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Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Strengthening Saudi Arabia's Biopharmaceutical Landscape Through Regulatory Modernisation and Local Capacity Building

Saudi Arabia's continued progress towards its Vision 2030 objectives is reflected in major institutional reforms across critical sectors including biotechnology. A notable development in this trajectory is the establishment and recent restructuring of an executive department dedicated to biologics at the Saudi Food and Drug Authority. This initiative forms a cornerstone of the National Biotechnology Strategy, aimed at transforming the Kingdom's biopharmaceutical landscape while laying the foundations for a robust, localised manufacturing ecosystem for biologic products.

The executive department's enhanced structure consolidates several specialized divisions under one strategic umbrella, ensuring a more integrated and agile approach to biologics regulation and oversight. These divisions include dedicated departments for Vaccines, Blood Products, and Biotherapeutics (encompassing biotechnology, biosimilars, and gene and cell therapies). These are further supported by in-vivo testing units, microbiology laboratories, and animal care services, each of which plays a critical role in ensuring the quality, safety and efficacy of advanced therapies. This institutional alignment reflects a wider vision of anticipatory governance, one that is capable of responding to rapid innovation in life sciences.

In parallel with structural reform, the department is actively investing in capacity building and operational readiness. This includes the recruitment and training of a highly skilled workforce, the adoption of continuous professional development programmes and the acquisition of next-generation laboratory instrumentation designed for high-precision biological analysis. These efforts are being complemented by strategic investment in artificial intelligence, with the aim of enhancing regulatory review, predictive modelling and data-driven decision-making.

The executive department is also intensifying its focus on research and development to support more sophisticated approaches to quality control. By improving analytical techniques and reinforcing mechanisms for ensuring consistency across biologic products, it seeks to uphold international safety and efficacy standards. These efforts are particularly timely given the growing complexity of the biologics sector, where innovations such as personalised medicine and cell-based therapies are reshaping regulatory expectations.

Alongside its internal development, the department is fostering a broader regional biotech ecosystem. The launch of a biotech community and the introduction of accelerated regulatory pathways – such as fast-track approvals – are designed to facilitate innovation while maintaining rigorous oversight. These initiatives also aim to attract international expertise and investment. By supporting local manufacturers through technology transfer, expert consultation and targeted workshops, the department is helping to cultivate an environment conducive to sustainable industrial growth.

Ultimately, the transformation of the biologics department serves to both strengthen national health security and contribute meaningfully to economic diversification by bolstering Saudi Arabia's strategic commitment to becoming a global player in biotechnology and life sciences.