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ASIA EDITION

Ã¢â?¬Å?We are seeing a shift towards localisation of supply chains Ã¢â?¬â?? from innovation to manufacturing and productionÃ¢â?¬Â•

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For developers of cell and gene therapies (CGT), translating a drug from a biological concept to a scalable and manufacturable treatment can be the largest challenge in achieving commercial success. This is especially difficult in the CGT field, because there is a limited number of qualified personnel with both biological and process engineering know-how. Other challenges are evolving regulatory constraints and aggressive timelines from investors. Even for experienced teams, it can be tricky to balance the efforts of reaching the first clinical trial using a manual, open method with building a more commercially suitable process. In an interaction with BioSpectrum Asia Francis Van Parys, Vice President (Commercial) APAC, Cytiva shared his views on how can biopharma companies optimise their manufacturing process to capitalise on the rapidly growing CGT market and company's growth plans for the APAC hub in FY 22-23. Edited excerpts;



How can biopharma companies in Asia optimise their current manufacturing process for precision medicine, particularly in Cell and Gene Therapy (CGT), to capitalise on the rapidly growing market?

Advancement of technology has certainly influenced the way medicines are being developed. The power of genomics, big data, and new scientific discoveries are driving progress in personalised medicine. This leads to manufacturing wider varieties of monoclonal antibodies, for instance, in smaller quantities; in the case of cell and gene therapy, individualised treatment tailored for the individual patient.

Despite the increased number of precision medicine trials, the development of highly unique medicines however is still fraught with high manufacturing costs, complex logistics and supply chains, and high risks of failure.

Scalable integrated solutions to support the transition from clinical trials to commercialisation have been limited. Many of the multiple cell therapy manufacturing process steps remain largely unintegrated and manual, with open transfers between steps increasing contamination risk.

Cytiva was involved in the first successful paediatric trial of CAR-T therapy in 2012. During that time, we foresaw the challenges and the need for simplification and automation, we developed new technologies to help move toward an automatable closed end-to-end system/workflow/process.

Since the first CAR-T therapy trial, there have been more than 900 regenerative medicine trials underway globally, including trials in cell and gene therapy.

Risk reduction and time to market are critical parameters for success. Manufacturing technologies have also matured to allow for the reproducible manufacturing of cell therapies. Cytiva provides a range of innovative, flexible solutions that blend platforms and facilities with services and expertise.

How would you describe Cytiva's novel efforts in enabling the development and commercialisation of precision medicine in Asia?

Cytiva is tackling these challenges with a wide range of tools and services. We have developed a suite of offerings ranging from integrated scalable systems that can be adapted for Current Good Manufacturing Practice (cGMP) compliance in commercial production, to providing intuitive preventive maintenance services, to facilitating life cycle asset management – we are single-mindedly focused on equipping our research counterparts with the best available support. Most recently, we developed closed and semi-automated processing of CAR-T cell manufacturing workflow that saw an enhanced transduction efficiency greater than 80 per cent. We intend to continue fine-tuning each step while maintaining a robust and scalable process.

Last but not least, training of researchers, manufacturers, and on-site technicians, through our Fast Trak centre is crucial to the development and commercialisation of novel therapeutic candidates.

As biopharma global supply chains become more fragmented, how can Asia adapt and build its competencies?

We are seeing a shift towards localisation of supply chains – from innovation to manufacturing and production. This pursuit of self-reliance for countries that do not have an already developed capability is a massive undertaking; it requires skilling of the workforce, capital investment, policy, and regulatory development as well as infrastructure.

This is where public-private partnerships can play a role. Cytiva's Fast Trak centres are learning labs that facilitate training and development of the workforce, for instance. In Korea, Cytiva APAC Fast Trak centre is running our BioChallenge programme with the country's largest business media, MaeKyung, to accelerate access to the market for biotech startups. In the BioChallenge, entrants pitch their business and technical plans to a panel of experts for the chance to receive support from Cytiva in the form of access to resources at our Fast Trak centre as well as training and mentorship. The programme has been such a success that the Korean Ministry of Health and Welfare and the Ministry of Food and Drug Safety have both joined BioChallenge as co-sponsors.

Cytiva also contributes to the local ecosystem through a partnership with the government to support infrastructure development. One of the large-scale collaborations I've been really excited about here in Asia Pacific is China-Singapore Guangzhou Knowledge City (CSGKC). CSGKC is truly a joint effort, bringing together the governments of China and Singapore alongside thousands of commercial organisations. Cytiva is involved in CSGKC's development in association with BeiGene, Lonza and Akesobio, who have assisted in rapidly establishing manufacturing capabilities in the park with our KUBio prefabricated biopharma facilities.

I believe that countries looking to develop their ecosystem can benefit from opening the space for greater collaboration with the private sector – creating a 'win-win' for all.

Have there been recent investments to bring transformational biopharma manufacturing and diagnostics technologies to the APAC region?

Our mission is to continuously seek out and make available new, transformational biopharmaceutical manufacturing and diagnostics technologies globally. Earlier in 2019, we integrated automation, IT, and single-use solution expertise to build a bioprocessing operation that is flexible and scalable for the future. Recently we expanded the collaboration to APAC, where

Cytiva and Rockwell Automation will build an automation and digital transformation centre in Shanghai. We believe in enabling stronger integration, data collection, and analysis, and create a standardised manufacturing platform capable of core data management. To complete our biopharma 4.0 offering, we implemented an Augmented Reality solution. By tapping onto our platforms such as OptiRun View and My Equipment, downtime can be decreased and repairs can be sped up.

What are the plans for the APAC hub's growth in FY 22-23? Has there been any recent M&A activity or any in the pipeline?

We recognise that there is a wealth of discovery, technologies, and innovation taking place within the academic, scientific, and biotech community. Cytiva accesses and scales leading technological solutions by fostering partnerships and collaborations with both the public and private sector, and spearheading industry-wide initiatives, that enhance and/or enable the discovery and development of new diagnostics, vaccines, biologics, and novel cell and gene therapies. One such initiative is the Cytiva BioChallenge series, which was created with the aim to fuel biotech development by providing funding and services to support research, bioprocessing development, and commercialisation. The BioChallenge was launched in China, Korea, Australia/New Zealand, and will be launched in ASEAN in Q3 2022.

In addition to accessing these solutions, talents are the precursors of our industry's innovation, which led us to invest in our training centers, known as FastTrak, in Shanghai. The expanded centre will be fully operational by Q2 2023.

To manage the rapidly growing demand for medicines and health solutions, we have made investments in strategic collaborations with Wego, Rockwell Automation, and Pall Corporation over the past year tol support our growth plans in the region.

Additionally, we are investing in South Korea to build a single-use manufacturing facility to support vaccine production and to establish a stable and resilient supply chain for vaccine raw materials in the region.

We are confident that with the combination of these strategic approaches, our growth plans for APAC remain robust and optimistic.

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