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OXFORD BUSINESS GROUP

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Empowering Health Care Innovation:

Saudi Arabia's Pioneering Approach to Point-of-Care Medical Device Manufacturing

Saudi Arabia has taken a progressive step in health care innovation through its regulatory framework for point-of-care (POC) medical devices manufacturing. Established during the Covid-19 pandemic to address urgent medical supply shortages, this initiative has evolved into a structured pathway balancing regulatory oversight with the need for rapid, localized innovation. A guidance document (MDS-G009) from the Saudi Food and Drug Authority (SFDA) formalizes this approach, creating a unique ecosystem where health care facilities can develop and use medical devices tailored to their specific needs, without commercial intent.

Foundations of the Regulatory Framework

The legal foundation for this framework stems from the Medical Devices Law (Royal Decree No. M/54), which outlines critical provisions for device safety and monitoring. Notably, Article 8 prohibits the marketing of unapproved devices while allowing exemptions for non-commercial use, provided safety is verified. Meanwhile, Article 26 mandates SFDA oversight to ensure compliance with technical regulations, and Article 28 requires adverse event reporting to the National Centre for Medical Devices Reporting. These provisions are reinforced by the implementing regulations, which include exemptions for humanitarian and research applications, provided rigorous safety assessments are conducted.

Impact on Clinical Innovation

POC manufacturing encompasses a range of activities, including assembling devices from raw materials and developing artificial intelligence-based medical software. Crucially, this pathway is strictly non-commercial: devices produced under its purview are for internal use only, ensuring they meet immediate clinical needs without entering the broader market. The SFDA's streamlined evaluation process, completed within 30 working days for a complete technical file, enables facilities to quickly deploy custom solutions, such as 3D-printed prosthetics or laboratory calibration standards.

This initiative aligns seamlessly with the goals of Vision 2030 to foster a knowledge-based economy and advance local innovation. By empowering health care institutions to develop in-house solutions, the SFDA not only addresses gaps in medical device availability but also cultivates a culture of research and development. Saudi Arabia's leadership in this space is further underscored by its status as one of the first regulator globally to issue specific guidance for in-house in-vitro diagnostics (MDS-G022), setting a benchmark for regulatory innovation.

Future Outlook for Innovation

The POC manufacturing model exemplifies how regulatory frameworks can adapt to support both patient care and national strategic objectives. By combining flexibility with stringent safety standards, the SFDA has created an environment where health care providers can innovate responsibly, ensuring that Saudi Arabia remains at the forefront of medical technology development while prioritizing patient safety and quality of care. This approach not only meets immediate health care demands but also lays the groundwork for sustained innovation in line with the Kingdom's long-term vision.

For media inquiries:

Intl.Media@sfda.gov.sa