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ASIA EDITION

Scaling ASEAN's Biopharma Ecosystem: Structural Drivers, Regulation, Ecosystem Readiness

April 15, 2026 | News | By Hithaishi C Bhaskar

Krishna Karnati, General Manager, ASEAN, Cytiva Unlocking Biopharma Growth in ASEAN to Bridge Potential and Collaborative Growth

The biopharma industry in ASEAN is at a critical juncture, marked by rapid growth and significant challenges. As a high-growth region, it is driven by strong demand fundamentals such as a growing population, expanding healthcare access, and rising chronic disease prevalence. However, as Cytiva's Global Biopharma Index underscores, growth alone is insufficient; companies must convert innovation into clinical and commercial success. Persistent gaps in time-to-market, process scalability, and profitability highlight the need for stronger ecosystem foundations. These include talent availability, regulatory predictability, manufacturing agility, and supply-chain resilience to ensure innovation scales reliably and delivers meaningful

patient impact.

ASEAN's biopharma readiness varies widely, with advanced hubs like Singapore excelling in talent and regulatory maturity, while emerging markets like Thailand and Indonesia show progress in workforce development and supply-chain readiness. Regulatory clarity remains a key differentiator, as inconsistent frameworks hinder the adoption of advanced therapies. Additionally, local manufacturing capacity, while expanding, must prioritize agility and quality over mere scale to transition ASEAN into a globally competitive production hub. Collaboration, particularly through public-private partnerships, will be essential to address capability gaps, enhance affordability, and ensure sustainable growth in this dynamic region.**Krishna Karnati, General Manager, ASEAN, Cytiva** shared more recent insights with Biospectrum Asia.

- **ASEAN is often described as a high-growth biopharma region. From your perspective, what are the key structural drivers behind this growth today?**

ASEAN's biopharma growth is underpinned by strong demand fundamentals - a growing population, expanding healthcare needs and access, rising chronic disease prevalence, and sustained investment in biologics. However, Cytiva's Global Biopharma Index cautions that growth alone is not enough. While industry revenues are increasing globally, many companies are struggling to convert innovation into clinical and commercial outcomes. Persistent gaps remain in time-to-market, CMC expertise, process scalability, and profitability.

For ASEAN, the real long-term growth driver will be the strength of its ecosystem foundations. This includes talent availability, predictable and innovationâ??ready regulatory frameworks, manufacturing agility, and supply-chain resilience - so innovation can scale reliably and translate into meaningful impact for patient while delivering sustainable commercial outcomes.

- **Growth across ASEAN is not uniform—how would you compare more advanced ecosystems like Singapore with emerging markets such as Thailand, Vietnam, or Indonesia in terms of biopharma readiness?**

ASEAN's biopharma readiness varies significantly across the region. The Index ranks Singapore 6th globally (score 6.29), reflecting strengths across talent, manufacturing capability, and regulatory maturity, while Thailand ranks 17th (score 5.59), although it has made notable progress in talent development and supply chain readiness. Importantly, the Index also shows that economic strength is becoming a weaker predictor of biopharma success. Countries are increasingly able to improve performance by making targeting ecosystem investments rather than relying on scale alone. This suggests that emerging ASEAN markets can accelerate their progress by prioritizing workforce development, regulatory reform, and manufacturing capability, even if they start from a lower base than more established hubs like Singapore.

That said, regulatory clarity remains a critical differentiator. Biopharmaceuticals must be regulated in the markets where they are administered to patients. While regulatory frameworks in markets like Singapore are wellâ??established, greater standardization and predictability across the rest of ASEAN will be essential.

- **Cytiva's Global Biopharma Index highlights gaps in areas like talent, manufacturing agility, and regulatory consistency. Which of these are currently the biggest constraints to ASEAN's growth?**

High capital intensity, long validation timelines, and the need for mature quality systems continue to pose significant barriers-particularly for small and mid-sized manufacturers. The Index shows that ASEAN's constraints mirror global pressures, with persistent talent shortages across R&D and translational ecosystem, spanning both traditional biologics and advanced modalities. Globally, 38% of biopharma executives report severe shortages in specialist skills for areas such as cell and gene therapy and mRNA, alongside continued gaps in manufacturing (27%), digital (29%), and sustainability (34%) capabilities - all of which are essential for scaling next-generation biomanufacturing.

Regulatory inconsistency is another major friction point. Many executives cite unpredictable policy environments and regulatory processes that are not yet fit for advancing new therapies. While manufacturing capacity across the region is expanding, the Index makes clear that agility - rapid scale-up, quality, and standardization - remains a limiting factor. Challenges are deeply interconnected and must be addressed together. Globally, we are also seeing a growing emphasis on national strategies focused on self-sufficiency and risk mitigation, as reflected in markets such as the UK, China, the United

States, and India. The fastest progress occurs when governments, academia, biopharma innovators, technology transfer partners, and end manufacturers work together to align incentives, share data, and scale solutions that are fit for local market / country needs.

Within ASEAN, regulatory systems play a pivotal enabling role. While important regional frameworks such as the ASEAN Common Technical Dossier (ACTD) and ASEAN Common Technical Requirements (ACTR) are in place, implementation remains uneven. Member states differ in their depth of ICH guideline adoption, use of reliance mechanism, posâ??approval change management, and lifecycle oversight, resulting in duplicative submissions and added compliance burdens. At the same time, ongoing PIC/S expansion, WHO maturity benchmarking, and broader acceptance of reliance mechanisms are steadily improving regulatory predictability and supporting deeper integration of ASEAN manufacturing into global supply chains.

- **To what extent will local manufacturing capacity determine whether ASEAN can move from being a high-demand market to a true biopharma production hub?**

According to Cytiva's Global biopharma Index, 56% of biopharma leaders agree that domestic manufacturing of biologics is set to increase dramatically over the next three years, up from 50% who said this in 2023. Local manufacturing will be critical for ASEAN's evolution; however, there is an important distinction between capacity and agility.

While capacity is increasing, many organizations still struggle to scale production in a timely manner. The Index shows that around oneâ??third of biopharma companies would be slow to ramp up manufacturing for advanced modalities such as mRNA and cell and gene therapies. At the same time, the report points to a shift away from cost-driven manufacturing toward a stronger emphasis on quality, reliability, and regulatory readiness. ASEAN's opportunity lies in building flexible, digitally enabled manufacturing models, supported by skilled talent and robust partner networks, including CDMOs. It is this combination, rather than capacity alone, that will determine whether the region can transition into a sustainable and globally competitive biopharma production hub.

- **As the region grows, how can ASEAN countries ensure that innovation, particularly biologics and advanced therapies, remains accessible and affordable?**

Access challenges are closely tied to ecosystem efficiency. To address this, it is useful to look at innovation and manufacturing separately.

On the innovation side, to accelerate bringing therapy to market, we need to establish translational research centers with two clear objectives: first, to validate clinical assets that need technology transfer from other markets or academic centers; and second, to build local capability by outsourcing the process scalability to experienced solution providers like Cytiva and learning from them for subsequent clinical assets.

From a manufacturing perspective, many companies in emerging markets such as Thailand, Indonesia, and Vietnam typically begin by importing drug substance and conducting fill-finish locally as a first step, before venturing into drug substance manufacturing. As healthcare access expands across the region, the demand for biosimilars is increasing significantly. To meet this, companies will need to work closely with technology transfer partners to commence drug substance manufacturing, which also plays an important role in talent development.

Ultimately, when approval pathways are predictable and production systems are resilient, innovation can reach patients faster and at more sustainable cost. In this sense, access is not separate from growth; it is a direct outcome of how effectively the ecosystem functions.

- **Looking ahead, what are the top one or two priorities that will determine whether ASEAN can fully realize its biopharma growth potential over the next 3–5 years?**

Two priorities stand out for ASEAN over the next 3-5 years. The first is talent. Access to specialized skills remains one of the weakest pillars globally, and companies that perform well on talent acquisition and retention are more than seven times as likely to outperform commercially. This makes the need for national strategies focused on self-reliance and sufficiency through talent development, a top priority across the region.

The second priority is regulatory coherence. The Index highlights that policy inconsistency and legacy approval frameworks are increasingly misaligned with the pace of innovation, particularly for advanced therapies. Across ASEAN, regulators are strengthening harmonization through the ASEAN Pharmaceutical Regulatory Policy (APRP) and reliance mechanisms, moving from WHO Good Regulatory Practices toward deeper PIC/S and ICH alignment, albeit at differing paces.

Over the next three to five years, ASEAN's ability to build skilled workforces and establish more predictable, innovation-ready regulatory environments will be decisive in determining long-term growth outcomes.

- **ASEAN's biopharma growth will likely depend on collaboration. What types of partnerships, whether public-private, regional, or global, are most critical to accelerate growth in this region?**

The Index consistently shows that strong biopharma ecosystems are built on collaboration. Yet collaboration remains uneven. The Index shows that collaboration is a challenge across many markets, with many executives continuing to report difficulty finding high-quality partners across CROs, CDMOs, technology transfer, academia, and government institutions.

For ASEAN, partnerships are therefore essential to closing capability gaps quickly and sustainably. Governments are increasingly recognizing biomanufacturing as a strategic health and economic infrastructure, driving targeted incentives, public-private partnerships, and localization efforts. Public-private partnerships can also play a critical role in supporting workforce development and regulatory modernization, while manufacturing and CDMO partnerships help improve agility, quality, and speed to market. Importantly, collaboration is not optional - it is a practical mechanism for strengthening ecosystem pillars and enabling countries and companies to scale innovation more effectively than they could on their own. With a population of around 700 million, ASEAN must remain focused on expanding therapeutic access. In this context and the continued evolution and approval of biosimilars, strong partnerships will be central to improving affordability and patient impact across the region.

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