



Department for
International Trade

Taiwan: Healthcare Market Overview

2022





Taiwan Overview

- Strategic location in Asia Pacific region: ~3h flight to major APAC cities: Beijing, Hong Kong, Seoul, Shanghai, Singapore, Tokyo.
- Suitable environment for North East Asia market entry
- Mature healthcare system with high coverage of public health insurance and high density of primary healthcare across the island.
- 480 hospitals and over 10,000 clinics all over the island with sufficient medical capacity





Taiwan Overview

- Population: 23.9 million (2022)
 - GDP per capita: \$33,775
 - World's 21st largest economy
 - 8th largest economy in Asia
-
- **Economic growth:** Taiwan's economy grew 6.28% in 2021, continuing Taiwan's strong economic performance throughout the pandemic
 - Growth driven by surging global demand for Taiwan's tech products, with exports to both China and the US booming





Taiwan Healthcare Overview

- Top healthcare systems in the world
- Health authorities
 - Ministry of Health and Welfare (MOHW)
 - National Health Insurance Authority (NHIA)
 - Taiwan Food and Drug Administration (TFDA)
- National Health Insurance (NHI) covers 99.8% of Taiwan citizens and foreign residents.
- 93% of Taiwan's healthcare delivery system is delivered by the private sector.



衛生福利部食品藥物管理署
Food and Drug Administration



Taiwan's Industrial Strategy

5 + 2 Innovation Industries Plan

Asia Silicon
Valley

Biomedicine

Green Energy
and Smart
Machinery

New
Agriculture

Circular
Economy

Six Core Strategic Industries

Digital
Technology

Cyber Security

Medical
Technology and
Precision Health

Green and
Renewable
Energy

National
Defence and
Strategic
Industries

Strategic
Stockpile
Industries





Taiwan Demographics Overview

High Aging Population- The Council for Economic Planning and Development (CEPD) has estimated that the percentage of people 65 years or older will be over **20% in 2025**, which means Taiwan will soon become a "super aged society". **16.07%** of the Taiwan population being elderly since 2020.

Low Birth rate- 1.07 births per woman, far below the 2.1 needed to maintain its population.

Total health spend annually- The percentage of GDP spent on healthcare is currently **6.2%** in Taiwan in contrast to 8.3% in the UK, 10.7% in Germany or 11.6% in Switzerland.



Taiwan's COVID handling

- Government's 2-pronged approach: - keep the virus out
- prevent and control community spread
- Information transparency:
- Response measures: strict travel advisories and entry protocols tiered by the risk levels of countries, 14-day home quarantine protocols, contact tracing, mask wearing, social distancing and hand hygiene.
- Digital solutions: harnessing the national digital power
 - NHI MediCloud system
 - My Health Bank service
 - QR code registration system
- Vaccine roll out: Astrazeneca > Moderna > Medigen > BNT
- **Adult vaccine program Outcome:**
 - **86.5%** of the Taiwanese population have been fully vaccinated to date
 - **72%** had received booster jabs
- **Children/Toddler vaccine program:** Pfizer or Moderna COVID vaccine available
 - Children vaccines (5Y-11Y): **75%** coverage
 - Toddler vaccines (6m – 5Y): Started in July



- **Sophisticated medical device**
- **Pharmaceutical Industry**
- **Digital Healthcare**
 - Tele-Medicine
 - Health Information Systems (HIS)
 - Big Data & Artificial Intelligence Diagnosis
- **Advanced Medicine**
 - Precision Medicine
 - Cell/Gene Therapy





Market Entry

- Language: Mandarin, Taiwanese, English
- Cultural Customs
- Competitive and price sensitive environment
- National Health Insurance Administration (NHIA) dominant healthcare pricing and supply, specifically for pharmaceuticals
- Business networks: Local partners to act as agents or distributors





Pharmaceutical and Medical Device Consulting

MEDICA 2022
Company Presentation



Clare Chang 張人尹

Senior Consultant
ERM Taiwan
永豐環境管理顧問股份有限公司

At ERM, sustainability is our business.

As the *largest global pure-play sustainability consultancy*, we partner with the world's leading organizations, creating innovative solutions to sustainability challenges and unlocking commercial opportunities that meet the needs of today while preserving opportunity for future generations.

Together with the world's leading organizations, we are shaping a more sustainable future.



Our diverse team of world-class experts supports clients across the breadth of their organizations to operationalize sustainability, underpinned by our deep technical expertise in addressing their environmental, health, safety, risk and social issues. We call this capability our “**boots to boardroom**” approach for its comprehensive service model that allows ERM to develop strategic and technical solutions that advance objectives on the ground or at the executive level.

Work with **over 50%** of
the
Global **Fortune 500**
companies

Projects in
more than 170
countries

7500+ Experts
in **40 countries**
globally

50-year
History



ERM Services:

How We Face the Market



Corporate Sustainability and Climate Change

Partnering with leading organizations to address complex sustainability challenges, from climate change risk to human rights, by clarifying strategic direction, designing corporate programs, and enhancing transparency and the robustness of public disclosures.



Operational Performance

Helping global organizations mitigate risk, grow revenues, and manage costs by optimizing and transforming EHS functions to connect deeply to operations, integrating data-driven approaches, and delivering managed services.



Safety Services

Encouraging clients to move beyond traditional compliance and corrective programs so that they can maximize the return on their investments in safety - to safeguard lives, protect assets and strengthen reputation.



Mergers & Acquisitions

Helping clients mitigate environmental, social and governance (ESG) and sustainability risks to maximize and protect value throughout their investment lifecycle by delivering insight-driven, commercially-focused due diligence.



EHS Management and Compliance

Working with every level in the organization to define, design, and deploy programs that achieve and sustain compliance, effectively manage EHS issues, and also control operational costs and reduce risks.



Digital Services

Helping business leaders achieve a step-change in EHS and sustainability performance through tech-enabled innovation. We deliver these business outcomes at pace and scale through the integration of our global network, exceptional subject matter expertise and deep digital capabilities.



Capital Project Delivery

Helping clients keep capital projects on schedule and on budget by mitigating environmental, safety, and social risks from conception to final investment decision, through operational handover and ongoing management.



Liability Portfolio Management and Remediation

Managing risks through strategic approaches, digital applications and best-fit technical methods that identify, assess and manage environmental liabilities. Actively engage with clients to understand and respond to their specific and evolving needs and obligations through an end-to-end integration of site investigation, remediation, decommissioning and retirement.



Product Stewardship

Helping clients bring products to market safely, sustainably, and in compliance with global regulations, in a way that also meets their business goals and satisfies key stakeholders.

Product Stewardship

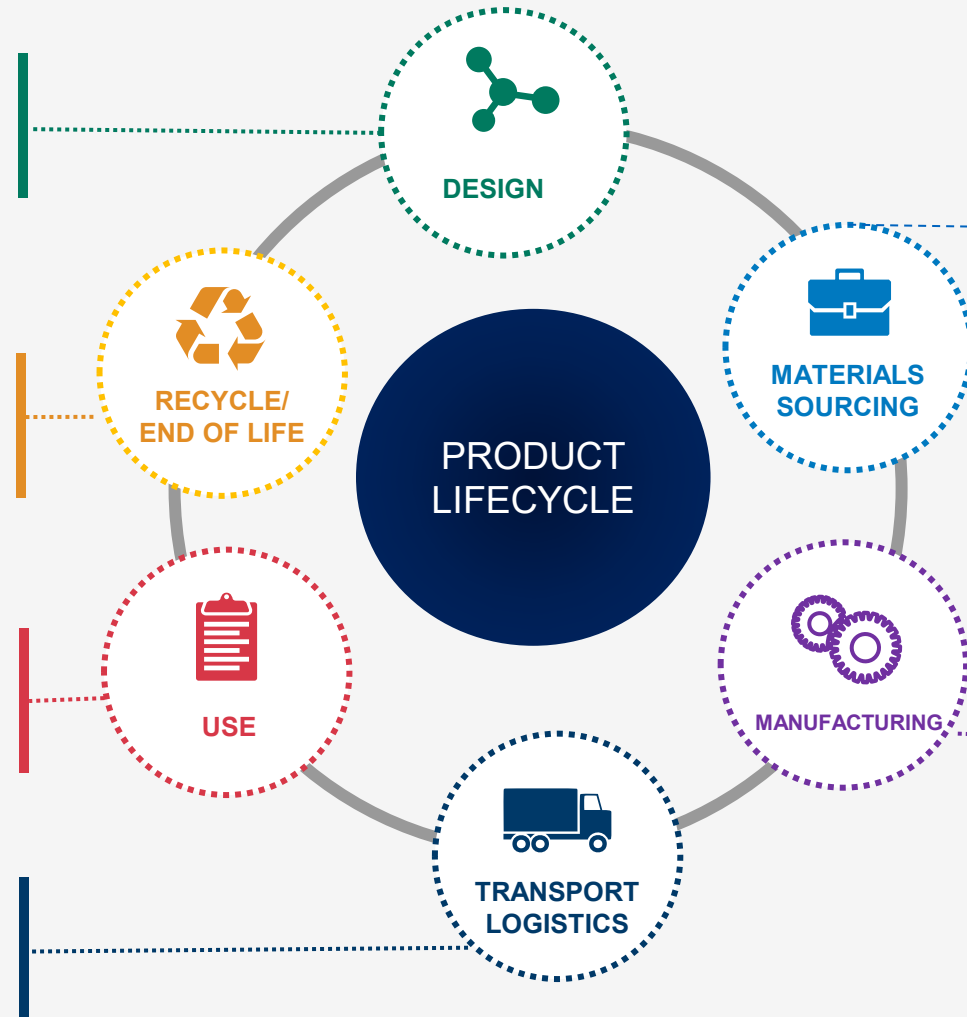


- Design for environment
- Life cycle assessments (LCA)
- Social life cycle assessment (sLCA)
- Materials substitution
- Social & environmental value analyses
- Carbon and water footprints
- eFate

- Product takeback
- Materials recovery
- Waste
- Field monitoring

- LCA validation
- sLCA validation
- Hazard communication (GHS)
- SDS
- Classification and labelling
- Technical advocacy

- Sustainable logistics
- Auditing
- Dangerous goods
- Permitting (storage)
- Customs clearance support



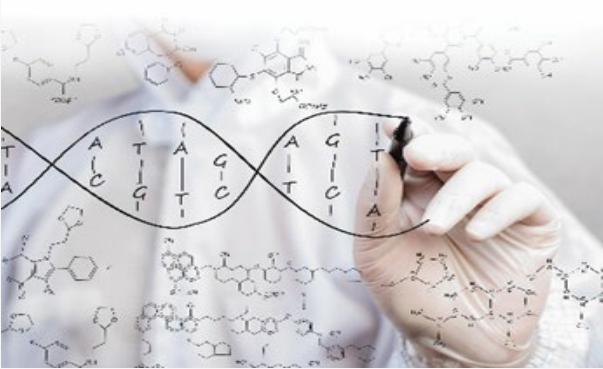
- Supply chain risk and materiality assessment
- Auditing
- Product compliance support
- (WEEE, ROHS, Conflict minerals, SVHC, POP, food contact, packaging, pharmaceutical and medical device)
- Marketability check
- Dangerous goods classification

- Transaction services
- Permitting
- Auditing
- Substance registration (agchem biocide, chemicals)
- Hazard communication
- Safety data sheet authoring and labelling
- Packaging
- Scientific support for exposure and risk assessment
- Product notification/authorization
- Study monitoring
- Data brokerage sharing
- Consortia management and lead registrant support
- Only representative and 3rd party representative

Product Stewardship

Pharmaceutical and Medical
Device Regulatory Consulting
Services in Taiwan

Pharmaceutical Industry in Taiwan



Cellular Therapy, Gene Therapy, Regenerative medicine

- Due to the rapid development of medical technology
- Global medical trend



Biologics

- Newly growth category of pharmaceutical products in Taiwan



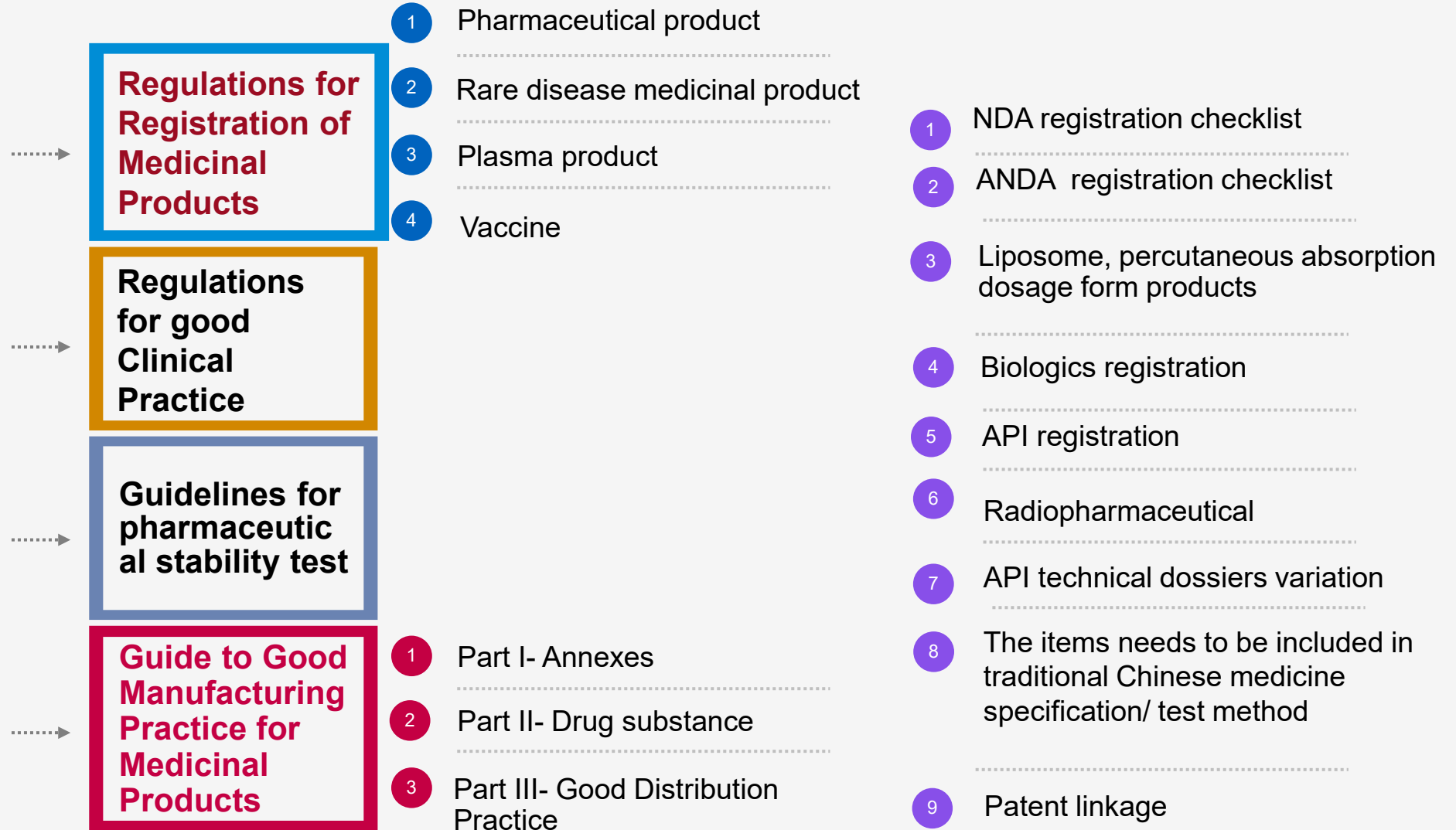
Digital Health

- Due to Covid-19 situation
- Global medical trend

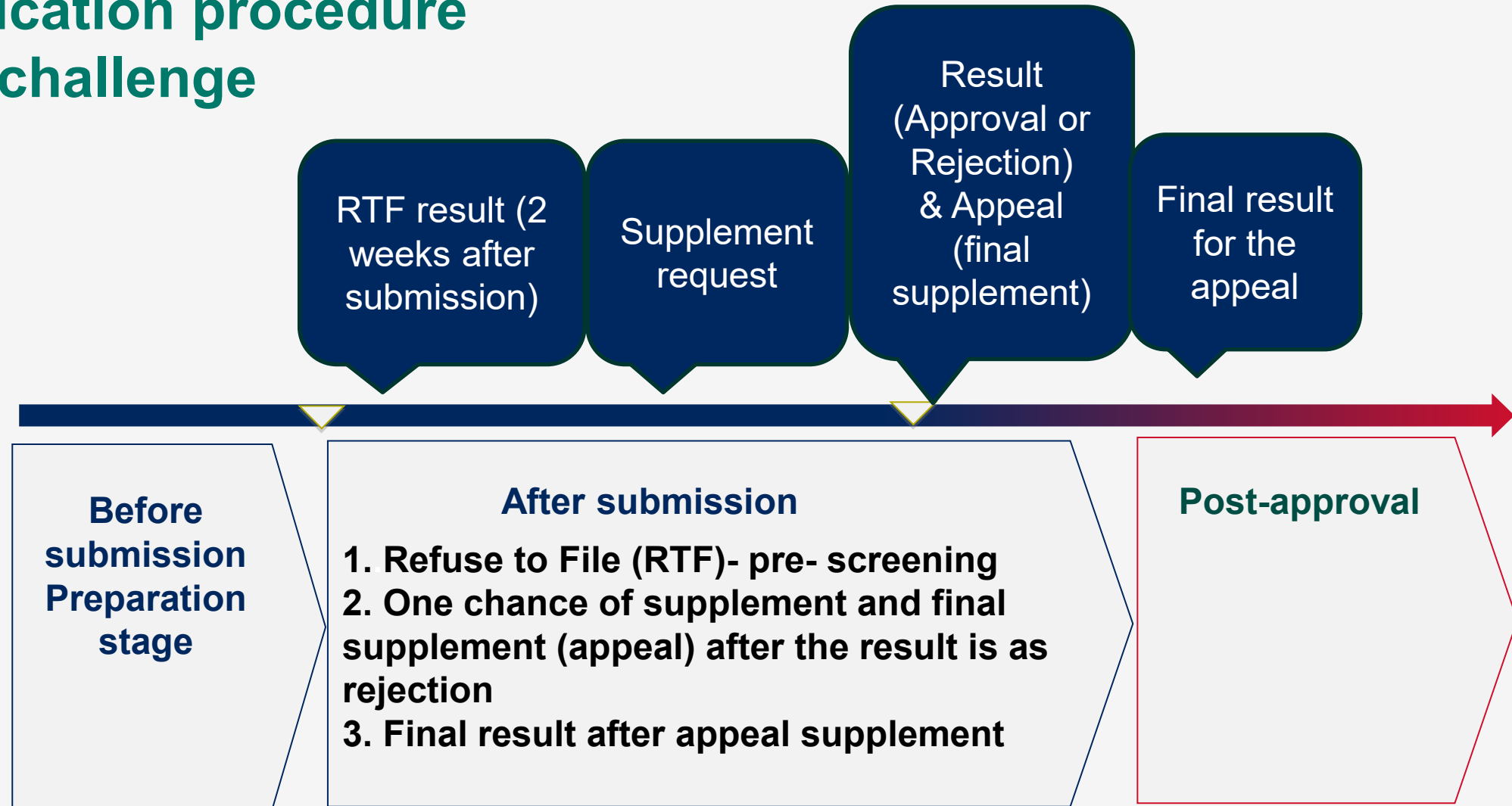
Regulation overview Pharmaceutical



**Pharmaceutical
Affairs Act
(amended 2018)
and Enforcement
Rules**



Application procedure with challenge



Medical devices market in Taiwan



- **The Government aims to grow biotechnology industry in Taiwan**, promoting the adaptation of digital and novel medical devices across healthcare sector.
- **COVID-19 pandemic creates the demand** for medical device materials such as face masks, sanitization products, and rapid test kits, which boosts growth and creates more business opportunities.

Medical devices market in Taiwan

USD

3.3 Bn

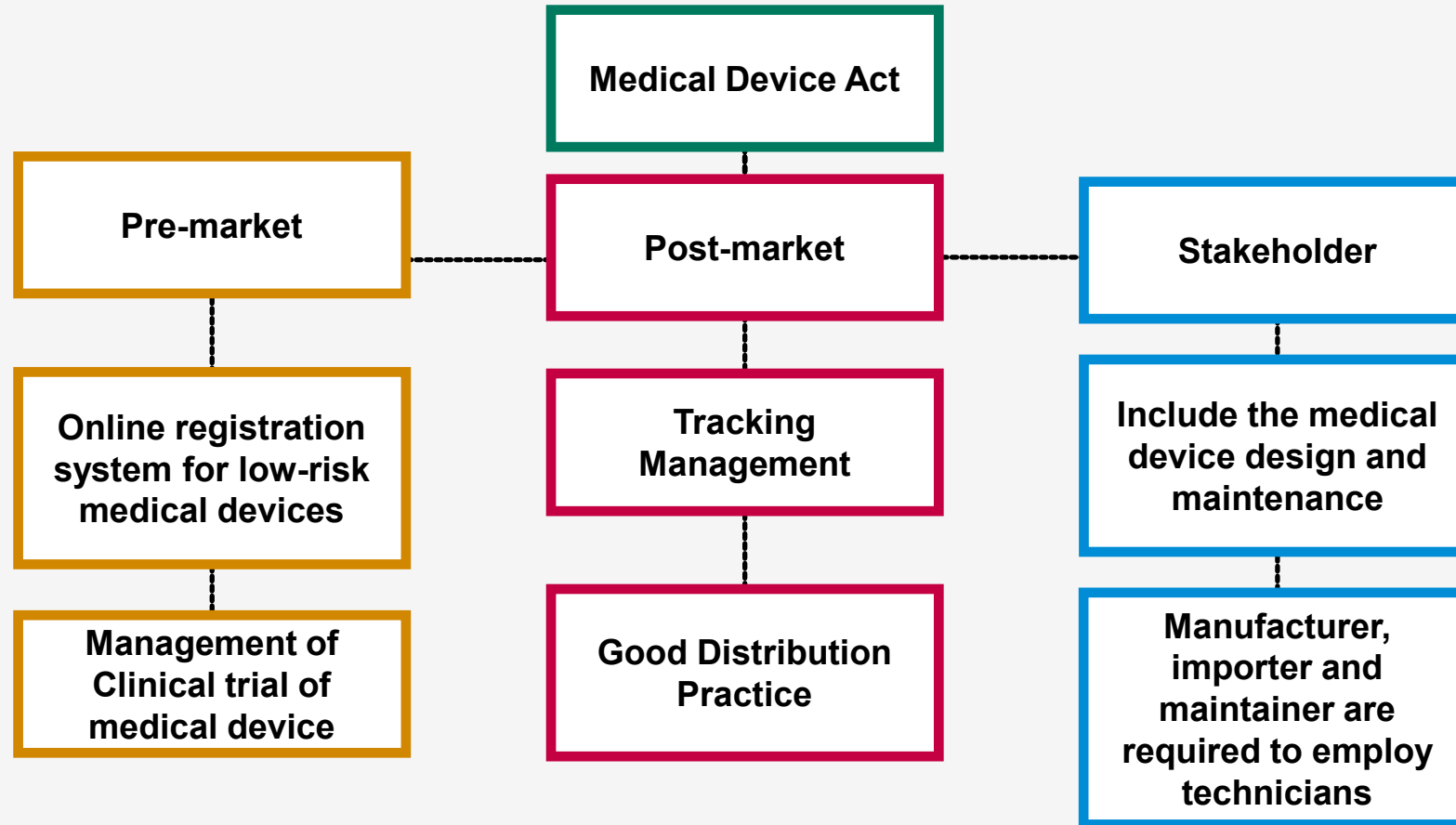
Average
Annual Growth

8.3%

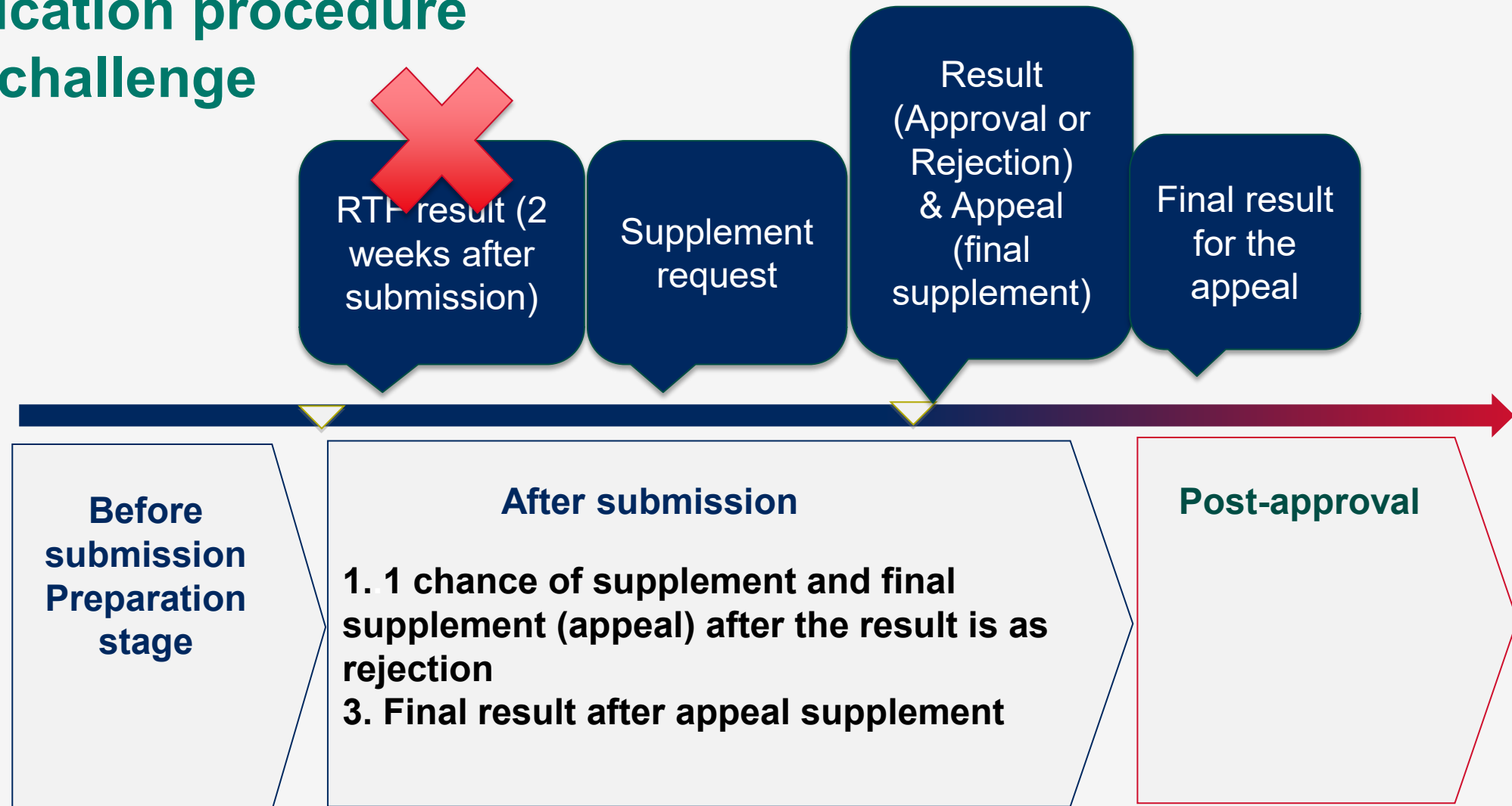
- In 2020, the total production value reached a record high – **of 3.3 billion USD, average annual growth of 8.3% in the past ten years.**
- The Medical Device Act was implemented in 2021, separated from the Pharmaceutical Affairs Act, and focuses on the medical device product lifecycle framework which follows the global trend - **creating a more suitable environment for medical device development than ever.**

*** From the newsletter of department of statistic**

What Is New to the Medical Device Act 2021?



Application procedure with challenge



Our Value & Strength

We are the pure player in pharmaceutical consultancy with strong regulatory background and solid technical knowledge.

We have strong engagement experience with government and familiar with the structures of queries raised by reviewer.

We have partnership with creditable laboratory/ Contract Research organization (CRO) and well-known law firms in Taiwan for comprehensive support.

We are a global consultancy with support from experts all around the world.

ERM TW Healthcare PS services ERM



**Regulation
Consultation**

Regulation training

**Product pre-market
Assessment**

**Packaging insert/
labelling review**

**Special permit
Import application**

**Hospital listing Issue
consultation**

**Pharmaceutical
product Registration**

**API DMF
Registration**

**PMF/ PICS GMP
Application**

**Product patent
Consultation**

**Medical device
product Registration**

**Medical device
class identification**

**QSD/ QMS
Application**

Food registration

**Cosmetic product
Information File (PIF)
service**

**Cosmetic product
ingredients
assessment and
label review**

Our experience in pharmaceutical products registration



New-drug registration (NCE, New route of administration, New indication, New combination, New dosage form, New dosage, New strength)



Biosimilar products

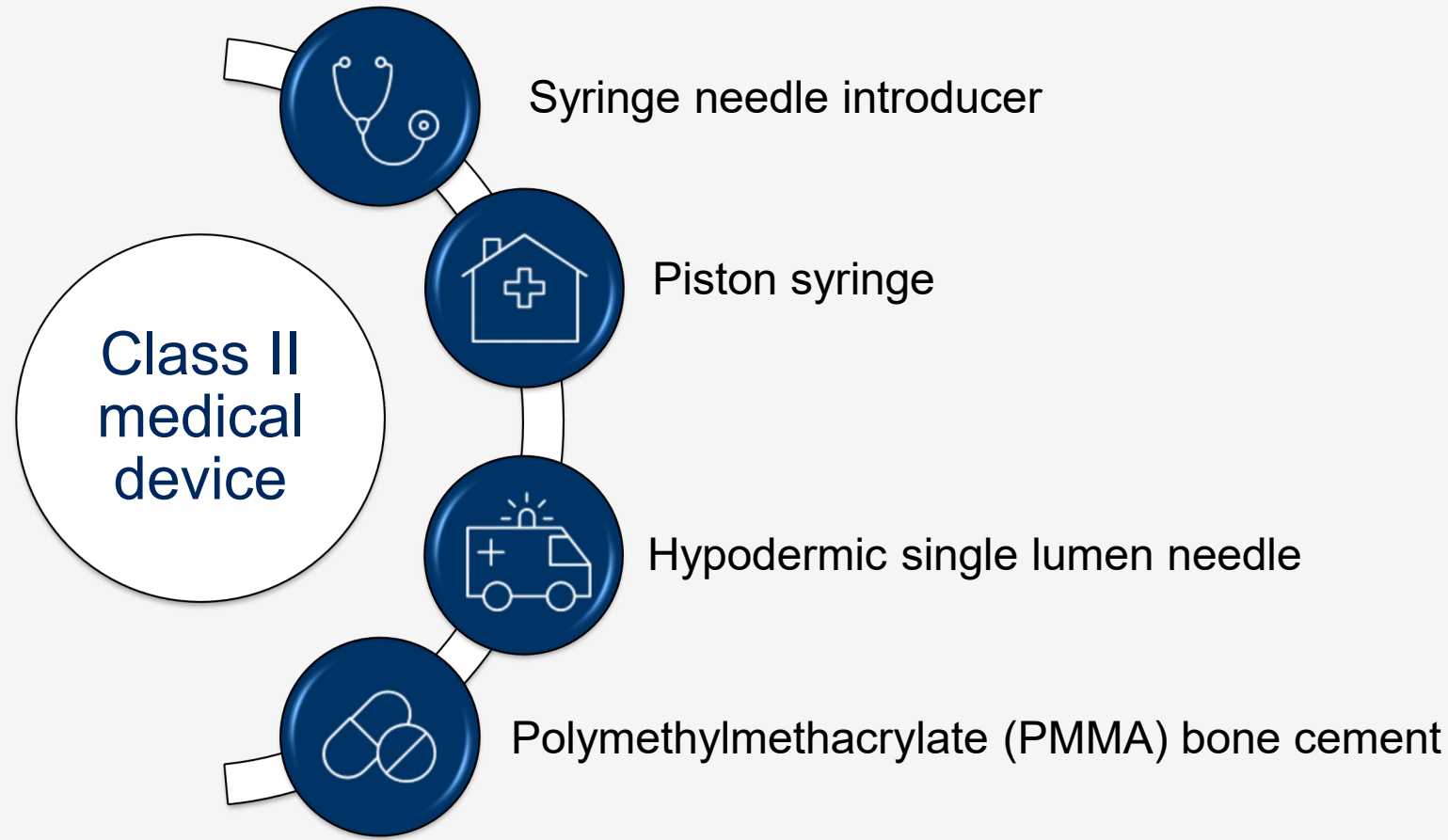


Generic products



Active Pharmaceutical Ingredient (API) registration

Our experience in medical device products registration



Case study 1- GDP and other relevant applications

Case background

New legal entity requires legal registration and to build its quality system (apply for GDP compliance). Other relevant applications are also required.



Pain point & Challenge

Requires lengthy communication regarding Taiwan's regulation, stringent timeline, and consideration for the available timeline of shipment/ release.



Processing

Applications and plans are on-track.



Current outcome

GDP project was approved in time and exceeded expectation. Other applications are on-track.



Lesson Learnt

Plan for all scenarios and all outcomes that might occur.

Case study 2- Biosimilar product Registration



Case background

It's biosimilar product registration. The product is only registered successfully in a few countries and requires approval in Taiwan as soon as possible.



Pain point & Challenge

Strict approval timeline



Processing & outcome

Approved within 12 months and it exceeded expectation (18 months initial estimation).



Lesson Learnt

Enhance the experience of cross-region/functional cooperation.

Case study 3- Medical device

Case background

- Company reorganization

Pain point & Challenge

- The period of the license transfer was shortened in case the importation/ exportation, and manufacturing are impacted.

Processing & outcome

- Intensive internal coordination, communication, and close discussion with TFDA for applicable and beneficial proposals of both sides. The actual transfer time was shorter than estimated.

Lesson Learnt

- Early participation of the project and have a comprehensive plan ahead.

Up-coming Webinar



ERM Webinar on Medical Device Act- Highlights and Challenges **3 Nov. 9:00 AM-10:00 AM EST time**

The Medical Device Act came into force on May 1st, 2021 in Taiwan. This led to the reinforcement of new regulations that are related to medical device tracking management, Good Distribution Practice (GDP) for medical device, and online registration for low-risk medical device. With that, ERM is hosting a webinar to share some insights regarding the Act and how it will affect businesses.

E-newsletter

醫藥法規動態

合規相關申請前評估與產品註冊
Compliance pre-assessment & Product registration/notification



Up-coming topic:
Regulatory strategy of
multi-sources of API /
finished product

SHAPING **SUSTAINABLE HEALTHCARE**





Department for
International Trade

Contact us:

Fandy Chen

UK DIT

E: fandy.chen@fcdo.gov.uk



Clare Chang 張人尹
Senior Consultant 資深經理

ERM Taiwan Co., Ltd.

永豐環境管理顧問股份有限公司 英商ERM集團
台北市中山區104松江路223號11樓之3

E: clare.chang@erm.com

T: +886 2 2501 2928 #220~223

M: +886 972083291



Dr. Ken Liu 劉耕硯
Principal Consultant 首席顧問

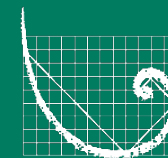
ERM Taiwan Co., Ltd.

永豐環境管理顧問股份有限公司 英商ERM集團
台北市中山區104松江路223號11樓之3

E: ken.liu@erm.com

T: +886 2 2501 2928 #250~251

M: +886 953638823



ERM