

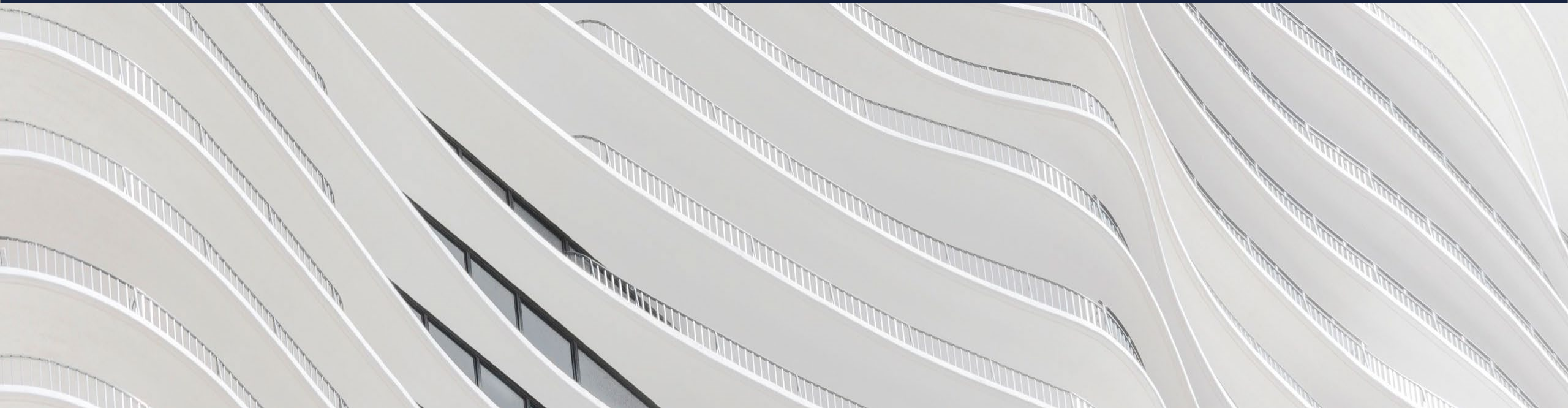


Challenges and Approaches for FDA-Regulated Companies Operating Globally

James Czaban
Anna Abram
Deborah Auter
Howard Sklamberg



The Sheer Number of International Regulatory Bodies and the Challenges of Collaboration and Partnerships



Regional & National Regulatory Authorities

Africa

- Algeria: Directorate of Pharmacy and Medicine
- Botswana: Ministry of Health
- Egypt: Egyptian Drug Authority
- Ghana: Food and Drugs Authority
- Kenya: Pharmacy & Poisons Board
- Morocco: Ministry of Health
- Namibia: Namibia Medicines Regulatory Council
- South Africa: Medicines Control Council
- Sudan: National Medicines and Poisons Board
- Tanzania Food and Drugs Authority
- Tunisia: Directorate of Pharmacy and Medicine
- Uganda: National Drug Authority
- Zimbabwe: Medicines Control Authority of Zimbabwe



Regional & National Regulatory Authorities

Asia - Pacific

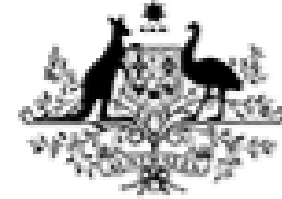
- ASIAN Harmonization Working Party (AHWP)
- Asia Pacific Economic Cooperation (APEC)
- Association of Southeast Asian Nations (ASEAN)
- Bangladesh: Directorate General of Drug Administration (DGDA)
- Brunei Darussalam: Ministry of Health
- China: China Food and Drug Administration
- Hong Kong: Drug Office, Department of Health
- India: Central Drugs Standard Control Organization (CDSCO)
- Indonesia: The National Agency of Drug and Food Control
- Republic of Korea: Ministry of Food and Drug Safety, Korea Food and Drug Administration
- Malaysia: National Pharmaceutical Control Bureau
- Mongolia: Ministry of Health
- Nepal: Department of Drug Administration
- Philippines: Department of Health, Philippine Food and Drug Administration
- Singapore: Health Sciences Authority (HSA), Health Products Regulation Group (HPRG)
- Sri Lanka: Ministry of Health
- Taiwan Food and Drug Administration (TFDA)
- Thailand: Food and Drug Administration
- Vietnam: Drug Administration of Vietnam



Regional & National Regulatory Authorities

Australia

- Australia New Zealand Therapeutic Product Agency (ANZTPA)
- Australia: Therapeutic Goods Administration (TGA)
- Australian Department of Health: Expert Review of Medicines and Medical Devices Regulation



Australian Government

Department of Health

New Zealand

- New Zealand: Medicines and Medical Devices Safety Authority



Regional & National Regulatory Authorities

Europe

- European Medicines Agency (EMA)
- European Heads of Medicines Agencies
- European Directorate for the Quality of Medicines & Healthcare
- European Commission: Medicinal products for human use
- Armenia: Scientific Centre of drug and medical technology expertise
- Austria: Austrian Agency for Health and Food Safety
- Azerbaijan: Azerbaijan Ministry of Health
- Belarus: Center for Examinations and Tests in Health Service
- Belgium: Federal Agency for Medicines and Health Products (FAMHP)
- Bulgaria: Bulgarian Drug Agency
- Croatia: Agency for Medicinal Products and Medical Devices of Croatia
- Czech Republic - State Institute for Drug Control
- Denmark: Danish Medicines Authority
- Estonia - State Agency of Medicines
- Finland - Finnish Medicines Agency
- France - French National Agency for the Safety of Medicine Health Products (ANSM)
- Germany: Federal Institute for Drugs and Medical Devices (BfArM)
- Greece: National Organization for Medicines
- Hungary: National Institute of Pharmacy and Nutrition
- Iceland: Icelandic Medicines Agency
- Ireland: Health Products Regulatory Authority (HPRA)
- Italy: Italian Medicines Agency
- Kazakhstan: National Center for Drug Expertise, Medical Devices and Medical Equipment



Regional & National Regulatory Authorities

Europe

- Latvia: State Agency of Medicines
- Liechtenstein: Office of Health/Department of Pharmaceuticals
- Lithuania: State Medicines Control Agency
- Luxembourg: Ministry of Health
- Malta: Medicines Authority
- Netherlands: Healthcare Inspectorate
- Netherlands: Medicines Evaluation Board
- Norway - The Norwegian Medicines Agency
- Poland: Chief Pharmaceutical Inspectorate
- Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
- Portugal: National Authority of Medicines and Health Products, IP (INFARMED)
- Romania: National Agency for Medicines Agency
- Russian Federation: Ministry of Public Health
- Slovakia: State Institute for Drug Control (SIDC)
- Slovenia: Agency for Medicinal Products and Medical Devices (ARSZMP)
- Spain: Spanish Agency of Medicines and Medical Devices (AEMPS)
- Sweden: Medical Products Agency (MPA)
- Tajikistan: Ministry of Health of the Republic of Tajikistan
- United Kingdom: Medicines and Healthcare Products Regulatory Agency (MHRA)



Medicines &
Healthcare products
Regulatory Agency

Regional & National Regulatory Authorities

North America

- Mercado Comun del Sur (MERCOSUR)
- Pan American Health Organization
- Pan American Network for Drug Regulatory Harmonization (PANDRH)
- Canada: Health Canada
- Mexico: Federal Commission for the Protection against Sanitary Risk (COFEPRIS)
- United States: Food and Drug Administration (FDA)



Central and South America

- Argentina: National Administration of Drugs, Food & Medical Technology
- Brazil: Health Surveillance Agency (ANVISA)
- Chile: Ministry of Health
- Colombia: National Institute of Food and Drug Monitoring (INVIMA)
- Costa Rica: Ministry of Health
- Cuba: Center for State Control of Drugs, Medical Devices
- Dominican Republic: Directorate General of Drugs and Pharmacies
- Honduras: Directorate General of Health Regulation
- Panama: Ministry of Health
- Peru: Ministry of Health
- Uruguay: Ministerio de Salud
- Venezuela: National Institute of Hygiene

Regional & National Regulatory Authorities

Middle East

- Jordan: Jordan Food and Drug Administration
- Israel: Ministry of Health
- Saudi Arabia: Saudi Food and Drug Authority
- United Arab Emirates: Ministry of Health
- Yemen: Supreme Commission for Drugs and Medical Appliances



UNITED ARAB EMIRATES
MINISTRY OF FINANCE

International Regulatory, Standards, and Harmonization Organizations

- ANDEAN Community
- International Coalition of Medicines Regulatory Authorities
- International Conference on Harmonisation (ICH)
- IPEC Federation
- International Generic Drug Regulators Programme
- International Medical Device Regulators Forum
- International Organization for Standardization (ISO)
- International Pharmaceutical Regulators Forum (IPRF)
- Organisation for Economic Co-operation and Development (OECD): Good Laboratory Practice (GLP)
- Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S)
- United Nations - Global Health
- World Health Organization (WHO)

**COMUNIDAD
ANDINA**

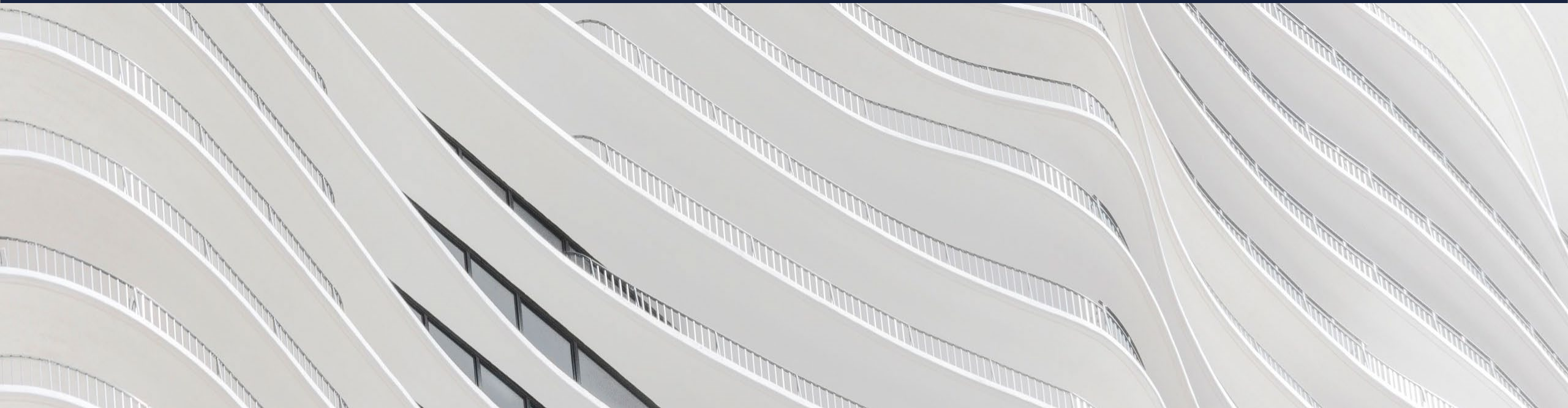


**World Health
Organization**



Brief Remarks by Anna Abram

Deputy Commissioner for Policy, Legislation, and
International Affairs, Office of the Commissioner



Today's Q & A Roadmap

Theme 1: COMPLIANCE	Theme 2: INNOVATION	Theme 3: EMERGING MARKETS
<p style="text-align: center;"><u>Topic A:</u></p> <p style="text-align: center;">Global Regulatory Partnerships and Collaboration</p>		
<p style="text-align: center;"><u>Topic B:</u></p> <p style="text-align: center;">Practical Advice for Global Businesses</p>		
<p style="text-align: center;"><u>Topic C:</u></p> <p style="text-align: center;">Trends to Watch</p>		

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COMPLIANCE

Topic A:

Global Regulatory Partnerships and Collaboration

Theme 2:
INNOVATION

Topic A:

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Theme 3:
EMERGING MARKETS

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Topic B:

Practical Advice for Global Businesses

Theme 2:
INNOVATION

Topic B:

Practical Advice for Global Businesses

Theme 3:
EMERGING MARKETS

Topic B:

Practical Advice for Global Businesses

Theme 1:
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Topic C:

Trends to Watch

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Topic C:

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Thank you