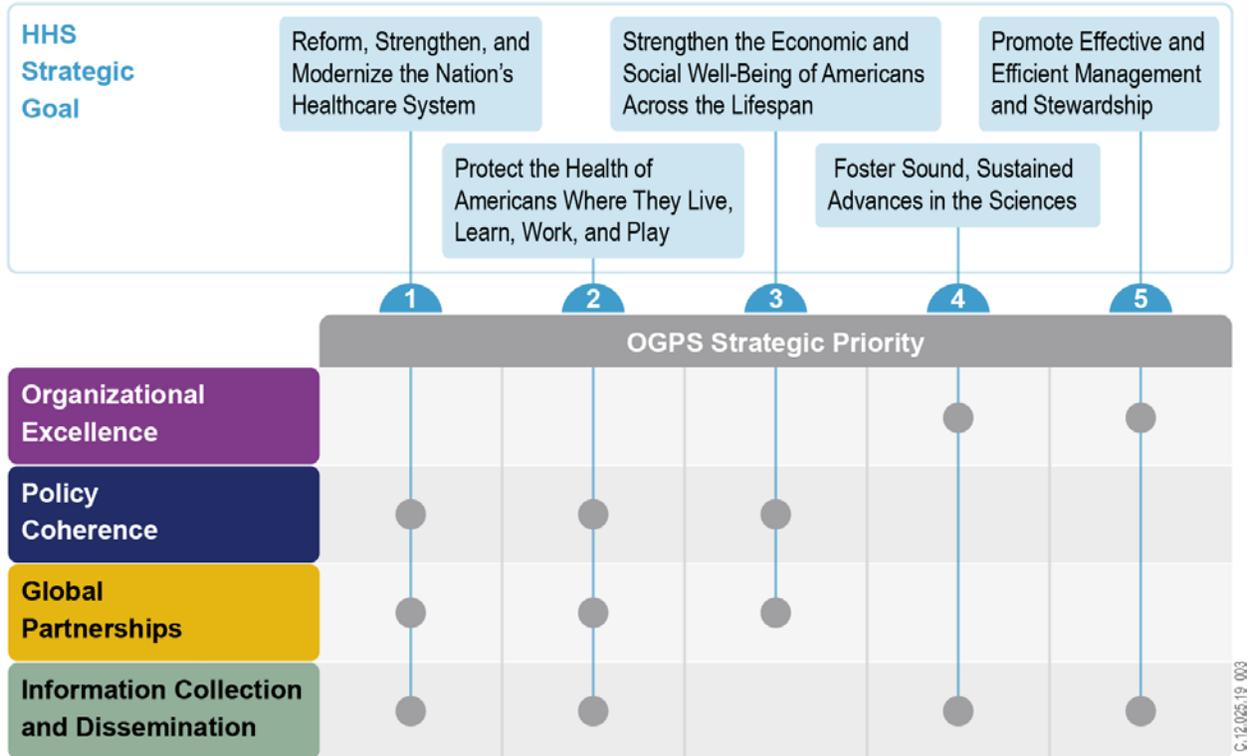


Figure 4: OGPS Strategic Priorities Alignment to HHS Strategic Goals

## Appendix B: Abbreviations

The following table contains abbreviations used throughout the strategic plan with their complete definition.

Table 5: Abbreviations

Abbreviation	Definition
EU	European Union
EVS	Employee Viewpoint Survey
FDA	U.S. Food and Drug Administration
FY	Fiscal Year(s)
GAC	Global Activities Council
HHS	U.S. Department of Health and Human Services
IT	Information Technology
KM	Knowledge Management
OGDP	Office of Global Diplomacy and Partnerships
OGO	Office of Global Operations
OGPS	Office of Global Policy and Strategy
OGROP	Office of Global Regulatory Operations and Policy
OIP	Office of International Programs
OPLIA	Office of Policy, Legislation, and International Affairs
OTMRIA	Office of Trade, Mutual Recognition, and International Arrangements
U.S.	United States
USG	United States Government

**FDA's Office of Global Policy and Strategy (OGPS) effectively advances globally the FDA's mission of protecting and promoting the public health.**

