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More Pre-Development Medtech Work Must Be In Singapore's Sights

by Ashley Yeo

Singapore is already deeply involved in "commercial" regulatory affairs, but it has the potential to increase the volume of "technical" RA work done locally. So says regulatory professional Jing Lim, who explained these definitions to Medtech Insight.

The ASEAN countries, including the regional medtech regulatory hub Singapore, are not yet known globally for medtech innovation manufacturing. While the region does much manufacturing under contract, when it comes to manufacturers *as product owners*, local examples are few and far between in the ASEAN markets, compared with Europe and the US.

That is something that could change, says Jing Lim, chief technology officer at the Singapore regenerative bone products innovator *Osteopore Ltd.* From the viewpoint at the company he joined in 2014, now listed on Australia's ASX stock exchange, Lim has been able to assess local and regional strengths and opportunities. He believes Singapore, in particular, should be able to expand its activities in the upstream medtech ecosystem.

He explained: "We have a lot of RA expertise in Singapore, but the focus is on getting registrations in the ASEAN and Asia Pacific countries." There is potential for more local input to extend to

RA And Regulatorism

Typically, successful commercial RA work is aimed at securing rapid file submission and engaging in efficient follow-up ahead of product registration and approval. This is the role of most country RA experts working in multinational companies, says Asia Regulatory Professional Association (ARPA) founder Jack Wong, an early advocate of the concept of "technical RA" and proponent of "regulatorism." (Also see "*'Regulatorism': A New Terminology For Medtech And Pharmaceutical Leadership Mindsets*" - In Vivo,

overseeing the whole submission, from ideation to prototyping clinical trials and getting market access, he said. In terms of regulatory input, "We see a lot of the second part of the work, but not so much of the first part."

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Lim uses the term "technical RA" to differentiate the elements of pre-market development from commercial RA. Medtech players in the ASEAN nations do not routinely handle high amounts of technical RA. But for Lim, if Singapore wants to encourage entrepreneurship and build up a medtech ecosystem, it is important that the city state does more of the initial part of the medtech regulatory work.

In that case, the country should not restrict itself to doing registrations based on approved dossiers, but must actually develop the dossiers ahead of getting them approved. He said: "It means tapping on a different skill set that is plentiful in US and Europe, but perhaps quite rare in ASEAN and APAC."

Technical RA Defined

Technical RA covers product development and how processes can be streamlined, resulting in an efficient and compliant system. There can be difficulties in establishing end-to-end connections within a company if product development and regulatory work sit at different sites. This can hamper access to information and guidance and ultimately hinder speed to market.

"Technical RA should be very closely integrated with the product development team in order to be directly on the project and focused. This helps the group to work through engineering, systems and regulatory policy issues in a more expeditious way."

"There are needs for skill sets in Singapore" – Jing Lim

There have not been many medtech product owners in Singapore in the past, but the government is now pressing for local companies to become product owners and to develop medtech, Lim observed. Moreover there is a growing need for this expertise locally, said Lim, recalling an instance when his own company came up empty-handed after a search for a local RA specialist. It had even enlisted the help of a head hunting firm.

The two skill sets are quite different. Commercial RA focuses on how to get products expeditiously to market, Lim stressed. The responsible person has a role across the whole value chain when a company executes on its activities. These skills need to be uplifted, said Lim.

He also pointed to a need to use precise language that is globally understood. A mix of many languages is used in Singapore, and sometimes there is a drift to use of "Singlish," which is a function of the many different languages used locally (including Mandarin, Cantonese, Hokkien, Malay, Teochew and Tamil).

"In RA, the choice of words is very important," said Lim, noting that English used in countries where it is a second – albeit widely used – language, can lead to misunderstandings, especially among non-native English speakers of other countries. There is often a need to continuously clarify what a person means so that the message and meaning cannot be misconstrued, he said.

There is a large amount of expertise, particularly of post-market activities, in ASEAN. This requires different skill sets, such as like knowledge of advertising and promotion and off-label use. The EU Medical Device Regulation has brought a further shift in mindset in ASEAN. It means effectively that findings from pre-market evaluations must be further evaluated as post-market clinical follow-up (PMCF) activity.

"From a technical point of view, there is a stream of ideas that need to come out and be reflected in the work that we do, and different skills are called for," said Lim. These are interchangeable skills, however. "It's just about how we must think in order to get there."

Training Is Largely On The Job

Courses in regulation are available that give a broad, overarching view, but a lot of regulatory training is on the job, occurring while executing plans and doing the necessary engagement with regulators. "What is missing is experiential training, and for that, we need people and processes in place to execute these activities," said Lim.

His own experience as a company CTO demonstrated the importance of good working relations with regulatory authorities. "A good working relationship goes a long way to making lives easier." This is regardless of the health system, he said, adding that putting a face to a name is always beneficial.

The International Medical Device School (IMDS) has a goal of promoting regulatory jobs and the profession generally. But for now, the talent pool remains limited, said Lim, noting the need for stakeholders to provide more insight about the potential opportunities that exist in Singapore. This would be an important step in further growing the country's reputation in the medtech

arena.

Technical RA Is Not An Unattainable Goal

Technical RA is a nascent activity in Singapore. “We are figuring our way around it,” said Lim, observing that companies will often drive to secure the expertise that helps them obtain a US 510k or a PMA, but will struggle to find a regulator who could cover their ASEAN market activity. “Everything is needs-driven, said Lim, noting that Osteopore is *en route* to building such an ecosystem.

Regulators and their capabilities will always be playing catch up to the technology. Technical advances can happen at a such a pace that it is difficult to keep up to date with developments, said Lim, painting a realistic picture of a regulator’s task. But that does not make the further integration of technical RA an unattainable goal in a market like Singapore. Far from it, as Lim sees it.

Global Ambition Of Singapore

Singapore is viewed highly within ASEAN as a local center for quality. It is seen globally as a market where there is strong respect for IP, good governance and implementation of standards. It has a sound reputation for keeping to rules and regulations. “To become a serious player in global medtech, we’d want to build up our ecosystem further. There are needs for skill sets in Singapore,” said Lim.