01 Organization and Policies

Bureau of Controlled Drugs

Pharmaceutical Affairs

Bureau of Food and Drug Analysis

Bureau of Food Safety

2013 Organizational reform project proposed by Executive Yuan

Taiwan Food and Drug Administration

Food

Medicinal products

Controlled drugs

Medical devices

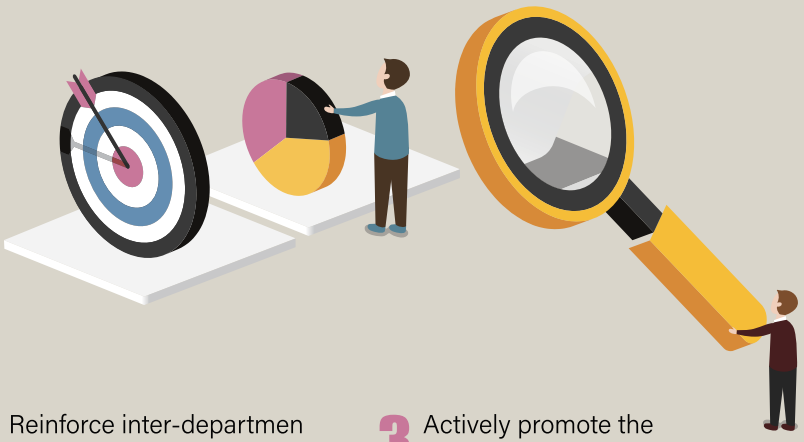
Cosmetics

Vision

"Being a reliable guardian on food and medical product safety," and "Creating a safe food and medicinal consumer environment"

Mission

Safe and effective medicinal products, safe and healthy food



2018 Administrative goals

1 Implement total product life cycle management of food, medicinal products and cosmetics, and maintain the reputation of MIT

2 Reinforce inter-departmen-tal collaboration, and combine the big data analysis of food and medicinal products, to construct a comprehensive safety and protection network of food and drugs

3 Actively promote the transparency of information, fulfill consumer right to know more, and strengthen the communication and promotion of food, medicinal products and cosmetics safety

01 Organization and Policies

Taiwan Food and Drug Administration of Ministry of Health and Welfare (TFDA) was founded on July 23, 2013, as part of the organizational reform in the Executive Yuan. To fulfill 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, medicinal products and cosmetics, through source, production and distribution management, TFDA continues to devote in establishing a comprehensive safety management system for food and drugs.

Figure1-1 TFDA visions and mission

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Section 1 Organization Framework

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 and 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 Risk Management (renamed as Division of Quality Compliance and Management from June 8, 2018) is responsible for laboratory management and authentication, manufacturers management and inspection of pharmaceutical and cosmetic products, and inspection of human organ bank; Division of Research and Analysis is responsible for the testing of food, medicinal products and cosmetics, methodological development and evaluation, pharmacopeia editing and compilation; TFDA also sets 3 District Centers (North, Central and South) which are responsible for laboratory testing of imported food, medicinal products and cosmetics; as well as distribution examinations and inspections. In addition, TFDA is also composed of 5 Administrative Units (Office of Secretariat, Office of Personnel, Office of Accounting, and Office of Information management) to support administrative/management matters. (Figure 1-2). Also, TFDA has two Task Forces (i.e. Manufacturing facility for controlled drug and Decision Support Center) to provide professional information and assistance through professional consultation units such as Center for Drug Evaluation, Taiwan and Taiwan Drug Relief Foundation.

Section 2 Administrative Goals

TFDA sets the administrative goals and focuses based on the administrative policies of Executive Yuan and administrative programs of MOHW along with the budget plans, current development highlights and social needs on food, medicinal products and cosmetics management in 2018.

1. Implement total product life cycle management of food, medicinal products and cosmetics, and maintain the reputation of MIT (Made in Taiwan) food, medicinal products and cosmetics on the premise of quality and safety assurance.
2. Reinforce vertical integration and horizontal inter-departmental collaboration, and combine

the big data analysis of food and medicinal products, to construct a comprehensive safety and protection network of food and drugs.

3. Actively promote the transparency of information, fulfill consumer right to know more, and strengthen the communication and promotion of food, medicinal products and cosmetics safety, to ensure the safety of food and medicinal products.

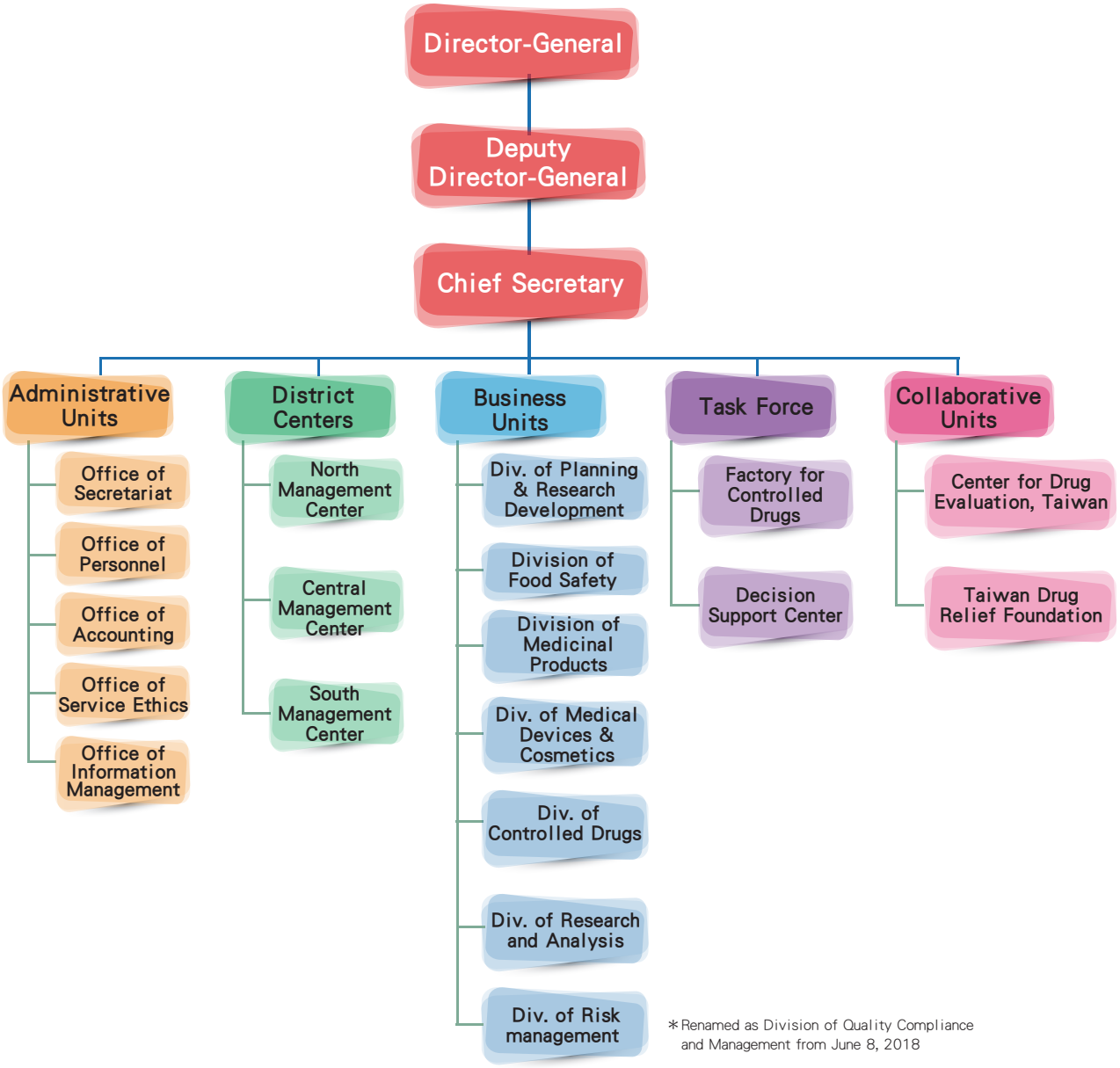

Figure 1-2 Organization framework

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Section 3 Food Management Overview

The structure of food management system is based on "farm-to-table" management. Only by ensuring the safety of products from raw materials to consumers at all stages, we can provide a stable cornerstone for public health and social stability. We carried out the "Five-point Food Safety Policy" reform plan (Figure 1-3) that integrates the strength of the government, industry and the general public, to improve the farm-to-table management system, enhance the management capability in the food industry, enhance consumer protection and communication, and ensure a "Safe and Healthy Food" environment (Figure 1-4).

To assure the public of wholesome and safe food, TFDA collected and referred to international standards and technologies for the stipulation and amendment of the "*Act Governing Food Safety and Sanitation*," to enhance the inspection capacity and capabilities, as well as to develop inspection methods. We will be continuously reinforcing the source control,

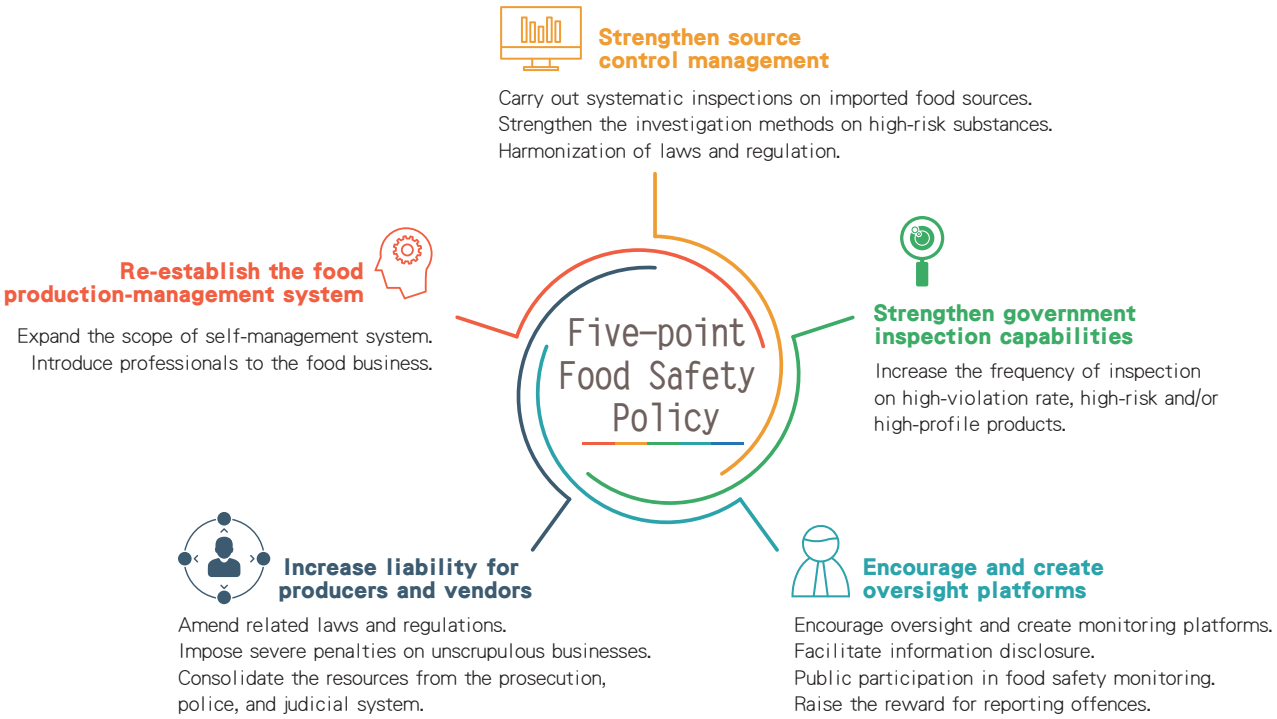

Figure 1-3 Five-point food safety policy

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enhancing the self-management ability of food business operators in the industry, establishing a dedicated personnel system, practically carrying out the supervision of food production and marketing chain, and applying systems to enhance efficiency and information disclosure, etc. TFDA and the health bureau of local government work together to carry out the food inspection project and post-marketing surveillance, to stop the sales of low quality food products and ensure the sanitation, safety and quality of food.

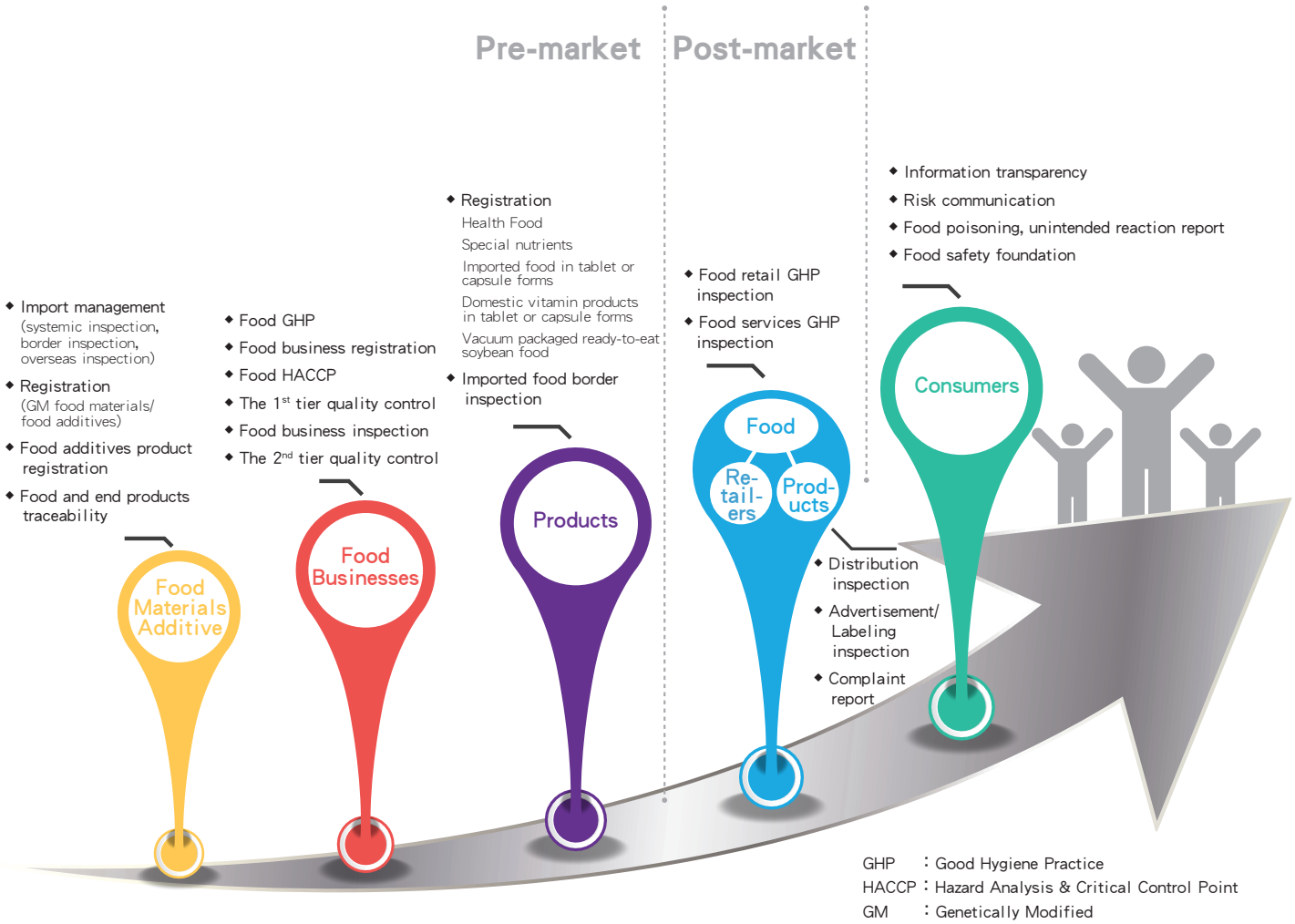

Figure 1-4 Food management framework

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Section 4 Overview of Drugs and Cosmetics Management

1. Medicinal products management framework

Unlike general consumer products, medicinal products are closely associated with the health and lives of fellow citizens. Medicinal products are therefore subject to strict regulations and must acquire drug permit licenses from the central competent health authority before they may be sold on the market. TFDA is constantly improving the review process and strengthening medicinal product monitoring systems to ensure the supplies of safe and quality drugs amongst the general public by revising pharmaceutical laws, harmonizing with international standards, establishing expedited review processes and monitoring the sources, distribution and quality of drug manufacturing, thus prohibiting illegal drug distributions , and enforcing controlled drug managements.

The life cycle of medicinal products from research and development to marketing, including preclinical validation, clinical trial, pre-market application, production and post-market surveillance shall be in compliance with various good operating practices. Therefore, TFDA has established a comprehensive medicinal product life cycle management by the

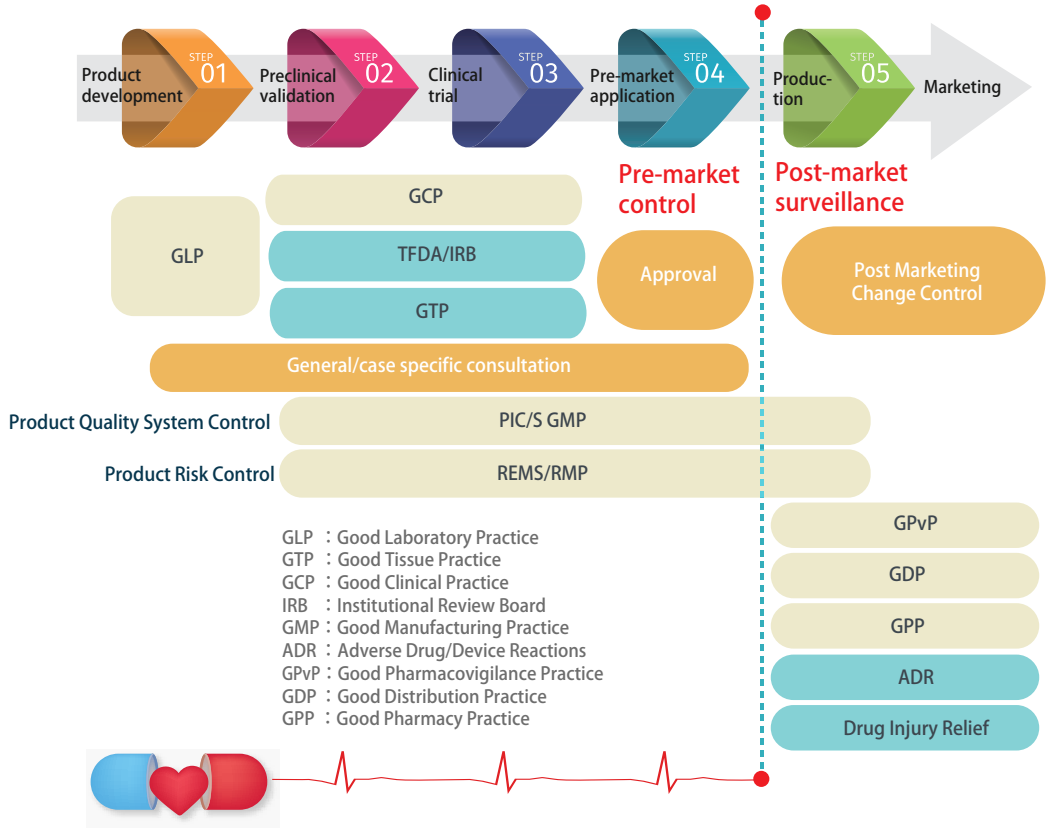


Figure 1-5 Product life cycle management framework for medicinal products

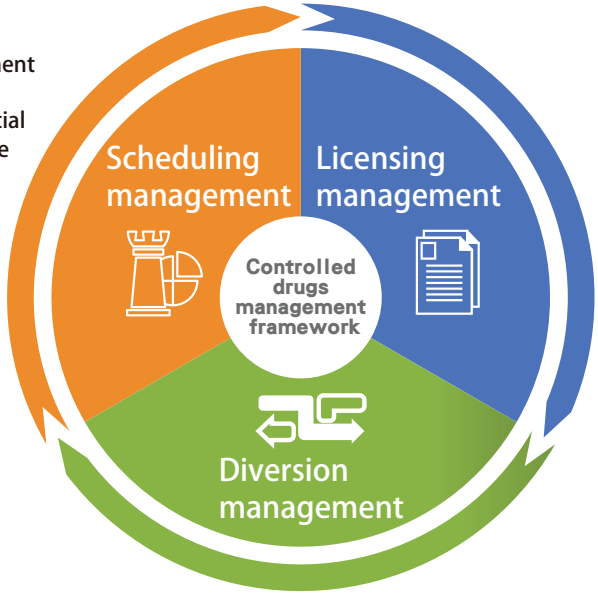
harmonization with international standards and regulations, production source management, pre-market control and post-market surveillance, as well as management of pharmaceutical companies and product distributions (Figure 1-5),thus to effectively control the safety, efficacy and quality of medicinal products while facilitating the development of domestic biotechnology and pharmaceutical industry, creating an environment beneficial for consumers, industry, and government.

2. Controlled drugs management framework

All countries value the importance of drug abuse issue nowadays, especially the addictive controlled drugs, as they will be likely to harm the citizens' health due to improper or illegal use. Therefore, the management of addictive controlled drugs and prevention of drug abuse are important issues to the society and the public health nowadays.

According to "*Single Convention on Narcotic Drugs (1961),*" "*Convention on Psychoactive Substances (1971)*" and "*Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of the United Nations (1988),*" Taiwan has imposed controls on narcotics, psychotropic substances and their preparations through the "*Narcotics Hazard Prevention Act.*" However, due to the necessity of controlled drugs in medical or scientific application, the "*Controlled Drugs Act*" has been established to give a control framework, which is composed of licensing, scheduling, and diversion management (Figure 1-6) to complete the management of controlled drugs.

Four schedules of management according to addictiveness, dependence, abuse, and social risks. The first schedule is the highest relative risk.



- Controlled drugs registration license (institutions and business operators)
- Controlled drugs prescription license (dentists, physicians, and veterinarians)
- Permit for exporting, importing and manufacturing (Source management)
- Relevant licenses: Transportation permit, letter of approval for medical education, research and trial purpose

Registration → Reporting → Inspection

Institutions — Health authorities

Figure 1-6 Controlled drugs management framework

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3. Medical devices management framework

The medical device industry is poised to become Taiwan's leading biotech industry in terms of development potential, given its rapid developments in technology and growing demands for healthcare technologies. In response to the growing prospects of the medical device industry in Taiwan, TFDA has established a Total Product Life Cycle (TPLC) management policy for medical devices (Figure 1-7) that includes harmonization with international standards and regulations, production source control, pre-market control, post-market surveillance, management of pharmaceutical companies and product distribution channels, and provision of professional counseling services. The purpose of the TPLC policy is to effectively control the safety, performance, and quality of medical devices, and to promote the developments of Taiwan's biotech and pharmaceutical industry, in order to create an environment beneficial for consumers, industry, and government.

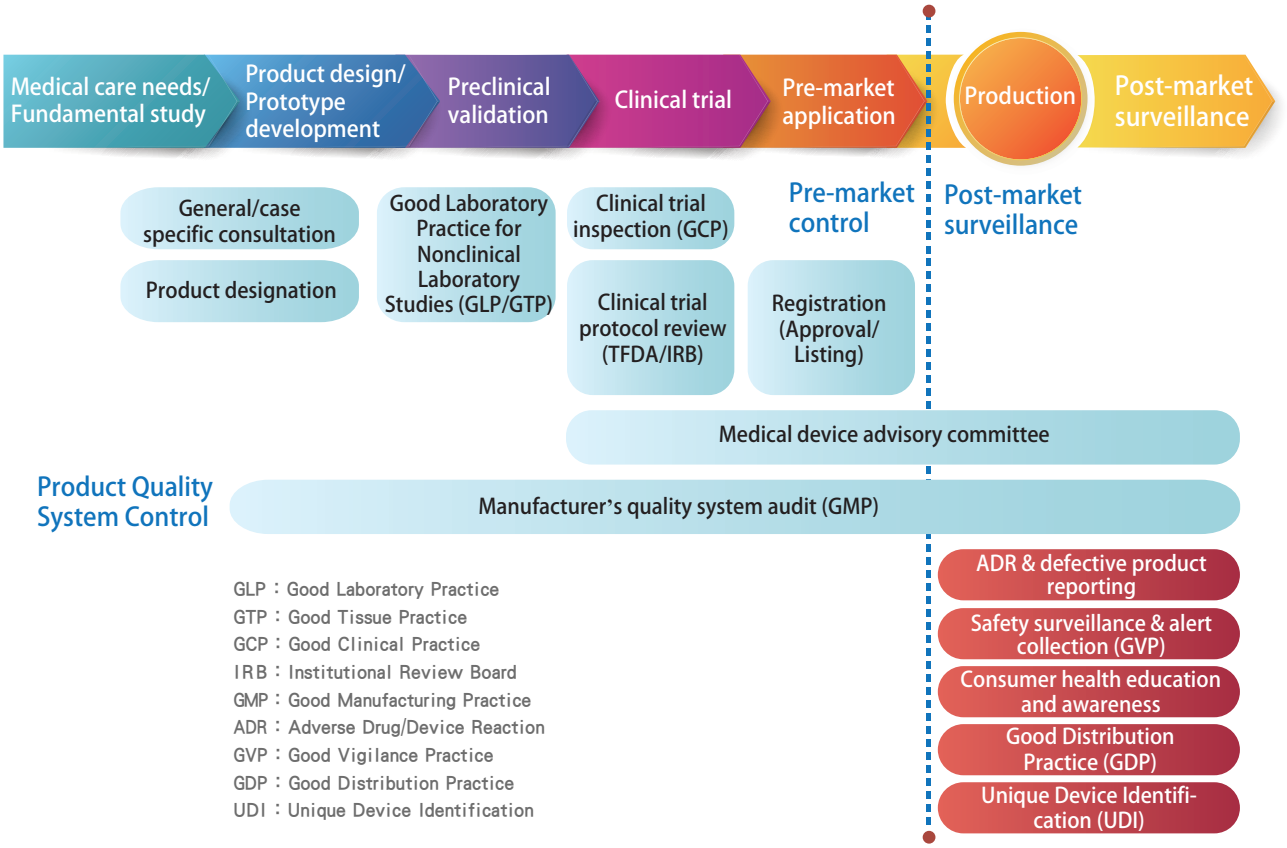

Figure 1-7 Total product life cycle management policy for medical devices

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4. Cosmetics management framework

The current cosmetics management system is divided into production source control, pre-market management, and post-market surveillance. (Figure 1-8) Source control management includes ensuring that manufacturers comply with Establishment Standards for Cosmetics Manufactory and promoting voluntary Good Manufacturing Practice (GMP) for cosmetics. Pre-market management includes registrations of specific purpose cosmetics, and post-market surveillance focuses on implementing cosmetics quality surveillance programs, joint audits spanning multiple counties and cities, establishing a product adverse event reporting system for cosmetics, monitoring of domestic and global cosmetic safety alerts regularly, and strengthening consumer awareness of safe cosmetics use to create a comprehensive cosmetics quality and safety protection network.

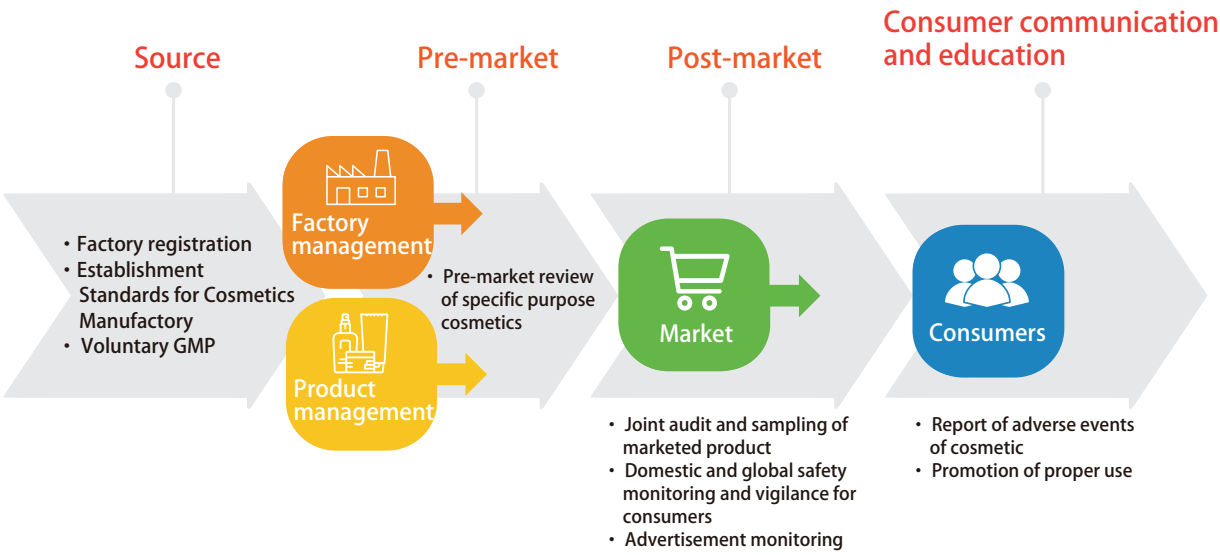

Figure 1-8 Cosmetics management framework

Note: The President announced the "*Cosmetic Hygiene and Safety Act*" on May 2, 2018. The Executive Yuan announced the enforcement date. Except for the relevant provisions of the information that shall be labeled on outer packaging or containers of cosmetics would be implemented on July 1, 2021, the remaining provisions would be implemented on July 1, 2019. The term "medicated cosmetics" revised to "specific purpose cosmetics." The current inspection and registration system for medicated cosmetics will be replaced by the product notification and product information file. The transition period for the new and old registration system is five years.

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Section 5 Future Perspectives

With the trends of global trade and the development of technology, the discovery of novel substances and the impact of emerging technologies and new chemicals, the safety and sanitary issues of food and medicinal products gradually become critical. In view of the importance of food and drug safety and the expectations from the public, TFDA integrates different departments and businesses, and expand the participation of the public to construct a safe protection network for food, medical products and cosmetics. Future important administrative plans include:

1. Adopt the Forward-looking infrastructure Development Program (infrastructure to ensure food safety) to respond to future challenges, and execute 4 sub-programs, i.e. "The construction plan of modern national food and drug laboratory and educational training buildings," "Efficiency improvement program to expedite border inspection system," "Program to strengthen health department's food safety audition and inspection capacity" and "Program to strengthen central competent authority's food safety, safe drug use and illegal drug inspection capacity."
2. Implement "Five-Point Food Safety Policy" reform plan, continue to expand the food safety management resources, combining business self-management and public participation to maximize the effectiveness of limited resources by executing these management strategies, the three-tier product quality management will be practically carry out, and the domestic food management capacity will be enhanced.
3. Improve the comprehensiveness of medicinal products legal environment, strengthen the control of drug suppliers, and promote the regulation of the Management of Regenerative Medicinal Products to ensure the safety of drug use for the citizens in Taiwan.
4. Actively promote the legislation of the *Medical Device Act* and announced the relevant sub-regulations such as the *Cosmetic Hygiene and Safety Act* to meet the international standards, enhance consumer protection, and facilitate the development of medical devices and cosmetics industry.