



สำนักงานคณะกรรมการอาหารและยา
Thai Food and Drug Administration

Navigating the Thai FDA

Your Trusted Partner
for Innovation and Growth

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Thai Food and Drug Administration

 Safe Products |  Trusted Regulation |  Sustainable Health

 Stronger Economy |  Better Future

2 Thailand's Regulatory Landscape

Facilitate Innovation through Efficient Regulation



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Thai Food and Drug Administration

1 RESEARCH & DEVELOPMENT



- Discovery & Innovation
- Internationally Aligned Research & Development

THAI FDA REGULATORY OVERSIGHT

Clinical Research & Development (Thai FDA Oversight)

- Drugs: IND (Investigational New Drug)
- Medical Devices: IDE (Investigational Device Exemption)
- Ensure safety, rights and well-being of study participants
- Review by Thai FDA before clinical trials can begin

2

THAI FDA REGULATORY OVERSIGHT

PRE-MARKET AUTHORIZATION

Science-based • Risk-based • Good Review Practices (GRevP)

2.1

MANUFACTURING ESTABLISHMENT LICENSE



- Ensure facilities meet Thai FDA requirements
- Comply with PIC/S (Pharmaceuticals), GMP / GMPMD / ISO 13485
- Maintain quality and safety standards

2.2

PRODUCT REGISTRATION



- Scientific evaluation of quality, safety and efficacy
- Risk-based assessment
- Good Review Practices (GRevP)

2.3

ADVERTISEMENT APPROVAL



- Review of advertising materials
- Compliance with Thai FDA requirements
- Clear requirements and timely decision

3

DISTRIBUTION & USE



- Track & Trace
- Reporting
- GDP (Good Distribution Practice)

4

POST-MARKET SURVEILLANCE



- Safety Monitoring & Surveillance (premises, products, advertising)
- Pharmacovigilance



PROTECT PUBLIC HEALTH

Ensure safety, quality and efficacy of health products for all Thais

THAI FDA'S DUAL MISSION



FACILITATE INNOVATION AND ACCESS

Support industry growth, encourage innovation and promote timely access to quality health products



SCIENCE-BASED
Decisions based on sound scientific evidence



RISK-PROPORTIONATE
Focus resources where risk is highest



TRANSPARENT & PREDICTABLE
Clear processes and timelines



INTERNATIONALLY ALIGNED
Harmonized with global standards and practices



COLLABORATIVE & SUPPORTIVE
Engage and work together with stakeholders



GOOD REGULATORY PRACTICES (GRP)
Regulatory excellence through internationally recognized good regulatory practices



Thai FDA is committed to a regulatory system that is reliable, efficient and internationally recognized, supporting timely access to safe, effective and quality health products in Thailand and beyond.



BETTER HEALTH



STRONGER INDUSTRY



PUBLIC TRUST

www.fda.moph.go.th

3 Pharmaceutical Investment Pathway

Invest in Innovation, Deliver Better Health



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THAILAND: A STRONG REGULATORY FOUNDATION FOR PHARMACEUTICAL INVESTMENT



1. PIC/S
Participating
Authority



2. WHO-Recognized
Vaccine Regulatory
System
Maturity Level 3



3. Japanese
Pharmacopoeia
is recognized



4. ICH Guidelines
are implemented



5. Strong
Pharmacovigilance
System



7. Reliance Pathways
Abbreviated Assessment
& WHO CRP
Leverage trusted regulatory
decisions to accelerate access



8. ASEAN Joint
Assessment
Collaborative review
with ASEAN
Member States

1. PRIORITY INVESTMENT AREAS

Focus on Innovative and High-Value Therapies



Innovative Medicines

First-in-class and best-in-class innovations



Targeted Therapies

Personalized treatment for better outcomes



Precision Medicine

Data-driven, targeted therapies
for better treatment outcomes



Biologics

Including monoclonal antibodies
and recombinant proteins



Advanced Therapy Medicinal Products (ATMPs)

Cell therapy, gene therapy,
tissue engineered products



Advanced Manufacturing Technologies

Continuous manufacturing,
digital and smart production

2. FLEXIBLE INVESTMENT MODELS

Work with Thailand in the Way That Fits You



Technology Transfer

Bring advanced technologies to Thailand
and build local capability



Joint Venture with Thai Pharmaceutical Companies

Leverage local strengths and capabilities
for mutual growth



Co-development and Collaborative Research

Develop innovative products together with
Thai partners and research institutions



Regional Manufacturing and Export Hub

Use Thailand as a strategic base to supply
high-quality products to ASEAN and global markets

3. THAILAND'S COMPETITIVE ADVANTAGES



High-Quality Healthcare Ecosystem

Modern healthcare system and increasing
demand for advanced therapies



Skilled Workforce and R&D Capability

Talented professionals and strong
scientific infrastructure



Competitive Manufacturing Environment

Cost efficiency with high quality
and regulatory reliability



Gateway to ASEAN and Global Markets

Access to more than 670 million people through
strategic location and trade agreements



Supportive Regulatory Environment

Predictable, science-based and
transparent regulatory system



Regulatory Reliance Pathways

Abbreviated assessment, WHO CRP
and ASEAN Joint Assessment facilitate
efficient regulatory review.

REGIONAL REGULATORY CONNECTIVITY: FASTER ACCESS, GREATER IMPACT



WHO CRP (Collaborative Registration Procedure)

Reliance on WHO collaborative registration
pathway to streamline evaluation and accelerate
patient access.



ASEAN Joint Assessment (JA)

Collaborative review of quality, safety and efficacy
with ASEAN Member States to reduce duplication
and improve efficiency.



Abbreviated Assessment (Reliance Approach)

Reliance on evaluation reports from stringent
NRAs (e.g., US FDA, EMA, PMDA, TGA, Health Canada)
to support efficient and risk-based review.



Government Agencies



Research Institutions



Hospitals



Industry Associations

A Collaborative Ecosystem for Health Innovation



Partner with Thailand to develop innovative medicines
for a healthier tomorrow



Better Health



Stronger Industry



Sustainable Future



1. REGULATORY FRAMEWORK



AMDD-aligned Regulatory System

Aligned with ASEAN Medical Device Directive (AMDD)



Risk-based Classification (Class 1 – 4)

Appropriate control according to risk level



Good Regulatory Practices (GRP)



Quality Management System GMP Medical Devices (GMPMD) / ISO 13485

Strong quality management and manufacturing capability

2. EFFICIENT ACCESS TO MARKET

Abridged Evaluation (Abridged Review)

For products with existing approvals from recognized reference jurisdictions



Japan
(PMDA)



US
(FDA)



EU
(Notified Bodies)



Australia
(TGA)



Canada
(Health Canada)



Reduced review time



English documents accepted

3. PREFERRED INVESTMENT MODELS



Joint Venture with Thai Manufacturers

Leverage local strengths and share success together



OEM / Contract Manufacturing (ODM/OEM)

Utilize Thailand's high-quality manufacturing capability



Technology Transfer

Bring advanced technologies and build local capability



Co-development

Collaborate on product development and innovation



Collaborative R&D

Partner with Thai universities and research institutes

4. THAILAND'S MANUFACTURING STRENGTHS



Strong Manufacturing Base

Many Thai manufacturers are GMPMD / ISO 13485 certified



Skilled Workforce

Qualified and experienced professionals across engineering, quality and regulatory disciplines



Mature Supply Chain

Comprehensive supply chain for medical devices and components



Competitive Manufacturing Environment

High quality with competitive manufacturing cost



Strategic Location

At the heart of ASEAN with excellent logistics infrastructure



Gateway to ASEAN Markets

Access to more than 670 million people through Thailand

5. THAILAND: YOUR REGIONAL MANUFACTURING AND DISTRIBUTION HUB



Central Location in ASEAN



Well-developed Logistics Network



Free Trade Agreements with Major Economies



Growing Healthcare Industry and Rising Demand



Innovate in Japan. Partner in Thailand.
Reach ASEAN and the World Together.



Better Health



Stronger Industry



Sustainable Future

How Thai FDA Supports Your Investment

Facilitating Regulatory Excellence and International Collaboration



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COMPREHENSIVE REGULATORY SUPPORT



One-stop Consultation

Your first contact for guidance on regulations, requirements and procedures.



Early Regulatory & Scientific Advice

Engage early to clarify development plans and regulatory pathways.



Digital Regulatory Services

E-submission, digital tracking and online services for efficiency and convenience.



Thai FDA is committed to regulatory excellence through integrity, transparency and scientific rigor while facilitating innovation and international collaboration.

PRIORITY INVESTMENT AREAS



Innovative Medicines

First-in-class and best-in-class innovations



Targeted & Precision Therapies

Personalized treatment for better outcomes



Precision Medicine

Data-driven, targeted therapies for better treatment outcomes



Biologics

Including monoclonal antibodies and recombinant proteins



Advanced Therapy Medicinal Products (ATMPs)

Cell therapy, gene therapy, tissue engineered products



Advanced Manufacturing Technologies

Continuous manufacturing, digital and smart production

CLINICAL RESEARCH ECOSYSTEM

Thailand offers a strong clinical development environment with international hospitals, recognized investigators and clinical research infrastructure to support global clinical development.



Leading Hospitals & Research Centers



Experienced Investigators



Clinical Research Infrastructure



High-quality Data & Standards



Support for Global Clinical Development



THAILAND-JAPAN REGULATORY COOPERATION

Long-standing Thailand-Japan Symposium on Pharmaceuticals and Medical Devices



Thai FDA



PMDA, Japan



Co-hosted by Thai FDA and PMDA



Supported by the MOU on Medical Products Regulation Dialogue and Cooperation Framework



Exchange of Regulatory Updates



Scientific Knowledge Exchange



Bilateral Regulatory Cooperation



Participation from Regulatory Authorities and Industry



Regulatory Reliance Pathways



Abbreviated Assessment (Reliance Approach)

- Reliance on unredacted evaluation reports from stringent NRAs (US FDA, EMA, PMDA, TGA, Health Canada)
- Applies to new drugs, biologics, vaccines, and medical devices
- Risk-based to ensure quality, safety and efficacy



WHO Collaborative Registration Procedure (CRP)

- Reliance on evaluation reports from WHO Prequalification (PQ) program
- For products assessed by WHO or listed by stringent NRAs
- Facilitates faster review for medicines of public health importance and improves access to quality medicines



ASEAN Joint Assessment (JA)

- Collaborative assessment with ASEAN Member States
- Joint Assessment Procedure (JAP) to share assessment results
- Reduces duplication, accelerates access and strengthens regional regulatory convergence

FLEXIBLE INVESTMENT MODELS



Technology Transfer

Bring advanced technologies to Thailand and build local capability



Joint Venture with Thai Pharmaceutical Companies

Leverage local capabilities for mutual growth



Co-development and Collaborative Research

Develop innovative products together with Thai partners and research institutions



Regional Manufacturing and Export Hub

Use Thailand as a strategic base to supply high-quality products to ASEAN and global markets



Trusted Regulator. Trusted Partner.



Better Health



Stronger Industry



Sustainable Future

Together for Better Health and Sustainable Growth

Thailand Can Be Your Gateway to ASEAN



สำนักงานคณะกรรมการอาหารและยา
Thai Food and Drug Administration

Strategically Located. Connected Regionally. Growing Together.

WHY THAILAND?



Strategic Location at the Heart of ASEAN

Central connectivity to
ASEAN and beyond



Skilled Workforce and R&D Capability

Strong talent pool in health,
science and technology



International Standards and Reliable Quality

Aligned with global standards
and best regulatory practices



Competitive Manufacturing Environment

Cost efficiency with high quality
and advanced infrastructure



Strong Healthcare System and Innovation Ecosystem

Growing healthcare demand and
collaboration across sectors

YOUR GATEWAY TO ASEAN AND BEYOND



Well-developed
Logistics Network



Extensive Trade
Agreements



Growing Demand
for Quality Health
Products



Regional Hub for
Manufacturing,
Innovation and
Distribution

WHY PARTNER WITH THAILAND?



Drive Innovation Together

Collaborate on R&D, technology and
product development



Flexible Partnership Models

Joint venture, technology transfer,
OEM/ODM and contract manufacturing



Access to Research and Talent

Strong academic and research networks
supporting life sciences and medtech



Expand to ASEAN and Global Markets

Use Thailand as your base to reach
ASEAN and global markets efficiently



Sustainable and Responsible Growth

Commitment to ESG, quality and
long-term sustainability



Thailand offers the right environment, the right people and the right partnerships
to help you **innovate, manufacture and grow—together.**



Better Health

Improving quality of life for all



Stronger Industry

Building a competitive
health product industry



Sustainable Future

Growing together for a healthier
and better future



Trusted Regulator. Trusted Facilitator.

Protecting public health and supporting
innovation and investment



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THANK YOU

Together for Better Health
and Sustainable Growth

