Knowledge Empowers Business – Forum 2025

A Workshop on Compliance and Global Market Access

Jingjiang, Jangsu, 10/11 July 2025

Friday, July 11 – Morning Session: USA and TARIFF MITIGATION

Time	Topic	Speaker(s)	Notes
09:00–11:00	**Introduction to US FDA Regulations**	**US Regulatory Team** (remote)	USA Import/export, registration, claims, enforcement
11:00–12:00	**US Tariff Mitigation Strategies (Panel)**	**Diego Sala** invited panelists	First Sale, FTZs, Binding Rulings, Q&A

Friday, July 11 – Afternoon Session: MEDICAL DEVICES: CHINA and ASEAN

Time	Topic	Speaker(s)	Notes
13:00-14:00	**Introduction to China NMPA – VMS**	**Aland** VMS Regulatory Team	XBEC, registration, licensing for vitamins, minerals, supplements
14:00–15:00	**Introduction to China NMPA – Medical Devices**	**Jland** Collagen Type III team	Medical-grade supplements, borderline classifications, recombinant collagen
15:00–16:30	**Medical Devices & ASEAN Outlook**	**15:00 Nipapat Phuakyod** **15:30 Anggita Septiani** **16:00 Melisa Leeau**	Focus on injectable products, regulatory comparison TH/ID/MY
16:30	**Final Regulatory Remarks & Q&A**	**Diego Sala**	Summary discussion and participant questions

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Pure Siam System Co., Ltd, based in Thailand, is part of Pure Global—a global consultancy specializing in medical device regulatory affairs. With over 15 offices across five continents, Pure Global ’s team of regulatory experts offers real-time, ongoing support for medical device registrations and post-market compliance.

We provide a wide range of Regulatory Services and Project Management for Healthcare Products in Thailand. We can register your products in Thai FDA under your Thai Company name or be your appointed License Holders and manage the market entry for you.

With our comprehensive understanding of the Thai regulatory services environment, we streamline the process, saving you time and resources while ensuring compliance with local laws and standards.

Whether you’re entering the market or expanding your presence, count on us to facilitate your success in Thailand and beyond.

Ms. Nipapat Phuakyod
Sr. Consultant
nipa.phuakyod@pureglobal.com

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Agenda:

1. **Thailand Medical device Regulation**
2. **Medical Device Registration Preparation and Submission**
3. **Medical Device : Injectable products**

3.1 Pre-assessment
3.2 Classification
3.3 Example : Hyaluronic acid +with Lidocaine
3.4 Required document
3.5 Timeline and Submission pathways

4. **Q&A**

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MEDICAL DEVICE : THAILAND

In Thailand, medical devices and in vitro diagnostics (IVDs) are regulated by the Medical Device Control Division (MDCD) within the Thai Food and Drug Administration (FDA). All medical devices and IVDs must receive premarket authorization from the Thai FDA before being imported or sold in the country.

Medical Device registration in Thai FDA, is regulated by the new Medical Device Act issued in 2019, followed by the new Medical Device classification issued in 2021. The new medical device classification is risk-based instead of policy-based and makes the full process more accurate and stricter.

The Thai FDA has implemented a four-tier classification system according to device risk.

Based on the risk classification, Medical devices are categorized into four risk classes:

Class 1: Low-risk devices (require a listing).
Class 2 & Class 3: Moderate-risk devices (require notification).
Class 4: High-risk devices (require a full license).

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Medical Device Registration Preparation and Submission,
the following steps will be performed to obtain the registration of your device(s):

-Appoint an In-Country Representative: Non-Thai manufacturers must designate a local representative licensed by the Thai FDA.
-Device Classification and grouping: Determine the risk class of the device based on Thai FDA guidelines.
-Prepare Documentation: Create a dossier that meets regulatory requirements for the specific class, including a Common Submission Dossier Template (CSDT) for Classes 2-4.
-Online Submission: Submit the application and required documentation via the Thai FDA's online system.
-Government Fee Payment: Pay the applicable registration fees.
-Review Process: Await the Thai FDA's review and address any additional requests for information.
-**Response the Thai FDA**: Provide an information within 10 working days
-Approval: Receive approval and marketing authorization upon compliance with Thai FDA standards

Additional Requirements
Foreign manufacturers must appoint an in-country representative to submit the registration application on their behalf. The representative must hold an establishment license.

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MEDICAL DEVICE/ THAILAND
INJECTABLE PRODUCTS

Pre-Assessment Device Classification and Grouping Checklist:

1. Product intended use : Please also check the GMDN code
2. Product code description / SKUs: Please indicate the specific differences—for example, volume or any other relevant characteristics.
3. Ingredients, specifically whether the device is derived from bovine, human, or porcine sources :
4. Does this product contain a formulation that includes Hyaluronic Acid? :
5. Does this product include any components classified as a registrable medicinal product? :

Example:

- **Class 4, Rule 13**

Devices incorporating, as an integral part, a medicinal product or a human blood derivative
Medical Device + Registrable Medicinal Product -> Device-Drug Combination Product

- **Class 4, Rule 14**

Devices incorporating non-viable cells, tissues or derivatives from animal, microbial or recombinant origin
Examples: collagen, heparin (anticoagulant), hyaluronic acid

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MEDICAL DEVICE/ THAILAND
INJECTABLE PRODUCTS

Example: Class 4, Rule 13

Devices incorporating, as an integral part, a medicinal product or a human blood derivative

Examples: injectable hydrogels based on bioresorbable crosslinked hyaluronan (HA) with Lidocaine (**Hyaluronic acid +with Lidocaine)**

-UMDN Code: 17876, Tissue Reconstructive Materials Synthetics
-GMDN Code: 47887, Synthetic-fluid tissue reconstructive material, anesthetic
Intended to correct moderate to severe facial wrinkles and folds and to increase lip volume.
It is indicated to be injected into the mid to deep dermis.

Announcement of the Ministry of Public Health on injectable hyaluronic acid with and without medicinal for correcting skin defects, B.E. 2562
กองควบคุมเครื่องมือแพทย์

Summary:

1. **Stability report as per the ICH Guideline for Stability Testing of New Drug Substances and Products or ASEAN Guideline on Stability Study of Drug Product**
2. Pharmaceutical Inspection Co-operation Scheme (PIC/S) or/and GMP or/and ISO 13485:2016
3. The label must be clearly legible in Thai. Other languages may be included, but the text in other languages must not conflict with or contradict the Thai text and the size must not be larger than the Thai text.
4. The text “The use of injectable hyaluronic acid to correct skin defects is for use only by medical or dental professionals” is displayed in red letters on the label.

*ICH = International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use

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MEDICAL DEVICE/ THAILAND
INJECTABLE PRODUCTS

Example: Class 4, Rule 14

Devices incorporating non-viable cells, tissues or derivatives from animal, microbial or recombinant origin

Examples: collagen, heparin (anticoagulant), hyaluronic acid

Risk class, Classification rule: Class 4, Rule 14

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MEDICAL DEVICE/ THAILAND INJECTABLE PRODUCTS

[FDA THAI : Food and Drug Administration, Thailand]

No.	Required Document
1	**Device labels**
2	**Packing insert / Instruction for use**
3	**Executive Summary**
4	**Device Description and features**
5	**Name and address of the manufacturing site** (include sterilization site), Manufacturing process and flow chart
6	**Essential Principles of Safety and Performance** of Medical Devices and Method Used to Demonstrate Conformity
7	**Summary Verification & validation** **Full test reports** - Summary of Design Verification and Validation Documents - Summary or Report of Test and Evaluation Report - Performance and safety - Biocompatibility - Sterilization validation - Stability and shelf-life Report - Packing validation report - Transportation test - Usability - Electrical safety and electromagnetic compatibility - Device containing biological material - Clinical Evaluation Report
8	**Risk analysis** Part 1: Risk Management Plan Part 2: Risk Evaluation Part 3: Risk Management Report
9	**Method of destruction and disposable of waste product**
10	**ISO 13485 Certificate / GMP** **(both manufacturing site & sterilization site)**
11	**Declaration of conformity** ***(Thai FDA Template, DocuSign is acceptable)***
12	**Letter of authorization** ***(Thai FDA Template, DocuSign is acceptable)***

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MEDICAL DEVICE/ THAILAND
INJECTABLE PRODUCTS

Thai FDA review and approval time / fee:

Class 1 : 15-200 days (Government fee US$ 105)
Class 2 : 250 days (Government fee US$ 1,635)*
Class 3 : 250 days (Government fee US$ 1,635)*
Class 4 : 300 days (Government fee US$ 2,470)*
Note: * Price including the specialist review fee

The Thai FDA (Food and Drug Administration) generally permits only one response per query related to an application, and the specified timeframe for submitting that response is 10 working days.

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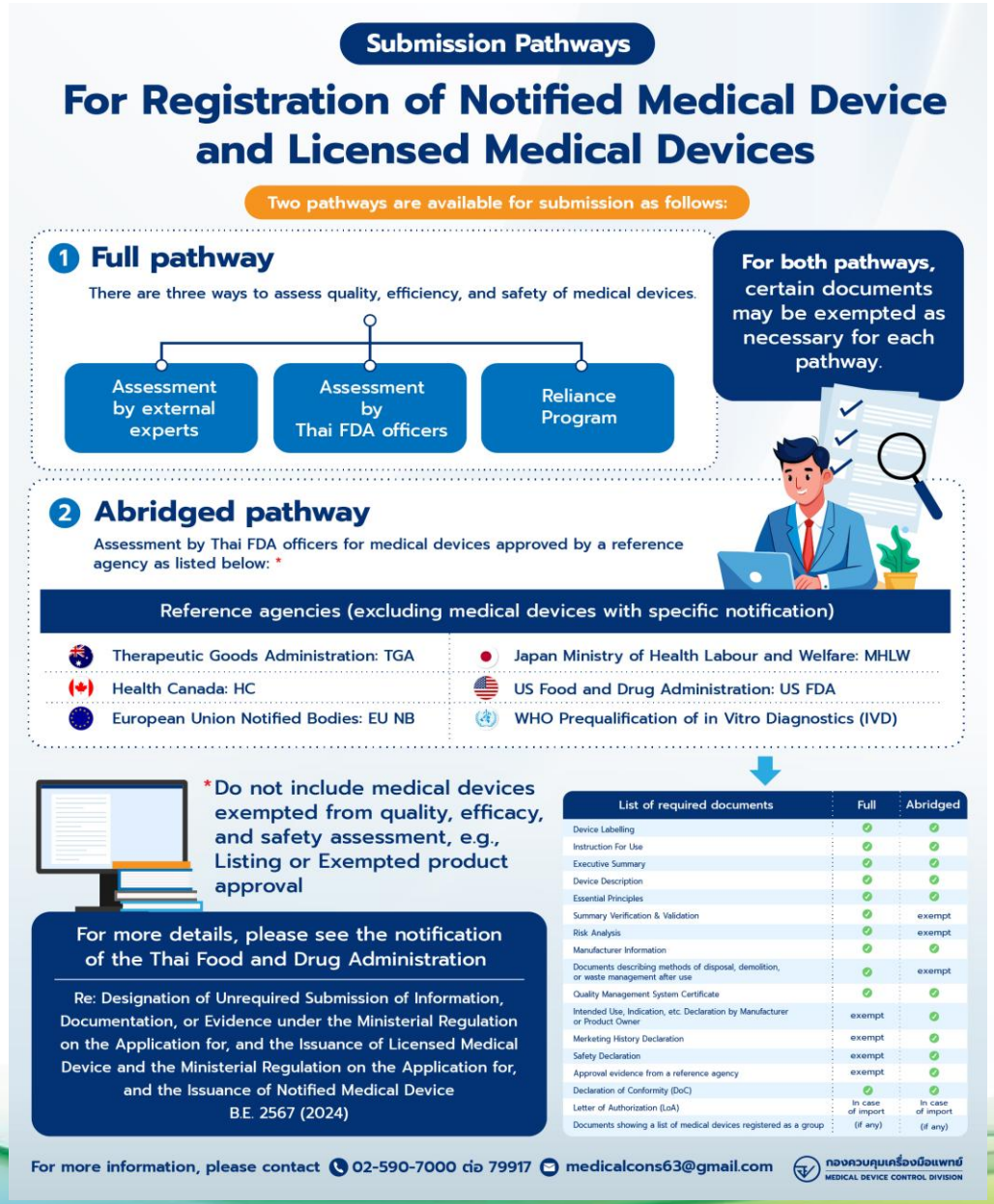
MEDICAL DEVICE/ THAILAND SUBMISSION PATHWAYS

Abridged	Therapeutic Goods Administration (TGA)
	Health Canada (HC)
	European Union Notified Bodies (EU NB)
	Japan Ministry of Health Labour and Welfare (MHLW)
	US Food and Drug Administration
	WHO PQ IVD
Reliance	Health Sciences Authority (HSA)



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Q & A

THANK YOU

Ms. Nipapat Phuakyod
Please email : nipa.phuakyod@pureglobal.com