1 Organization and Policies

Policy Objectives

- Optimize the production and marketing network of food products and the life cycle management of drugs
- Enhance the source flow management and complete the traceability system
- Reinforce the border inspection, audit, and self-regulation of industry operators
- Strengthen international harmonization of laws and regulations, upgrade food and drug testing technology capabilities
- Top up the effectiveness of food and drug safety communication

01 Organization and Policies

Taiwan Food and Drug Administration of the Ministry of Health and Welfare (TFDA) was founded on July 23, 2013, as part of the organizational reform in the Executive Yuan. To fulfill the Ministry of Health and Welfare's commitment of promoting the health and wellbeing of the public, TFDA takes "Safe and effective medicinal products, safe and healthy food." as its mission, under the vision of "Being a reliable guardian on food and medicinal product safety, creating a safe food and medicinal consumer environment." (Figure 1-1) Upholding the core value of "total product life cycle management" of food, medicine, and cosmetics, through the source, production, and distribution management, TFDA continues to devote itself in establishing a comprehensive safety management system for food and drugs to ensure the safety and quality of food and drugs for consumers.

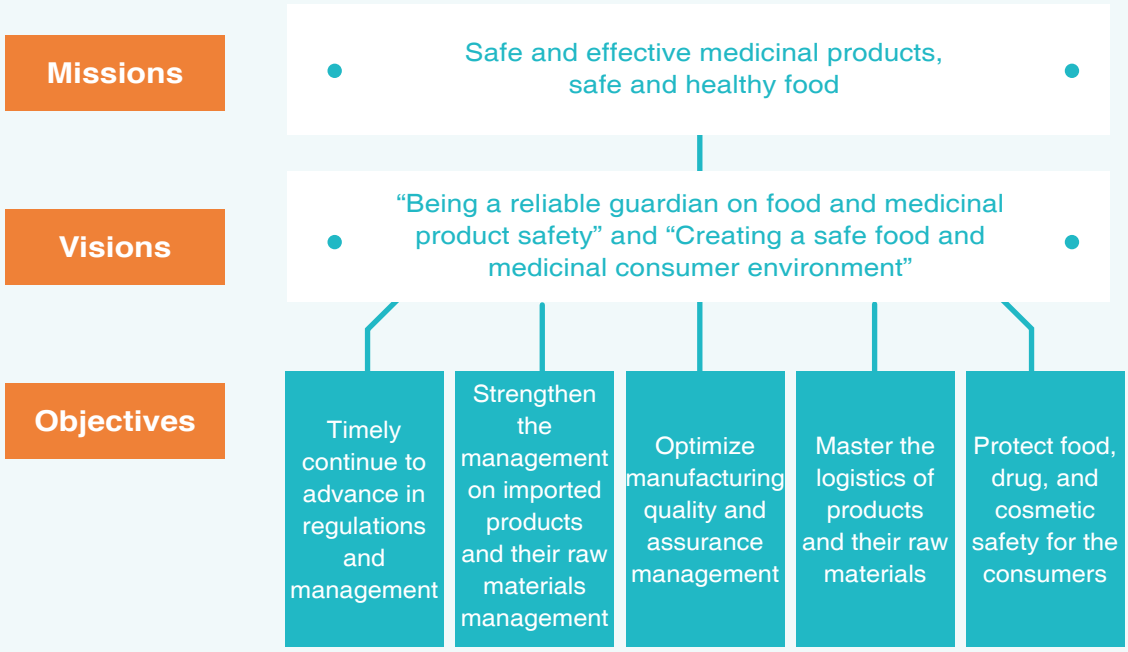


Figure 1-1 Visions and Missions of TFDA

■ Section 1

Organizational Structure

Led by the Director-General, TFDA is composed of two Deputy Director-Generals, one Chief Secretary and seven business units. Including: Division of Planning and Research Development, which is responsible for planning and management, technical planning management, international cooperation, legal system, consumer protection, etc.; Division of Food Safety, Division of Medicinal Products, Division of Medical Devices and Cosmetics, as well as Division of Controlled Drugs, are responsible for products management, policies, and relevant regulations of their managed products; Division of Quality Compliance and Management is responsible for manufacturers management and inspection of pharmaceutical, medical devices, and cosmetic products, laboratory management and authentication, inspection of human organ bank, and second tier food inspection; Division of Research and Analysis is responsible for the testing of food, medicinal products, medical devices and cosmetics, test methods development and evaluation, pharmacopeia editing and compilation; TFDA also sets 3 District Centers (North, Central and South) which are responsible for inspections, distribution examinations, and laboratory testing of imported food, medicinal products, and cosmetics. In addition to the business divisions, we have also established five administrative units, including Office of Secretariat, Office of Personnel, Office of Service Ethics, Office of Accounting, and Office of Information Management, to assist in administrative management (Figure 1-2). In addition, TFDA sets up two Task Forces of Factory for Controlled Drugs and Decision Support Center. TFDA also obtains professional information and assistance from its consultation units such as Center for Drug Evaluation and Taiwan Drug Relief Foundation.

■ Section 2

Policy Objectives

In accordance with the 2021-year policy direction of the Executive Yuan and the policy plan of the Ministry of Health and Welfare, and in line with the budget, in response to the current development priorities and social needs in the management of food, drugs, medical devices and cosmetics, TFDA sets the following policy objectives:

I. Optimize the production and marketing network of food products and the life cycle management of drugs, medical devices and cosmetics; guard the hygiene and quality of food and drug and create a safe consumer environment.

II. Enhance the source flow management and complete the traceability system; reinforce the border inspection, audit, and self-regulation of industry operators to improve the quality monitoring system.

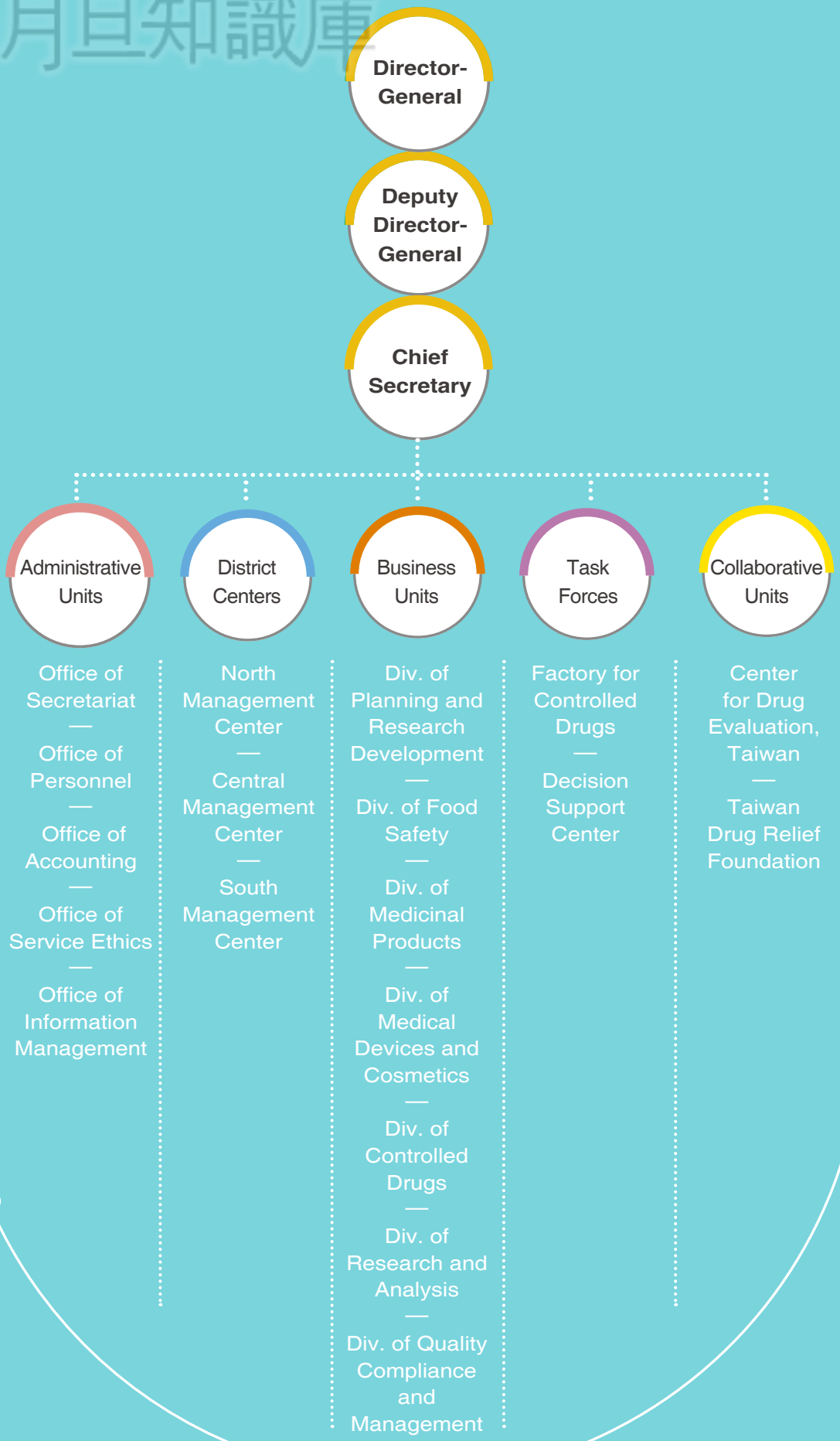


Figure 1-2 Organizational Chart

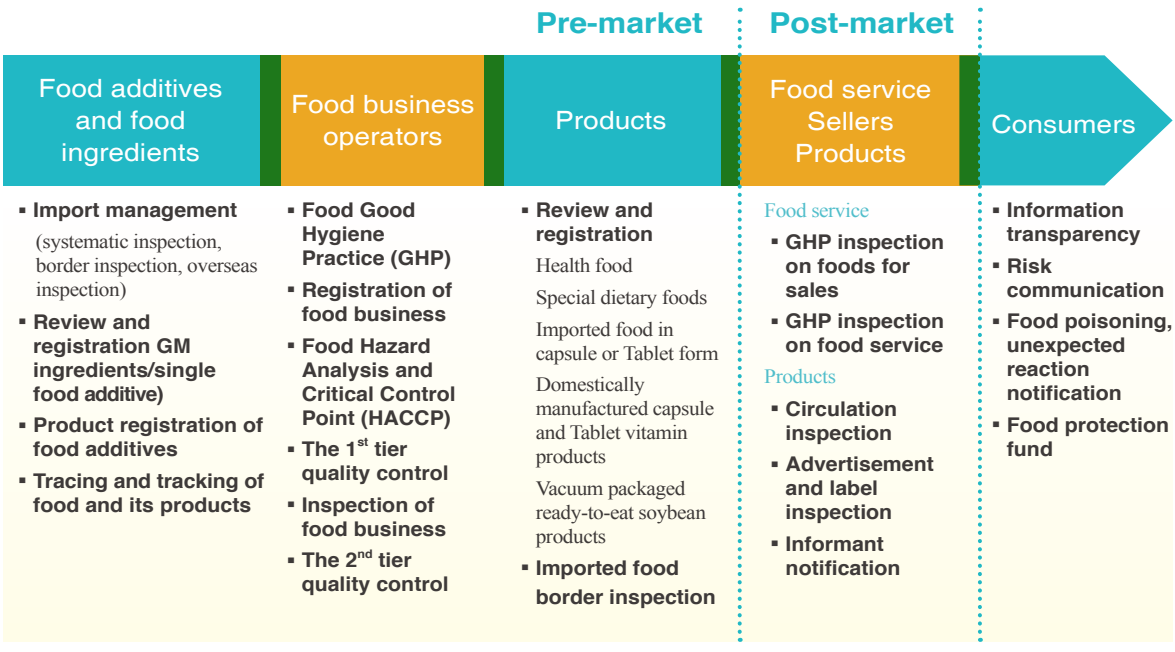
III. Strengthen international harmonization of laws and regulations, upgrade food and drug testing technology capabilities; top up the effectiveness of food and drug safety communication to raise public's correct awareness.

■ Section 3

Food Management Overview

Food safety is closely related to the health of the people. With the liberalization of global trade, booming technology, and rapidly changing food safety issues, aspects of food management appear to become more diversified, innovative, and informative. TFDA adopts the "farm-to-Table" whole life cycle management model to ensure the product hygiene and safety (Figure 1-3) in each step from the manufacturing of raw materials to the sales and circulation process. Reinforce the implementation of the "Five-points Food Safety Policy" (Figure 1-4) to co-construct the food safety protection net through government management and self-discipline of the industry and public participation.

TFDA actively collects and refers to international food management regulations and technologies, continuously updates regulations relevant to the "*Act Governing Food Safety and Sanitation*", and actively develops novel food analytical and testing methods. In addition, TFDA establishes a central-local vertically and cross-agency collaboration practice to conduct border inspection, special food projects inspection and post-market monitoring. TFDA also utilizes big data to improve risk management and early warning detection efficiency to ensure food hygiene, safety, and quality.



GHP: Good Hygiene Practice HACCP: Hazard Analysis & Critical Control Point GM: Genetically Modified

Figure 1-3 Food Management Framework

Figure 1-4 Five-Points Food Safety Policy

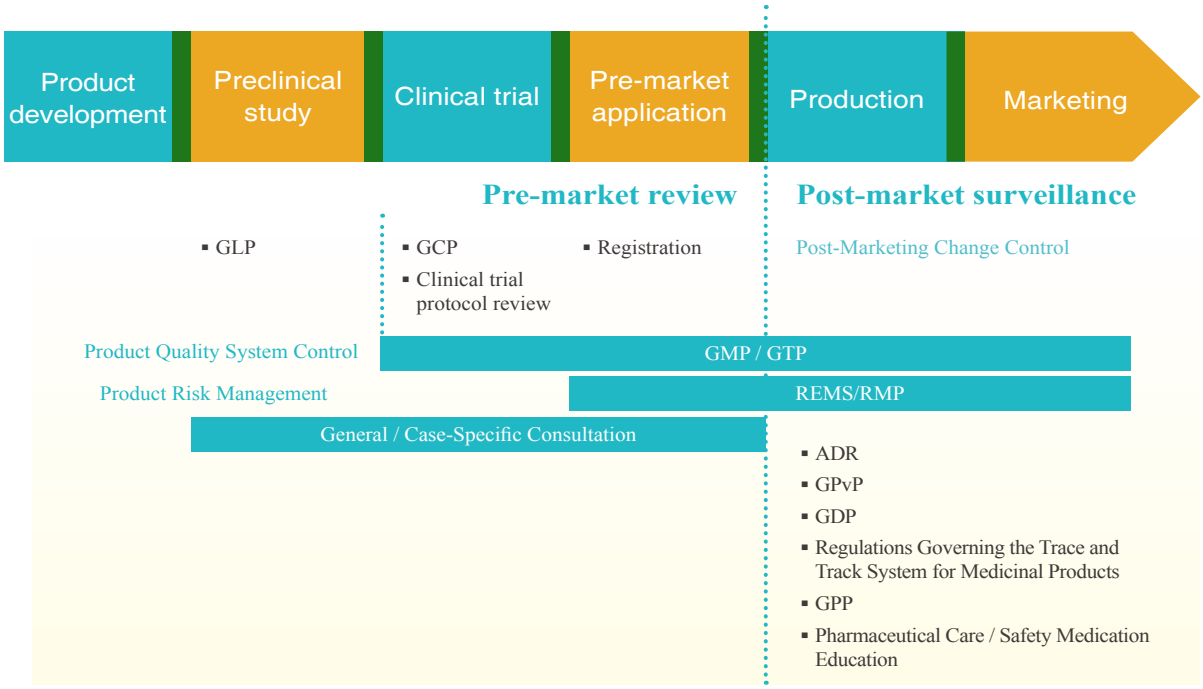
■ Section 4

Overview of Drugs and Controlled Drugs Management

I. Medicinal products management framework

In the life cycle management of medicinal products, including product development, preclinical trials, clinical trials, marketing authorization application, manufacturing and marketing, etc., must be followed by each good operating practice. Unlike general consumer goods, medicines can only be sold on the market after obtaining marketing authorizations issued by the central competent health authority. To ensure the safety of the public, TFDA continues to strengthen the quality management policy throughout the drug product life-cycle (Figure 1-5) through the following aspects, harmonization with international regulations, establishment of various priority review mechanisms, digital management, standardization of quality and safety surveillance, inspection of illegal drugs, and the management of pharmaceutical vendor and drug circulations, etc.

All the measures aim to ensure the safety, efficacy and quality of medicinal products, to increase the timely access to the medicines for people in need, to facilitate the development of biotechnology industry in Taiwan, and hereby creates a win-win situation among consumers, industries and the government.



GLP: Good Laboratory Practice
GMP: Good Manufacturing Practice
REMS: Risk Evaluation & Mitigation Strategies
ADR: Adverse Drug Reaction
GDP: Good Distribution Practice
GCP: Good Clinical Practice
GTP: Good Tissue Practice
RMP: Risk Management Plan
GPvP: Good Pharmacovigilance Practice
GPP: Good Pharmacy Practice

Figure 1-5 Life Cycle Management Framework for Medicinal Products

II. Controlled drugs management framework

Controlled drugs refer to addictive narcotic drugs, psychotropic drugs, and other drugs that require regulations and may only be used for medical and scientific purposes. If used improperly or illegally, they can easily cause health hazards to the people. According to the "*Controlled Drugs Act*", controlled drugs are categorized into four Schedules according to their potential for addictiveness, dependence, abuse and danger to society. The source management of various types of users (such as institutions, industry operators, physicians, dentists, veterinarians or paraveterinary workers) is conducted through certifications such as controlled drugs registration license, prescription license, and export, import and manufacture permit. The flow management is also strengthened, users are required to register and declare the income, expense and balance of controlled drugs in ledgers to prevent the misuse or abuse of controlled drugs. Its management structure is shown in Figure 1-6.

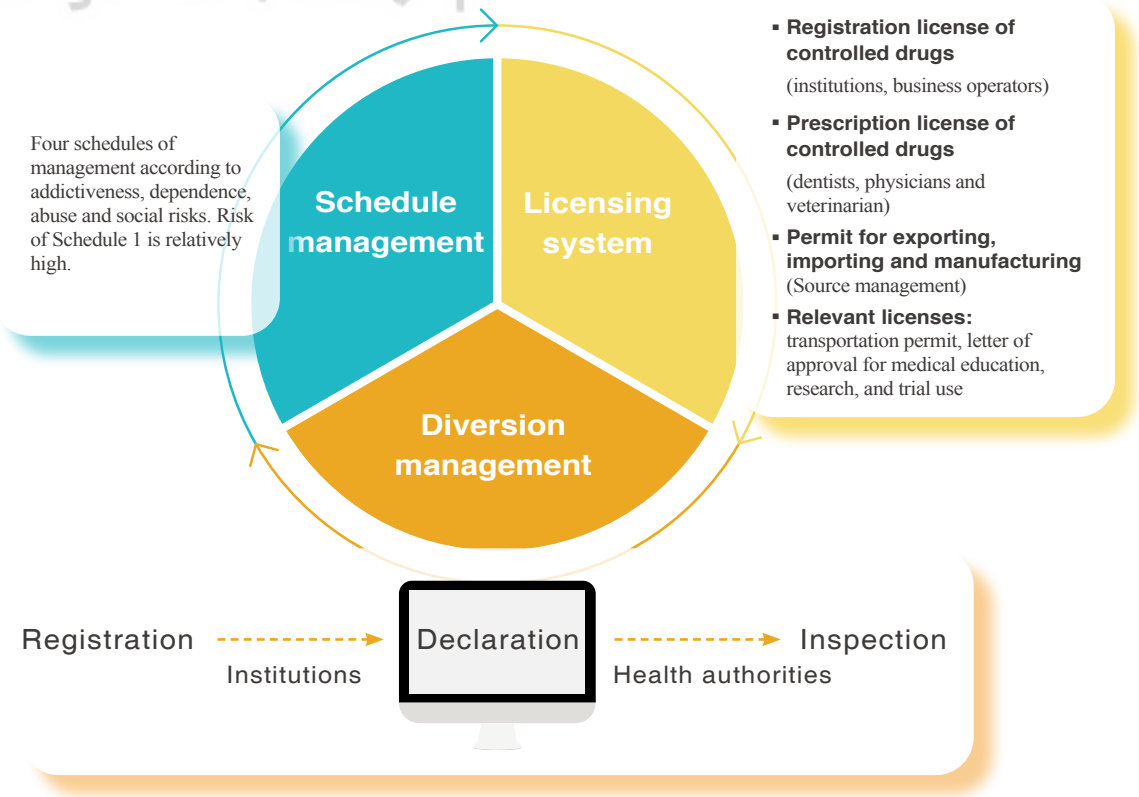


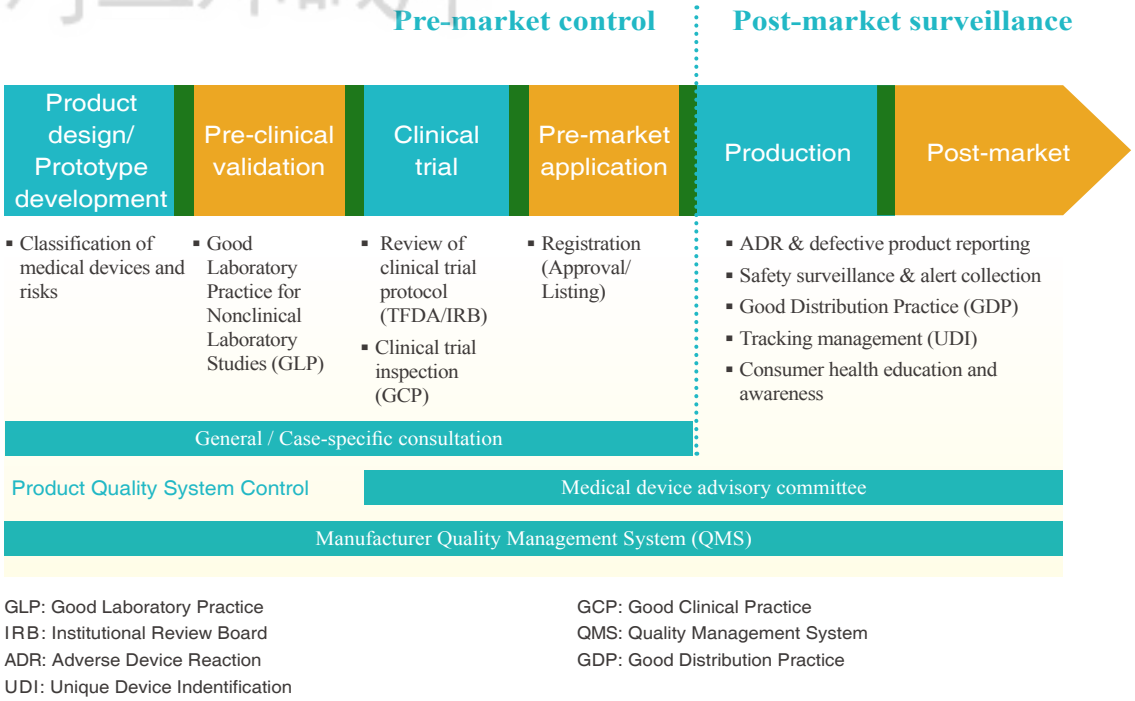
Figure 1-6 Management Framework for Controlled Drugs

■ Section 5

Overview of Medical Devices and Cosmetics Management

I. Medical devices management framework

Following technological advancement and increasing demand for technological medical and health devices, the medical device industry has become one of the most promising industries in the biotechnology sector in Taiwan. In response to the booming development of the domestic medical device industry, TFDA has established a full life-cycle management system for medical devices covering various aspects, including internationalization of regulatory management, tracking management, pre-market inspections, post-market surveillance, management of medical device firms and product circulation management (Figure 1-7). The system can effectively



GLP: Good Laboratory Practice
IRB: Institutional Review Board
ADR: Adverse Device Reaction
UDI: Unique Device Indentification
GCP: Good Clinical Practice
QMS: Quality Management System
GDP: Good Distribution Practice

Figure 1-7 Full Life-cycle Management System for Medical Devices

control the safety, efficacy, and quality of medical devices; at the same time, it can facilitate the development of biotechnology and the pharmaceutical industry, so to create a win-win situation for consumers, business operators and the government.

II. Cosmetic Management Framework

The current cosmetics management system includes three parts: production source control, pre-market management and post-market surveillance (Figure 1-8). The production source control includes ensuring that manufacturers comply with the Establishment Standards for Cosmetics Manufactory and promotion of Cosmetics Good Manufacturing Practice Regulations (GMP); the pre-marketing management includes notification of cosmetic products and establishment of product information file to replace the registration of specific purpose cosmetics; post-market surveillance focuses on the quality monitoring plan and inspections of the cosmetic products across counties and cities, the establishment of product adverse event reporting system for cosmetics, regular monitor of the safety alert for domestic and global cosmetics and strengthening consumer awareness of safe cosmetics use to create a comprehensive cosmetics quality and safety protection network.

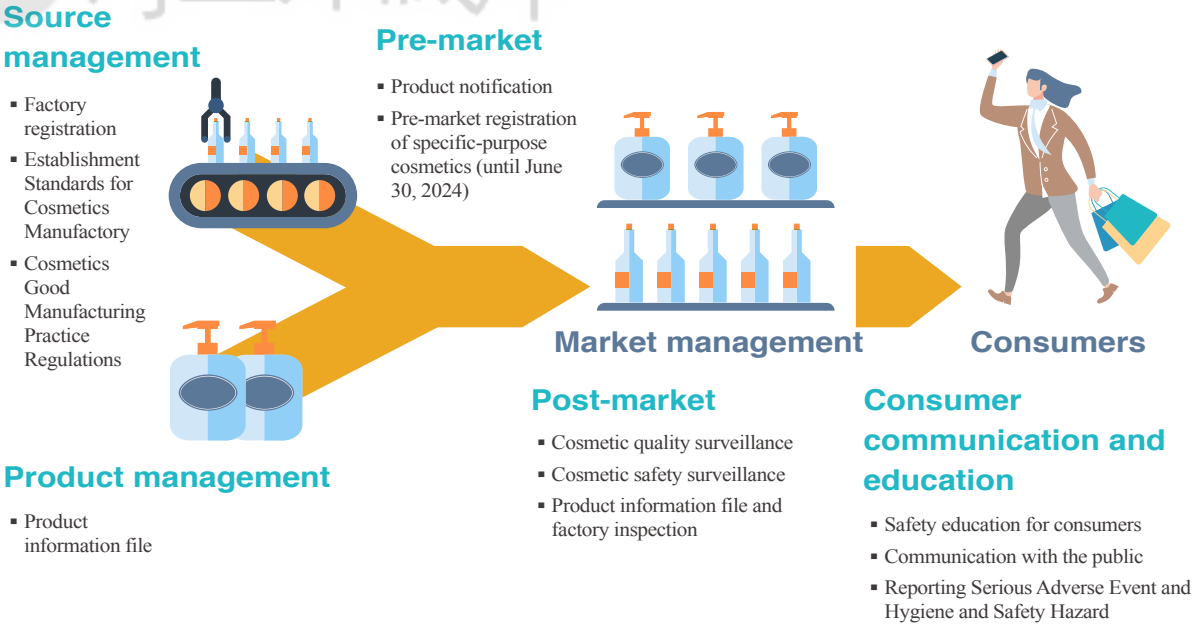


Figure 1-8 Cosmetic Hygiene and Safety Management Framework

■ Section 6

Future Prospective

With more novel substances, the impact of emerging technologies and new chemicals, the safety and sanitary issues of food and medicinal products have gradually become complicated. TFDA integrates different government departments, industries, and consumers to expand the participation of the general public to construct a safe protection network for food, medicinal products, and cosmetics. Key future policy plans include:

I. Implement the forward-looking "Food Safety Construction Plan", which includes the construction plan for a modernized food and drug national laboratory and educational training building, the enhancement of border inspection and clearance management system, the program to strengthen health department's food safety governance of testing effectiveness and quality, the program to strengthen central competent authority's food safety testing capacity and the program to improve the testing research capacity and standardization of medical products for emerging infectious disease and foodborne pathogens. Build an international standard modern national food safety laboratory, purchase high-precision testing equipment, comprehensively improve the efficiency of food safety testing and research and development, further strengthen the management capacity of local and central government agencies.

II. Complete the regulation framework for regenerative medicinal products, continue to provide guidance to the research and

development industry, speed up the reviews of COVID-19 vaccines and medicinal products, establish an anticipatory management system, improve the mechanism for handling shortages of essential drugs, fully electricize the clinical trial applications, strengthen the self-production capacity of key pharmaceuticals and APIs, grasp the supply capacity of critical pharmaceuticals, improve the efficiency of shortage notification and evaluation, and help stabilize the supply of medical supplies.

III. Continue to promote various regulations stipulated in the "Medical Device Act" and the "Cosmetic Hygiene and Safety Act"; enhance harmonization and communication of international regulations; respond to innovative technologies and product developments; establish forward-looking management regulations; provide comprehensive regulatory consultation and assistance in order to facilitate industry growth, improve post-market product safety regulation and strengthen consumer protection.

IV. Strengthen the incorporation of intelligence technology into food and drug safety risk management and continue to optimize the "Five-Point Food Safety Policy" environment. Enhance the country's food management capacity and to protect public health through inter-ministerial resource integration and expansion of food safety management resources; reinforce trace and track system, border inspection, inspection, and industry self-management.