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Is evolving APAC healthcare ecosystem addressing current regulatory bottlenecks?

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“A common theme with many of the new regulatory requirements is data—data and system integrity, data standards, data and evidence generation, and data transparency and traceability,” says Edwin Ng, GM SVP, APAC, Life Science, Dassault Systèmes

With the innovation boom in Asia and many early-stage assets emerging, the time is ripe for Asian economies to establish cross-border business relationships by systematically tapping potential markets for successful market penetration. Regulatory compliance and patient protection are simultaneously enhanced by increasing investments in technology to meet quality and efficacy which are paramount in the pharma/biopharma and clinical trial space. Yet, with the rapidly changing regulatory expectations, certain regions in APAC experience regulatory inertia which can hinder development and bilateral trade. Despite the challenges, Asian economies are adopting evolving policies and regulations supporting operations. However, can regulatory reforms bring down the cost and time required to bring a product to market? **Edwin Ng, Senior Vice President, General Manager (Asia-Pacific) at Dassault Systèmes** shares more insights with *Biospectrum Asia*.

- **What are the most challenging market access issues pharma and biopharma companies are facing across the APAC region?**

One of the biggest challenges in market access to life science and healthcare solutions are regulatory hurdles in clinicaltrials. Only 10% of drugs that complete Phase I trials ever reach patients – this low success rate is largely a result of a highly inefficient clinical trial process. The risks presented by regulatory non-compliance, and the associated significant delays, have a substantial impact on any company’s business and outputs. Sponsors that preempt regulatory obstacles can gain an advantage by reducing time-to-market, creating significant shareholder value, and getting their drug to patients faster. The ability to use big data to create transparency, mitigate risks and operate in real-time is critical for life science leaders.

The life science and healthcare industries are among the most heavily regulated industries in the world. Regulations and guidelines change constantly due to globalisation and advancements in technology, along with improvements in patient outcomes and safety. Increasing demands from patients, consumers, and regulators have led to an evolution in the world of the patient experience, which now sees patients at the heart of the process. The medical device industry for instance has been significantly affected by recent events. The level of regulatory change over the past few years and to date is unprecedented, further emphasised by the COVID-19 pandemic, where we have experienced a plethora of new regulatory updates for medical devices as a result. Companies need to constantly adapt to the new regulatory landscape to accurately and effectively meet compliance or potentially risk financial and reputational ramifications.

- **How essential is it for an Asian country to bring its regulation standards closer to international norms to encourage transnational businesses and investors alike?**

As an industry, to be able to bring new drugs and devices to patients faster, we need to advocate for a universal regulatory ecosystem that is more harmonised and not fragmented. Today, we have the tools to digitise and run clinical trials in multiple countries simultaneously – where practitioners can see the data coming in from multiple sources in real-time. As soon as data is entered into the system, all users have access; a principal investigator is able to sign off the data, a CRA is able to review it remotely without coming into the site, and a data manager can then approve the data, and the sponsor or CRO is able to track the study's progress. The benefits of electronic data capture systems and cloud platforms during the pandemic cannot be overstated - many clinical trials were able to continue due to electronic and remote data capture. Medidata's support brought one of the leading COVID-19 vaccines through the full clinical trial lifecycle in under one year—enrolling 30,000 subjects in just 12 weeks. With a unified or harmonised regulatory framework that streamlines efforts, we will be able to unleash a new era of clinical discoveries that the industry had never seen before.

Preempting the practical hurdles to comply with stringent regulations and using appropriate technology solutions can be beneficial for companies. For example – device manufacturers, with increasing frequency, are being required by FDA to implement a tracking system for certain types of devices. This requires devices to be tracked from the time of manufacture through the entire distribution chain. The purpose of device tracking is to ensure that these manufacturers will be able to promptly locate devices in commercial distribution to facilitate notifications and recalls ordered by the FDA in the case of serious risks to health. Today, most medical device trials are still relying on manual efforts to track devices and perform product accountability; there is a possibility of increased risk and decreased regulatory compliance. Randomisation and trial supply management solutions can be implemented to reduce that risk and address the common regulatory challenges associated with medical device trials.

- **How do you outline strategic transformative solutions in a regulatory ecosystem to deliver a smarter and accelerated market access regimen?**

To evolve the regulatory ecosystem, it is important to understand what the current bottlenecks are? The primary concern of the regulatory authorities is patient safety, so implementation of any new policy must benefit patients, while at the same time maintaining a wide range of regional, national, and international compliance standards. This has prevented the regulatory ecosystem from being agile for changes. The industry could certainly do with more harmonisation. The differences, not just in the rules but also in the punishments, are vast.

In the current dynamic regulatory landscape, some of the future changes will need to adhere to regarding data and how data is used to drive meaningful insights and trends. As technology keeps advancing, the national regulatory authorities will need to align on issues such as the use of wearable devices to collect data, remote monitoring of patient volunteers, etc.

- **How critical is it for startups and SMEs to comply with the regulatory framework in order to raise standards of innovation and thereby increase value for startups?**

In this environment, companies that preempt regulatory obstacles in clinical trials can gain an advantage by reducing time-to-market, creating significant shareholder value, and getting their drug to patients faster. In such an environment, it is not uncommon for startups and SMEs to be boggled with the regulatory obstacles with detrimental delays on project timelines. In addition, the ability to use big data to create transparency, mitigate risks in navigating regulatory hurdles, and operate in real-time is critical for life science leaders.

Many solutions are now available today that can benefit an inexperienced startup or a budding SME. The solutions, developed after years of experience in regulatory requirements, minimise the chances for risks and delays. A common theme

with many of the new regulatory requirements is data—data and system integrity, data standards, data and evidence generation, and data transparency and traceability. Electronic data collection and cloud-based data storage can immediately solve or mitigate these issues. AI and advanced analytics can help companies confidently manage regulatory submissions and significantly reduce risk. These are important industry developments that can help companies navigate the existing regulatory frameworks and accelerate speed-to-market – these are a boon for executives, employees, shareholders, and most importantly, patients in need of care.

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