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“The global trend is moving beyond centralised hubs toward distributed networks and domestic capability”

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King Faisal Specialist Hospital & Research Centre (KFSHRC) and US-based Germfree Laboratories have announced a strategic partnership to develop Saudi Arabia's first fully integrated, modular Advanced Therapy Medicinal Product (ATMP) Manufacturing Campus. The new facility will be located at KFSHRC's main campus in Riyadh and will serve as a critical milestone in advancing Vision 2030 and the National Biotechnology Strategy, two national initiatives aimed at transforming the Kingdom into a global hub for life sciences, biomanufacturing, and to become a global biotech hub by 2040. To find out more about Germfree’s role in this collaboration, BioSpectrum Asia spoke to Kevin Kyle, Chief Executive Officer, Germfree Laboratories.

As Saudi Arabia accelerates its biotech ambitions, what specific infrastructure investments or technological advancements are being prioritised to support domestic ATMP manufacturing?

Under Vision 2030 and the Kingdom's National Biotechnology Strategy, Saudi Arabia is prioritising infrastructure that creates repeatable national capability, not one-off facilities. That means good manufacturing practices (GMP) environments designed for ATMP workflows, integrated quality control (QC) laboratories and release infrastructure, and a digital backbone that supports traceability, data integrity, and scalable operations. The technology direction is clearly toward standardised, closed and increasingly automated processing platforms, with digital manufacturing systems that strengthen chain-of-identity/chain-of-custody and enable faster, more reliable release. The goal is to build a resilient capability that can support clinical trials, routine patient access, and future export-ready manufacturing as the ecosystem matures.

What are the most significant challenges the Kingdom faces in building this capability from the ground up, and what steps are needed to overcome them?

The hardest part of building ATMP manufacturing from the ground up is that success depends on an integrated operating system; people, quality, supply chain, and clinical coordination must mature together. Workforce depth and GMP operating culture are a universal constraint, and QC strategy and release readiness often become the real bottleneck, not cleanroom construction. Under Vision 2030, the most effective approach is to pair infrastructure investment with deliberate capability transfer: embedding experienced GMP leadership early, building competency-based training programmes, standardising platforms to reduce variability, and establishing Saudi Food and Drug Authority (SFDA)-aligned quality systems from day one. When quality, training, and digital traceability are designed into the programme upfront, the Kingdom can compress the learning curve and scale sustainably.

Are other countries taking cues from Saudi Arabia's progress, and do you anticipate a broader global trend toward nations developing their own ATMP manufacturing ecosystems?

Yes, Saudi Arabia's trajectory is part of a broader global shift toward national and regional ATMP ecosystems, driven by patient access, resilience, and industrial strategy. What stands out in the Kingdom's Vision 2030 framing is the coordination between healthcare priorities and economic diversification: manufacturing capability is viewed as a strategic national asset that supports clinical excellence, innovation translation, and high-value jobs. As more nations confront capacity bottlenecks, fragile supply chains, and long treatment timelines, the global trend is moving beyond centralised hubs toward distributed networks and domestic capability—often anchored to leading global clinical centres and enabled by standardised platforms and shared quality systems.

Germfree is collaborating with KFSHRC on the Kingdom's first ATMP Manufacturing Campus. What is the expected timeline for launch, and what early milestones should the industry be watching for?

In our work with KFSHRC, the programme is designed to align with Vision 2030 by delivering capability in practical stages rather than waiting for a single "big bang" moment. The expected pathway begins with a BioGO Box deployment to enable early cGMP training and tech transfer, then scales toward a broader campus model that can expand to 16 multi-modal production suites. We have previously communicated an operating readiness trajectory of roughly 18 months post-contract signing, with milestones that matter most being operational finalisation of the operating model and quality framework, commissioning and qualification gates, selection and standardisation of core platforms, and early tech transfer runs that demonstrate repeatability under SFDA-aligned quality systems. Those indicators are the clearest signals of durable capability.

How much is being invested towards establishing the new facility?

Under Vision 2030 and the National Biotechnology Strategy, the meaningful investment is not limited to the facility shell, it includes QC laboratories, validation and qualification, workforce development, cold chain readiness, and the digital infrastructure required for traceability and compliance. Because this is a partner-led programme with defined governance, investment figures are best cited when formally cleared by stakeholders; however, the intent is clear: to fund an end-to-end capability that can scale from early clinical manufacturing through broader clinical and commercial demand as Saudi Arabia builds a sustainable ATMP ecosystem.

What are the primary forces driving countries to onshore ATMP production in Saudi Arabia?

The forces are both healthcare-driven and nation-building in the Vision 2030 sense. ATMPs are time-sensitive and logistically complex, and proximity to patients and clinical centres improves reliability, scheduling, and ultimately access. At the same time, onshoring reduces dependency on limited global capacity and strengthens national resilience against supply-chain disruptions. For Saudi Arabia specifically, this also advances the National Biotechnology Strategy objective of becoming a global biotechnology hub, building high-skill jobs, accelerating clinical research and trials, and establishing advanced manufacturing capability as a pillar of economic diversification.

How might regional manufacturing capacity change the accessibility and affordability of cell and gene therapies (CGTs) for local patient populations?

Regional manufacturing improves accessibility primarily through predictability and reliability: fewer handoffs, reduced cold-chain risk, and better synchronisation between clinical operations and manufacturing schedules. That can expand the number of patients who can be treated consistently and reduce delays that are unacceptable in time-sensitive therapies. Affordability is more complex than labour or facility costs alone, but regional capacity can improve the economics through standardisation, automation, higher utilisation, and improved right-first-time performance reducing deviations, batch failures, and turnaround times. In ATMPs, reliability is often the most powerful lever for lowering the fully loaded cost per treated patient.

How are countries like Saudi Arabia approaching the challenge of building a specialised workforce for ATMP manufacturing?

Saudi Arabia’s approach is increasingly aligned with Vision 2030’s focus on capability building: combining early expertise importation with structured knowledge transfer and local talent pipelines. The most successful models start with experienced GMP and quality leadership embedded from the beginning, while simultaneously developing competency-based training for manufacturing, QA/QC, validation, and supply chain roles. Partnerships with clinical centres, universities, and ecosystem collaborators become essential not only to train, but to retain talent through clear career paths in advanced manufacturing. Over time, this turns workforce development from a project requirement into a national capability that supports scale.

What has surprised you most about the pace or nature of global interest in establishing domestic ATMP manufacturing?

What has been most striking is how quickly the conversation has shifted from “building facilities” to “building operating capability.” Countries are now asking about quality culture, release strategy, workforce competency, platform standardisation, and digital traceability because they recognise that the building is not the bottleneck; execution is. The pace of interest has accelerated as patient need and supply-chain fragility have become more visible, and Saudi Arabia’s Vision 2030 / National Biotechnology Strategy framing has helped elevate ATMP manufacturing from a technical initiative to a strategic national priority with clear healthcare and economic outcomes.

Dr Manbeena Chawla

(manbeena.chawla@mmactiv.com)