

# Pioneering Digital Transformation in Drug and Cosmetic Safety:

## Saudi Arabia's Regulatory Innovation Journey



Saudi Arabia is establishing itself as a regional leader in digital health regulation through the Saudi Food and Drug Authority's (SFDA) groundbreaking integration of advanced technologies into pharmacovigilance and cosmetic safety oversight.

Aligned with Vision 2030's digital transformation goals, these initiatives are setting new benchmarks for proactive, data-driven regulatory systems that enhance public health protection.

The background image shows a hand in a white lab coat hovering over a tablet. The tablet screen is dark with various white icons overlaid, including chemical structures, a globe, a stethoscope, a head with a brain, and a caduceus. The overall color scheme is blue and white.

# Modernising Pharmacovigilance Through Digital Platforms

The transformation began with modernising the National Pharmacovigilance Centre's adverse reaction reporting system. Moving from paper-based submissions to the fully digital "Saudi Vigilance" platform marked a significant step forward. The introduction of smart reporting forms featuring structured data

fields and behavioural nudges based on psychological principles significantly improved reporting quality and completion rates. This digital foundation enabled the development of centralised dashboards that provide real-time adverse event analysis, allowing early identification of safety signals and under-reporting trends.



# Harnessing Automation for Efficiency and Accuracy

A key innovation has been the strategic implementation of Robotic Process Automation (RPA) to streamline pharmacovigilance operations. By automating repetitive tasks such as report triage and initial data verification, the SFDA has achieved remarkable efficiency gains. The recently launched RPA signal detection

service exemplifies this progress, reducing processing times while enhancing the accuracy of safety signal identification. These technological solutions have optimised workflows and improved employee satisfaction by removing monotonous manual tasks.





# Extending Digital Innovation to Education, Error Prevention and Cosmetics

The SFDA's digital transformation extends to proactive risk minimisation through innovative educational platforms. The aRMMs e-learning system, featuring 112 instructional videos covering high-risk medications, has revolutionised health care professional training. Perhaps more impactful has been the

integration of digital risk minimisation measures directly into hospital information systems across 12 facilities. This pioneering approach embeds safety alerts and educational content into clinical workflows, ensuring critical information reaches prescribers at the point of care.

Medication error prevention has similarly benefited from digital innovation. The transition from the Phonetic and Orthographic Computer Analysis system to the advanced Saudi Name Registration (SNR) platform has enhanced the detection of potentially confusing drug names. With improved algorithms covering both Arabic and English nomenclature, along with real-time alerts and automatic updates, the SNR system represents a significant upgrade in pre-market safety screening.

Looking ahead, the SFDA is preparing to extend this digital transformation to cosmetic product safety. Proposed artificial intelligence (AI)-driven initiatives include computer vision systems for regulatory violation detection, automated ingredient compliance checking and natural language

processing tools to analyse consumer feedback for early warning signals. While these projects remain under development, they demonstrate the SFDA's commitment to applying cutting-edge technology across all regulatory domains.

This comprehensive digital transformation strategy positions Saudi Arabia at the forefront of regulatory innovation. By successfully integrating AI, automation and data analytics into its operations, the SFDA is enhancing current pharmacovigilance capabilities and building the foundation for future advancements in consumer product safety. These efforts collectively support Vision 2030's ambition to create a knowledge-based economy while ensuring the highest standards of public health protection for Saudi citizens.

