

# **Knowledge Empowers Business – Forum 2025**

*A Workshop on Compliance and Global Market Access*

*Jingjiang, Jangsu, 10/11 July 2025*



## **ASEAN Focus – Malaysia & Singapore**

Speaker Profile: Melisa Leeau, Managing Director  
T T Medical Management Sdn Bhd (since 2014) &  
T T Training & Consulting Sdn Bhd(since 2002)

Melisa is a seasoned professional with over two decades of experience in quality management, regulatory compliance, and business leadership.

She holds a Bachelor of Commerce (Honors) degree from the University of Windsor, Canada, and has since built a distinguished career.

Since 2015, she has been the Managing Director at T T Medical Management Sdn Bhd, specializing in medical devices registration services in Malaysia and Indonesia. Completed over 7000 successful registrations and holds over 300 device licenses as Authorized Representative and Licensee for 70 foreign manufacturers worldwide. Making the company – T T Medical as one of the earliest and reputable registration company in the country.

In 2024, she was invited as a speaker at the China International Medical Device Regulatory Forum (CIMDR) in Wuhan and recently share at a few industries areas in Changzou, Wuzi and Suzhou on the medical device registration framework in Asean.



ASEAN Focus – Malaysia & Singapore		
Aspect	Malaysia (NPRA)	Singapore (HSA)
Regulatory Authority	NPRA (Ministry of Health)	HSA (Ministry of Health)
Regulatory Framework	Controlled via DCA & Sale of Drugs Act <a href="https://www.npra.gov.my/index.php/en/health-supplement-main-page.html">https://www.npra.gov.my/index.php/en/health-supplement-main-page.html</a>	Self-regulated under Health Products Act <a href="https://www.hsa.gov.sg/health-supplements/overview">https://www.hsa.gov.sg/health-supplements/overview</a>
Definition	Supplements to diet; no disease claims	Supplements to diet; no therapeutic claims
Product Classification	Mandatory if unclear	Self-assessment or submit to HSA
Pre-Market Requirement	Product registration required (MAL No.)	No pre-market approval if compliant, voluntary notification
Registration Timeline	Approx. 6–9 months	Immediate if compliant
Evaluation Type	Full review: quality, safety, labeling	No review unless flagged
GMP Requirement	Yes – recognized GMP cert needed	No GMP required pre-market



<b>ASEAN Focus – Malaysia &amp; Singapore</b>		
<b>Aspect</b>	<b>Malaysia (NPRA)</b>	<b>Singapore (HSA)</b>
Labeling	Strict NPRA format + MAL No. + hologram	Comply with HSA label guide
Permissible Ingredients	From NPRA-approved list or submit safety	Must meet HSA's positive list
Product Claims	Nutritional support only	Structure/function claims only
Importation	Local Marketing Authorization Holder needed	Importer must be registered locally
Post-Market Surveillance	Active: AE, renew every 5 yrs	Passive: AE reporting encouraged
Product Recalls	Mandatory under DCA	Mandatory under HSA
Borderline Products	Submit classification application	Submit to HSA if uncertain





## Malaysia vs Singapore: Functional Food vs Health Supplement Registration

Aspect	Malaysia: Functional Food	Malaysia: Health Supplement	Singapore: Functional Food	Singapore: Health Supplement
Definition	Food with health/nutritional function (e.g. protein bars)	Products in dosage form with health functions (e.g. tablets, capsules)	Food in conventional form with added functional ingredients	Dosage-form products (e.g. capsules, tablets, liquids)
Regulatory Authority	MOH - Food Safety & Quality Division (FSQD)	NPRA (National Pharmaceutical Regulatory Agency)	SFA (Singapore Food Agency)	HSA (Health Sciences Authority)
Governing Law	Food Act 1983 & Food Regulations 1985	Control of Drugs and Cosmetics Regulations (CDCR)	Sale of Food Act & Food Regulations	Medicines Act / HSA Guidelines



## Malaysia vs Singapore: Functional Food vs Health Supplement Registration

Aspect	Malaysia: Functional Food	Malaysia: Health Supplement	Singapore: Functional Food	Singapore: Health Supplement
Registration Required?	No registration, import products <b>MUST</b> obtain labelling approval	Yes, product registration under NPRA (category N)	No registration, but importer must register with SFA	No registration; must meet safety, claims, labeling standards
Product Format Accepted	Bars, drinks, sachets, conventional food forms	Capsules, tablets, powders, soft gels (dosage forms)	Bars, drinks, cereal, sachets	Capsules, tablets, liquids only
Claims Allowed	Nutritional & limited function claims	Nutrient function, functional claims with supporting data	Nutritional & general health claims (non-medicinal)	Structure/function claims only



## Malaysia vs Singapore: Functional Food vs Health Supplement Registration

Aspect	Malaysia: Functional Food	Malaysia: Health Supplement	Singapore: Functional Food	Singapore: Health Supplement
Prohibited Claims	No disease prevention or treatment claims	No disease claims unless specifically allowed	No therapeutic or medicinal claims	No disease risk reduction claims
Pre-Market Approval?	No (except for novel food ingredients)	Yes – product approval required	No (except for novel ingredients/additives)	No pre-market approval required
Examples	Protein bars, collagen drinks, probiotic yogurt	Vitamin C tablets, fish oil, calcium + D3	Whey drinks, herbal jellies, enriched snacks	Multivitamins, probiotics in capsule form





## Summary of Key Differences Malaysia vs. Singapore

Category	Malaysia	Singapore
Market Access	Regulated, slower	Self-regulated, faster
Compliance Burden	Front-loaded (before market)	Back-loaded (after market)
Risk of Entry	Lower after approval	Higher due to post-market checks
Strategic Flexibility	Lower – more regulator control	Higher – company manages compliance



## Market Consumption Overview – Malaysia vs. Singapore

Metric	Malaysia	Singapore	Source
Vitamins & Minerals Market (OTC, 2025 est.)	US \$172.5M	—	Statista, ResearchGate
Total Dietary Supplements (2023–2024)	~US \$519–544M (2020 baseline)	US \$560.9M (2024)	ResearchGate, Grand View Research
Nutritional Supplements (2024)	—	US \$7,440.5M	Grand View Research
Digestive Health Supplements (2023)	—	US \$96.8M	Grand View Research
Sports Nutrition Market (2023)	—	US \$487.4M	Grand View Research



## Healthcare Supplement Market Entry Comparison

Country	Authority	System Type	GMP	Labeling	Claims	Local Agent	Time to Market
Malaysia	NPRA	Registration	✓ Local or PIC/S GMP	✓ Pre-approved	✓ Structure /function only	✓ Yes	6–12 months
Singapore	HSA	Self-regulated	✓ PIC/S GMP	✓ Self-checklist	✓ Substantiated claims only	✓ Yes	2–6 weeks
Thailand	Thai FDA	Registration	✓ ASEAN GMP	✓ Required	✓ Limited, approved only	✓ Yes	6–12 months
Indonesia	BPOM	Registration	✓ ASEAN/ Local GMP	✓ Required	✓ Strict claims control	✓ Yes	6–12 months
China	NMPN	Registration	✓ China GMP or equivalent	✓ Required	✓ Only approved functional	✓ Yes	12–24 months
USA	FDA (DSHEA)	Post-Market	✓ cGMP (21 CFR Part 111)	✓ General rules	✓ With disclaimer	✗ Not required	Immediate
Canada	Health Canada	Registration	✓ Canadian GMP	✓ Approved label	✓ Must be supported	✓ Yes	3–6 months

## ASEAN Focus – Malaysia & Singapore



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### Thursday, July 10 – Morning Session: Thailand and ASEAN

Time	Topic	Speaker(s)	Notes
09:00–09:30	<b>Opening Remarks &amp; Agenda Overview</b>	ALAND Group Siam Trade Development	ASEAN context, Thailand market positioning
09:40–10:10	<b>Geopolitical Landscape and Tariffs</b>	ALAND Group Siam Trade Development	China–US–EU, RCEP, FTAs, Preferential Rules of Origin
10:10–11:10	<b>Thai FDA Regulatory Framework – Food &amp; Supplements</b>	<b>Diego Sala</b> <b>Nitwaree Kanjanasurakit</b>	Definitions, ingredient types, registration, export
11:10–11:50	<b>Local Manufacturing Strategies &amp; Export from Thailand</b>	Diego Sala	BOI, company setup, Thai Foreign Business Act – Case Study: Vitamin C market

### Thursday, July 10 – Afternoon Session: Russia & ASEAN

Time	Topic	Speaker(s)	Notes
13:00–13:40	<b>Regulatory Framework in Russia</b>	<b>Irina Shchemerova</b> Siberian Wellness	Russian Local vs. export regulation Europe, Vietnam, Thailand comparison
13:40–14:10	<b>ASEAN Focus – Indonesia</b>	<b>Syifa Amirta Sani</b> Inspiry Indonesia Konsultan	Indonesian Key regulations, harmonization
14:10–15:00	<b>ASEAN Focus – Malaysia &amp; Singapore</b>	<b>Melisa Leeau</b> TT Medical Management	Malaysia and Singapore: Product registration, ASEAN gaps
15:00–17:00	<b>Round Table and Team Outing</b>	-	-





### 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