01

Management Overview

Product Life Cycle

Source Management & Manufacturing Control

Food businesses management (Registration/ GHP/ HACCP mandatorily conduct tests/ food safety monitoring plan/ traceability system)
PICS/S GMP
Cosmetics manufacturing & management

Registration

Specific food products (health foods, food additives etc.)
Medicinal produts
Medical devices
Medicated cosmetics

Pre-market control

Post-market Surveillance

Distribution Management

Food GHP Inspection
GDP Inspection

Customers

Information transparency
Risk communication
Food poisoning, unanticipated reaction report
Food safety foundation
Adverse medicinal product/ adverse event report
Adverse cosmetics event report

Product Quality Surveillance

Distribution inspection
Advertisement/Labeling inspection
Complaints report
Warnings collection
Medicinal product safety surveillance

01 Management Overview

Taiwan Food and Drug Administration (TFDA) has taken up the mission of constructing a sound and safe food and medicinal products management system and building a public trustworthy food and medicinal products consumer environment. Under the vision of "Safe and healthy food, safe and effective medicinal products", TFDA upholds the core concepts of food and medicinal products "Total product life cycle management"(Figure 1-1), and serves as the guardian of public health through the management of sources, manufacturing, circulation and surveillance.

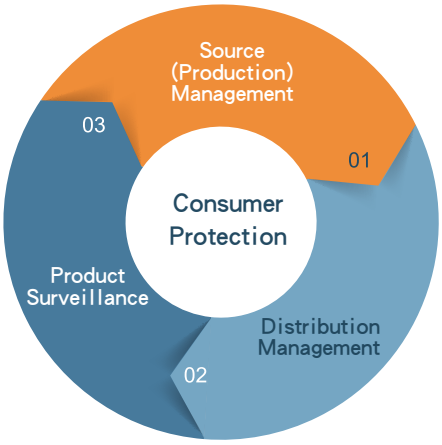


Figure 1-1 Product life cycle management

Section 1. Food Management Overview

To maintain public confidence in food sanitation and safety, TFDA continues to compile and reference international standards and revise laws related to food sanitation and safety management provision. TFDA also actively promotes food business registration system, establishes food traceability system, and strengthens domestic food businesses self-management in order to implement border inspection of imported food, specific food registration and source control. TFDA works with local governments and health bureaus to carry out programs for the inspection, sampling and testing, as well as post-marketing

surveillance of food products, in order to ensure food sanitation, safety and quality. TFDA also uses multiple channels to communicate with consumers in order to promote and provide correct knowledge and risk management concepts (Figure 1-2).

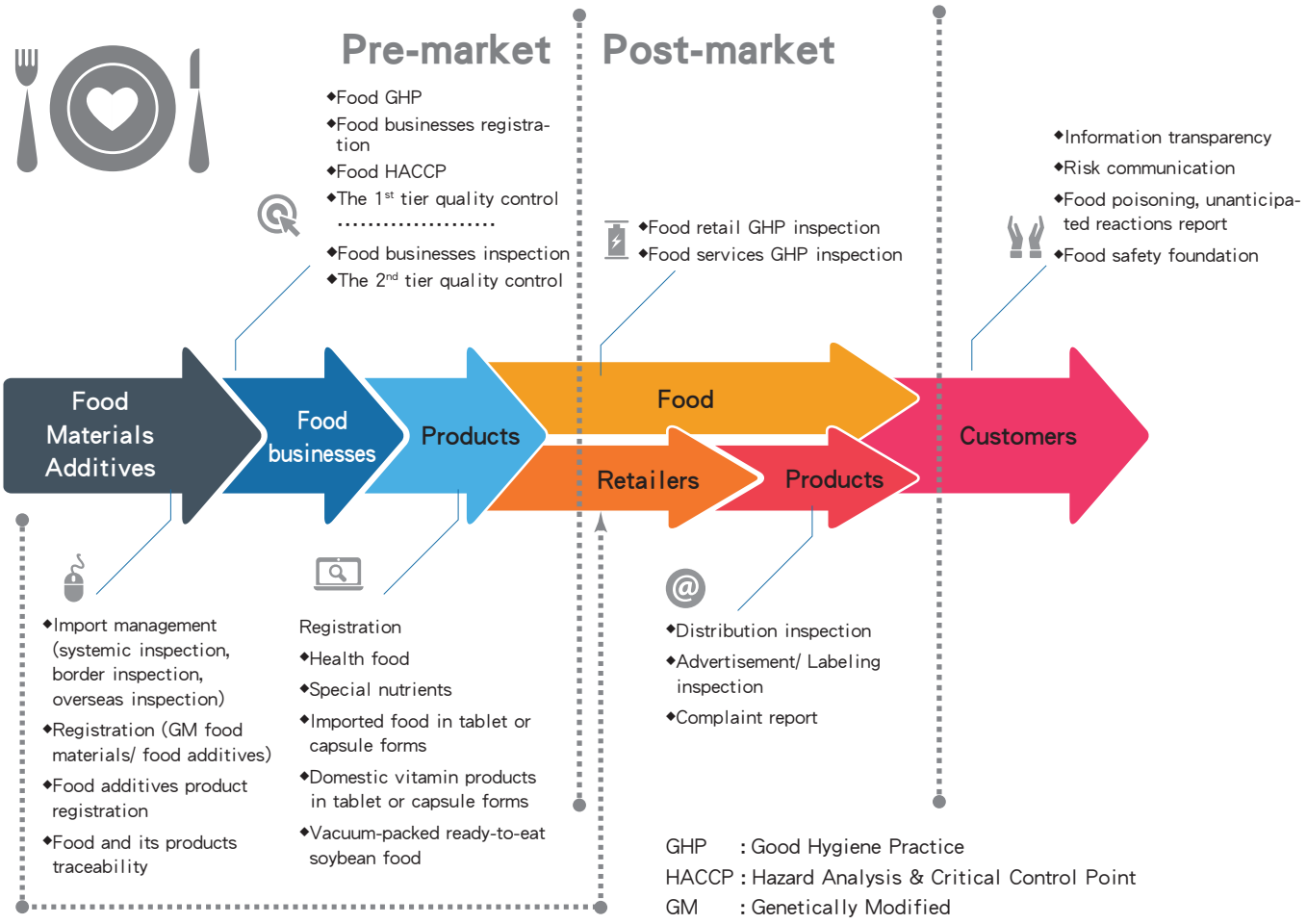


Figure 1-2 Food life cycle management

Section 2. Medicinal Products and Cosmetics Management Overview

1. Medicinal product 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 approved drug permit licenses from the central health authority before they may be sold on the market. TFDA is constantly reviewing and strengthening medicinal product monitoring systems to ensure drug use safety

amongst the general public by revising pharmaceutical laws and harmonizing them with international standards, establishing expedited review processes, monitoring the sources, distribution, and quality of drug manufacturing, thus prohibiting illegal drugs, and enforcing controlled drug management measures.

Medicinal product life cycle from research and development to market release include following steps: fundamental research, non-clinical studies, clinical trials, registrations, manufacturing, and market distribution. Reviews, audits, and inspections were conducted at each step to ensure compliance with various specifications (GXP), forming a comprehensive medicinal product life cycle management framework (Figure 1-3). For example, GLP and GCP inspections will be carried out to ensure study quality during non-clinical studies and clinical trial phases. Manufacturing processes shall be audited for compliance with GMP. Where necessary, pre-market release inspection and analysis as well as post-market sampling tests shall be carried out to ensure continuing compliance to Good Pharmacovigilance Practice (GPvP). These measures will improve measures for medicinal product quality and safety surveillances and achievement of all medicinal product life cycle management objectives.

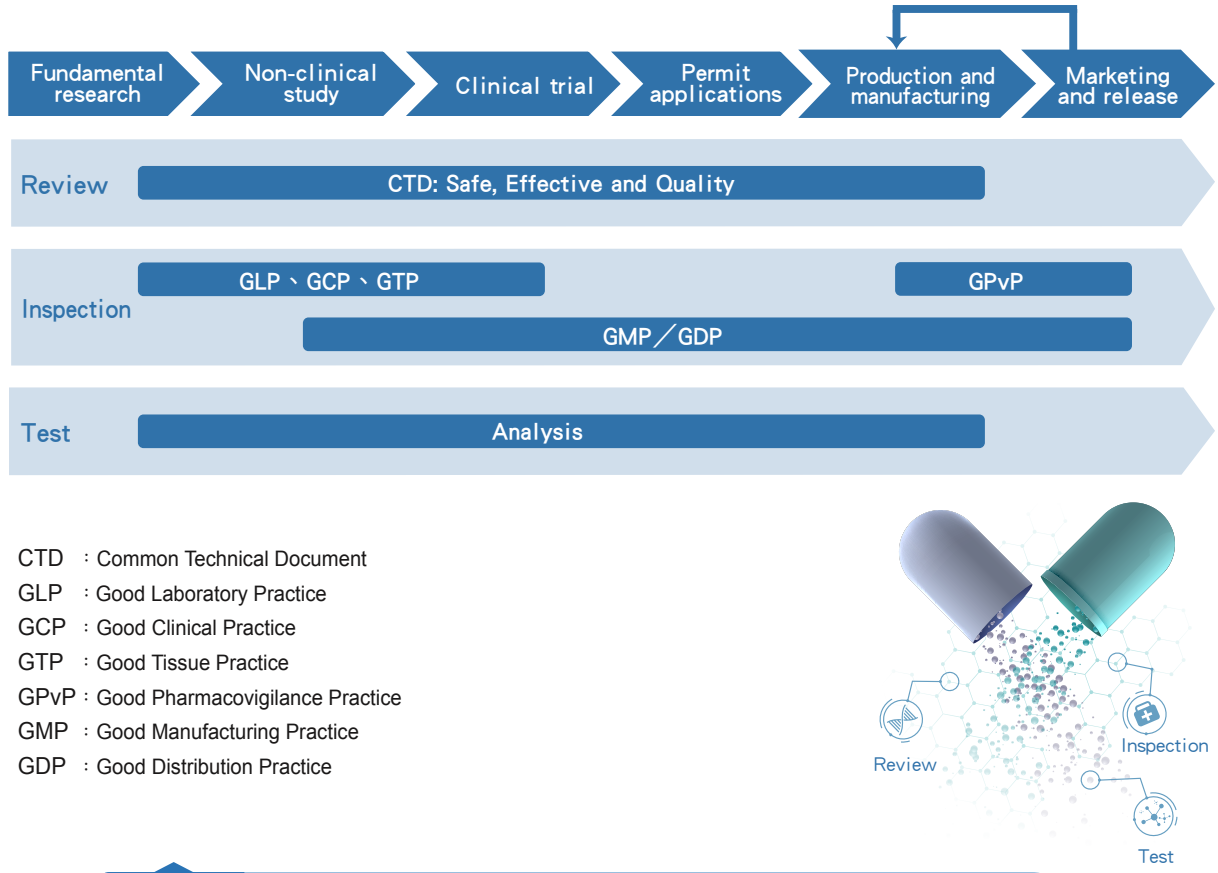


Figure 1-3 A comprehensive medicinal product life cycle management framework

2. Controlled drug management framework

Drug abuse has been a common problem which is faced by various countries around the world. Therefore, the control of addictive drugs becomes more important. At the same time, TFDA prevents controlled drugs from abusing or illegal distributing with vigilance monitoring, abuse prevention and control measures to ensure the physical and mental health of fellow citizens and promote social stability.

According to the "*Single Convention on Narcotic Drugs*", "*Convention on Psychotropic Substances*", and the "*Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of the United Nations*" , 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 applications or scientific research, the "*Controlled Drugs Act*" has been established to give a control framework which is composed of license, scheduling, and distribution management (Figure 1-4).

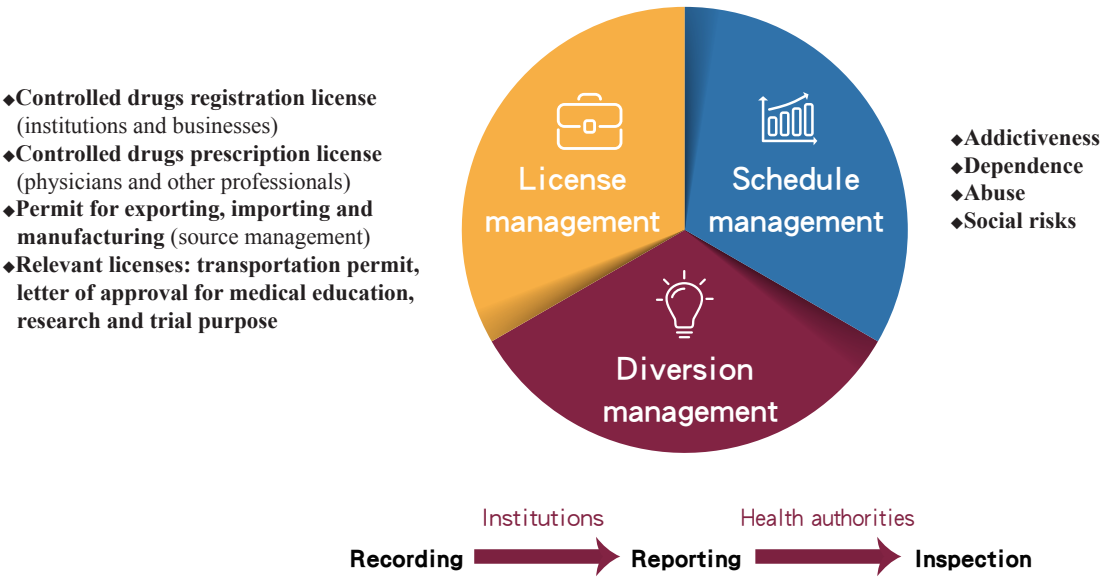


Figure 1-4 Controlled dugs management framework

3. Medical device 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 growing prospects of the medical device industry in Taiwan, TFDA has established a Total Product Life Cycle (TPLC) management policy for medical devices (Figure 1-5) 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 developments of Taiwan's biotech and pharmaceutical industry, creating an environment beneficial for consumers, industry, and government.

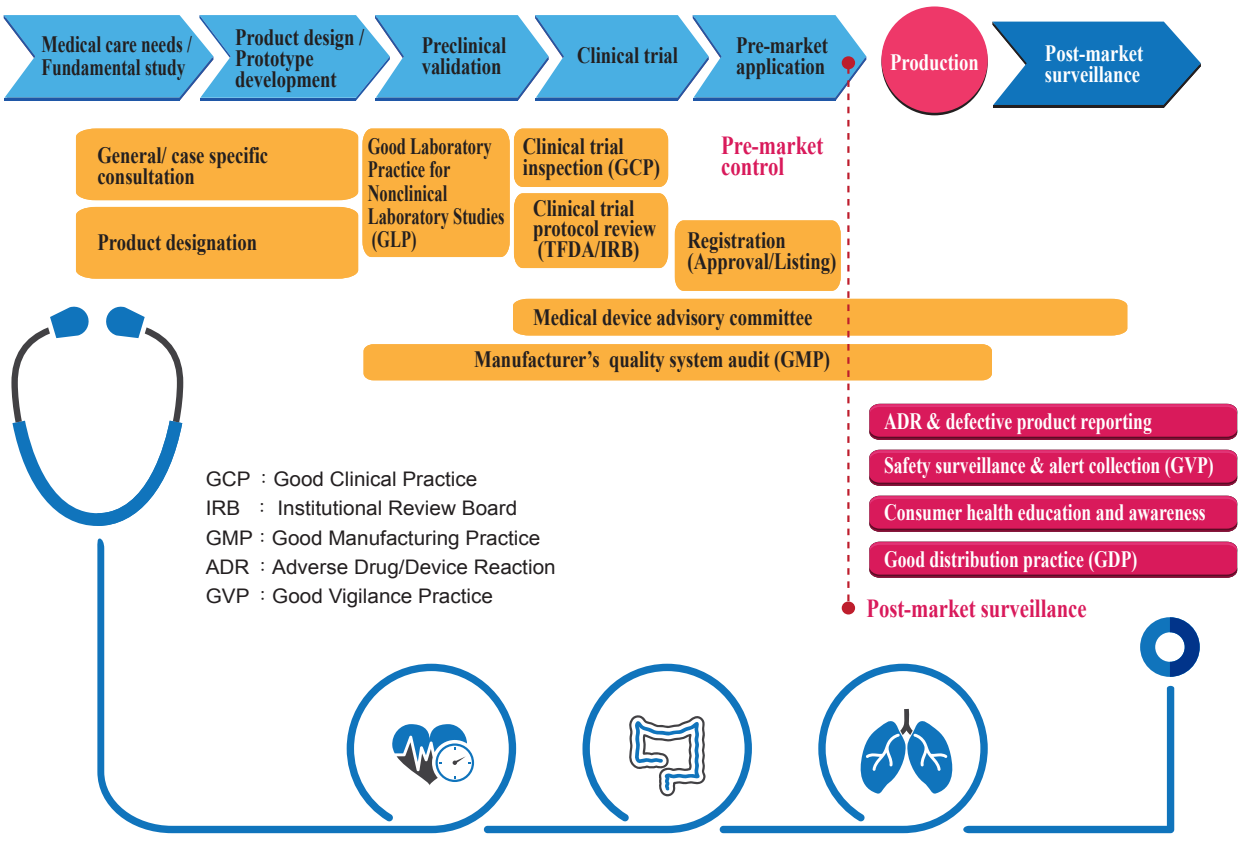
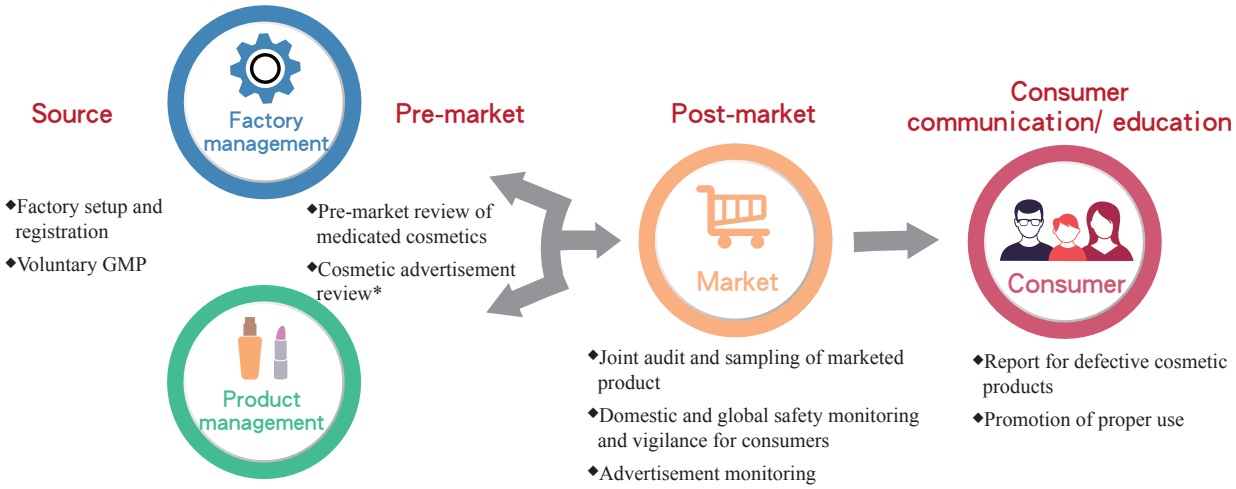


Figure 1-5 Total product life cycle management policy for medical devices

4. Cosmetics management framework

The current cosmetics management system is divided into production source control, pre-market management, and post-market surveillance (Figure 1-6). Source control management includes ensuring manufacturers comply with Establishment Standards for Cosmetics Manufactory and promoting voluntary cosmetic *Good Manufacturing Practice* (GMP) for cosmetics. Pre-market management includes registrations of medicated cosmetics and examination of cosmetic advertisements before broadcasting. 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, regular monitoring of domestic and global cosmetic safety alerts, and strengthening consumer awareness of safe cosmetics use to create a comprehensive cosmetics quality and safety protection network.



*Note: According to the Interpretation from Justices of the Constitutional Court, Judicial Yuan, the preview of cosmetic advertisement shall be discontinued starting from January 06, 2017.

Figure 1-6 Total product life cycle management policy for cosmetics