

FDA-Latin America Office Overview

February 25, 2019

Katie Serrano, Director Latin America Office

FDA's Latin America Office

- LAO covers:
 - 44 nations/territories
 - Mexico
 - Central America
 - Caribbean
 - South America
- LAO hosts 3 posts across the Americas
 - **San Jose, Costa Rica**
 - Mexico City, Mexico
 - Santiago, Chile



FDA-Latin America Regional Office's Structure



OIP-Latin America Regional Office

Katherine Serrano, Regional Director

Michelle Rodriguez*, Deputy Regional Director

OIP-LAO-Mexico

Michelle Rodriguez*
(Deputy Director)

Patricia Oliva Romero (Admin.)

Kenneth Nieves (IRS, Foods)

Janete Oliveira* (CSO, Foods)

Ana Patricia Pineda (LES, Medical
products)

Ana Lilia Sandoval (LES, Foods)

Phone: +52 55 5028-5441

Commissioned Corps
USG Civilian
LES

*to be deployed

OIP-LAO-Costa Rica

Katherine Serrano
(Regional Director)

Vacant (Admin.)

Nicole Conklin (IRS, Foods)

Jason Cornell* (IRS, Foods)

Allan Gonzalez (LES, Foods)

Phone: +506-2519-2224

OIP-LAO-Chile

Soledad Muñoz (Admin.)

Peter Baker (IRS)

Gonzalo Ibanez (LES, Foods)

Phone: +52 2 2330-3035



LAO by the Numbers

- Conservative estimate: 40% US consumed produce originates in Latin America
 - 80% of imported produce is from Mexico alone
 - 8 of the top 10 produce exporters to the US are within LA region (by volume in 2017)
- In FY 2018, 25% of medical devices exported into the US were from countries in Latin America.
 - 2 of the top 5 devices exporters to the US are in the LA region
- Mexico was among the top 10 human drugs and biologics exporters of in FY 2018.

FDA-LAO Focus

- Engagements with governments, local stakeholders to:
 - Identify challenges to compliance with FDA law/regs
 - Identify opportunities for collaboration to improve compliance with relevant FDA laws, regulations and policies
 - Share information to gain better intelligence for FDA decision-making
- Provide support to local stakeholders
- Provide support to FDA Investigators



Food Initiatives and Projects

- FDA-Mexico Produce Safety Partnership
 - Implement preventative practices and verification measures to support compliance with produce safety standards, guidelines and best practices
 - Timely information exchange on food outbreaks and non-compliant commodities
- Work with IICA and stakeholders in the region to increase compliance with Produce Safety Rule training requirements
 - Facilitation of training materials in Spanish targeted to Latin America countries
 - Develop a Cadre of Lead trainers in Latin America that will be able to train growers on FDA's Produce Safety rule in the region



Food Initiatives and Projects cont'd

- On Farm Readiness Review (OFRR) Program
 - Translated into Spanish and shared the OFRR tool directly with farmers
 - Foster OFRRs in Latin America
 - Collaborate with government and academy
- Food Inspections by LAO staff
 - Allow for sharing best inspectional practices with the authorities in-country



Medical Products Activities and Initiatives

- Promote participation in international initiatives on medical devices such as the International Medical Devices Forum (IMDRF)
 - Collaborate with government and stakeholders to identify opportunities for alignment with international standards
 - Outreach on 21CFR820 alignment with ISO13485
- Bilateral collaboration on human drugs inspections
 - Improve understanding of inspectional approaches, compliance criteria and risk-based inspections.
 - Encourage alignment with PIC/S



Medical Products Activities and Initiatives

- Participation in multilateral initiatives:
 - Pan American Network of Drug Regulation Harmonization (PANDRH). Engaged in Regulatory Convergence project, shared information on regulation of biosimilars, advanced therapies, etc.
 - National Regulatory Authorities of Regional Reference (NRAR).
- Support platforms to facilitate outreach and information sharing in Latin America:
 - DIA Latin America Regulatory Conference,
 - APEC Regulatory Harmonization Steering Committee workshops
 - ICH trainings.

Thank you for your attention

US-FDA-LAO@fda.hhs.gov



U.S. FOOD & DRUG
ADMINISTRATION

www.fda.gov