Pharmaceutical and Medical Device Consulting

MEDICA 2022
Company Presentation

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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.

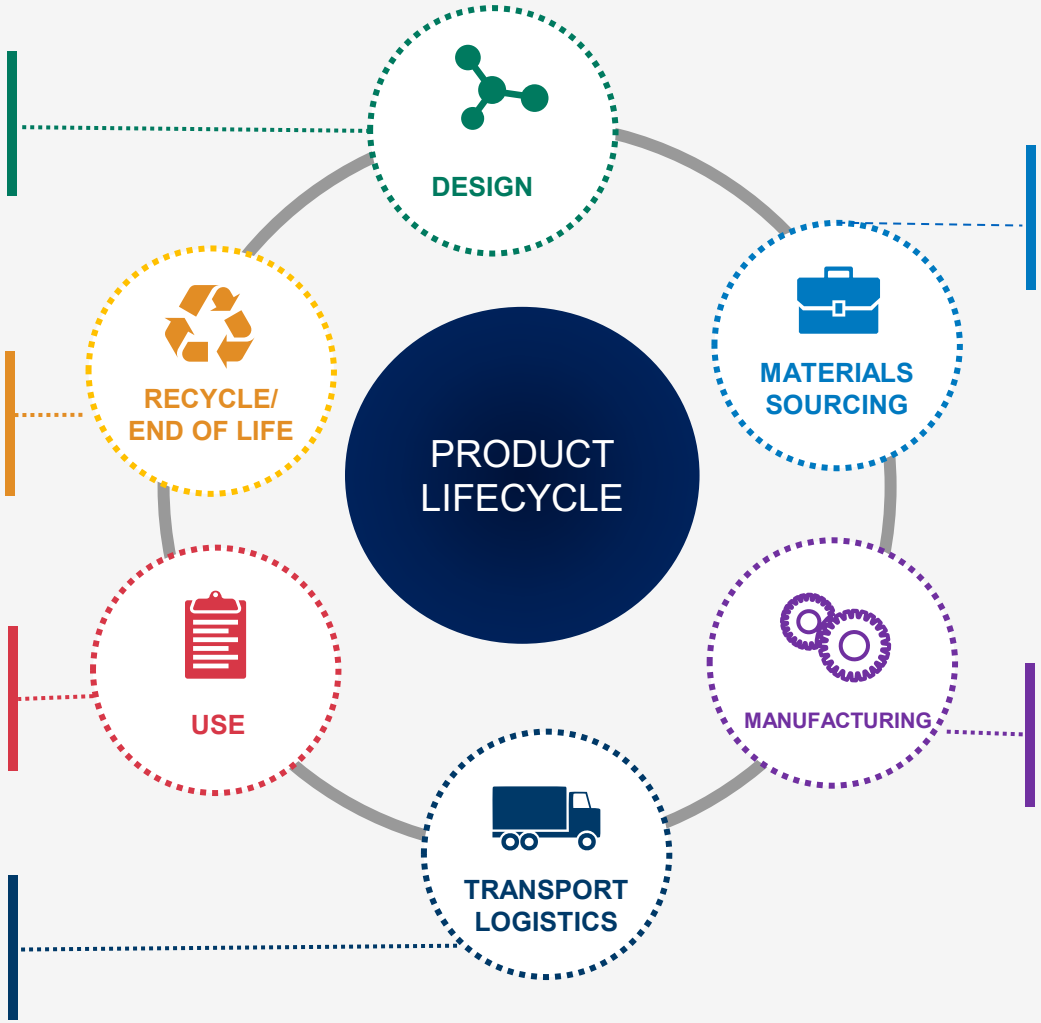
Product Stewardship

- 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



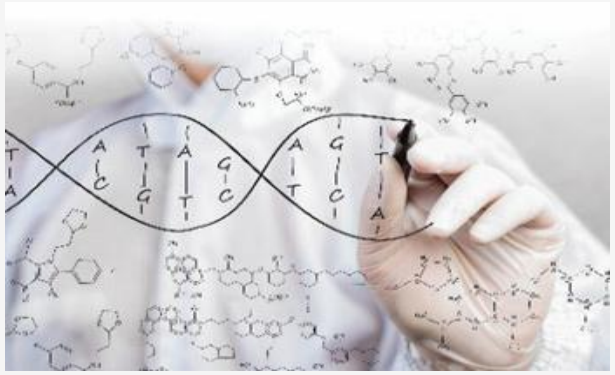
- Supply chain risk and materiality assessment
- Auditing
- Product compliance support
- (WEEE, ROHS, Conflict minerals, SVHC, POP, food contact, packaging, pharmaceutical and medical device)
- Marketability check
- Dangerous goods classification

- 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

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.

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.

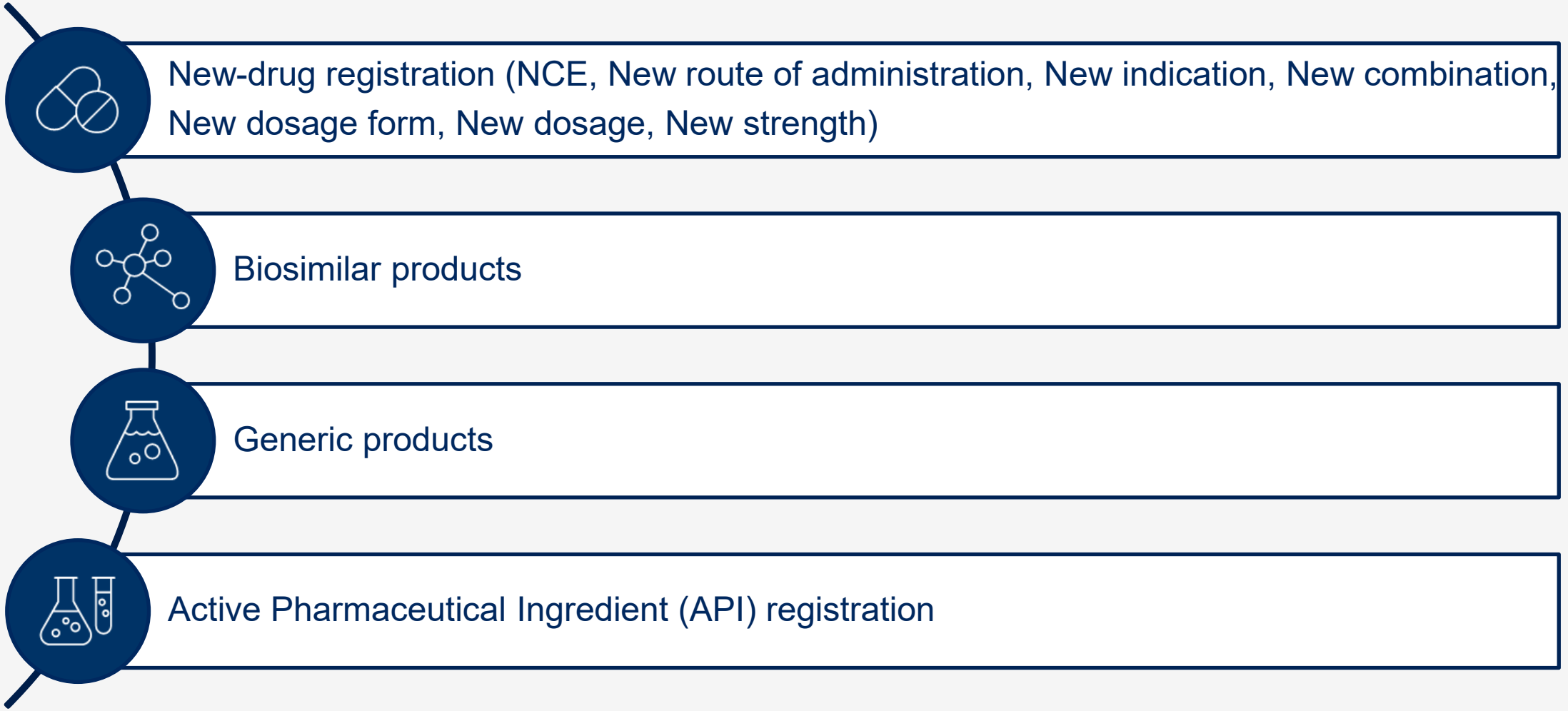
We have partnership with creditable laboratory/ Contract Research organization (CRO) and well-known law firms in Taiwan for comprehensive support.

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

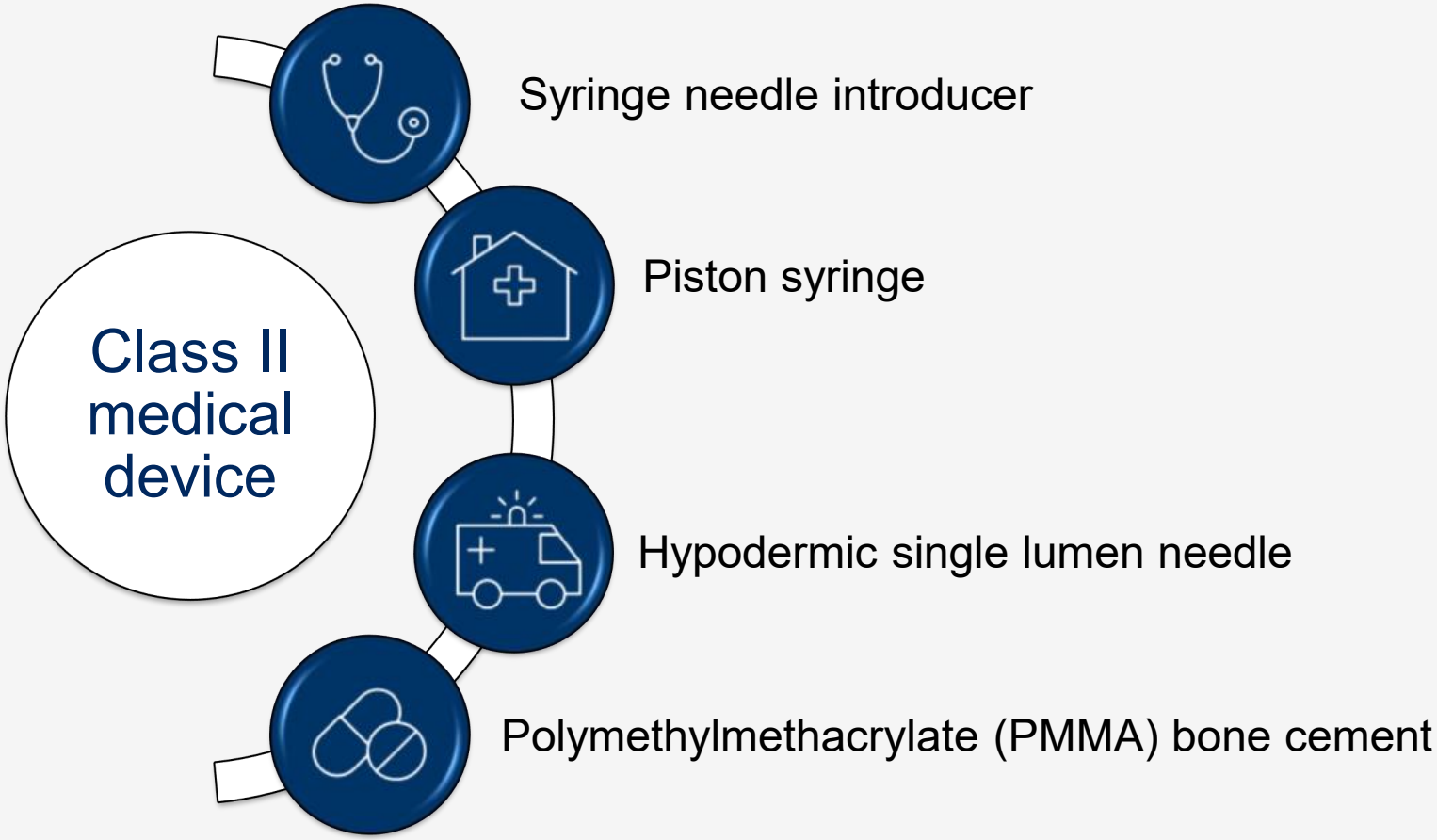
ERM TW Healthcare PS services ERM

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



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

ERM Webinar on Medical Device Act- Highlights and Challenges

3 Nov. 9:00 AM-10:00 AM EST time (3:00 PM-4:00 PM CET time)

The Medical Device Act came into force on May 1st, 2021 in Taiwan. This lead 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.

www.erm.com

E-newsletter

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

Contact us:

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