



IMDRF International Medical Device
Regulators Forum



25 YEARS AND BEYOND

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SINGAPORE MANUFACTURING FEDERATION

Bridging Markets and Regulation

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新加坡制造商总会
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HSA
Health Sciences Authority

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WHO WE ARE

Who We Are: A Unified Industry Voice Built Around SMEs

5,000

SMF members across 10 industry groups

90%

of members are small and medium enterprises

94

years representing Singapore manufacturing

What MTIG does

- Provides a unified voice for Singapore's MedTech industry to government and regulators
- Advocates for the diverse needs of member companies, most of them SMEs
- Organised around ten pillars, including a dedicated Regulatory Sub-Committee

Why SMEs matter here

SMEs carry the same regulatory obligations as multinationals, with a fraction of the resources. Proportionate regulation is what keeps them in the market.



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WHERE WE FOCUS

Our Two Regulatory Focus Areas

01

Local engagement

Close collaboration with local authorities

Shaping a regulation-friendly environment at home, so compliance stays workable for smaller firms.

Why it matters: the cost of compliance falls hardest on the smallest firms.

How we get there — three strategic steps

02

Market expansion

Singapore as the regulatory launchpad

Turning a Singapore approval into a credential that opens markets across the region.

Why it matters: one strong submission should not have to be rebuilt market by market.

What it delivers — market access

The same work does both jobs: a stronger local framework is what makes a Singapore approval travel.



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FOCUS AREA 1 — LOCAL ENGAGEMENT

How We Deliver It: Three Strategic Steps

Step 1 — Regulatory Sustainability

Smart regulation, not more regulation

Working with regulators to simplify processes and make compliance easier to navigate, without lowering the safety bar

IN PROGRESS

Live: unique device identification (UDI) readiness, digital submissions, hazardous substances, packaging reporting

Step 2 — Partnership

A standing channel between industry and regulators

Institutionalised dialogue with local authorities to strengthen collaboration and exchange perspectives towards mutually beneficial outcomes

IN PROGRESS

Live: MTIG whitepaper and annual dialogue on the evolving landscape

Step 3 — Capacity Building

Building regulatory know-how in SMEs

Raising dossier quality and regulatory literacy so smaller firms submit right the first time

EXPLORING

Exploring: training on regulatory fundamentals and dossier preparation, with guidance on market entry beyond Singapore



FOCUS AREA 2 — MARKET EXPANSION

Market Access: Singapore as the Regulatory Launchpad

6**reliance partners**

Australia, Hong Kong, the Philippines, Thailand, Sri Lanka and Malaysia

500+**applications**

processed through Thailand and Australia's reliance on an HSA approval (Sep 2025)

2026**full implementation**

Singapore–Malaysia reliance moved from pilot to ongoing implementation on 1 Mar 2026, with reduced review times (HSA)

How local engagement pays off abroad

- Since 2 Oct 2025, the Health Sciences Authority's Health Products Regulation Group (HPRG) Innovation Office and SMF MTIG have partnered to combine SME Centre@SMF services with HSA regulatory expertise
- Regulatory reliance and convergence is one of the Innovation Office's key focus areas — fewer duplicated dossiers, lower fees and shorter review times



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Industry meeting, HSA CEO dialogue, and the Health Products Regulatory Conference at MedTech Day 2025

Thank You!



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