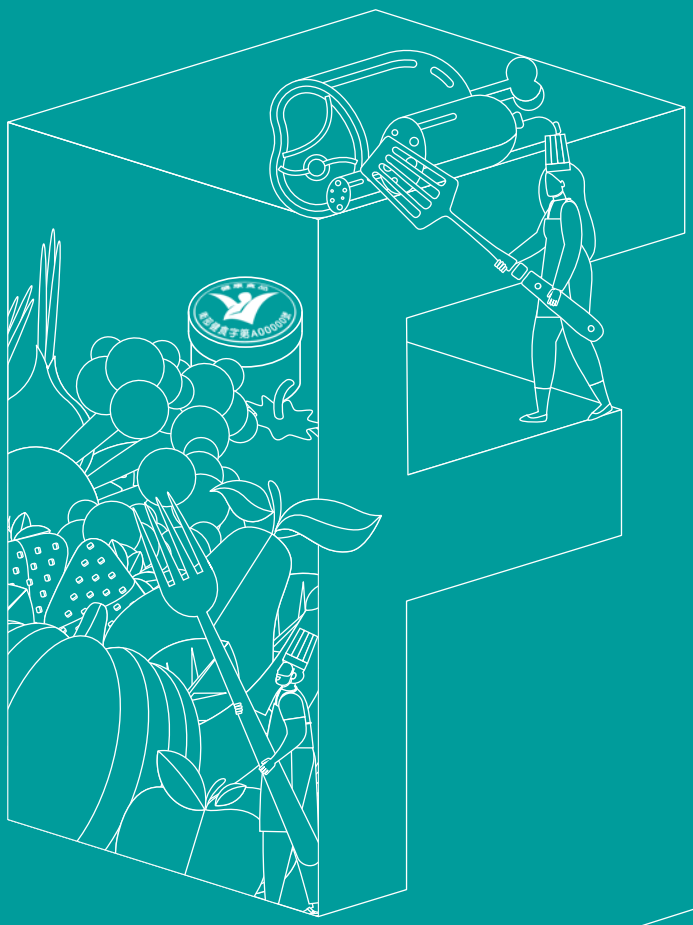
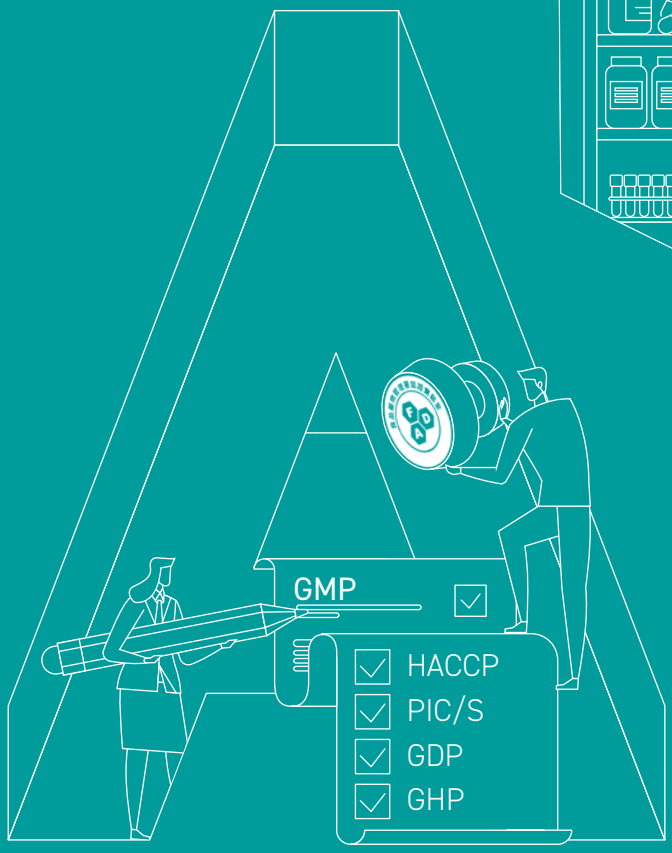
衛生福利部

食品藥物管理署



服務・專業・品質・創新

Service, Profession, Quality, and Innovation



FDA

Taiwan Food and Drug Administration, Ministry of Health and Welfare

衛生福利部

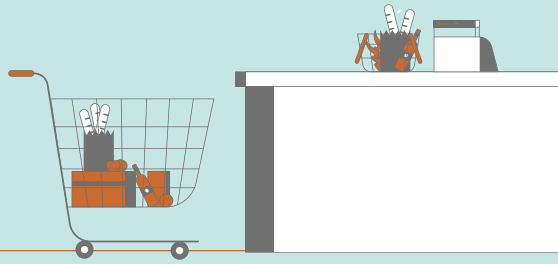
食品藥物管理署

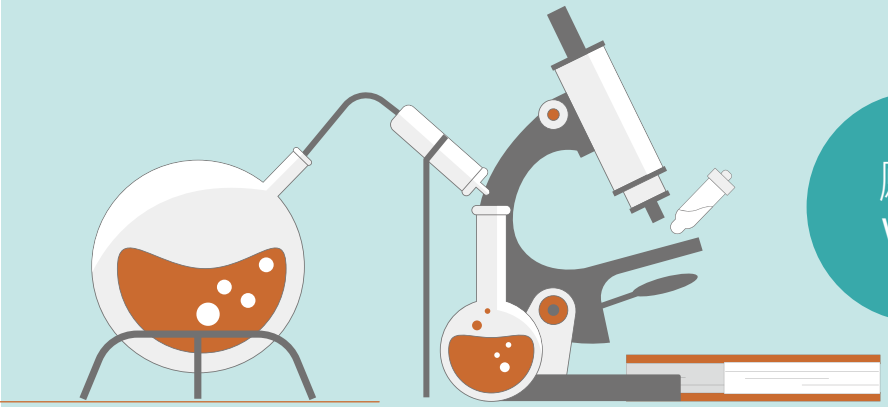
TAIWAN FDA

使命 Mission

藥求安全有效，食在安心健康

Safe and effective medicinal products, safe and healthy food.





願景 Vision

全民信賴的食藥安全守護者，創造食品藥物安全消費環境

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

未來展望 Future Outlook

建構國際化管理法規，促進生技產業發展

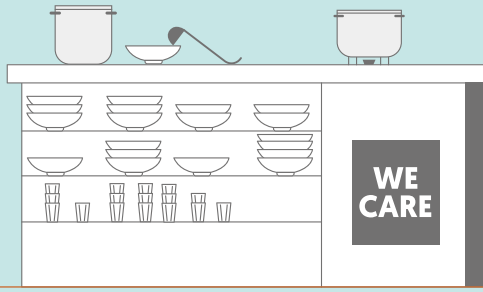
強化食品原料管理，提升食品製造品質

建置完整藥物安全網，保障人民用藥安全

擴大市場稽查及品質監測，加強消費者保護

積極加入國際組織，拓展國際食藥合作

運用大數據輔助管理，發揮預警預判效能



Establish a regulatory system based on a global perspective and promote the growth of the biotechnology industry.

Strengthen the management of food raw materials and improve the food manufacturing process.

Establish a complete safety net for drugs to protect consumers.

Expand the scope of market inspection and quality monitoring for the protection of consumers.

Proactively participate in international organizations to increase collaboration opportunities for food and drugs.

Use big data to assist in management and bring into play the effectiveness of early warning and judgment.

Chronicle of History
歷史沿革

衛生福利部（前身為行政院衛生署）積極進行組織變革，以保護消費者健康為核心，整併原行政院衛生署食品衛生處、藥政處、藥物食品檢驗局及管制藥品管理局等單位之職掌業務，於 2010 年 1 月 1 日成立「行政院衛生署食品藥物管理局」，2013 年 7 月 23 日又配合行政院組織改造，改制成「衛生福利部食品藥物管理署」。成立後，從相關整體管理政策規劃到相關措施之執行過程大幅縮短且效率提升，而食品藥物資訊公開、透明迅速及多元化，讓所有消費者在食品、藥品、醫療器材及化粧品的安全品質上獲得保障。

As part of its organizational restructuring effort to protect the health of the consumers, the Ministry of Health and Welfare (formerly known as the Department of Health, Executive Yuan) combined the organizations formerly known as the Bureau of Food Safety, Bureau of Pharmaceutical Affairs, Bureau of Drug and Food Analysis and Bureau of Controlled Drugs under the Department of Health into the Food and Drug Administration, Department of Health on January 01 of 2010. On July 23 of 2013, as part of the Executive Yuan's organizational restructuring, the Taiwan Food and Drug Administration under the Ministry of Health and Welfare was established. The restructured organization not only greatly shortened the time taken to plan and implement management policies, but also promoted the transparent, rapid and diverse disclosure of food and drug information, guaranteeing safety of the quality of food, drug, medical device and cosmetic products for all consumers.

前身
Predecessor

行政院衛生署食品衛生處
Bureau of Food Safety, Department of Health

行政院衛生署藥政處
Bureau of Pharmaceutical Affairs, Department of Health

藥物食品檢驗局
Bureau of Food and Drug Analysis

管制藥品管理局
Bureau of Controlled Drugs

成立
Establish

2010.01.01

行政院衛生署食品藥物管理局
Food and Drug Administration, Department of Health

改制
Restructure

2013.07.23

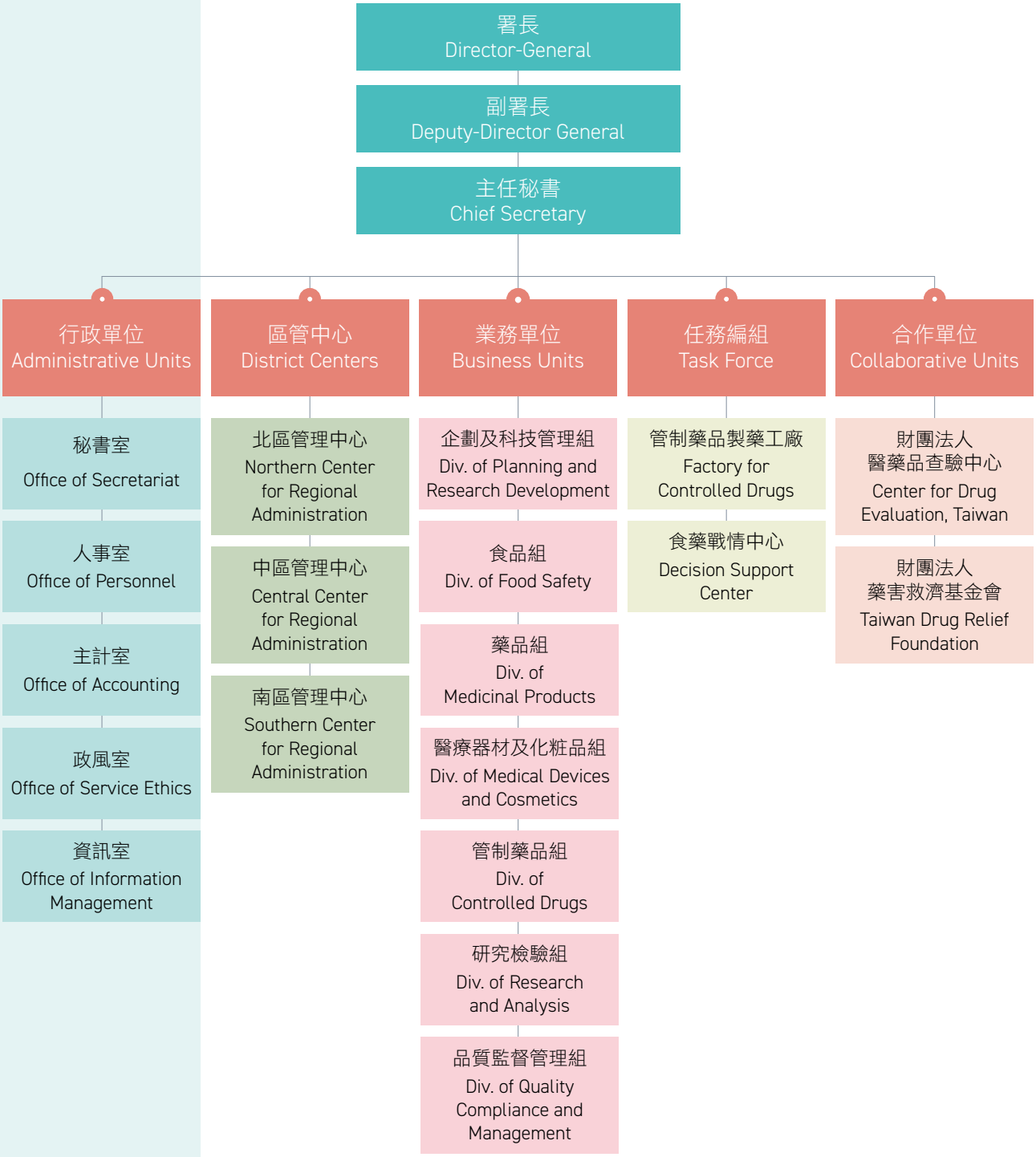
衛生福利部食品藥物管理署
Taiwan Food and Drug Administration, Ministry of Health and Welfare

組織架構

食品藥物管理署置署長 1 人，副署長 2 人及主任秘書 1 人，並設置 7 個業務單位、5 個行政單位及北、中、南三區管理中心。另設有管制藥品製藥工廠及食藥戰情中心，此外更積極透過專業諮詢單位如財團法人醫藥品查驗中心及財團法人藥害救濟基金會等，與之建立密切合作夥伴。

Organization Framework

The TFDA executives consist of a Director-General, two Deputy-Director Generals and one Chief Secretary. There are seven operational divisions, five administrative offices and three district Centers covering the Northern, Central and Southern Taiwan. There are also task forces on Factory for Controlled Drugs and Decision Support Center, and collaborative institutes such as the Center for Drug Evaluation, Taiwan and the Taiwan Drug Relief Foundation.

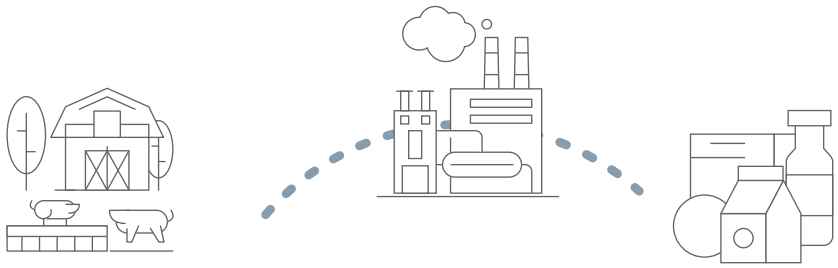


Food Management

食品管理

食品管理架構為「從農場到餐盤」的管理體系，以確保產品從原料至消費者手中各階段的安全。並透過食安改革方案，結合政府、產業、民間三大力量，完善「從農場到餐盤」的管理體系，提升食品業者管理能力，強化消費者保護與溝通，維護「食在安心健康」的消費環境。

負責單位 食品組、區管中心、品質監督管理組、研究檢驗組、企劃及科技管理組



食品原料、添加物
Food Materials, Additives

- 食品輸入管理
  系統性查核、邊境查驗、境外查廠
- 查驗登記
  基因改造食品原料／單方添加物
- 食品添加物產品登錄
- 食品及其產品之追溯追蹤

- Food import management
  systemic inspection, border inspection, overseas establishment inspection
- Registration
  GM food raw materials/ food additives
- Food additives product registration
- Food and end products traceability

食品業者
Food Businesses

- 食品業者登錄
- 第一級品管
- 食品 GHP
- 食品 HACCP
- 第二級品管
- 食品實驗室認證管理
- 第三級管理

- Food businesses registration
- The 1st tier quality control
- Food GHP
- Food HACCP
- The 2nd tier quality control
- Food laboratory certification management
- The 3rd tier quality control

產品
Products

- 查驗登記
  健康食品
  特殊營養食品
  輸入膠錠食品
  國產維生素膠錠食品
  真空包裝黃豆即食食品
- 輸入食品邊境查驗

- Registration
  Health food
  Special dietary food
  Imported foods in tablet or capsule form
  Domestic tablet and capsule vitamin products
  Vacuum-packed ready-to-eat soybean food
- Imported food boarder inspection

法規

- ☑ 食品安全衛生管理法
- ☑ 食品良好衛生規範準則／食品安全管制系統準則
- ☑ 健康食品管理法

核心業務

- ☑ 食品安全衛生管理法修訂推動
- ☑ 食品輸入管理（系統性查核、邊境查驗、境外查廠）
- ☑ 食品三級品管制度（自主品管、機構驗證及政府稽查）
- ☑ 食品業者管理（GHP、HACCP、業者登錄）
- ☑ 食品管理（安全性評估、查驗登記、標示、追溯追蹤）
- ☑ 食品安全保護基金

The structure of food management system is based on "farm-to-plate" management. We carried out the food safety reforms that integrates the strength of the government, industry and the general public, to improve the farm-to-plate management system, enhance the management capability in the food industry, enhance consumer protection and communication, and ensure a "Safe and Healthy Food" environment.

Responsible Units

Div. of Food Safety, District Centers, Div. of Quality Compliance and Management, Div. of Research and Analysis, Div. of Planning & Research Development

GHP : Good Hygiene Practice（食品良好衛生規範）
HACCP : Hazard Analysis & Critical Control Point（食品安全管制系統）
GM : Genetically Modified（基因改造）

上市前 Pre-market | 上市後 Post-market

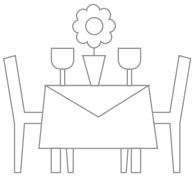
食品業者 GHP 查核
Food businesses GHP inspection

- 餐飲業
- 販賣業者
- 物流業者
- Food services
- Food retailers
- Logistics

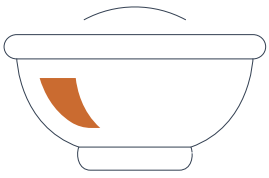
產品
Products

- 流通稽查
- 廣告標示稽查
- 檢舉通報
- Distribution inspection
- Advertisement/ Labeling inspection
- Complaint report

消費者
Customers



- 資訊透明
- 風險溝通
- 食安基金
- 食品中毒、非預期反應通報
- Information transparency
- Risk communication
- Food safety foundation
- Food poisoning, unintended reaction report



Laws

- Act Governing Food Safety and Sanitation
- Regulations on Good Hygiene Practice for Food (GHP) / Regulations on Food Safety Control System (Hazard Analysis & Critical Control Point, HACCP)
- Act Governing Health Foods

Core Missions

- Amendment and promotion of Act Governing Food Safety and Sanitation
- Food importation and inspection management (systemic inspection, border inspection, overseas establishment inspection)
- 3-tier food quality management system (self-management, institution validation and government auditing)
- Food businesses management (GHP, HACCP, Registration)
- Food management (Safety evaluation, Registration, Labeling, Traceability)
- Food Safety Protection Fund

Pharmaceutical Management

藥品管理

藥品管理架構從其研發到上市，包括產品開發、臨床前試驗、臨床試驗、上市申請，及生產製造與上市等階段，皆需依循各項優良作業規範，此外，藉由法規管理國際化、生產源頭控管、上市前把關、上市後監控及藥商與產品流通管理等面向，建立藥品品質管理政策，有效控管藥品的安全、效能及品質。

負責單位

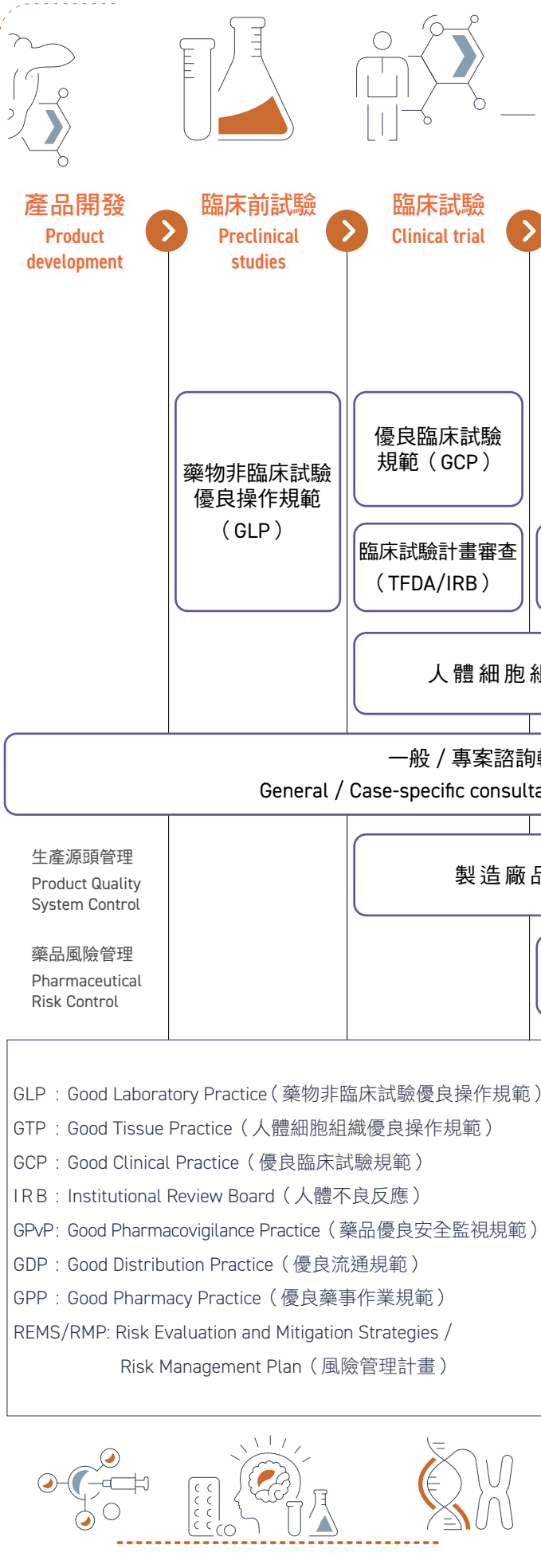
藥品組、品質監督管理組、研究檢驗組、區管中心、企劃及科技管理組

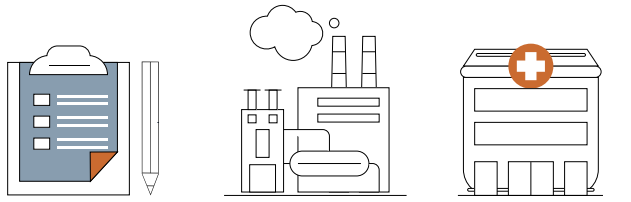
法規

- ☑ 藥事法
- ☑ 藥物優良製造準則／西藥優良運銷準則
- ☑ 藥害救濟法

核心業務

- ☑ 藥事法及相關法規修訂、推動及國際調和
- ☑ 藥品查驗登記及諮詢輔導
- ☑ 藥品非臨床（GLP）與臨床試驗（GCP）管理
- ☑ 國內外藥廠 GMP 管理
- ☑ 推動實施西藥 GDP
- ☑ 藥品追溯追蹤
- ☑ 藥害救濟相關
- ☑ 藥事服務管理





上市申請 Pre-market application → 量產 Production → 上市 Marketing

上市前管理 Pre-market management

上市後管理 Post-market management

- 查驗登記 Registration
- 上市後變更 Post Marketing Change Control
- 優良操作規範（GTP）
- 系統稽查（PIC/S GMP）
- 風險管理計畫（REMS/RMP）
- 藥品優良安全監視規範（GPvP）
- 藥品流通（GDP）
- 藥事照護服務（GPP）
- 不良事件通報（ADR）
- 藥害救濟 Drug Injury Relief

The pharmaceutical management framework encompasses procedures from product development to market approval, including R&D, pre-clinical studies, clinical trials, application for market approval, manufacturing and post-market management. Each of these steps shall comply with various good practice (GxP) standards and regulations. In addition, comprehensive pharmaceutical management policies has been established through the harmonization of international regulations, production sources control, pre-marketing control, post-marketing surveillance, and management of product distribution and pharmaceutical vendors. These are all effective strategies to ensure the safety, efficacy and quality of the pharmaceutical products.

Responsible Units

Div. of Medicinal Products, Div. of Quality Compliance and Management, Div. of Research and Analysis, District Centers, Div. of Planning and Research Development

Laws

- ☑ Pharmaceutical Affairs Act
- ☑ Pharmaceutical Good Manufacturing Practice Regulations (GMP)/ Western Pharmaceuticals Good Distribution Practice Regulations (GDP)
- ☑ Drug Injury Relief Act

Core Missions

- ☑ Drafting and amendment of Pharmaceutical Affairs Act and relevant regulations, promotion and international harmonization.
- ☑ Drug inspection, registration and consultation guidance
- ☑ GLP and GCP management
- ☑ GMP management for domestic and foreign pharmaceutical plants
- ☑ Promotion and implementation of GDP for Western Medicine
- ☑ Drug traceability and tracking
- ☑ Relief for drug-related hazards
- ☑ Management of pharmaceutical affairs services

Medical Devices Management

醫療器材管理

醫療器材管理架構，以消費者保護為核心，從產品設計、臨床前測試、臨床試驗、上市申請到上市後等階段建立相對應管理機制，藉由完整涵蓋「設計」、「製造」、「販賣」的全生命週期管理體系，有效控管醫療器材之安全、效能及品質。此外，因應國際法規趨勢，掌握環境脈動，加速建構與時俱進且與國際趨勢接軌管理政策，促進產業發展。

負責單位

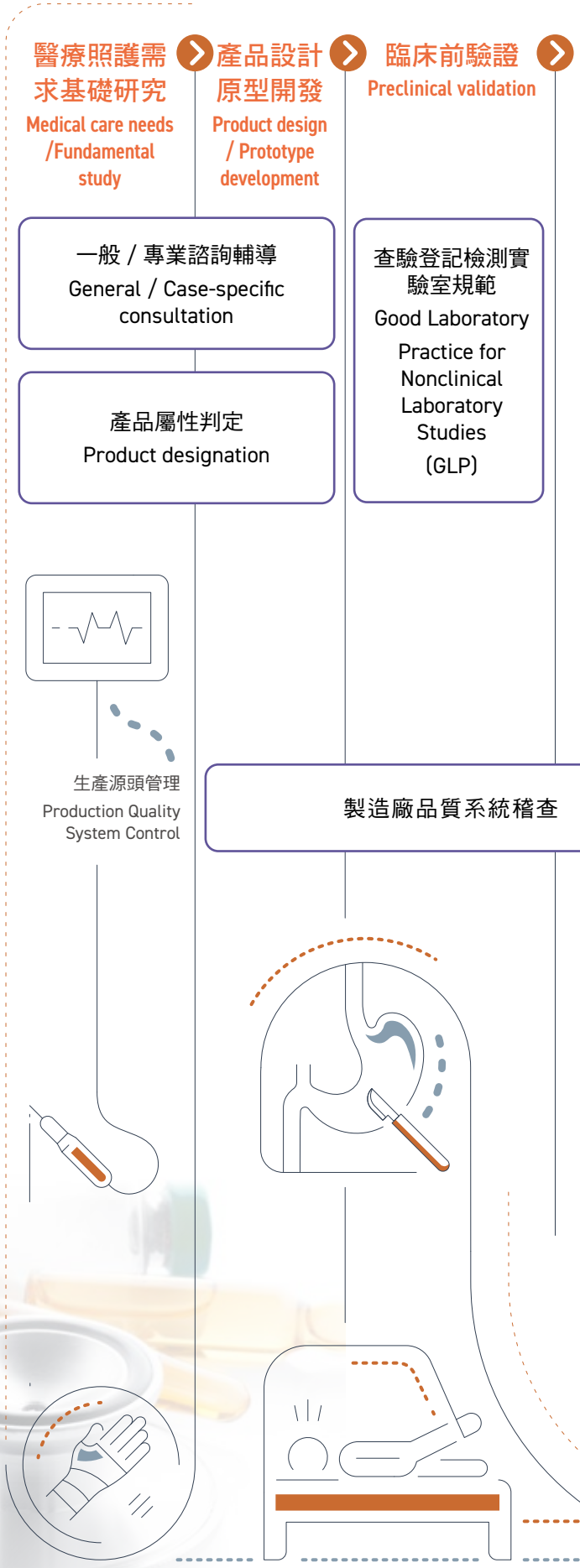
醫療器材及化粧品組、品質監督管理組、研究檢驗組、企劃及科技管理組

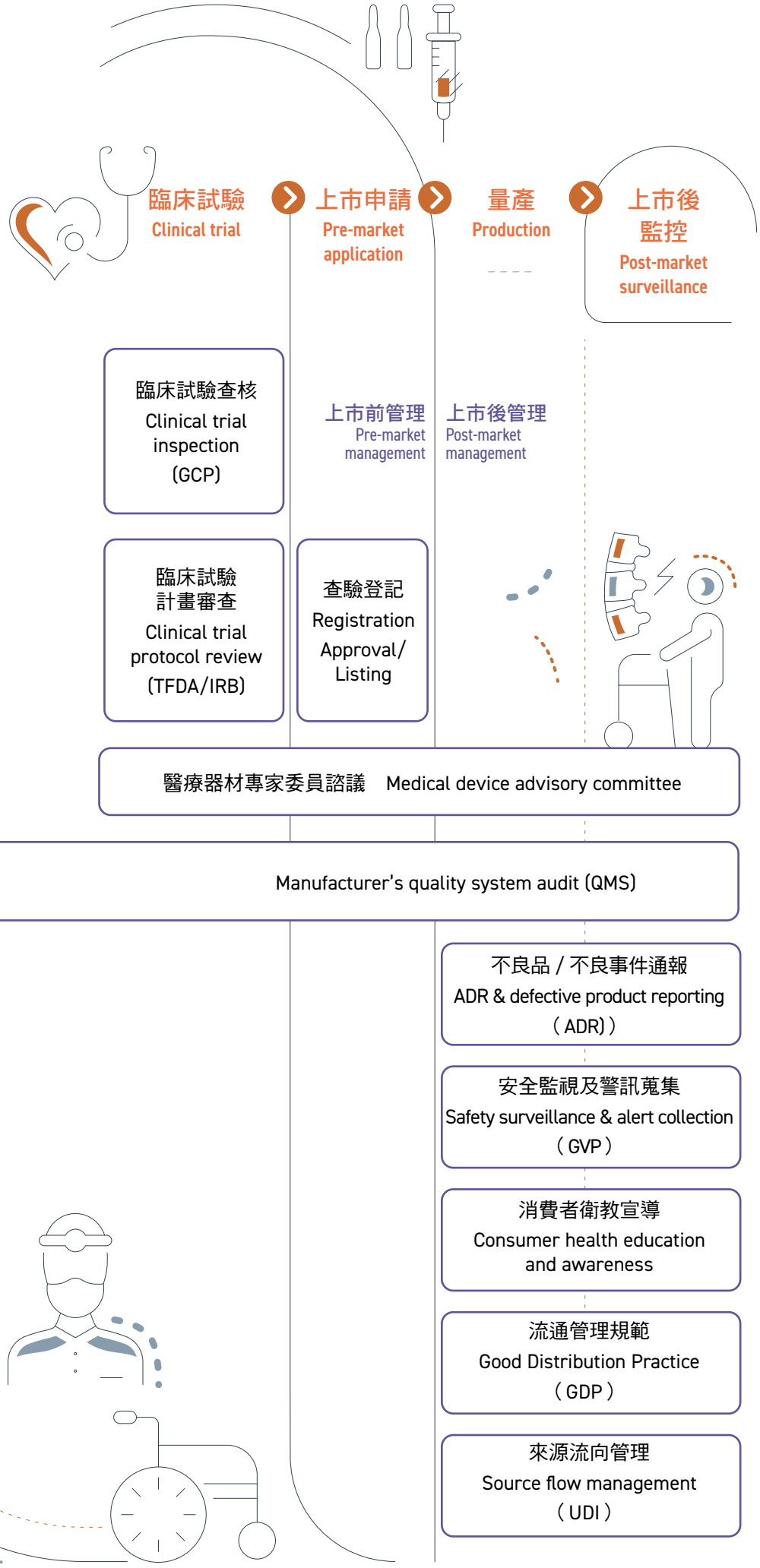
The framework of medical device management is centered on protection of consumers. It establishes corresponding regulatory mechanisms for the phases from product design, pre-clinical testing, clinical trial, pre-market application, to marketing. By covering fully the "design," "production," and "sale" of total product life cycle management system, the safety, effectiveness, and quality of medical devices are efficiently managed. Furthermore, to respond to the international regulatory trends and cope with the ever-changing environment, regulatory policies that may keep pace with the times and can be in line with international trends are being developed at an accelerated rate to promote the industry development.

Responsible Units

Div. of Medical Devices and Cosmetics, Div. of Quality Compliance and Management, Div. of Research and Analysis, Div. of Planning and Research Development

GLP : Good Laboratory Practice（實驗室優良操作規範）
GCP : Good Clinical Practice（優良臨床試驗作業規範）
IRB : Institutional Review Board（人體試驗委員會）
QMS : Regulations Governing the Quality Management System（品質管理系統準則）
ADR : Adverse Drug / Device Reactions（藥物不良反應）
GVP : Good Vigilance Practice（優良安全監視規範）
GDP : Good Distribution Practice（優良流通規範）
UDI : Unique Device Identification（醫療器材單一識別系統規範）





法規

- ☑ 醫療器材管理法
- ☑ 醫療器材分類分級管理辦法
- ☑ 醫療器材品質管理系統準則

核心業務

- ☑ 醫療器材管理法規修訂、推動及國際調和
- ☑ 醫療器材查驗登記與諮詢輔導
- ☑ 醫療器材國內外製造廠管理（QMS/QSD 認證）
- ☑ 醫療器材法規諮詢及專案輔導機制
- ☑ 醫療器材臨床前及臨床試驗管理
- ☑ 醫療器材商及產品追溯管理
- ☑ 醫療器材上市後安全監控及流通稽查

Laws

- ☑ Medical Devices Act
- ☑ Regulations for Governing the Management of Medical Device Classification and Categorization
- ☑ Medical Device Quality Management System Regulations

Core Missions

- ☑ Drafting, amendment, promotion, and international harmonization of regulations on medical device management
- ☑ Registration and market approval and consultation assistance of medical devices
- ☑ Management of domestic and foreign medical device manufacturing plants (QMS /QSD certification)
- ☑ Consultation and case-specific assistance mechanisms for medical device regulations
- ☑ Pre-clinical and clinical trial management of medical devices
- ☑ Medical device firm and product traceability management
- ☑ Post-market safety monitoring and circulation inspection of medical devices

Cosmetics Management

化粧品管理

化粧品管理架構主要分為生產源頭控管、上市前管理及上市後監督三部分。從生產源頭控管包括製造廠需符合設廠標準、化粧品優良製造準則（GMP）；上市前管理為特定用途化粧品查驗登記，以及上市後執行監督產品品質，透過跨縣市聯合稽查，建立化粧品不良事件通報系統，定期監控國內外化粧品安全警訊與加強消費者安全使用宣導，以建構化粧品全方位品質安全防護網。

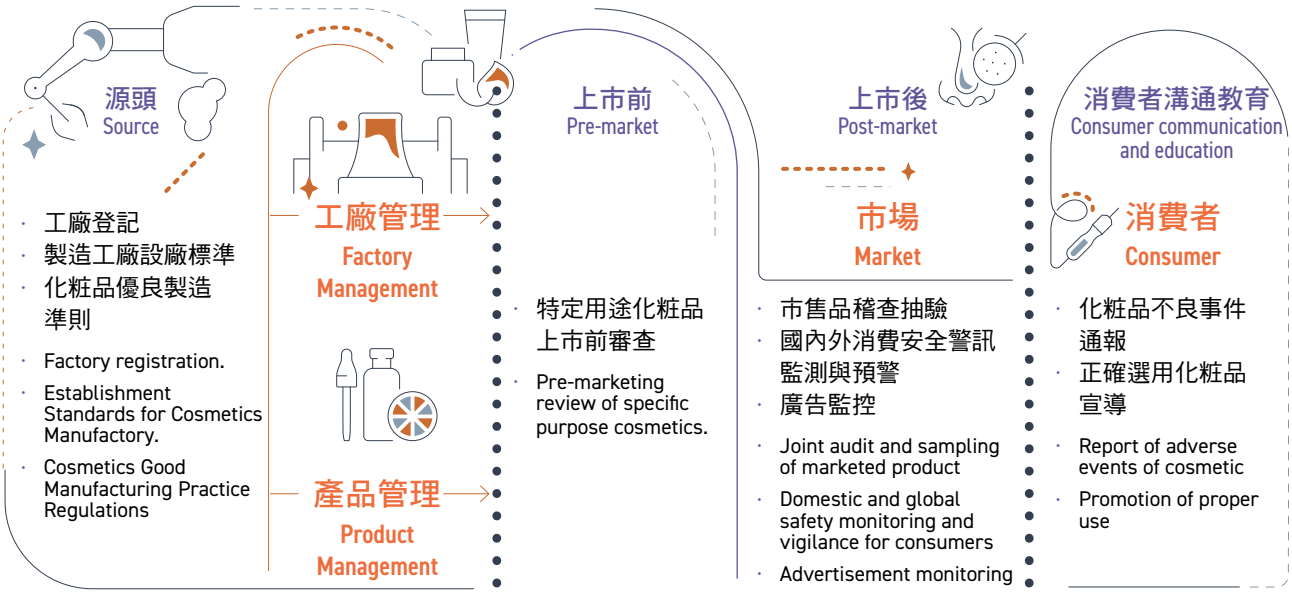
負責單位

醫療器材及化粧品組、品質監督管理組、研究檢驗組、區管中心、企劃及科技管理組

The cosmetic management system is divided into production source control, pre-market management, and post-market surveillance. Source control management includes ensuring that manufactories comply with the Establishment Standards for Cosmetics Manufactory and Cosmetics Good Manufacturing Practice Regulations (GMP). Pre-market management includes registration specific-purpose cosmetics. Post-market surveillance that 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.

Responsible Units

Div. of Medical Devices and Cosmetics, Div. of Quality Compliance and Management, Div. of Research and Analysis, District Centers, Div. of Planning and Research Development



法規

- ☑ 化粧品衛生安全管理法
- ☑ 化粧品優良製造準則（GMP）

核心業務

- ☑ 化粧品管理法規修訂、推動及國際協和
- ☑ 特定用途化粧品查驗登記
- ☑ 化粧品工廠源頭管理
- ☑ 化粧品法規諮詢及輔導機制
- ☑ 化粧品上市後安全監控及流通稽查

Laws

- ☑ Cosmetic Hygiene and Safety Act
- ☑ Cosmetics Good Manufacturing Practice Regulations (GMP)

Core Missions

- ☑ Drafting, amendment, promulgation and international harmonization of regulations on cosmetic management
- ☑ Registration of specific-purpose cosmetics
- ☑ Source management of cosmetics manufactory
- ☑ Consultation and assistance mechanisms for cosmetic regulations
- ☑ Post-marketing safety surveillance and circulation inspection of cosmetics

Controlled Drugs Management
管制藥品管理

為防範管制藥品遭不當使用或流於非法，致民眾健康危害，我國採行嚴謹之管理機制管控管制藥品之使用與流向。另建置藥物濫用監測機制，針對國際上或近期出現的新興濫用物質進行流行趨勢分析，並提供法務部毒品列管參考。依管制藥品管理條例設置全國唯一專責輸入、輸出、製造及販賣第一、二級管制藥品之製藥工廠，其並通過 PIC/S GMP 符合性評鑑，持續朝著 4 大目標 - 提升製藥與服務品質、提高績效與增加產能、提升國產管制藥品自製率、促進研發及加速轉型邁進。

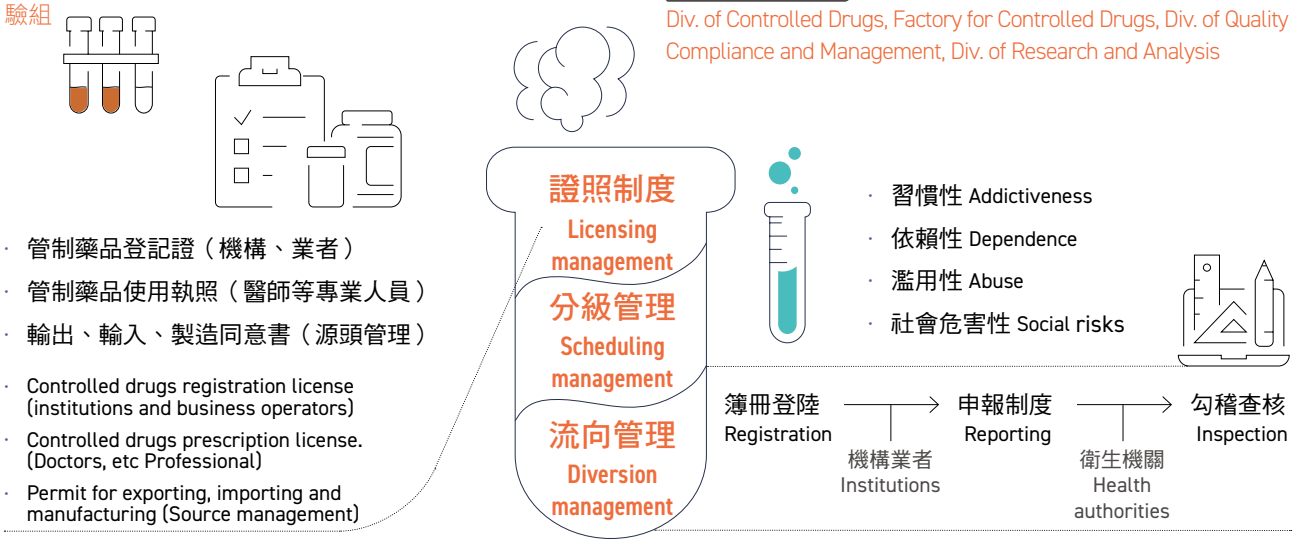
負責單位

管制藥品組、管制藥品製藥工廠、品質監督管理組、研究檢驗組

To prevent improper or illegal usage of controlled drugs and related health hazards to the public, TFDA has implemented a rigorous management system to control the usage and diversion of controlled drugs. TFDA also establishes a drug abuse surveillance system that could provide the data of current global novel substances abused trends, and offers the Ministry of Justice reference information for controlled substance scheduling. Under the Controlled Drug Act, TFDA oversees the import, export, manufacture and selling of the Schedules I and II controlled drugs, and ensure that the manufacturer passes the PIC/S GMP accreditation system. The four objectives of controlled drug management are to increase drug and service quality, improves efficiency and production capacity, increases the rate of domestic controlled drug production, and promotes the acceleration of development and industry upgrade.

Responsible Units

Div. of Controlled Drugs, Factory for Controlled Drugs, Div. of Quality Compliance and Management, Div. of Research and Analysis



法規

- ☑ 管制藥品管理條例

核心業務

- ☑ 管制藥品管理、政策及相關法規之研擬
- ☑ 管制藥品使用與登記證照之核發及相關同意書之核發、管理
- ☑ 管制藥品流向申報資料之審查、建檔及管理
- ☑ 管制藥品之教育宣導、調查、通報、預警及成效評估
- ☑ 第一級、第二級管制藥品之輸入、輸出、製造及販賣業務督導
- ☑ 研發醫療所需之第一、二級管制藥品，提升國產管制藥品自製率

Laws

- ☑ Controlled Drugs Act

Core Missions

- ☑ Management, policy and drafting statutes of controlled drugs
- ☑ Reviewing and issuing certificates of use and registration of controlled drugs; issuing and management of such related approvals.
- ☑ Reviewing, filing, and managing the diversion of controlled drugs
- ☑ Education, investigation, reporting, warning, and evaluation of controlled drugs.
- ☑ Supervising the import, export, manufacture and sale of Schedules I and II controlled drugs.
- ☑ Develop Schedules I and II controlled drugs for medical purposes, and increases the domestic production rate of controlled drugs.

Research and Analysis

研究檢驗

食品藥物管理署職掌全國食品、藥品、醫療器材、化粧品等檢驗方法研訂、調查或稽查檢驗、方法推廣、標準品製備及供應、查驗檢驗、封緘檢驗、突發事件檢驗、協助或服務檢驗等。面對突發事件迅速釐清發生始末、提出因應策略及科學證據，化解民眾疑慮。另，積極參與國際事務與國際檢驗訊息接軌交流，並強化與其他機關部門及地方業務單位之溝通合作及檢驗技術諮詢支援，多向發展創新檢驗技術與量能提升，以鞏固食藥安全。

負責單位 研究檢驗組

TFDA governs the establishment of testing methods for foods, drugs, medical devices and cosmetics, and is also in charge of investigation or surveillance testing, promotion of testing methods, preparation and supply of standard, registration testing, lot release testing, emergency events testing, and assistance or serving testing. When emergency occurs, TFDA timely clarify the situation and propose strategies and scientific evidences to dispel the public's concerns. Additionally, TFDA proactively takes participation in international affairs to exchange testing information, enhances the communication, collaboration and technique support with other departments and local government sectors, and diversely develops the innovative testing technique and increase testing capacity to solidify food and drug safety.

Responsible Units Div. of Research and Analysis

法規

- 標準品製備及供應
- 動植物物種鑑別參考質體（9 項）
- 生物性國家標準品（9 項）
- 天然物成分標準品（7 項）

核心業務

- 食品藥物化粧品之檢驗、研究及評估
- 食品藥物化粧品檢驗方法之擬訂
- 緊急應變檢驗能量之規劃及建置
- 藥典之修訂及編撰
- 地方衛生主管機關及相關單位之檢驗技術支援

Laws

- Preparation and supply of standards and reference materials.
- Reference plasmids (9 items) for classification of animal and plant species
- National Biological Standards (9 items)
- Natural Compound Standards (7 items)

Core Missions

- Testing, research and evaluation on food, medicinal products and cosmetics.
- Establishment of testing method for food, medicinal products and cosmetics.
- Development of testing methods for emergency events.
- Revision and elaboration of the Chinese Pharmacopeia.
- Technical support for the local health authorities and other government agencies

Quality Compliance and Management

品質監督管理

食品藥物管理署負責藥品／醫療器材／化粧品／營養保健食品之製造GMP/QMS、藥商運銷作業GDP、人體細胞組織物操作GTP符合性管理及實驗室認證與管理等業務。透過建置專業GxP稽查體系，導入風險管理原則落實管理，並持續推動相關GxP管理法規、制度與規範與國際接軌，確保產品品質，維護認證實驗室檢驗品質及公信力，進而保護消費者健康及使用安全。

負責單位 品質監督管理組

TFDA is responsible for enforcing manufacturers of drugs/medical devices/cosmetics/health supplements to comply with Good Manufacturing Practice (GMP)/Quality Management System (QMS), the compliance of Good Distribution Practice (GDP) for pharmaceutical vendors, laboratory accreditation and management, and management in compliance with Good Tissue Practice (GTP). By establishing a profession GxP auditing system and introduces principles of risk management, TFDA is continuously promoting the regulatory legislations, standards and systems of GxP to be in line with international standards, so as to ensure product quality, guarantee the test quality of the accredited laboratories, maintain credibility and protect the health and safety of consumers.

Responsible Units Div. of Quality Compliance and Management

法規

- ☑ 藥物製造業者檢查辦法／藥物製造許可及優良製造證明文件核發辦法
- ☑ 藥物優良製造準則（GMP）／西藥優良運銷準則（GDP）
- ☑ 化粧品優良製造準則（GMP）
- ☑ 人體器官保存庫管理辦法
- ☑ 食品檢驗機構認證及委託認證管理辦法／藥物檢驗機構認證及委託認證管理辦法／化粧品檢驗機構認證及委託認證管理辦法
- ☑ 濫用藥物尿液檢驗及醫療機構認可管理辦法

核心業務

- ☑ 藥品優良製造及運銷規範（GMP/GDP）之稽查及管理
- ☑ 醫療器材優良製造規範（QMS/QSD）之稽查及管理
- ☑ 化粧品優良製造準則（GMP）之檢查及管理
- ☑ 人體細胞組織物稽核之管理
- ☑ 食品藥物化粧品檢驗機構認證之規劃及管理
- ☑ 精準醫療分子檢測實驗室列冊及管理（實驗室開發檢測服務）

Laws

- ☑ Regulations of Medicament Manufacturer Inspection/ Regulations for the Issuance of Medicinal Products and Medical Devices Manufacturing Licenses and Evidentiary Documents for Good Manufacturing Practices
- ☑ Pharmaceutical Good Manufacturing Practice Regulations (GMP)/ Western Pharmaceuticals Good Distribution Practice Regulations (GDP)
- ☑ Cosmetics Good Manufacturing Practice Regulations (GMP)
- ☑ Regulations for Administration on Human Organ Bank
- ☑ Regulations Governing Accreditation and Outsourced Accreditation Management of (Food/Pharmaceutical/Cosmetic) Testing Institutions
- ☑ Regulations Governing Accreditation and Management of Drug Abuse Urine Testing and Medical Institutions

Core Missions

- ☑ Auditing and management of GMP/GDP
- ☑ Inspection and management of QMS/QSD
- ☑ Inspection and management of cosmetics GMP
- ☑ Auditing and management of human cells and tissue products
- ☑ Planning and management of certification of food, drug and cosmetic analytical institutions
- ☑ Listing and management of precision medicine molecular testing laboratories (laboratory developed test and service, LDTS)

Consumer Knowledge Diversity

消費者知能多元化

食品藥物管理署透過建置多元化新興媒體，傳遞消費者正確食品、藥品、醫療器材及化粧品安全知能。

負責單位 企劃及科技管理組

TFDA advocates the correct consumer awareness on foods, drugs, medical devices and cosmetics through the following media outlets.

Responsible Units Div. of Planning and Research Development

食藥闢謠專區

Special area for stopping rumors and myths of food and drugs

破解各類網路上食藥醫粧不實謠言

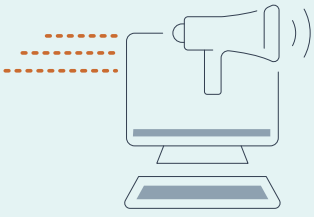
Debunk online myths and rumors about foods, drugs, medical devices and cosmetics

藥物食品安全週報

Drug Food Safety Weekly

定期提供民眾即時且正確食藥醫粧資訊

Regular and real-time update on correct information about foods, drugs, medical devices and cosmetics



食藥膨風廣告專區

Section of misleading advertisement of food and drug

公告國外網站違規食藥廣告相關資訊

Announcing information on websites of oversea food and drug advertisements that are in violation

食藥好文網

Good online publication articles of food drugs

專業好文傳遞食藥醫粧正確資訊

Distributes good online articles on correct information regarding foods, drugs, medical devices and cosmetics

「食用玩家」FB 粉絲團

TFDA Facebook

運用圖文即時宣導本暑重要政策及新制

Use graphics and texts to convey important TFDA policies and new systems in real-time

TFDA 食藥暑 Line@

TFDA Line@

運用 LINE@ 加速擴散食藥醫粧議題

Use Line@ to accelerate the advocacy of foods, drugs, medical devices and cosmetics issues

International Cooperation and Exchange
國際合作交流

為提升我國食品、藥品、醫療器材及化粧品產品品質與產業於國際之能見度，食品藥物管理署透過參與國際組織、辦理國際法規研討會、建構雙邊合作平台等方式，交換重大資訊、與國際社會接軌，達成法規協和化、醫藥衛生合作發展。

負責單位 食品組、藥品組、醫療器材及化粧品組、研究檢驗組、品質監督管理組

To improve the product quality of Taiwan's food, drugs, medical devices and cosmetics, and to promote Taiwanese industries, TFDA is proactively engaged in international cooperation. Through participating in various international organizations, hosting international regulatory conferences, and establishing bilateral collaboration platforms, TFDA has achieved the goal of critical information exchange and regulations harmonization with other countries' health authorities.

Responsible Units

Div. of Food Safety, Div. of Medicinal Products, Div. of Medical Devices and Cosmetics, Div. of Research and Analysis, Div. of Quality Compliance and Management

參與國際組織現況
Participation in international organizations

國際醫藥法規協和會（ICH）
The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

歐洲總體官方藥品管制實驗室網絡（GEON）
General European Official Medicines Control Laboratory Network

國際化粧品法規合作會議（ICCR）
International Cooperation on Cosmetics Regulation

世界貿易組織（WTO）
World Trade Organization

亞洲生產力組織（APO）
Asian Productivity Organization

歐洲藥典委員會（EPC）
European Pharmacopoeia Commission

歐洲藥品品質與衛生保健局官方化粧品管制實驗室（OCCLs）
The European Network of Official Cosmetics Control Laboratories

國際醫藥品稽查協約組織（PIC/S）
Pharmaceutical Inspection Co-operation Scheme

美國藥典委員會（USP）
The United States Pharmacopeia Convention

亞洲醫療器材法規調和會（AHWP）
Asian Harmonization Working Party

國際醫療器材法規論壇（IMDRF）
International Medical Device Regulators Forum

亞太經濟合作（APEC）
Asia-Pacific Economic Cooperation

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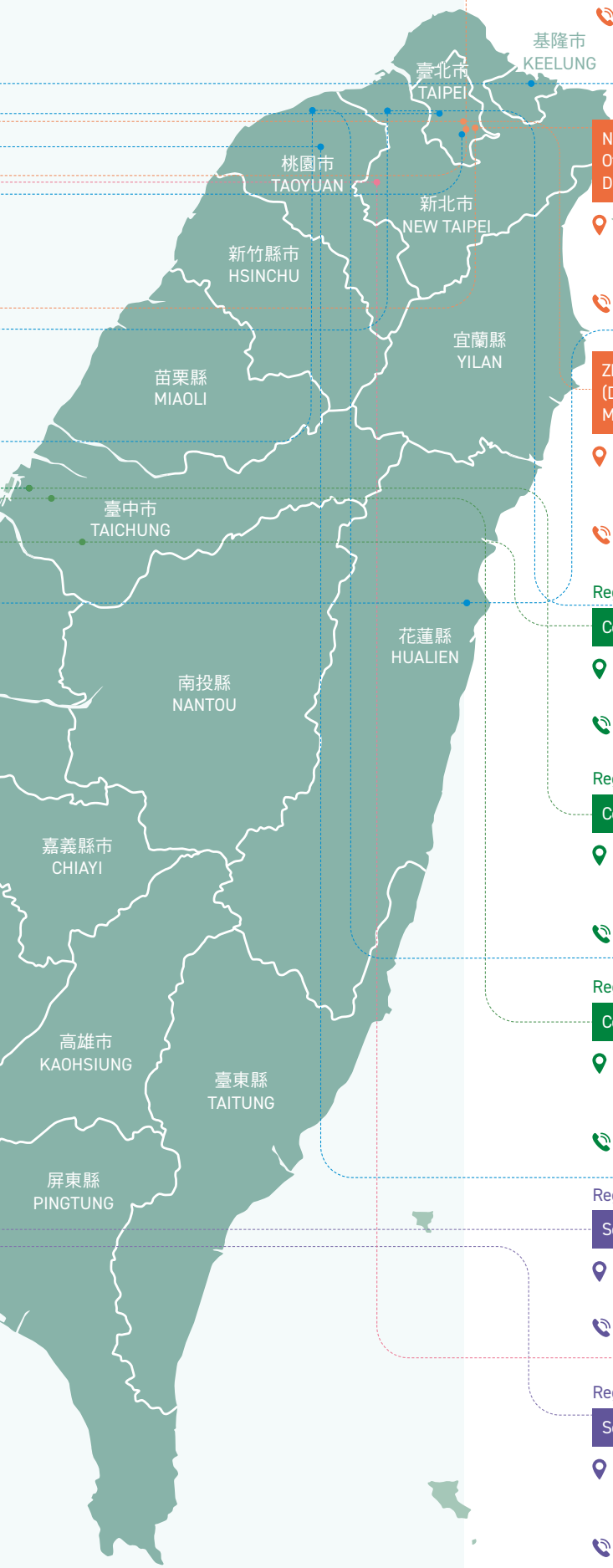

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食藥醫粧齊守護 健康安全我來顧

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Ministry of Health and Welfare

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National Food Safety Hotline: 1919

Safeguarding Health and Safety for Foods, Drugs, Medical Devices and Cosmetics

官網

TFDA

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