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INNOVATING FOR A HEALTHIER TOMORROW: THE SFDA'S ANNUAL REPORT

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

SFDA in Brief

PRODUCT REGISTRATION AND APPROVAL

211,265
Food Products

781
Drug Products
Including:
492 Generic
86 Biologics & Biosimilars

77,827
Medical Devices

8,271
Feed Products

INSPECTION

78,985
Visits

48,201
Food

25,368
Drug and Medical Devices

5,416
Pesticides and Feed

LABORATORY

Completion of
72 Research Projects and Scientific Studies

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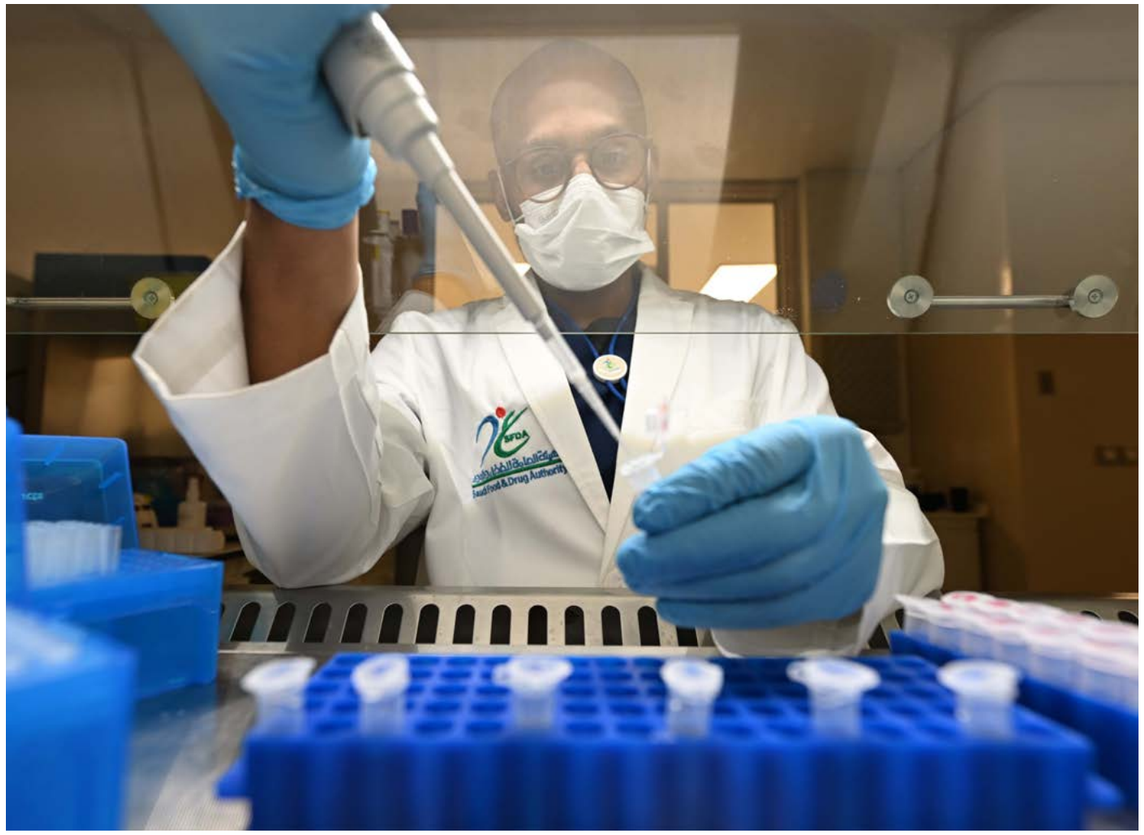
An Introduction to the SFDA



Established in 2003, the SFDA is a key regulatory authority, dedicated to promoting public health and safety across Saudi Arabia. Headquartered in Riyadh and operating throughout the Kingdom, the SFDA oversees the regulation of essential products such as food, drugs, medical devices, cosmetics, pesticides, and animal feed. Our broad mandate is rooted in a commitment to scientific evidence and best practices, ensuring these products meet high standards of quality, effectiveness, and safety. By engaging with both the public and private sectors, the SFDA aims to provide the population with safe and reliable products, ultimately helping to contribute to a healthier society – supporting progress towards national and international goals.

The Authority's vision—to become a leading international food and drug regulator—reflects its ambition to set global standards in health regulation. The SFDA's goals are tightly aligned with Saudi Vision 2030, the Kingdom's economic diversification strategy that seeks to transform the health, economic, and industrial sectors. Vision 2030, with its emphasis on public health and sustainable growth, has guided SFDA's efforts to foster an agile and innovative regulatory environment that supports the Kingdom's expanding population and industrial sector.

Our strategic focus extends beyond regulatory functions to include active participation in transforming the health care sector. Through initiatives aligned with Vision 2030's Health Sector Transformation Programme, we contribute to ongoing reforms aimed at improving health care quality, efficiency, and accessibility.

The SFDA's role is increasingly critical given anticipated demographic and national changes. According to UN-Habitat, Saudi Arabia's population is expected to reach approximately 31.5m by 2030. This growth underscores the need for a resilient health care system capable of addressing rising lifestyle-related diseases and evolving health demands. Furthermore, with the national objective to attract more than 30 million visitors for the Hajj and Umrah pilgrimages by 2030, there is a pressing need for robust health infrastructure capable of handling this large influx of international visitors while maintaining the highest safety standards.

By adopting this comprehensive approach, the SFDA directly supports several UN Sustainable Development Goals (SDGs), by ensuring food and feed safety (SDG 2: Zero Hunger), strengthening health standards and public awareness (SDG 3: Good Health and Well-being), regulating bottled water and ice production (SDG 6: Clean Water and Sanitation), promoting responsible consumption of food and drugs (SDG 12: Responsible Consumption and Production), and fostering international partnerships to accelerate global progress (SDG 17: Partnerships for the Goals).

The SFDA's extensive remit helps it secure public confidence and uphold high standards in line with global standards. The SFDA enforces rigorous regulatory practices designed to ensure all products meet national standards for safety, quality, and compliance.

Product safety is a primary focus of the SFDA. Its comprehensive oversight spans all points in the production chain, from origin to final sale, and is executed through a strong system encompassing inspections at ports of entry and production centres, detailed verification of ingredients, hygiene practices, and product labelling, alongside licensing, research, and public awareness initiatives. By closely monitoring both imported and domestically produced items, we play a central role in protecting consumers and fostering a safe, secure marketplace.

FOURTH STRATEGIC PLAN: The SFDA's Fourth Strategic Plan (2023–27) marks a pivotal step in shaping the future of Saudi Arabia's regulatory landscape. Designed as a comprehensive blueprint, it not only reinforces the Authority's mandate to protect public health but also strengthens the Kingdom's position as a global leader in regulatory innovation.

Built Around Three Central Themes:

THEMES

- Product Safety
- Local and International Partnership
- Operational Excellence

The plan lays the groundwork for a transformative approach that will safeguard citizens, promote international cooperation, and enhance operational effectiveness.

REGULATORY DEVELOPMENTS AND SYSTEMS

Saudi Arabia's regulatory environment for health products and medical technologies is governed by a comprehensive framework under the supervision of the SFDA. Covering medical devices, pharmaceuticals and related operations, the framework ensures that all products meet defined standards of safety, quality and performance. Supported by clear legislation and technical guidance, it promotes consistency in registration, manufacturing and post-market oversight. Recent initiatives in biotechnology-based devices, innovative therapies and point-of-care manufacturing highlight the SFDA's focus on aligning with international standards while advancing national goals for innovation and local industry development under Vision 2030.

The regulatory framework for medical devices in the Kingdom is a cornerstone in ensuring public safety and fostering innovation. The primary legislative foundation for this is the Medical Devices and Supplies Law, established by Royal Decree No. M/54. This law outlines stringent requirements for the registration, marketing authorisation and post-market surveillance of medical devices, offering a well-established legal structure for product safety and effectiveness throughout Saudi Arabia.

To operationalise the core legislation, our team has developed a series of guidance documents clarifying regulatory and technical requirements. Among these, the Guidance on Biotechnology-Based Medical Devices (MDS-G016) provides detailed standards for the design, manufacturing and authorisation of biotech-oriented devices. Similarly, Guidance on AI and Machine Learning Technologies based Medical Devices (MDS-G010) sets directives for the classification and control of AI-driven medical technology, highlighting the Authority's integration of emerging technologies into evolving regulations.

The recently launched Guidance on Innovative Medical Devices (MDS-G002) expedites the regulatory process for novel technologies that demonstrate significant advantages over existing products.

Guidance for Points of Care (POC) Medical Devices Manufacturing (MDS-G009) establishes comprehensive requirements for point-of-care medical device manufacturing within health care facilities. It mandates the rigorous documentation of manufacturing processes, staff qualifications and design validation. Facilities must maintain detailed records of sterilisation procedures, biocompatibility testing and clinical evaluation to ensure that locally manufactured devices meet safety and performance standards comparable to commercial products. Meanwhile, the Guidance on the Development of In-Vitro Diagnostics (IVDs) for In-House Use (MDS-G022), outlines the regulatory framework and technical requirements for design validation, clinical and analytical performance, and post-approval monitoring of In-House IVDs. Stakeholders such as manufacturers and importers must notify users and the SFDA of safety issues, submit detailed corrective action plans, implement approved corrections and verify completion through a process of standardised documentation – further strengthening the Kingdom's consumer protection and regulatory oversight.

Deepening our commitment to innovation, the SFDA recently launched a major initiative focused on developing diagnostic laboratory equipment and advancing 3D printing in hospitals, informed by the regulatory frameworks outlined in MDS-G009 and MDS-G022. This initiative ensures that diagnostic equipment produced within health care facilities adheres to stringent safety and performance standards aligned with global best practices.

Simultaneously, the initiative incorporates MDS-G022's structured approach to field safety corrective actions, reinforcing a proactive regulatory environment for locally manufactured medical devices. The programme strengthens the national industry and supports the domestic manufacturing of diagnostic equipment and reagents, aligning with the SFDA's strategic goals of empowering innovators, supporting local industry and bolstering investor confidence in medical products.

By streamlining regulatory approvals and fostering innovation, the SFDA aligns with the Kingdom's Vision 2030 objective to position Saudi Arabia as a global destination for medical technology. Our responsiveness to technological advancement, coupled with adaptive governance, underscores our commitment to ensuring safety while promoting investment in the medical devices and biotech sectors.

The strong enforcement of regulatory requirements forms a critical pillar of the SFDA's regulatory architecture. This includes conducting routine inspections, identifying violations, issuing penalties and – when necessary – referring cases to the Public Prosecution or other relevant competent authorities. These actions are applied across manufacturers, warehouses and retail outlets.

For e-commerce and social media violations, the SFDA's Regulatory Enforcement Department reviews cases and refers them to the relevant authorities. Measures such as these ensure regulatory compliance and protect public health across the Kingdom.

We implement strategies to support the development and evaluation of innovative therapies, particularly those offering major advances over existing treatments. These initiatives address specific medical needs and ensure Saudi patients have access to a wide range of effective and appropriate medicines.

WHAT WE DO FOR YOU

We safeguard the safety, quality and performance of all health products and medical technologies used in the Kingdom. Through clear regulations, technical guidance and strong oversight, we ensure that products entering the Saudi market comply with national standards and international best practices.

A national biotech strategy, launched in January 2024, is projected to contribute $34.6bn to Saudi Arabia's non-oil GDP by 2040 – underscoring its significance for the Kingdom's economic diversification.

In 2024, we significantly expanded our regulatory framework, issuing more than 60 new laws, guidelines and requirements across the food, drug and medical device sectors. These measures reflect the Authority's broad commitment to strengthening public health, promoting innovation and aligning national regulations with international standards. The new framework encompasses critical areas such as food safety and nutrition, pharmaceutical evaluation and medical device oversight – introducing comprehensive policies that enhance consumer protection, improve product quality, and foster a more resilient health ecosystem across the Kingdom.

The SFDA continues to play a key role in advancing public health through the implementation of comprehensive food safety and nutrition regulations. As part of our strategy to promote healthier dietary habits, we focus on improving the nutritional environment, particularly in out of-home dining. In 2024, the SFDA introduced a series of measures to enhance the quality, safety and transparency of food products, strengthening public health standards and supporting the sector's shift toward safer and more nutritious offerings.

The SFDA continued to advance public health and nutrition in 2024 through the implementation of new dietary guidelines and regulatory measures. These initiatives aim to improve food quality, empower consumers to make informed choices and encourage healthier dietary practices across the Kingdom.

1. National Nutrition Guidelines (Developed by the National Nutrition Committee – NNC)

Under SFDA supervision, the NNC introduced a comprehensive framework to promote balanced nutrition for all population groups. The key components include:

- Saudi Healthy Plate Guide – A culturally adapted visual tool promoting balanced and nutritious meals.
- Nutritional Specifications for Food Baskets Provided by Charitable Organisations – Ensuring the quality and adequacy of donated food.
- Nutrient Profiling Model of Saudi Arabia – A scientific model for classifying foods based on nutritional value, guiding policies such as front-of-pack labelling and marketing restrictions.
- Guidelines for the Nutrition of Specific Population Groups – Tailored dietary recommendations for pregnant and lactating women, children, seniors, people with disabilities and pilgrims.

2. Consumer-oriented Regulations for Food Establishments

As part of our efforts to enhance transparency and promote healthier food choices, the SFDA introduced a set of new regulations to be enforced in mid-2025:

- Declaration of Caffeine Content on Food Menus (SFDA.FD 5023) – Requires display of caffeine content per 100 ml or per cup, including a disclaimer on recommended daily limits for adults.
- Labelling of High-Salt Meals (SFDA.FD 5026) – Mandates clear identification of meals high in sodium using a saltshaker icon to help reduce risks such as hypertension and heart disease.
- Physical Activity Labelling on Menus (SFDA.FD 5029) – Requires indication of estimated physical activity time needed to burn the calories of a meal, encouraging more mindful consumption.

> **“ The SFDA has introduced several new regulations targeting food establishments.**

3. Research and Innovation Support

- Guideline for Research and Development (R&D) Centres in Food and Feed Plants – Establishes best practices for creating R&D centres in food and feed facilities to foster innovation and strengthen the sector's scientific capacity.
- Guideline for Research and Innovation Support Requests in Food or Feed – Outlines eligibility, evaluation criteria and support mechanisms for research proposals aligned with national food safety and nutrition priorities.

In line with our mandate to safeguard drug safety and efficacy, the SFDA issued 26 guidelines and regulations in 2024, key examples of which are outlined below:

- Economic Evaluation Studies Guidelines
- Guidance on the Equivalence of Topical-Products
- Breakthrough Medicine Programme
- Veterinary Antimicrobial Products Classification
- Guideline on Good Pharmacovigilance Practices (GVP): Consideration for Pregnant and Breastfeeding Women
- Guide to Good Manufacturing Practice for Natural Health Products
- General Considerations for Preclinical Studies Submissions

We continue to strengthen our regulatory framework for pharmaceuticals through a structured approach that integrates digital transformation, scientific advancement and governance efficiency. Leveraging technologies such as electronic submissions, data analytics and AI-driven evaluation tools, the Authority is streamlining registration and approval processes, reinforcing pharmacovigilance and enhancing transparency in regulatory operations. These efforts reflect the SFDA's institutional commitment to regulatory excellence, improved industry performance and the protection of public health within Saudi Arabia's evolving pharmaceutical landscape.

DRUG REGULATORY FRAMEWORK: Accelerated digital innovation is driving the refinement of the SFDA's regulatory framework for drugs. The transition from the common technical document (CTD) format to the electronic CTD (eCTD) format for human medicine in 2015, and the adoption of a veterinary non-eCTD electronic submissions format in 2019, reflect the Authority's ongoing commitment to modernisation. A phased implementation of version four of the eCTD is expected by 2027, underscoring a long-term strategic vision for regulatory efficiency. Enhancements to the Saudi Drug Registration system remain central to this digital transformation and align with our strategic goals for 2024-2027.

Key initiatives include the use of advanced data analytics for market trend assessment, greater automation in registration and approval processes, and integration with national and international health databases. User-friendly interfaces have also been prioritised to enhance accessibility for stakeholders, while strengthened cybersecurity measures protect sensitive regulatory data and maintain system integrity.

Beyond digitalisation, the Authority is incorporating AI into its scientific evaluation processes. AI tools are being tested to support evaluators' decision-making by drawing on historical data to improve accuracy and speed. The SFDA is also developing the Saudi Clinical Trial Register, a new submission system designed to streamline applications and enable future integration with other government platforms. Another key step is the adoption of electronic labelling through the Saudi Drug Information platform – granting health care professionals and patients immediate access to updated drug data, including variations in indications and side effects.

Our regulatory enhancements also extend to pharmacovigilance. We are integrating pharmacogenomic data into drug safety monitoring and maintaining a database of medicines with pharmacogenomic biomarkers to improve medication safety and mitigate adverse drug events. We have also undertaken a rigorous review of drug labelling, ensuring that risks linked to genetic factors are appropriately reflected in product information. A systematic safety review process draws from both global and local data sources to identify new safety signals. Together, these initiatives position the SFDA as a forward-thinking regulator in the global arena, setting benchmarks for innovation, safety and evidence-based decision-making.

Despite these gains, challenges persist. The adoption of new digital frameworks requires widespread stakeholder adaptation, and ensuring interoperability with international regulatory systems remains a complex task. While AI and automation promise greater efficiency, their success depends on overcoming technical constraints and ensuring continued regulatory compliance.

COMMUNICATION AND AWARENESS: We recognise that an effective regulatory framework must be complemented by strong public engagement and education. In 2024, the Authority implemented a wide range of awareness initiatives, using both digital and traditional communication channels to maximise outreach. The execution of electronic campaigns, participation in global awareness days and delivery of educational lectures reflect our proactive approach. Through field campaigns and digital interactions, including social media, the SFDA has made regulatory information more accessible and transparent.

A targeted strategy underpins these initiatives, aligning campaigns with key public health priorities such as Ramadan-related food and drug safety, vaccination advocacy, back-to-school health education, and specialised programmes for pregnant and breastfeeding women. This reflects the Authority's intent to integrate health education into everyday life and ensure the timely dissemination of critical information.

Nonetheless, as with many regulatory authorities, the SFDA continues to face challenges in communication. Its diverse audience – including consumers, health care professionals, businesses and international stakeholders – necessitates tailored messaging, and the complexity of regulatory information can hinder comprehension. Persistent issues such as misinformation and limited awareness of regulatory updates also remain, compounded by behavioural and cultural factors that influence dietary habits and medication adherence.

To address these challenges, the Authority has implemented a multipronged strategy, simplifying information through user-friendly guides, infographics and interactive digital tools. A key example is the Paracetamol Calculator, which promotes safer medication use by helping caregivers calculate accurate doses for children. Other innovations, including calorie calculators and e-labelling platforms, expand public access to reliable health data. Our website and mobile applications provide real-time updates, reinforcing the SFDA's commitment to public health and safety.

Engagement with the private sector forms another key pillar of the strategy. Through workshops and ongoing dialogue, we promote voluntary compliance and encourage proactive adherence to health-focused initiatives. Meanwhile, fostering community involvement in regulatory decision-making is another focal point – with a focus on building trust and enhancing public participation in health governance. The launch of a national awareness campaign and the Good Clinical Practice (GCP) training programme strengthen stakeholder communication and research quality.

Continued technological adoption will remain essential to enhancing public awareness and regulatory communication. While progress is evident, ongoing adaptation remains necessary to address myriad challenges – including regulatory complexities and stakeholder engagement – across Saudi Arabia.

STRATEGIC INITIATIVES

National Transformation Programme (NTP), Health Sector Transformation Programme (HSTP) and Biotech-based Medical Devices Project

Aligned with Vision 2030, we play a central role in advancing the objectives of the NTP and HSTP – two national initiatives driving progress in public health, innovation and regulatory efficiency. Through these programmes, we have strengthened food safety, modernised drug regulation, expanded research infrastructure and enhanced oversight of medical devices. These efforts advance national priorities in economic diversification, technological development and sustainable health outcomes across the Kingdom.

NTP: ADVANCING REGULATORY EXCELLENCE AND FOOD SAFETY

Under the NTP, our team has advanced our mandate through a comprehensive approach combining regulatory reform, capacity-building and digital transformation. The programme has reinforced the national food safety framework by introducing stricter regulations, modernising inspection systems and deploying digital tools to monitor compliance across the supply chain. Training initiatives have enhanced staff capabilities and public awareness campaigns promote

nutrition and food safety, fostering a health-conscious society. These measures safeguard public health, ensure product quality and support the NTP's goal of improving governance, efficiency and innovation within the regulatory ecosystem.

PROMOTING R&D IN DRUG AND BIOTECHNOLOGY

As part of its fourth strategic plan to advance research and innovation, the SFDA launched a national initiative to strengthen collaboration with universities, research centres and the private sector. In 2024, we conducted field visits to key academic and research institutions across the Kingdom to raise awareness of regulatory standards in pharmaceutical innovation. These visits helped researchers align their work with regulations, enhancing the quality and impact of research and supporting the local development of biologics and novel therapies. Additionally, the initiative identified challenges, proposed solutions and fostered more effective communication between researchers and regulators to strengthen collaboration and knowledge exchange.

FOSTERING LOCAL DRUG MANUFACTURING

A cornerstone of the NTP's drug strategy is the promotion of local production to strengthen national self-sufficiency and economic resilience. The SFDA plays a critical regulatory role, ensuring that locally produced medication meets stringent quality and safety standards. Reforms have streamlined approval pathways, enabling faster market access for essential drugs. Meanwhile, our team launched the Expediting Clinical Trials Approval Initiative with national partners to enhance the clinical trials ecosystem and accelerate review processes. By fostering a more responsive framework, these efforts aim to attract investment in pharmaceutical research and speed the availability of innovative treatments. Maintaining the balance between efficiency and safety, however, remains an ongoing challenge.

STRENGTHENING MEDICAL DEVICE REGULATION

The SFDA's oversight of medical devices has been notably enhanced under the NTP. Reforms have reinforced the regulatory system, ensuring that devices meet high safety and performance standards. The programme also encourages public-private collaboration, promoting innovation and compliance. This partnership has been key to advancing technology and aligning practices with international benchmarks.

> **"Investment in research infrastructure is a cornerstone of the National Transformation Programme, with funding directed towards modernising laboratories that support the SFDA's activities.**

ADVANCING RESEARCH AND LABORATORY CAPABILITIES

Investment in research infrastructure is a cornerstone of the NTP, with significant funding directed towards modernising laboratories that support the SFDA's activities. These upgrades enable more rigorous testing of food, drugs and medical devices, enhancing evidence-based regulatory decisions.

Collaborative data-sharing platforms between research institutions and the Authority further support regulatory efficiency. However, sustaining such advancement will require continued investment and the development of a strong national research ecosystem.

HSTP: ESTABLISHING NUTRITIONAL STANDARDS

As part of the HSTP, we have focused on developing nutritional guidelines to address rising obesity rates and promote healthier eating habits within the Kingdom. These guidelines aim to improve public health outcomes by encouraging better dietary practices across the population. Coupled with advanced food safety monitoring systems, these initiatives ensure compliance with safety standards throughout the supply chain – from farm to table. While aligned with the Saudi Vision 2030 health objectives, shifting long-standing dietary habits remains a gradual process.

ENHANCING PHARMACOVIGILANCE AND DRUG REGISTRATION

Under the HSTP, we have strengthened pharmacovigilance systems to improve post-market monitoring of drug safety. Its oversight ensures the prompt reporting and management of adverse drug reactions. At the same time, streamlined registration processes have accelerated access to safe and effective treatments. While these initiatives demonstrate substantial progress towards national objectives, further refinements will be necessary during the years ahead in order to balance speed with the rigorous evaluation of new therapies.

REGULATING MEDICAL DEVICES AND DIGITAL HEALTH TECHNOLOGIES

Regulatory reforms under the HSTP have bolstered the oversight of medical devices, ensuring that these tools meet international safety standards before reaching consumers. Simultaneously, the programme promotes the integration of digital health technologies – enhancing the SFDA's ability to monitor and regulate medical devices throughout their lifecycle. These advancements are critical for aligning Saudi Arabia's health care system with global best practices. Nonetheless, ensuring the widespread adoption of digital health solutions in the coming years will require overcoming barriers such as cost and technical expertise.

EXPANDING RESEARCH AND LABORATORY INFRASTRUCTURE

The HSTP's emphasis on collaborative research initiatives has fostered partnerships between health care providers and research institutions, driving innovation in drug development and medical devices. Significant investment in laboratory capacity-building has further enhanced the Authority's ability to conduct quality assurance testing – thereby improving public health outcomes. While these developments mark a significant step forwards, maintaining momentum will depend on sustained funding as well as the continuous upskilling of laboratory personnel within the Kingdom.

NTP AND HSTP: OUTLOOK FOR STRATEGIC INITIATIVES

Our contribution to the NTP and the HSTP highlights our pivotal role in realising Saudi Arabia's long-term objectives under Vision 2030. Progress in food safety, drugs, medical devices and research infrastructure has established a strong foundation for transformative growth. With continued innovation, streamlined regulations and strategic partnerships, the SFDA appears well equipped to drive lasting improvements in public health and economic resilience across the Kingdom in the coming years.

STRATEGIC PROJECT FOR BIOTECH-BASED MEDICAL DEVICES

We have initiated a strategic project aimed at capacity-building for biotech-based medical devices, as well as the development of a robust regulatory framework for these devices. This initiative encompasses next-generation gene sequencing, biomarkers, companion diagnostics and in-house developed IVDs. As part of these efforts, our team has already published MDS-G022 and has also drafted regulatory guidelines for companion diagnostics – scheduled for publication by mid-2025.

WHAT WE DO FOR YOU

We advance the Kingdom's long-term health objectives by shaping and implementing strategic initiatives that strengthen regulation, promote innovation and build national capability.

ACHIEVEMENTS AND MILESTONES

Major accomplishments in product safety & public health

The SFDA has substantially advanced its efforts to strengthen product safety and public health in line with its Fourth Strategic Plan (2023-27). Through regulatory updates, international collaboration, and evidence-based research, oversight has been enhanced across the food, drug, and medical device sectors, supporting food security, improving laboratory standards, and facilitating the safe introduction of new medical technologies. These developments collectively underscore Saudi Arabia's broader commitment to aligning with global standards in health protection and regulatory excellence.

The SFDA significantly amplified Saudi Arabia's role in global governance and standard-setting. The Kingdom's leadership in food safety was affirmed by its election as Vice-Chair of the Codex Alimentarius Commission (CAC) during its 47th Annual Meeting held in Geneva. Furthermore, SFDA took a proactive stance on global public health by chairing the WHO Trans Fat Elimination Technical Advisory Group (TFATAG). The Authority also expanded its influence in complementary medicine, contributing to drafting the WHO Ten-Year Global Traditional Medicine Strategy 2025–2034, and demonstrated technical regulatory leadership by chairing the ICH E11A Pediatric Extrapolation Working Group within the International Council for Harmonisation (ICH).

The SFDA has substantially enhanced its role in global medical device regulation, achieving "Official Observer" status in the International Medical Device Regulators Forum (IMDRF) and actively chairing the Scientific and Technical Committees (TCs) and several Working Groups (WGs) within the Global Harmonization Working Party (GHWP). Domestically, SFDA streamlined approval pathways for innovative devices, facilitating faster market access while maintaining stringent safety standards. Concurrently, the SFDA reinforced post-market surveillance via the National Centre for Medical Devices Reporting and established compliance with national diagnostic reference levels for radiation safety, complementing these efforts with capacity-building initiatives like the "Safe Use of Medical Devices" training programmes.

The SFDA strengthened its food safety protocols through rigorous monitoring and intervention. The Authority strengthened preventive measures by reviewing over 2,400 disease reports from food-exporting countries, resulting in 24 targeted interventions such as adjusted import restrictions. Additionally, the National Food Monitoring and Control Programme (2020–23) was instrumental in detecting chemical and microbial contaminants in both local and imported products, enhancing compliance and advancing national food control procedures. The SFDA also established a local partnership with the National Center for Complementary and Alternative Medicine to collaborate on regulatory legislation and awareness regarding herbal and health products.

The SFDA continues to strengthen its research and laboratory capacities, enhancing the safety of regulated products. The Authority's standing was affirmed by ISO/IEC 17043:2023 accreditation for three reference laboratories as proficiency testing providers, and the Safety Level 3 Laboratory achieved accreditation according to WHO requirements, establishing its position as an international reference facility. The National Drug Control and Calibration Laboratory (NDCCL), whose ISO/IEC 17025:2017 accreditation affirms its technical competence, continues to play a central role in testing biologicals (such as vaccines and blood components). Supporting these efforts, the Bioinformatics and Cheminformatics Reference Laboratory provides advanced computational tools for precise risk assessments and evidence-based regulatory decisions.

SFDA demonstrated a continuous commitment to excellence and efficiency. The Authority successfully maintained its ISO 9001:2015 Quality Management System Certification for the twelfth consecutive year. Building on this foundation, SFDA also obtained the ISO 56002 Certification in Innovation Management Systems, reflecting its dedication to implementing global best practices. Internally, SFDA employed Robotic Process Automation (RPA) to enhance the efficiency and accuracy of evaluating adverse event reports and detecting drug safety signals.

This is a significant milestone for Saudi Arabia and a testament to our commitment to global food safety and standards," said Dr. Hisham S. Aljadhey, the CEO of SFDA, "By assuming the role of Vice-Chair of CODEX, we aim to further strengthen international collaboration, promote sustainable food practices, and ensure the well-being of consumers worldwide. We look forward to working closely with our international partners to shape the future of food safety and quality.

Key Projects Completed in 2024

In 2024, the SFDA implemented key initiatives to strengthen product safety, regulatory efficiency and international alignment across the food, biologics, medical devices and drug sectors. These projects advanced public health protection through enhanced research, capacity-building and collaboration – supporting national self-sufficiency, innovation and the Kingdom's wider Vision 2030 goals.

In 2024, we advanced targeted initiatives in food safety, nutrition and global regulatory alignment. A key achievement was the comprehensive risk assessment of 3-MCPDE and GE in infant formula and baby food sold domestically. The study identified concerning contaminant levels, particularly in palm oil-based products, prompting swift regulatory action and the introduction of strict maximum limits to protect infant health.

To strengthen evidence-based policymaking, we convened the inaugural meeting of our International Scientific Advisory Board in 2024, bringing together global experts to guide new food safety regulations and procedures in line with international best practices.

Examples of key projects in 2024:

- Leading an International Drug Regulation Project: Under the umbrella of the International Pharmaceutical Regulators Programme (IPRP), Saudi Arabia led a global project in collaboration with the European Commission and the European Medicines Agency (EMA). This initiative involved experts from leading global authorities, including Swissmedic, the US FDA, Health Canada, Japan (PMDA), the UK (MHRA), and the EDQM.
- Successful Implementation of the Medical Devices and Supplies Law: The law's implementation resulted in 65 local manufacturers obtaining 180 marketing authorizations for 717 medical devices and supplies through the Local Manufacturers Support Initiative. In 2024, 20 new local manufacturers obtained 74 marketing authorizations for 270 medical devices and supplies.
- Developing the Drug Track and Trace System (RSD): The system's infrastructure was updated, and version 2 (RSD 2.0) was launched, raising the actual inventory conformity rate to 99% for local factories and 98% for pharmaceutical agents/distributors.
- Managing the 2024 Proficiency Testing Programme: SFDA administered 53 proficiency tests in the food and cosmetics sectors to its regulatory laboratories and licensed and designated private laboratories. A total of 373 individuals participated in the programme.
- Establishing a Digital Platform for the One Health Microbial Biobank: A platform was created to provide accurate information on foodborne and feedborne illnesses, supporting research and innovation and enhancing scientific decision-making.
- Developing a Genomic Database for Foodborne Illnesses: A comprehensive database was created to provide accurate information on the genes and genetic factors of microbes, supporting the monitoring and analysis of foodborne pathogens and illnesses.

A risk-based lot release programme for biologic drugs was also introduced, enabling rigorous pre- and post-market assessment of product quality in collaboration with manufacturers. Additionally, the formation of an international biotherapeutics governance committee improved oversight and accelerated approval processes, facilitating faster access to advanced therapies while ensuring a robust, adaptive regulatory framework.

The Kingdom's medical devices sector also witnessed significant milestones in 2024, particularly through regulatory enhancement. The SFDA introduced the Department of Clinical Trials and Biotechnology, centred on the evaluation of innovative biotech-based medical devices, including IVDs. The new department is tasked with developing expertise to ensure the safety and effectiveness of such medical devices, facilitating their entry into the domestic market.

To advance localisation efforts, we introduced in-house regulations and a regulatory guidance framework for IVDs, developed in collaboration with national clinical laboratories. These initiatives mark the start of broader efforts to strengthen domestic manufacturing capabilities and technical know-how, enhancing Saudi Arabia's capacity to produce advanced biotech medical devices aligned with Vision 2030 economic diversification objectives.

Launched by His Royal Highness Prince Mohammed Bin Salman in January 2024, the National Biotechnology Strategy marks a Saudi-wide effort – one the SFDA aligns with through its regulatory endeavours. This initiative represents a major step towards localising bio-manufacturing and reducing dependence on imported biopharmaceuticals, including vaccines and biosimilars. By focusing on self-sufficiency, the strategy aligns with the Kingdom's broader Vision 2030 objectives and positions Saudi Arabia as a leading biotech centre within the region and beyond.

Our regulatory efforts were integral to the success of this biotech strategy. Streamlined approval pathways for innovative therapies facilitated clinical trials, reducing entry barriers for investors and manufacturers. The strategy's projected $34.6bn contribution to the non-oil GDP by 2040 highlights its value for economic diversification. Our team has also encouraged investment in specialised logistics and cold chain infrastructure to support biologics distribution and export potential, improving access to advanced medical products across the Kingdom.

RESEARCH AND INNOVATION

Highlights from SFDA research day 2024

In 2024, the SFDA advanced its regulatory science agenda through initiatives that strengthened evidence-based policymaking, digital innovation and cross-sector collaboration. From the annual Regulatory Research Day – which fostered knowledge exchange and showcased applied research across food, drug and pesticide regulation – to the integration of artificial intelligence (AI) and data analytics in oversight mechanisms, the Authority reinforced its commitment to science-driven decision-making. These efforts enhance product safety, promote public health and position Saudi Arabia as a leader in regulatory innovation and biotechnology within the region.

Regulatory research plays a crucial role in enhancing effective decision-making among regulatory bodies. To promote knowledge exchange, we hold an annual Regulatory Research Day, supported by our leadership, as a platform for researchers to present studies that inform operational practices and policy development.

In October 2024, we hosted our fourth Regulatory Research Day, reflecting an ongoing commitment to aligning scientific inquiry with regulatory practices. The event attracted 250 scientific papers, including 194 from SFDA researchers, distributed across our core areas: (i) food, feed and pesticides; (ii) human drugs, veterinary drugs and herbal products; (iii) cosmetics; and (iv) medical devices and supplies.

Key presentations addressed advances in human and veterinary medicine, herbal product safety and foodborne pathogen control, aligning with national efforts to raise food safety standards. A notable study on pesticide regulation examined residue levels in non-organic produce, finding most within international limits but recommending closer monitoring of potential long-term exposure risks, particularly for children.

The event underscored the SFDA's role in advancing science-based regulation, fostering collaboration, and supporting research that directly contributes to product safety, consumer protection and public health.

Topics covered at the 2024 event within these areas included:

- **Human and Veterinary Medicine**
  - Presentations included advancements in drug safety and efficacy evaluations for human and veterinary applications.
- **Herbal Products**
  - Discussions centred on the regulation and safety assessment of herbal medicine, emphasising the need for rigorous scientific evaluation for consumer safety.
- **Food Safety**
  - Research on foodborne pathogens and contamination prevention strategies was highlighted, with an emphasis on improving food safety standards in the Kingdom.

The 10 outstanding scientific posters awarded serve as recognition of the exceptional quality of the presented research and innovation. The evaluation criteria were aligned with our strategic objectives, which encompass developing the regulatory system, advancing regulations for new technology and biotech products, enabling investment, improving communication and awareness, and enhancing the use of advanced digital technologies.

The SFDA's achievements in regulatory science were highlighted at the event, including recognition by the WHO for achieving maturity level four for medicine and vaccine regulation.

Research outcomes play a role in shaping regulatory policies and ensuring the safety and quality of products.

This signifies advanced performance in ensuring the safety and efficacy of medical products.

The event showcased our commitment to advancing scientific research and fostering knowledge exchange in critical fields. The event's research outcomes play a pivotal role in shaping regulatory policies and ensuring the safety and quality of products in the market. We remain steadfast in our dedication to cultivating an environment that nurtures innovation and empowers the Kingdom's researchers to excel.

WHAT WE DO FOR YOU

We harness scientific research, digital innovation and cross-sector collaboration to strengthen evidence-based regulation. By advancing AI-driven tools, supporting national research activity and aligning emerging technologies with global standards, we ensure safer products, faster decision-making and a more resilient regulatory system for the Kingdom.

Innovation in Regulatory Science and Technology

Enhancing public health by integrating cutting-edge technologies, including AI and big data, underpins the SFDA's regulatory framework. This modernisation exemplifies an innovation-driven approach to food safety oversight.

A cornerstone of this agenda is the Digital Employee project, which applies robotics and machine learning to automate data collection from verified sources for contaminant evaluation. This initiative enhances operational efficiency, enabling faster risk assessment while reducing the manual effort required. Such advancement illustrates our commitment to leveraging technology for precision and time efficiency within regulatory processes.

Moreover, our team employs AI-powered tools to analyse extensive datasets from inspections, laboratory tests and consumer reports. These technologies facilitate the prediction of food safety risks, allowing for early hazard detection and proactive intervention. By adopting data-driven methods, we enhance our capacity for outbreak prediction by streamlining inspections and making risk assessment more predictive than reactive.

This dual focus on digital transformation and AI integration positions the SFDA as a leader in leveraging innovation to strengthen regulatory science, reinforcing public health protection in an increasingly complex global food system.

Integrating AI and emerging technologies into the medical devices sector is critical to our team's efforts to foster regulatory innovation. The establishment of the Department of New Technologies and Digital Health underscores our commitment to adapting regulatory frameworks to meet the challenges posed by AI-enabled medical devices, and to unlock the organisation's transformative potential. This department is crucial in developing specialised expertise and adaptive guidelines to keep pace with technological progress.

Key initiatives include the creation of a dedicated Digital Health Section focused on maintaining rigorous safety standards for AI devices and addressing potential issues such as algorithmic bias and cybersecurity risks. By aligning with international standards and developing clear industry guidelines, this section plays a pivotal role in supporting the global harmonisation of AI regulation. Our team's strategic recruitment drive aims to bolster this section with additional expertise, thereby facilitating greater innovation in digital health technologies.

Likewise, Guidance on AI and Machine Learning Technologies based Medical Devices (MDS-G010) along with the ongoing development of guidelines for other emerging technologies like mobile health apps, highlights our proactive approach to ensuring a robust regulatory environment. By offering support to software developers navigating the regulatory landscape, our team not only fosters innovation but also ensures that new technology is safely and effectively integrated into health care. These initiatives exemplify a balanced approach to facilitating innovation while ensuring patient safety and device efficacy, positioning Saudi Arabia as an emerging leader in regulatory science and technology.

> **"The SFDA fosters innovation, and also ensures that new technologies are safely and effectively integrated into health care.**

The SFDA is strategically positioning itself at the forefront of regulatory science and technology, aligning its research and innovation agenda with global progress in biotech and medical research. By addressing emerging trends, the Authority is refining its own frameworks to foster innovation while safeguarding public health.

A major focus is the development of guidelines for personalised medicine, gene and cell therapies and regenerative treatments, ensuring precise evaluation and robust safety standards. We are also updating our regulatory mechanisms to address the rise of digital health technologies, including telemedicine and health applications, while managing emerging issues such as data privacy and cybersecurity.

Incorporating AI and big data analytics into regulatory decision-making marks another pivotal shift. These tools enhance post-market surveillance and allow for more dynamic monitoring of product safety and efficacy. This integration represents a forward-thinking approach, enabling our team to manage the increasing complexity of modern biopharmaceuticals.

Our focus extends beyond the technology itself to encompass sustainability, fostering eco-friendly research and manufacturing practices. By aligning our initiatives with global sustainability goals, we demonstrate our adaptability to evolving industry priorities. Furthermore, our team's commitment to global health and crisis preparedness was bolstered by the Covid-19 pandemic experience – driving the development of agile surveillance systems and rapid response frameworks to mitigate future crises.

Complementing these efforts, the SFDA is advancing health equity by promoting accessibility and affordability of biotech innovations through various policies focusing on pricing, reimbursement and market access. Through rigorous clinical trial oversight and high manufacturing standards, we are building a comprehensive regulatory ecosystem that fosters innovation and strengthens Saudi Arabia's position as a regional leader in biotechnology, driving progress that benefits patients, industry and the wider health sector.

Public Health and Safety

Public Health Protection Through Awareness and Consumer Education

Public awareness and education are central to our mission to safeguard public health. Recognising that lasting improvements in food safety and nutrition depend on informed consumer choices, our team integrates behavioural insight, cultural engagement and evidence-based communication into its strategy. Our initiatives extend beyond regulation to empower communities with practical knowledge on healthy eating, food handling and risk prevention. By aligning national awareness campaigns with international health frameworks and cross-sector partnerships, we foster a culture of prevention and shared responsibility that strengthens public trust and advances the Kingdom of Saudi Arabia's broader public health goals.

We take a multifaceted approach to safeguarding public health within the Kingdom of Saudi Arabia's food sector, emphasising education and awareness to address critical challenges in food safety and nutrition. Through our Healthy Food Strategy, launched in 2018, we have placed public education as the centre of efforts to promote healthy dietary behaviour. Targeted educational campaigns empower consumers to make informed nutritional choices, focusing on reducing sugar, salt and fat consumption. These initiatives are inclusive, addressing the needs of diverse population segments – including infants, children, adults and pregnant women.

Since the introduction of the Healthy Food Strategy, we have embraced an integrated approach that aligns public awareness efforts with progressive regulatory measures. Each new regulation aimed at improving dietary patterns and the broader nutritional environment is reinforced by corresponding awareness campaigns. By disseminating evidence-based information and collaborating with stakeholders across a wide range of sectors, our team fosters a national culture of health awareness and preventive nutrition.

Recognising the critical role of behavioural science in shaping effective health communication, in 2024 we established a specialised department for nutrition behaviour. This unit designs campaigns informed by public health theories and behavioural insights to ensure messages engage diverse audiences. Through this work, we aim to better understand people's everyday choices and the real barriers they face, creating practical solutions that fit their lives. This synergy between regulation and education is central to encouraging healthy eating habits and reducing obesity and related health risks across the Kingdom of Saudi Arabia.

Beyond nutrition, our food safety initiatives reflect a commitment to raising awareness of chemical contaminants such as pesticide residues and providing practical guidance on reducing exposure. Programmes on animal feed safety highlight the link between sustainable agriculture, food quality and environmental health. Public awareness initiatives use diverse channels – including social media, schools and community organisations – supported by a communication strategy under the Fourth Strategic Plan (2023-27), developed with the UN Development Programme (UNDP), to boost engagement and transparency.

At the regional level, communication campaigns extend these efforts beyond Saudi borders – addressing food, drug and medical device safety while promoting broader public health goals. Cultural engagement remains a distinctive feature of our outreach. By incorporating food safety messages into festivals celebrating iconic Saudi products – such as honey in Al Baha, coffee in Jazan, roses in Al Taif and dates in Al Qassim – we deliver health messages through culturally relevant platforms. This alignment between public health and heritage enhances resonance and community connection.

To ensure relevance and efficacy, our team conducts regular surveys to gauge consumer knowledge and behaviour, particularly in relation to pesticide use. Insights from these surveys inform communication strategies and improve engagement. The development guidelines tailored to specific groups and occasions – such as Hajj – reflects a nuanced understanding of varied consumer needs. Through interactive campaigns, community outreach and participation in international initiatives like World Food Safety Day, we combine education with engagement. Direct communication channels, including a unified call centre, provide accessible scientific information and reinforces public trust.

Sustained implementation and adaptation will be fundamental to the long-term success of our framework for consumer education amid emergent public health challenges. With our team's evidence-based, collaborative approach, we continue to lead the way in food safety and nutrition awareness across the Kingdom.

WHAT WE DO FOR YOU

We protect public health by giving communities clear, evidence-based guidance on nutrition, food safety and risk prevention. Through behaviour-led campaigns, cultural engagement and cross-sector partnerships, we help people make safer choices and strengthen a national culture of health and trust.

Efforts to Manage Health Crises and Emergencies

Our approach to food safety is anchored in prevention, rapid response and interagency coordination to safeguard public health. Through decisive action, coordinated investigation and effective communication, we have demonstrated operational resilience and institutional accountability. This section outlines the measures undertaken to contain the outbreak, support clinical response and strengthen preparedness systems – reflecting our organisation's evolving capacity to protect consumers and reinforce confidence in the Kingdom of Saudi Arabia's food safety ecosystem.

The containment and mitigation of the 2024 botulism outbreak underlines our dedicated team's capacity for swift and coordinated crisis management within the food sector. The incident, traced to contaminated mayonnaise served at a restaurant chain, affected 75 individuals, with 19 requiring hospitalisation and several experiencing severe symptoms. It served as a critical test of our professionals' resilience, inter-agency coordination and public communication during health emergencies.

Upon receiving reports of illness, our experts promptly collaborated with the Ministry of Health and municipal authorities to launch an investigation. Laboratory testing quickly identified the source, enabling rapid containment. The SFDA ordered an immediate recall of all affected products, suspended production at the implicated facility and mandated full sanitation measures. This decisive response underscored our specialists' ability to leverage technical expertise and cross-sector coordination to mitigate public health threats.

A robust public communication strategy played a pivotal role in mitigating the crisis. Clear and timely advisories were issued to inform the public about the risks and preventive measures, reinforcing transparency and trust. This incident also highlighted the importance of further refining communication frameworks to counter misinformation and maintain public confidence during health emergencies.

In terms of the clinical management of affected individuals, our organisation supported the administration of botulinum antitoxin and other therapeutic interventions to facilitate recovery. This highlights our team's recognition of our role not only in regulatory enforcement but also in contributing to the health care response during foodborne outbreaks. The event further emphasised the need for health care systems to maintain readiness protocols, including access to antitoxins and specialised treatment options.

Following containment, our experts conducted extensive inspections to verify the absence of further contamination and launched a post-incident review to identify lessons learned. The review focused on strengthening coordination, tightening regulatory oversight and enhancing preparedness for future outbreaks.

Given the rarity of botulism in the Kingdom of Saudi Arabia, the incident provided valuable insights for national health security. It reinforced the importance of rigorous compliance with food safety standards and the ongoing training of health care professionals to manage rare but severe illnesses.

Overall, the management of the 2024 botulism outbreak exemplified our team's effectiveness in responding to complex foodborne threats through decisive action, coordinated interagency efforts and transparent public engagement. The incident unfolded over a well-defined timeline: the initial cases were reported in early May; a nationwide recall was issued within 48 hours; targeted interventions ranging from source tracing to import controls were deployed within the week; and, by late June, recovery measures and post-market surveillance had been fully implemented. This structured response demonstrated a maturing framework for crisis preparedness and regulatory resilience, further solidifying the SFDA's role as a guardian of public health.

We at the SFDA continue to strengthen public health protection through a proactive and risk-based approach in the medical devices sector. Comprehensive risk management guidelines have been implemented across departments to ensure patient safety and enable rapid responses to device-related incidents. These guidelines define the responsibilities of specialised task forces in investigating adverse events, processing complaints and issuing safety alerts that may require corrective action or device withdrawal.

By establishing clear criteria and policies for risk assessment alongside escalation procedures tailored to the severity of identified risks, our dedicated team ensures a systematic approach to managing potential hazards. Moreover, such guidelines facilitate the prompt mitigation of risks while also enhancing the overall efficacy of regulatory processes within the Kingdom of Saudi Arabia.

Our organisation's emphasis on prevention, continuous monitoring and evidence-based decision-making reflects our commitment to maintaining high standards of safety and reliability in the Kingdom of Saudi Arabia's health care system. Through these measures, our specialists have significantly contributed to safeguarding public health – efforts that are in line with national objectives – while also improving the quality of medical devices available in the domestic market.

WHAT WE DO FOR YOU

We act fast to contain health risks, coordinate recalls and communicate clearly during emergencies. Across food, medical devices and drugs, we monitor safety, manage incidents and strengthen preparedness to protect you.

Collaboration and Partnerships

Building International Partnerships that Advance Public Health and Regulatory Excellence

Our collaborative partnerships with global and local organisations are central to advancing the SFDA's regulatory excellence and public health mission. Within the food sector, these alliances strengthen institutional capacity, foster knowledge exchange and promote the integration of advanced technologies in regulation. Through cooperation with the UNDP, WHO and the International Islamic Fiqh Academy (IIFA), our specialists leverage technical expertise and shared best practices to modernise our frameworks, enhance food safety oversight and align national policies with global standards. These partnerships not only reinforce consumer protection but also position the Kingdom of Saudi Arabia as an emerging leader in global food governance and regulatory innovation.

Building on our experience, collaboration with the UNDP has been pivotal in supporting the SFDA's Fourth Strategic Plan. This $13m initiative focuses on modernising regulatory practices through the integration of biotechnology, the enhancement of digital infrastructure, and the application of AI and big data to improve decision-making and streamline import clearance.

In addition to these collaborative efforts, our team of nutrition advocates maintains a strategic partnership with the IIFA to address sharia compliance in new food products, particularly in halal certification. Through joint symposia and collaborative legislative research, both organisations work to help advance international halal standards and align regulatory frameworks with Islamic jurisprudence, reinforcing the integrity and credibility of halal legislation.

Engagement with bodies like the International Heads of Food Agencies Forum underscores our organisation's commitment to integrating global best practices and fostering knowledge exchange. Our collective efforts demonstrate a commitment to enhancing food safety, navigating complex regulatory challenges and ultimately positioning the Kingdom of Saudi Arabia as a leader in food sector governance.

Fostering international and local partnerships is essential to the regulation of medical devices in the Kingdom of Saudi Arabia. Such collaboration plays a crucial role in ensuring the safety, efficacy and consistency of medical devices, aligning our regulatory frameworks with global standards and facilitating access to international markets. Our team's proactive approach reflects its recognition of both the interconnected nature of the medical device sector and the need for robust regulatory oversight to meet global challenges.

Our team of nutrition advocates participates in forums such as the International Medical Device Regulators Forum and the Global Harmonisation Working Party, enabling the SFDA to help shape global standards while integrating emerging best practices. Through technical working groups, our health professionals contribute to developing guidelines on pre-marketing requirements and quality management systems, demonstrating leadership in advancing scientific and regulatory benchmarks.

In line with global standards, our team aligns its regulatory frameworks with the International Organisation for Standardisation, as well as the International Electrotechnical Commission, reducing barriers for manufacturers and supporting the Kingdom of Saudi Arabia's integration into global medical device markets. This consistency in evaluation criteria builds trust in the quality and safety of devices approved under its oversight. Partnerships with global regulatory bodies enable the exchange of critical information, joint inspections and coordinated market surveillance, crucial for managing the complexities of a rapidly evolving sector. Moreover, joint training and capacity-building programmes further strengthen institutional capabilities, ensuring teams meet international standards and respond effectively to new challenges.

Establishing strategic partnerships with international drug regulatory organisations is a cornerstone of our team's efforts to enhance regulatory practices across the drug and herbal product sectors throughout the Kingdom of Saudi Arabia. In 2024 our organisation was elected as a member of the management committee of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), becoming the first entity in the Middle East to achieve this distinction. This underscores our dedicated team's active role in global regulatory harmonisation – with 42 technical experts from the SFDA participating in ICH scientific committees.

Membership in the ICH management committee reflects our broader goal of aligning national frameworks with international best practices and strengthening our role within the global regulatory community. Participation in the ICH's top decision-making body enhances our researchers' capacity to shape global technical guidelines, foster knowledge exchange and strengthen regulatory convergence in the pharmaceutical field.

Through continued collaboration with the ICH and the WHO's International Regulatory Cooperation for Herbal Medicines, our team supports the development of harmonised frameworks and contributes to scientific guideline formulation. Active engagement in technical working groups ensures the integration of emerging global standards, enabling our team of nutrition advocates to stay at the forefront of regulatory innovation and continuous improvement.

These initiatives ensure that medicinal products available in the Kingdom of Saudi Arabia meet rigorous standards for safety, quality and efficacy, while reinforcing our team's commitment to public health protection and international cooperation across all aspects of the pharmaceutical sector.

WHAT WE DO FOR YOU

We work with leading global and local partners to strengthen food, drug and medical device safety. Through shared standards, expert collaboration and joint oversight, we ensure the products you rely on meet trusted international benchmarks.

Through engagement with international bodies, our team of professionals contributes to the advancement of harmonised regulatory frameworks while aligning national practices with globally recognised standards.

INTERNATIONAL MEMBERSHIPS

- Joined the Regulatory Agencies Global Network against AMR (RAGNA).
- Became a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).
- Granted approval to participate in the activities of the World Cancer Research Fund and to provide the global "NOURISHING database" with SFDA's nutritional legislation.
- Joined the International Medical Device Regulators Forum (IMDRF).

INTERNATIONAL PARTNERSHIPS 2024

BAHRAIN
National Health Regulatory Authority

A new MOU signed to enhance collaboration on the approval of pharmaceuticals and medical devices - September 2024

CHINA
National Medical Products Administration (NMPA)

Cooperation in the regulation of pharmaceuticals, medical devices, and cosmetics - November 2024

SFDA'S GLOBAL LEADERSHIP AND PARTICIPATION

- Chairing the WHO Trans Fat Elimination Technical Advisory Group (TFATAG).
- Alternate at the Uppsala Monitoring Centre (UMC).
- Vice-Chair of the Codex Alimentarius Commission (CAC).

EVENTS AND WORKSHOPS in 2024

FEBRUARY

Philippines Workshop (Feb 11): Clarified the requirements and sourcing standards in Saudi Arabia regarding food and personal care products.

Australia Workshop (Feb 25): Focused on preparing technical regulations and standards, the mechanism for accrediting food exporting facilities, and food product registration procedures.

Denmark Workshop (Feb 28): Focused on healthcare topics.

MARCH

GCC Ministerial Meeting (Mar 7): The Gulf Cooperation Council (GCC) Ministerial Committee for Food Safety held in Doha, Qatar.

Bahrain Workshop (Mar 24): Reviewed SFDA's experiences regarding clinical trial regulations.

APRIL

Denmark Workshop (Apr 30): Focused on preparing technical regulations and standards for food, particularly organic food, and the mechanism for accrediting food exporting facilities.

MAY

Bahrain Workshop (May 6): Benefiting from SFDA's experience in artificial intelligence used in the medical devices and pharmaceutical sectors.

Malaysia Workshop (May 9): Provided an overview of the regulatory framework governing food, beverages, and cosmetic safety, with guidance on successful entry into Saudi Arabia's halal market.

Australia Workshop (May 20): Focused on food traceability.

UK Workshop (May 29): Focused on medical devices.

JUNE

Thailand Workshop (Jun 26): Explained and clarified the pharmaceutical availability project.
Poland Workshop (Jun 27): Focused on drug registration procedures.

WHO Regional Training Programme (June): A regional training programme held in cooperation with the Saudi Ministry of Health and WHO on monitoring Adverse Events Following Immunization (AEFI).

JULY

IPRP Workshop (July): Discussed the current status of drug pricing - Pharmaceutical Pricing and Reimbursement Information Network (PPRI)

Bahrain Workshop (Jul 24): Reviewed SFDA's experience in developing its Fourth Strategy.

AUGUST

Thailand Workshop (Aug 21): Explained SFDA's requirements for accrediting establishments and exporting food products, including halal requirements.

SEPTEMBER

Oman Workshop (Sep 10): Outlined SFDA's mechanism and steps to be included on the list of countries permitted to export to the European Union for products containing animal derivatives.

Immune Cell Production Workshop (Sep 17): A workshop presented by international experts in the field of immune cell production (CART cells).

Codex Training Programme (September): A training programme for members of the FAO/WHO Coordinating Committee for Near East (CCNE).

Jurisprudential Seminar (Sep 24-25): Entitled " Shari'ah Ruling on the Consumption and Marketing of Genetically Modified Foods of Animal Origin," in cooperation with the International Islamic Fiqh Academy (IIFA).

OCTOBER

Germany Workshop (Oct 1): Focused on effective regulations and controls to ensure food safety.
New Zealand Workshop (Oct 16): Focused on the national halal system.

WHO Regional Expert Meeting (Oct 20-21): Regional Expert Joint Meeting on Nutrition Policies for the Eastern Mediterranean Region (EMRO).

Botulinum Awareness Workshop (Oct 28): Focused on Clostridium botulinum bacteria Presented by international experts.

NOVEMBER

Korea Workshop (Nov 24): Focused on cosmetics, health products, biotechnology products, medical devices, and food products.

Qatar Workshop (Nov 24): Introduced the mechanism for accreditation of the official regulatory body and facilities in the exporting country to Saudi Arabia.

Codex Alimentarius Commission (CAC47): Held in cooperation with Singapore, a side event titled 'Addressing Food Safety Challenges from the Production of Cell-based Foods and the Role of Codex.'

DECEMBER

OIC Meeting (Dec 17-18): The third meeting of the Heads of National Medicines Regulatory Authorities (NMRAs) of OIC Member States.

Rising to the Challenge

Strengthening our Foundation to Build a Resilient Regulatory Future

We at the SFDA continue to operate within an increasingly complex regulatory environment shaped by rapid technological progress, evolving market dynamics and rising public health expectations. From managing the safety of emerging food technologies to tackling supply chain constraints and boosting efficiency across our advanced laboratories, we meet these challenges with agility and foresight. Through collaboration, capacity building and digital innovation, our team transforms challenges into opportunities – enhancing regulatory resilience, protecting public health and advancing Vision 2030.

The introduction of novel food products and the rapid advancement of production technologies present growing challenges to food safety in the Kingdom of Saudi Arabia. Many new products lack historical consumption data, complicating safety assessments and highlighting the need for stronger scientific methodologies. To address this issue, we have intensified our collaboration with international scientific bodies and redoubled investment in advanced research tools to establish reliable safety data and standards, aiming to ensure that these new products meet rigorous safety requirements.

At the same time, technological progress in food production calls for agile and responsive regulation. We continue to prioritise harmonisation with international standards through participation in initiatives led by the Codex Alimentarius Commission; the WTO; and regional bodies such as the GCC Standardisation Organisation, and the Standards and Metrology Institute for Islamic Countries. This approach ensures alignment with best practices while considering the local dietary and cultural context to maximise regulatory impact. By fostering international cooperation and continuously refining its frameworks, our team is positioning itself to safeguard public health while enabling technological progress in the Kingdom of Saudi Arabia's food sector.

Our organisation faces an evolving landscape within the medical device, laboratory and biologics sectors – characterised by the dual challenges of technological advancement and operational complexities. The rapid evolution of health care technology – coupled with emerging fields such as diagnostics, biomanufacturing and data analytics – necessitates continuous investment in advanced laboratory infrastructure and modern instruments. However, maintaining such infrastructure is costly, particularly when prioritising budgets across diverse regulatory and operational sectors.

Our operational efficiency is further tested by the need to recruit and retain skilled professionals to operate modern technologies. Continuous staff training is essential to keep pace with evolving methodologies and regulatory updates, creating a resource-intensive environment. In addition, global supply chain dependencies for critical instruments, reagents and consumables expose operations to disruption, highlighting the need for localisation and supply chain diversification.

The maintenance and calibration of advanced equipment demands significant financial and technical resources, often requiring specialised international support. Adopting predictive maintenance tools, including AI and machine learning, offers an opportunity to improve efficiency and reduce costs.

On the regulatory front, effective communication with stakeholders is crucial for enhancing compliance with SFDA standards among health care providers. Leveraging digital tools supports real-time engagement and transparency, while ongoing regulatory streamlining ensures frameworks remain responsive to industry evolution.

Meeting these challenges calls for clear focus on infrastructure, workforce development, supply chain resilience and digital integration. By investing in local expertise, fostering collaboration and accelerating digital transformation, we are able to strengthen the SFDA's operational framework in line with the evolving demands of health, food and drug safety.

WHAT WE DO FOR YOU

We strengthen the systems that underpin safe, efficient and predictable regulation. By investing in advanced science, modern laboratories, skilled professionals and digital tools, we create a regulatory environment that is more responsive, more transparent and better equipped.

Technologies such as AI and machine learning offers an opportunity to mitigate inefficiencies and reduce costs.

Case Studies: Problem-Solving Approaches

Drawing on our experience in managing chemical contaminants and implementing international food safety standards, the SFDA continues to demonstrate its ability to apply data-driven and collaborative solutions to complex regulatory challenges. Together, these efforts show how our team of dedicated professionals turns obstacles into opportunities to strengthen consumer safety and align with global best practices.

The food sector in the Kingdom of Saudi Arabia has navigated significant hurdles to enhance public health and align with global benchmarks in recent years, demonstrating resilience and a commitment to progress. Our team's structured and innovative approach to problem-solving, as exemplified by its strategies for prioritising chemical contaminants and implementing international food safety standards, is key to addressing these challenges. Together, these case studies illustrate the sector's complexity and the potential for transformative outcomes through collaborative frameworks.

The principal challenge for managing chemical contaminants in food products stems from the wide variety of potential hazards present in both domestic and imported foods – with examples including pesticides, heavy metals and mycotoxins. To address this, our organisation adopted a risk-ranking methodology based on a comprehensive scoring matrix. This system evaluates contaminants using four critical criteria: consumer exposure levels; the severity of adverse health effects; prevalence data derived from national monitoring programmes; and alignment with established regulatory standards to ensure targeted interventions and efficient allocation of resources that protect consumers. This evidence-based approach ensures that resources are directed to the most pressing risks, minimising public health threats and enhancing regulatory compliance. While effective, such a system requires ongoing refinement and robust data collection to adapt to novel risks, underscoring the challenge in maintaining food safety.

> **"Our efforts to implement international food safety standards highlight the complexities of aligning local practices with global norms.**

Implementing international food safety standards also revealed challenges in aligning local practices with global norms. Initial resistance from smaller businesses and limited resources slowed progress, yet sustained commitment yielded clear gains. Expanded market access made local producers more competitive internationally – attracting foreign investment and fostering innovation. Initiatives such as the Saudi Calorie Declaration system further strengthened transparency in food labelling, encouraging healthier consumer choices and informed consumption. These measures have enhanced public trust and advanced a stronger culture of food safety across the Kingdom of Saudi Arabia.

While our organisation's strategies have proven effective, they are not without challenges. Sustained success will depend on ongoing stakeholder engagement, investment in technology, and adaptation to evolving international standards and consumer expectations. These case studies highlight the importance of strategic problem-solving to help address the multifaceted challenges of the food sector, offering a robust model for balancing public health imperatives with economic growth.

Sustained success in the years ahead will depend on ongoing stakeholder engagement, investment in technology and adaptation to evolving international standards and consumer expectations.

Future Outlook

Plans and Goals for 2025

Our 2025 agenda focuses on innovation, digital transformation and global collaboration to strengthen public health and regulatory excellence. Across all industries – food, laboratories, medical devices and drugs – our team aims to enhance efficiency, transparency and alignment with international standards while advancing the Kingdom of Saudi Arabia's Vision 2030 goals.

Our organisation's headline goals for 2025 reflect a proactive approach to addressing evolving challenges in food safety and public health. By prioritising the development of robust risk assessment policies, we aim to tackle growing concerns surrounding chemical contaminants and novel food products – indicating our commitment to evidence-based regulation.

The adoption of AI-driven predictive models for exposure assessments underscores a shift towards leveraging technology for more precise risk anticipation and enhanced decision-making. Meanwhile, our focus on consumer education and transparent food labelling demonstrates a recognition of the vital role of public awareness in fostering informed choices and reducing health risks. Strengthening sanitary measures for imported food and tightening pesticide control highlight our dedication to preserving the integrity of the national food supply chain. Collectively, these initiatives position our health professionals to manage emerging risks and enhance food system resilience in an increasingly complex global landscape.

With a clear roadmap for 2025, our team is positioned to become a leader in modernisation, innovation and cross-sectoral integration within the laboratories and biologics sector. At the heart of our strategy is the modernisation and expansion of laboratory infrastructure. This is designed to accommodate advanced testing capabilities and address emerging public health challenges, such as antimicrobial resistance and foodborne illnesses. The incorporation of AI and machine learning into routine processes aims to streamline operations, improve predictive analytics and bolster evidence-based decision-making – thereby reinforcing the regulatory framework across the Kingdom of Saudi Arabia's food, drug and medical device industries.

The creation of a bioinformatics and cheminformatics reference laboratory further underscores our commitment to computational tools for genomic, proteomic and chemical analysis, enhancing risk assessment and regulatory precision. A strategic emphasis on product safety, through the development of robust scientific evidence and expanded testing capacity, emphasises our dedicated team's holistic approach to public health. Achieving these ambitions will require close sectoral collaboration and effective implementation, positioning our organisation as a regional benchmark for regulatory innovation and safety assurance.

The Kingdom of Saudi Arabia's medical device industry is entering a phase of accelerated transformation under an agenda focused on regulatory advancement, innovation and global collaboration. Our specialists aim to refine regulatory frameworks, ensure safety and efficacy, and foster an innovative environment that improves access to health care.

By aligning medical device regulations with international standards and deepening engagement with multilateral partners, our experts aim to stay at the forefront of global trends. Beyond pre-market regulation, efforts to enhance post-market monitoring, integrate advanced technologies and expand professional education reinforce its long-term commitment to safety.

A major focus is the expansion of biotech and digital health, with harmonised regulations for biotech-based devices and expanded support for AI-driven tools and wearable technologies. Collaboration with academia and workforce upskilling will ensure competitiveness and sustainable innovation as the Kingdom of Saudi Arabia advances towards its Vision 2030 targets.

Our 2025 strategy strengthens regulatory innovation through advanced technologies and greater international engagement. AI-enabled tools will enhance drug evaluation processes – including for herbal medicine – with the dual objectives of improving scientific consistency and accelerating review timelines.

To reinforce its global presence, our health advocates will host international regulatory meetings and assume leadership roles in crucial organisations, positioning the Kingdom of Saudi Arabia as a major player in international drug governance. A cornerstone initiative is the creation of a multi-use herbal plants database designed to support research, regulation and public health through data-driven decision-making.

In parallel, our organisation is advancing its capacity to assess complex generic drugs, aiming to stimulate innovation in drug manufacturing. Our proposed reliance-based assessment process reflects a strategic shift towards leveraging evaluations conducted by reputable international regulators in order to streamline workflows and reduce redundancy. While this approach enhances efficiency, it necessitates strong mechanisms to ensure that international standards align with domestic requirements.

The regulation of Advanced Therapy Medicinal Products presents another frontier of the authority's strategic priorities. Given the diverse ethical and regulatory landscapes globally, our team is developing specialised guidelines and investing in institutional capacity to support the oversight of advanced treatments such as allogeneic CAR-T cell therapy. Progress in publishing clear guidelines and offering technical support to developers illustrates a proactive, solution-oriented stance – although success will require sustained resources and cross-sector collaboration.

Continued engagement with pharmaceutical companies will advance the development and availability of generic medicines, ensuring equivalence in quality, safety and efficacy to branded counterparts. Partnerships with the private sector and increased use of AI and digital tools will enable us to build a responsive, innovation-driven regulatory ecosystem that safeguards public health while supporting industry growth.

Working Together for Innovation and Lasting Progress

Our team's strategy for continued improvement focuses on strengthening regulation, advancing technology and deepening global collaboration. By integrating AI, data analytics and smart infrastructure, our team of dedicated professionals aims to enhance efficiency and predictive capabilities while aligning with Vision 2030 goals of innovation, sustainability, and global leadership in public health and safety.

A forward-looking strategy underpins our efforts to advance food safety through targeted initiatives in product safety, global partnerships and operational efficiency. Central to our strategy is the enhancement of regulatory frameworks to address evolving food sector risks. Leveraging advanced tools such as AI for predictive risk assessments and blockchain for transparent supply chains, our experts strive to elevate safety standards and pre-emptively mitigate hazards. The planned expansion of smart laboratories and the adoption of automated testing systems signify a robust effort to improve efficiency in food monitoring and safety oversight. Integrating these technologies effectively will require substantial investment in technical infrastructure and workforce capabilities.

On the global stage, our team of nutrition advocates is strategically positioning the Kingdom of Saudi Arabia as a thought leader in food safety. Active collaboration with international organisations such as the Codex Alimentarius Commission and the WHO highlights ambitions to shape global regulatory norms, particularly in areas such as novel food products and biotech. The SFDA's Vice-Chairmanship of the Codex Alimentarius Commission offers a platform for influencing international standards, reinforcing its status as a key player in the global food safety dialogue. Simultaneously, our health promoters aim to expand the export potential of Saudi food products, ensuring compliance with both domestic and international safety benchmarks.

Operational excellence forms another critical pillar of our vision. Investment in automation, cloud-based systems and robotics is expected to streamline decision-making processes – enhancing both the speed and accuracy of regulatory management. Efforts to upskill staff reflect recognition of the importance of human capital to sustain innovation. While reliance on advanced technologies may pose fiscal challenges, financial sustainability remains a guiding priority.

Looking ahead to 2025-30, our focus on predictive AI, blockchain and sustainable food systems positions our team to navigate future challenges successfully. However, realising these ambitions will demand sustained collaboration, technological foresight and a relentless focus on building institutional resilience. This will be critical to ensuring that our experts remain adaptive and impactful in a dynamic global environment.

Our strategic focus on continued improvement and innovation emphasises advancing scientific capabilities and adapting to emerging drug trends. The development of frameworks for real-world evidence, drug repurposing, advanced clinical trials and criteria for special populations such as paediatrics and geriatrics is key. By prioritising these areas, our team seeks to modernise its regulatory processes while addressing underserved medical needs.

We, as public health professionals, have committed to the continuous development of regulatory guidelines, scientific publications and workshops, alongside sustained collaboration with academic and industry stakeholders, to enhance the scientific rigour of our assessments. Meanwhile, efforts to strengthen the clinical trial ecosystem – including the enhancement of the Saudi Clinical Trial Registry – reflect a commitment to a transparent and efficient R&D environment – crucial as global demand grows for localised clinical data and region-specific research. Encouraging international participation and addressing operational inefficiencies will be essential to sustain this progress.

Integrating advanced technologies into pharmacovigilance and leveraging big data highlight our organisation's shift towards data-driven regulation. These advancements, however, require continued investment in infrastructure and training to ensure lasting impact.

Lastly, partnerships with universities and research centres underline our role as a catalyst for innovation within the Kingdom of Saudi Arabia. Through these initiatives, the SFDA is solidifying its position as a regional leader in scientific and regulatory excellence on the path to 2030, reinforcing its commitment to collaboration and the advancement of national health priorities.

الهيئة العامة للغذاء والدواء

Saudi Food & Drug Authority