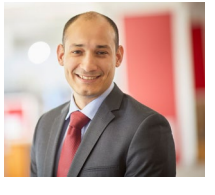
BRANDWOODCKC

Efficient Registration and Commercialization Strategies of Healthcare products for S. Korea, Philippines and Singapore

7th Global Access Program (GAP) Keynote
September 2020



Luis Jimenez

Who We Are

A premium regulatory, quality systems and commercialisation consultancy serving international health science innovators for more than 20 years.

We are headquartered in Sydney with international offices in Los Angeles, Wellington, Beijing, Taipei and Hong Kong.

Through our merger in 2019, Brandwood CKC brings together two of Australia's pre-eminent names in health science regulatory and technical consulting: **Brandwood Biomedical and Capital K Consulting.**

Brandwood CKC combines our complementary technical strengths and diversity with a shared commercial focus and global market view across all areas of therapeutics and diagnostics. Our multilingual team are positioned to deliver comprehensive support in major international markets.

Whether your market ambitions are local or global, we are with you every step of the journey.

What We Do

- Global Regulatory Strategy and Submissions
- Quality Management Systems
- In-house Regulatory Resourcing
- Due Diligence and Technical Assessment
- Biosimilar and Biotechnology Medicine Development
- Authorised Device Representation, Sponsorship and Distribution
- R&D Strategy
- Literature-Based Medicine Submissions
- Reimbursement: Strategy and Advice
- Post Market Compliance and Surveillance
- Reclassification and Rescheduling Strategy Submissions
- Regulatory and Administrative Appeals

Today's Speaker

Luis Jimenez

VP of Business Development
Brandwood CKC

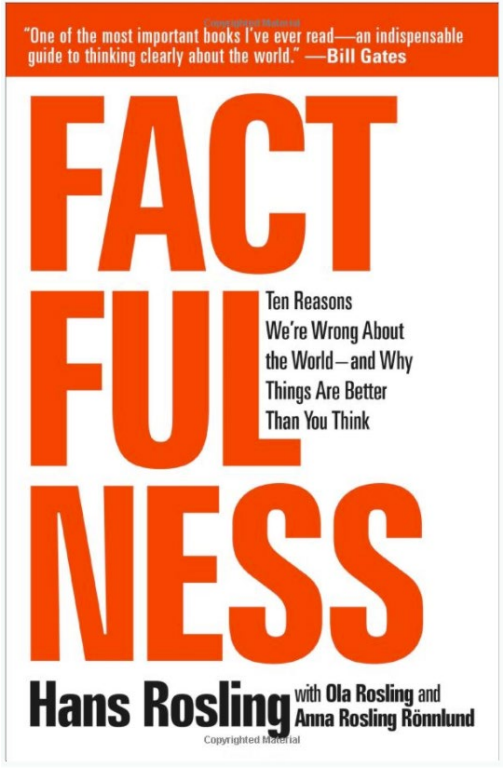
Luis Jimenez serves as the Vice President of Business Development for BrandwoodCKC and is the current President of OCRA (Orange County Regulatory Affairs). His experience includes operations, quality control in cGMP manufacturing, regulatory affairs for manufacturing, design engineering, technology transfer and project management within a start-up and large corporations such as Johnson & Johnson and Express Scripts.

Luis's background includes Chemical Engineering, Cum Laude with focuses on Computer Science and Economics, and an MBA with Academic Excellence. His trajectory in diverse health-related companies including building a class III medical device bio-tech company from the bottom-up provides him with hands-on experience solving the challenges of navigating regulatory approvals. Luis is passionate about the juncture between life sciences innovation, entrepreneurship, and regulatory frameworks.

Introduction

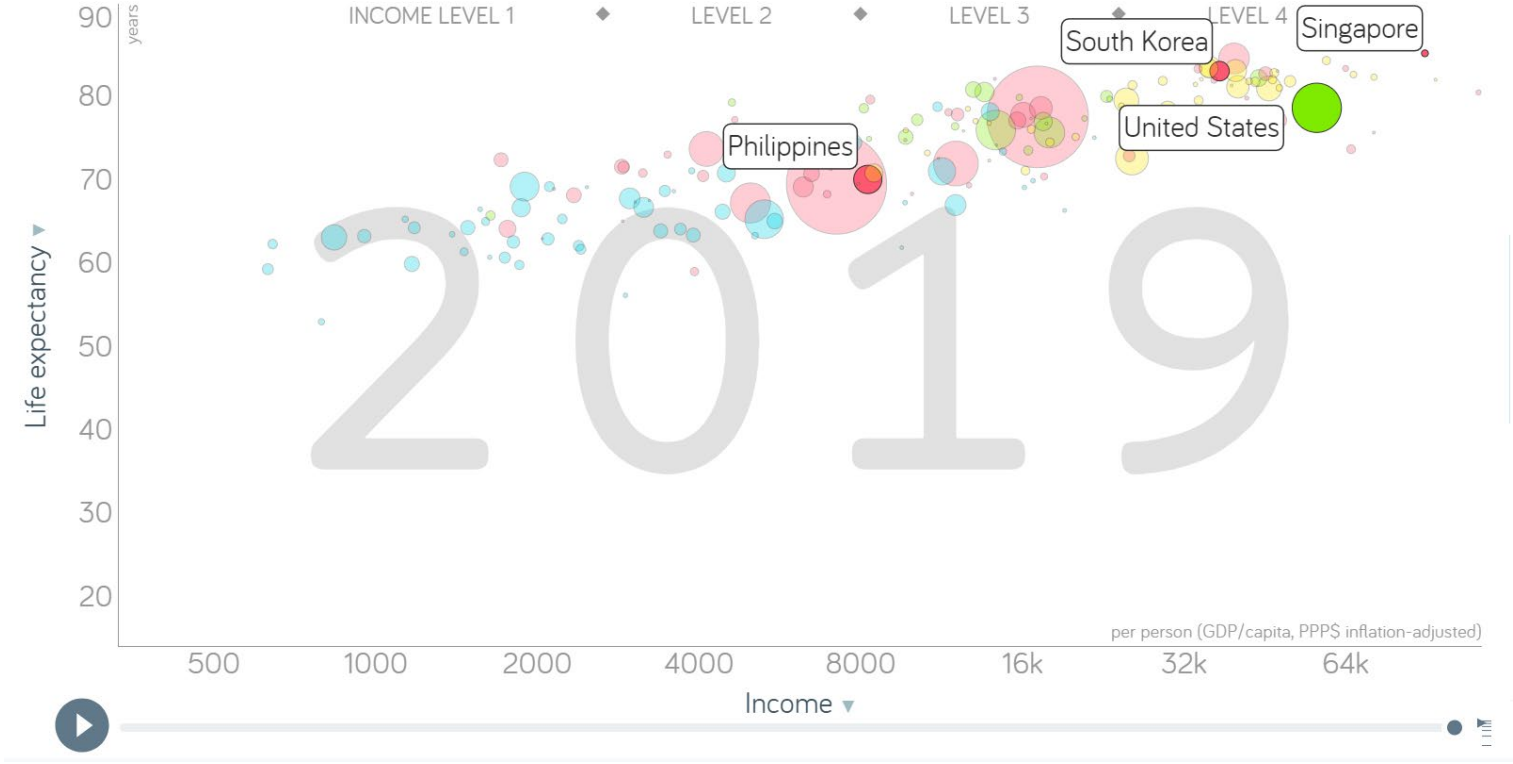
Edwards Lifesciences CEO Mike Mussallem

Advice



Global Mindset

Telling a Story through Graphs



Bubble Size= Population
Y axis= Life Expectancy
X axis= GDP/Capita

Source: The Gap Minder Project

Economics (2019)

	Singapore	S. Korea	Philipines	United States
Population (million)	5.7	51.8	108	327
GDP per capita (USD)	65,390	31,731	3,480	62,869
GDP (USD bn)	371	1,646	377	20,580
Exports (USD billion)	439	542	70.9	1,643
Imports (USD billion)	342	503	112	2,497

https://www.focus-economics.com/countries

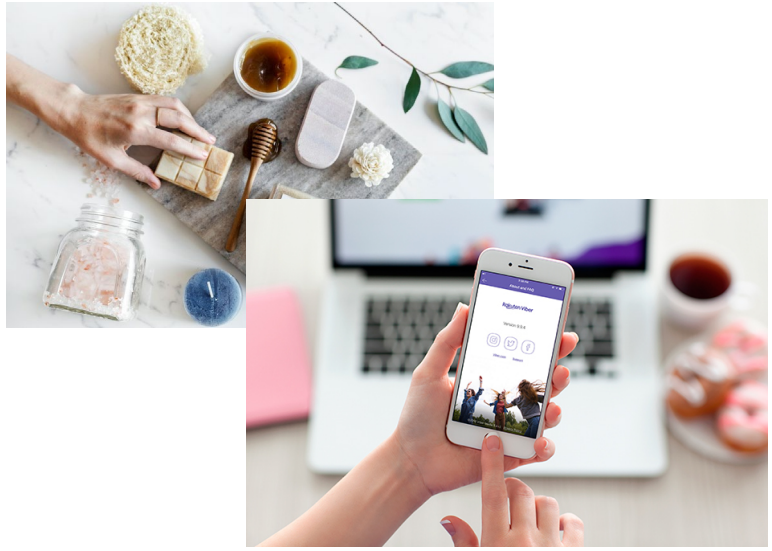
Do you have a regulated Product?

Medical Devices & IVD

- Surgical Instruments
- Software as medical device
- Implantable devices

Wellness Apps and Health

- Foods
- Apps
- Cosmetics



Advice For Non-Regulated Products

Leverage Digital Economy
- Leverage Strengths
- Leverage Local Resources/Opportunities
- Mitigate Risk

Establish local support:
- Digital Marketing Campaigns
- Local Users and Consumer Groups
- Distributors (Regional vs. National)
- Franchising?

Conduct SWOT Analysis:
- Less Competition?
- Intellectual Property and Legal Framework?
- Import, Tariffs, and Logistics

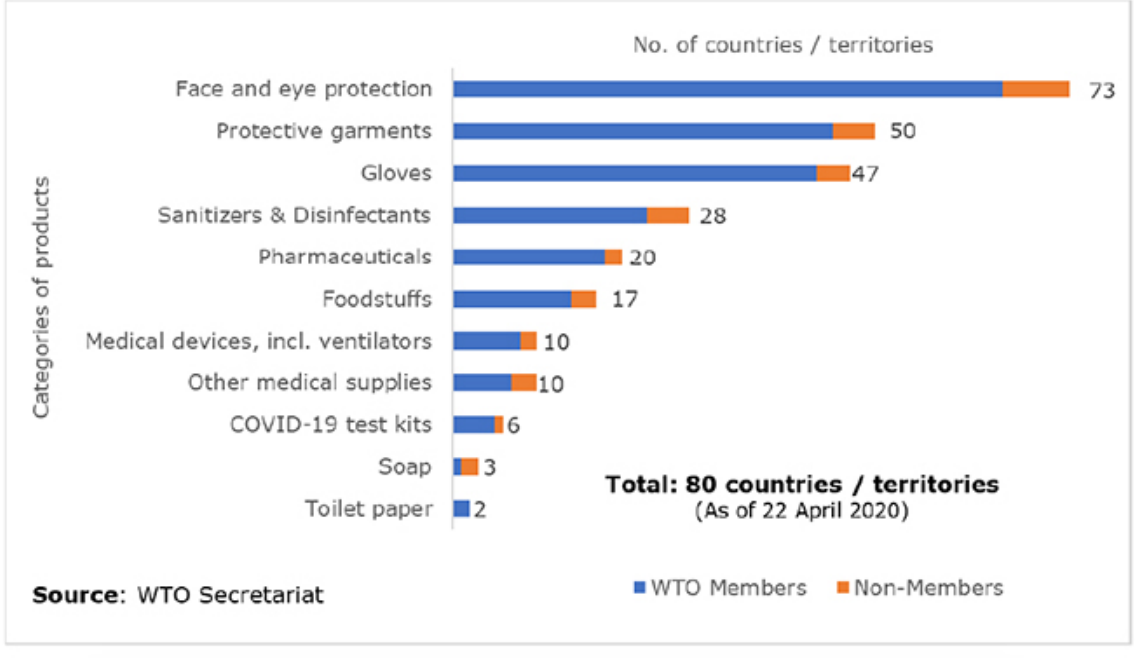
Internet, Modern Source of Global Connectivity

Jumping into the world of Medical Devices and Diagnostics…

COVID Update and EUAs

Efficient Regulatory and
Commercialization Processes
FDA-Singapore-Philippines-S. Korea

COVID Update - Export Bans



Global Export Restrictions In Response To COVID-19

Countries that have imposed temporary export restrictions on products due to COVID-19*

* Products affected include personal protection equipment, pharmaceutical products, hand sanitizer and food.
** Germany has lifted export bans on medical equipment.
Source: International Trade Centre

statista

COVID-19 Emergency Use Authorizations

Criteria for EUA

- Agent (Coronavirus) specified in the declaration of emergency can cause a serious or life-threatening disease or condition.
- Reasonable scientific belief that the product is effective.
- The known and potential benefits outweigh the known and potential risks.
- There is no adequate, approved, and available alternative

COVID-19 IVD Test Kits

- Molecular & Serology (208)
- Authorized for Use in CLIA labs of varying capabilities (35).

PPE (20), Ventilators and Others (26)

- Masks
- Respirators
- Sterilizers
- Diaphragmatic pacing
- ECMO
- Infusion Pumps

(Data as at 9 September 2020)

Date EUA First Issued	Entity	Diagnostic (Most Recent Letter of Authorization) (PDF)	Technology[3]	Authorized Setting(s)[1]	Authorization Labeling[2] (PDF)
09/01/2020	OPTOLANE Technologies, Inc.	Kaira 2019-nCoV Detection Kit (141KB)	Molecular	H	HCP (153KB) Patients (141KB) IFU (3.56MB)
09/01/2020	Detectachem Inc.	MobileDetect Bio BCC19 (MD-Bio BCC19) Test Kit (139KB)	Molecular	H	HCP (151KB) Patients (138KB) IFU (801KB)
08/31/2020	BayCare Laboratories, LLC	BayCare SARS-CoV-2 RT PCR Assay (289KB)	Molecular	H	HCP (86KB) Patients (92KB) EUA Summary (444KB)
08/31/2020	Mammoth Biosciences, Inc.	SARS-CoV-2 DETECTR Reagent Kit (313KB)	Molecular	H	HCP (141KB) Patients (129KB) IFU (461KB)
08/31/2020	MiraDx	MiraDx SARS-CoV-2 RT-PCR assay (294KB)	Molecular, Home Collection, Screening, Saliva	H	HCP (105KB) Patients (95KB) EUA Summary (438KB)
08/31/2020	T2 Biosystems, Inc.	T2SARS-CoV-2 Panel (314KB)	Molecular	H	HCP (137KB) Patients (124KB) IFU (1.26MB)
08/31/2020	University of Arizona Genetics Core for Clinical Services	COVID-19 ELISA pan-Ig Antibody Test (339KB)	Serology Total Antibody, ELISA	H	HCP (149KB) Recipients (132KB) EUA Summary (302KB)
08/31/2020	TBG Biotechnology Corp.	TBG SARS-CoV-2 IgG / IgM Rapid Test Kit (332KB)	Serology IgM and IgG, Lateral Flow	H, M	HCP (146KB) Recipients (133KB) IFU (548KB)
08/31/2020	Color Genomics, Inc.	Color COVID-19 Test Unmonitored Collection Kit (136KB)	Home Collection Kit		EUA Summary (133KB) IFU (103KB)

Source: FDA's Approved EUAs

EUA – What's waived, and what's not

FDA waivers under EUA

- General controls
- Registration and listing
- QSR
- UDI
- 510(k) During EUA only

NOT waiving

- Adverse event reporting
- Recalls
- Claims of "FDA Approved"

Remember it's an Emergency Use **AUTHORIZATION**, not an **APPROVAL**

US Classification and Requirements

Class I	General Controls: GMP, Labelling etc. No premarket review
Class II	Special Controls: Device specific guidances and standards Premarket Notification and 510(k) clearance
Class III	Full Safety and Efficacy review including clinical data Premarket Approval (PMA)

FDA Requirements

Premarket Product Review	PMA – New devices/technology
	510(k) "substantial equivalence"
	***De novo* classification petition** (no predicate or classification but device risk does not justify PMA)
	HDE – Humanitarian Device Exemptions (Safety only, <8,000 patients/year, Ethics oversight)
Quality Systems	GMP Quality Systems Audit (Factory Inspections)
	FDA uses 21 CFR 820 *Quality Systems Regulations* Plan is to Convert to ISO 13485 (but delayed to 2021)
	Audits are prerequisite for PMA but are *after* first supply for 510(k)/De Novo Class II devices

Target Country Regulatory Bodies

Singapore

S. Korea

Philippines

Global Harmonization

GHTF

Founding Members in 1993:
Australia, Canada, Japan, the European Union, and the United States of America.

2012 GHTF Was Converted to IMDRF

IMDRF International Medical Device Regulators Forum

The current members are:
Australia, Brazil, Canada, China, Europe, Japan, Russia, Singapore, South Korea, and the United States of America.

Key Framework Comparison (premarket)

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GHTF

- Rules-based device classification
- Regulatory Intervention based on Class
- Essential Requirements of S&E
- Standards as means of compliance
- Technical File construction
- Appointment of Local Representative

- Product Code-based classification
- Regulatory Intervention based on Class
- Clinical experience or predication as means of compliance
- Appointment of Local Representative

All jurisdictions within the GHTF Model have similar processes, but there are some country specific considerations…

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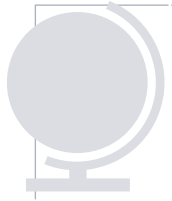
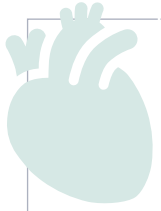


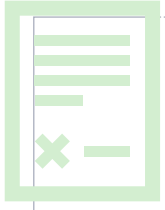
Essential Principles Checklist

- GHTF-based checklists
- However need separate reports
- Wording of the Essential Principles differs between jurisdictions (e.g. EU/AU/Canada)



Classification

- Most classes will align
- Some devices will be different (e.g. Central Circulatory System, Disinfectors, Contacting CNS)



Declaration of Conformity

- When required (e.g. EU and AU), they must meet specific format for each jurisdiction

Clinical Evaluation Report

- AU must be signed by a clinician
- EU / AU have special requirements for certain high risk devices (E.g. Total Joints, Electrical pulse)

Other

- Patient Leaflets and Implant Cards
- Unique Product Identifier (UPI)
- Post-Market Reports
- Unique Device Identifier (UDI)

What is the Technical File (STED)?

Objective evidence that your device meets the Regulatory requirements

- Scope (Specific Device(s))
- Admin Info
- Declarations of Conformity and Regulatory Classification
- Overview product description
- Specifications
- Product documentation, labels, manuals
- Risk Analysis Report
- Summary of Testing Reports / Certificates
- Essential requirements check list
- Clinical Evaluation Report
- Overall manufacturing and inspection plan
- Product history

IMDRF International Medical Device Regulators Forum

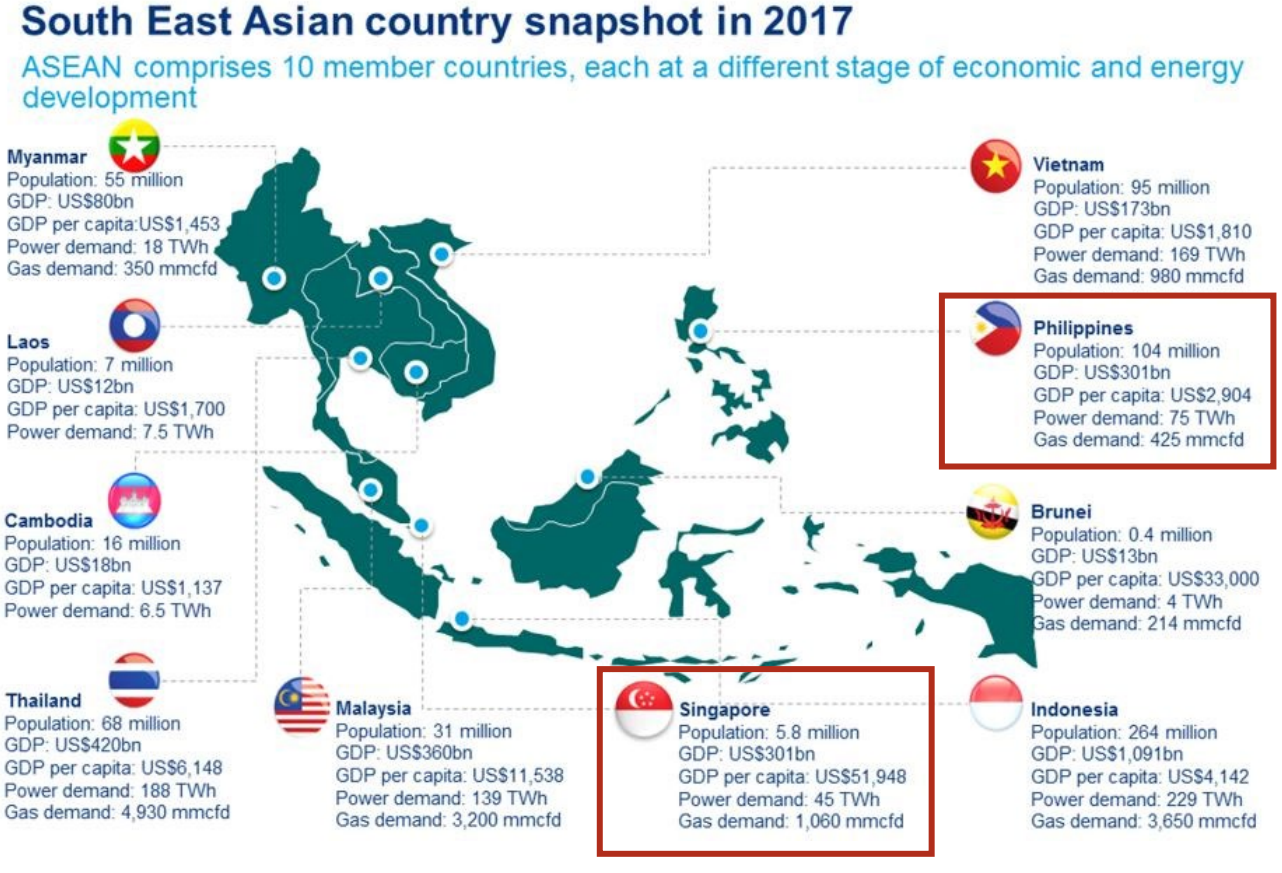
What is it?

- **Collection of technical documents**
  - **Description of device design, use**
  - **Risk Management**
  - **Testing and Clinical evaluation**
  - **Manufacturing**

What is it for?

- **Evidence that the device complies with regulations**
  - **Safe and Efficacious**
  - **Performs as intended**
  - **Manufactured under appropriate controls**

(ASEAN) Association of Southeast Asian Nations



ASEAN is not a union , but political and economic alliance (each country has its own regulation & policy)

Singapore:

- Highest GDP Per Capital
- Longest Life Expectancy

Philippines:

- Slated to be 10th largest economy
- Largest by population 110M

ASSOCIATION OF SOUTHEAST ASIAN NATIONS

Market Assess Roadmap: Philippines and Singapore

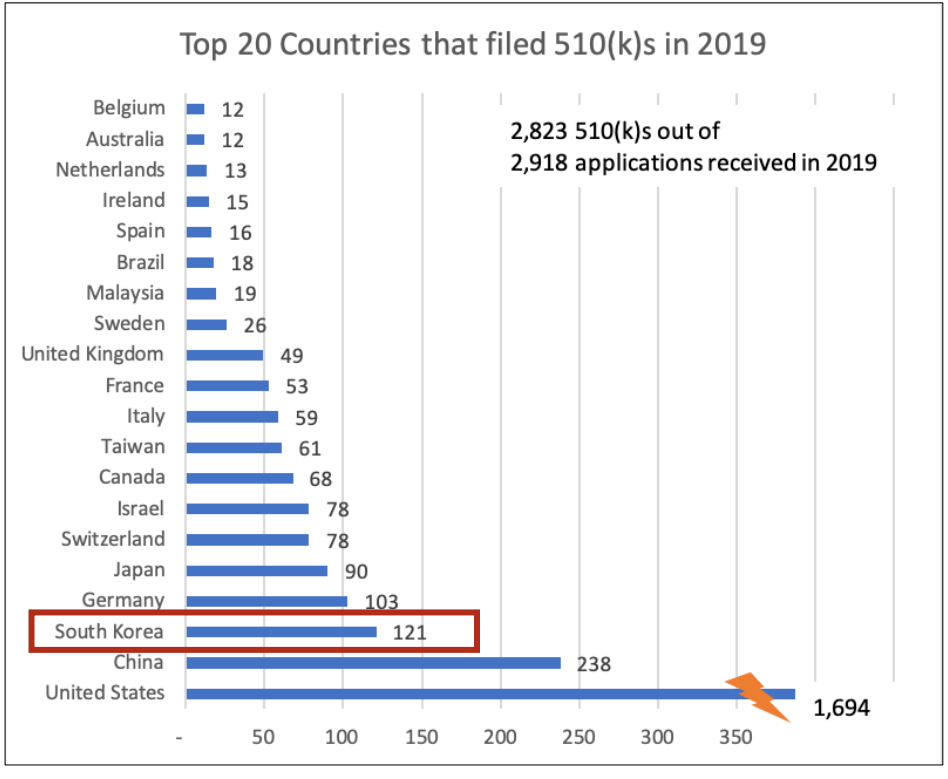
Country	Device License Holder (LH)	Importer	Distributor
Philippines 	• Own entity • Distributor • 3rd party	• Must be LH	• Any entity appointed by LH with license to Operate (LTO) for MD
Singapore 	• Own entity • Importer/Distributor • 3rd party	• Any entity with GDPMD or ISO 13485 & registered with HSA as Importer • appointed by LH	• Any entity with GDPMD or ISO 13485 & registered with HSA as Wholesaler • appointed by LH

GDPMD=Good distribution Practices for Medical Devices

S. Korean Regulatory Body and Market

- Used to be like FDA but is migrating to EU (GTHF/IMDRF) Framework
- The **Ministry of Food and Drug Safety (MFDS)**, formerly known as the Korea Food & Drug Administration (KFDA), oversees the safety and efficacy of drugs and medical devices in Korea.
- The MFDS is divided into five bureaus. The **Pharmaceutical Safety Bureau** and the **Medical Device Safety Bureau** are the two divisions holding primary responsibility for pharmaceutical and medical device regulations.

KOREA
MINISTRY OF FOOD AND DRUG SAFETY



Source: Brandwood CKC Analysis of 2019 US 510K's

S Korea
Approval Pathways and Data Requirements

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➢ MFDS offers different approval pathways depending on risk class:

- Class I devices require only an online Notification (with automatic approval).
- Class II devices require application for a General Technical Review which requires submission of laboratory safety data.
- Class III and IV devices require application for a Safety and Efficacy Review which adds a review of Clinical Evaluation data on top of the General Technical Review.

A successful MFDS review results in issue of a Notification of Conformity. The manufacturer may then apply for a certificate of product approval.

There exists a parallel pathway in which the Application for Technical Review and for certificate of product approval may be applied for at the same time and both certificates are issued at the satisfactory conclusion of the technical review.

➢ Type Testing

➢ Clinical Data

Wrapping it up

Regulatory frameworks are working to converge

Setting the foundation for Quality Systems and Technical Files is the most efficient way to obtain regulatory approvals

Singapore, S Korea and Philippines generally following the GHTF classification framework and IMDRF approval process.

One approval fits all, not yet, but we are moving in that direction!

Commercialization should consider new ways of doing business, consider telemedicine, and local groups

Emerging markets constitute a great opportunity

GAP Business Connections
Send your business profile

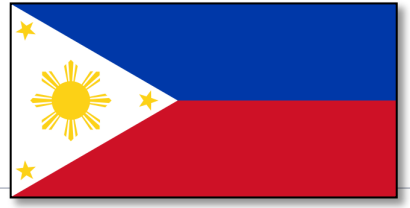
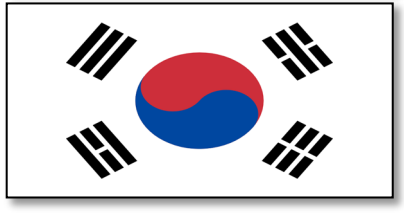
Be included in the Business Director by sending:

- Name
- Company
- Website
- Business Details (Max 50 words) (e.g. Interest country, category or type of produt/service)

To: cgm@csusb.edu

Incluede a one-minute video product/service pitch on your product or service to be potentially showcased in the next country-focused event.

Stay Connected with GAP!

	Country	Date	Focus
Philippines		**Oct. 8 l 5:30 - 7 p.m.**	GAP focus on Fashion and beauty products and retail services in the Philippines
S Korea		**Nov. 19 l 5:30 - 7 p.m.**	GAP focus on agriculture, food, and beverage products and services/business in South Korea, Singapore, & the Philippines
Singapore		**Feb. 12 l 5:30 - 7 p.m.**	GAP focus on Property development and remodeling services in Singapore

Key References:

Philippines FDA:
https://www.fda.gov.ph/

Singapore Health Science Authority:
https://www.hsa.gov.sg/

Korea KMDFA:
https://www.mfds.go.kr/eng/index.do

World Economic Data:

https://ourworldindata.org/

https://www.healthsystemtracker.org

Asean MDD:
https://asean.org/storage/2016/06/22.-September-2015-ASEAN-Medical-Device-Directive.pdf

GHTF Classification Rules:
http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n15-2006-guidance-classification-060627.pdf

Key Resources

Consulate General of the Republic of Korea in Los Angeles
consul-la@mofa.go.kr / http://overseas.mofa.go.kr/us-losangeles-en/index.do

Korean American Chamber of Commerce of Orange County
info@kaccoc.com / http://www.kaccoc.org
serves as the bridge between Korean Business, main stream business, local government, neighborhood minority business association, and the general business community in Orange County.

Philippine Consulate General, Los Angeles, California
LosAngeles@dti.gov.ph / losangeles@philippinetrade.org
https://www.philippineconsulatela.org/
https://www.philippineconsulatela.org/other-services/for-doing-business-in-the-philippines
Doing business and investment in the Philippines

Planet63, Ferdinand B. Soriano
Info@planet63.com / https://planet63.com/
Philippine Product Procurement & Logistics Management Company. Brings products to US

GRIIT, Sarita D. Jackson, Ph.D., President and CEO
sarita@griit.org / www.griit.org
1) customized global market research, 2) strategy design, and 3) connection with network of overseas trusted advisors (e.g., finance, compliance, tax, digital marketing)

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South Korea & Australia/Healthtech, Wearables, AI, ICT, SaaS/Investor, Channel Partnerships)

U.S Small Business Administration, Orange County/Inland Empire District Office
Paul I Smith, Economic Development Specialist, District International Trade Officer
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Small Business Loans and Commercialization Support

Q&A

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Webinars
We hold monthly free webinars on current topical issues in medical devices regulation and market access. These can be viewed on demand via **brandwoodckc.com/videos** at any time.

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