www.kfda.go.kr

KFDA Korea Food & Drug Administration

KFDA (Headquarters) | 363-951 187, Saengmyeong2-Street, Osong, Gangoe-myeon, Cheongwon-gun, Chungcheongbuk-do
Tel : +82-1577-1255 http://kfda.go.kr/

National Institute of Food and Drug Safety Evaluation | Osong Health Technology Administraion Complex, 187 Osongsaengmyeong2(i)-ro, Gangoe-myeon, Cheongwon-gun, Chungcheongbuk-do, Korea 363-951
Tel : +82-43-719-4114 http://www.nifds.go.kr/

Seoul Regional KFDA | 158-050 5, Mosaemi-Street, Yangcheon-gu, Seoul
Tel : +82-2-2640-1300 http://seoul.kfda.go.kr/

Busan Regional KFDA | 614-720 14-15th Floor, Nurien-Building, 11, Jayupyeonghwa-Street, Busanjin-gu, Busan
Tel : +82-51-602-6100 http://busan.kfda.go.kr/

Gyeongin Regional KFDA | 402-835 137, Juan-Street, Nam-gu, Incheon
Tel : +82-32-442-4600 http://gyeongin.kfda.go.kr/

Daegu Regional KFDA | 704-940 405, Seongseo-Street, Dalseo-gu, Daegu
Tel : +82-53-592-7133~7140 http://daegu.kfda.go.kr/

Gwangju Regional KFDA | 500-480 315, Cheomdankwaki-Street, Buk-gu, Gwangju
Tel : +82-62-602-1300 http://gwangju.kfda.go.kr/

Daejeon Regional KFDA | 302-828 166, Cheongsa-Street, Seo-gu, Daejeon
Tel : +82-42-480-8700 http://daejeon.kfda.go.kr/

24/7
More **Safely,** More **Healthily**

KFDA Korea Food & Drug Administration

24/7
More **Safely**
More **Healthily**

24/7 More Safely, More Healthily

The KFDA will always be on the side of the people.
By virtue of every venture towards the improvement of the quality of life, the KFDA will leap forward to be one of the Global Top 5 National Healthcare Countries in the world.
The KFDA pursues the 'Promising Future 2020' for a safer and healthier life of the people.

CONTENTS

KFDA
Korea Food & Drug Administration

The main motive of the KFDA logo is light. It embodies the light on the safety of the peoples' lives and describes the image of the KFDA expanding the area of safety to every corner of society for the sake of pursuing a bright and healthy future.

Safe Food, Pharmaceutical Control
It's the promise to the people...

We are living in a society with various risk factors and uncertainties, and this increases the demands of the people for safety and health and puts the 'more important than ever' KFDA's role to protect and enhance the public health on the spotlight.

Since its establishment in 1998, the KFDA has experience difficulties and setbacks from contaminated Kimchi, melamine in the baby formula and cookies and asbestos talc in the baby powder. However, KFDA has overcome all of these obstacles and developed the more advanced organization system. Despite these efforts and developments, there still needs to improve human and material resources in many areas. In addition, the relocation to Osong calls for the historical mission to complete requirements that the new generation asks for.

Greeting the new era of Osong, KFDA has established 「Promising Future 2020」 project with dreams and hopes of about 1,400 staff. The project includes aims and directions for the next 10 years to secure healthier and safer life of the people. We hope we can be a modest, but strong and effective organization through this project.

The KFDA shall perform various policies one by one with greater responsibilities. Here, of course, there needs a great deal of effort and strong challenging spirit. We need a huge degree of discipline and a strong enduring spirit. We will do our best to serve the people at all times and stand by them.

KFDA

365, Happier Korea

KFDA is protecting the safety and healthy life of people.

The Top 6 Priority Tasks

1. Enhancement of precautionary risk management system

- Establishment of a '3-year plan on the enhancement of food and pharmaceutical safety'
- Establishment and improvement of safety standards for new risk factors to protect the public health

2. Tightened safety control from raw materials to consumption

- Reinforcement of the food safety control system in site
- Reinforcement of the quality and safety control of pharmaceuticals and etc.
- Establishment of the advanced safety control system for medical devices
- Establishment of the advanced safety control system from raw materials to consumption for cosmetics

3. Support for competitive new growth engine industries

- Support for the reinforcement of international competitiveness of biopharmaceuticals
- Support for the development of high value-added medical devices
- Expansion of support system to enhance competitiveness of pharmaceuticals
- Promotion on product development of natural material pharmaceuticals and health functional food

4. Reform of the regulations on food and medicine promoting voluntariness and fairness

- Leading zero-based reform for regulations to enhance industrial autonomy
- Reasonable revisions or adjustment of standards for punishment and penalty to reinforce autonomy and responsibility of industries

5. Vitalization of communication to spread sympathy of safety

- Systematization of risk communication and diversification of communication channel
- Expansion of a provision for information based on everyday life for each object

6. Strengthening cooperative system to establish safety basis

- Expansion of a cooperation in establishing safety infrastructure for food and pharmaceuticals
- Raising international reliability of test or laboratory institutions
- Leading the global network for food and pharmaceuticals and enhancing mutual cooperation

Missions

We will protect and improve the public health by securing the safety of food, pharmaceuticals, medical devices and etc. and promoting competitiveness of healthcare industries

Korea Food and Drug Administration (KFDA) (Headquarter)

Strategic organization based on development of safety control policies and control tower

- Performance of top 5 roles in reinforcing political and strategies
  ① Development of policies ② Establishment of standards ③ Pre-market approval
  ④ Post-market inspection ⑤ Management of product quality system
- Evaluation department conducts establishment of standards, approval and review

National Institute of Food and Drug Safety Evaluation (NiFDA)

A think-tank for scientific safety control

- Research and development, risk assessment, test analysis, development of test methods and approval and evaluation methods, and etc.
- Establishment of the scientific and technical support system to conduct KFDA's policy and political affairs of the nation

Regional KFDA

Reinforcement of abilities as a regional specialized institution and complete differentiation from local government

- Conduct HACCP and GMP inspection and etc.
- Cooperation with local government for sanitary inspection and etc.

August 2011 Headquarters, 1 Government, 5 Bureaus, 49 Sections, 1 Team, 1,460 Employees

2010 The National Tax Service transferred Liquor Safety Management responsibilities of to the KFDA
Adverse Effect inspection Team of the Nation Institute od Food and Drug Safety Evaluation was abolished and became Pharmaceutical Safety Information Team under Pharmaceutical Safety Bureau of the KFDA
Evaluation Science Division of the NIFDS changes their name to Pharmaceutical Standardization Research and Testing Division
The KFDA relocated to Osong Health Technology Administration Complex, Osong, ChungBuk during November

2009 The KFDA Headquarters was previously comprised of 1 Officer, 5 Bureaus(5 Departments), 65 Divisions, but the composition was changed to 1 Officer, 5Bureaus(1 Officer and 4 Departments), 48 Divisions. Criminal Investigations Office, and Foreign Inspection Division were established
National Institute of Toxicological Research was transformed into National Institute of Food and Drug Safety Evaluation(3 Departments, 18 Divisions → 3 Departments, 29 Divisions)

2008 Innovation Planning Officer, and Laboratory Test Management Team were abolished, and creation and innovation Officer, and Laboratory Audit Team were newly formed instead
Headquarters were changed to bureaus, and the Team-based System became Division-based
The responsibility of treating and caring narcotic addicts was transferred to the ministry for Health, welfare and Family Affairs

2007 Spokesperson system was introduced for the advanced system for the press coverage, KFDA also reinforced its staff and newly created 5 teams

2006 Bureau for Risk Management, information Management Team, Customer Support Team, Novel Food Team, Clinical Management Team, Herbal Medicine Management Team, Cosmetics Evaluation Team, Biologics Management Team, Herbal Medicine Evaluation Team, Medical Devices Quality Management Team were founded

2005 The organization of 2 Offices, 2 Bureaus, and 6 departments was restructured into 6 Headquarters, and 4 Departments. Team-based system was introduced to all Divisions

2004 The organization was restructured with the creation of Medical Devices Management Division, and Bioproduct Technical Support Division

2003 KFDA newly established Health Functional Food New Division, Health Functional Food Standardization Division, and Biologics Standardization Division along with the increase in staff

June 2002 The National Center of Toxicological Research was reorganized to National institute of Toxicological Research

February 1998 The Korea Food and Drug Safety Headquarter was raised to the status of adminstration(Korea Food and Drug Adminstration)

April 1996 Korea Food and drug Safety Headquarter and six Regional Offices were established
Four departments of the National Institute of Health were reorganized to six Safety Evaluation departments
The National Institute of public Health Safety Research was reorganized to National Center of Toxicological Research

Commissioner

- Spokesperson
- Deputy Commissioner
  - Criminal Investigations Office
    - Audit and Inspection Officer
  - General Services Division
  - Office of Planning & Coordination.
    - Enhancement of the competitiveness of healthcare industries through transparent/predictable regulation
    - Reinforcement of the cooperation with a consumer group and provision of a civil affairs administration service
    - Establishment/provision of a general information service on food and drugs
    - International trade and cooperation on food and drugs
  - Risk Prevention Policy Bur.
    - Anticipative safety control of hazardous materials by gathering, analysis, sharing of hazard information
    - Prevention of accidents related with safety on food and drugs
    - Take on the role of a control tower to take immediate action during crisis or safety accidents
  - Food Safety Bur.
    - Establishment of a scientific/reasonable management system to secure food safety
    - Management of the prevention of food poisoning, management of GMO food, etc.
    - Safety control, promotion, support for health functional food
    - Management of dietary life for the enhancement of national health
    - Office of Nutrition Policy
    - Food Standardization Dept.
  - Pharmaceutical Safety Bur.
    - Establishment of a safety control system for drugs, etc., promotion/support for the pharmaceutical industry
    - Establishment of a standard for the production of drugs and quality management
    - Approval screening for drugs, etc.
    - Collection and evaluation of information on the side effects of drugs
    - Information on the collection and evaluation of the side effects of drugs
    - Drug Evaluation Dept.
  - Biopharmaceuticals & Herbal Medicine Bur.
    - Establishment of a safety control system for biological drugs such as vaccines, herbal medicine, natural drugs, cosmetics, etc.
    - Establishment of a standard for production and quality management
    - Screening of quality, safety, effectiveness of biological drugs, gene therapy products, cell therapy products
    - Biopharmaceuticals & Herbal Medicine Evaluation Dept.
  - Medical Device Safety Bur.
    - Establishment of a safety control system of medical device
    - Establishment of a standard for the production, import, and quality management of medical device
    - Reporting side effects of medical device, establishment of advertisement management system
    - Support for the commercialization of high tech fusion/complex medical device
    - Medical Device Evaluation Dept.

Attached institutions

- National Institute of Food and Drug Safety Evaluation
  - Food Safety Evaluation Dept.
  - Pharmaceuticals & Medical Devices Research Dept.
  - Toxicological Evaluation & Research Dept.
  - Research Planning & Management Division
  - National Center for Lot Release
- Regional KFDA
  - Seoul Regional KFDA
  - Busan Regional KFDA
    - Jaseongdae Imported Food Inspection Center
    - Shinseondae Imported Food Inspection Center
    - Yangsan Imported Food Inspection Center
    - New Port Imported Food Inspection Center
  - Gyeongin Regional KFDA
    - Uiwang Imported Food Inspection Center
    - Incheon International Airport Imported Food Inspection Center
    - Pyeongtaek Imported Food Inspection Center
  - Daegu Regional KFDA
  - Gwangju Regional KFDA
  - Daejeon Regional KFDA
- Present condition of committees
  - Food sanitation deliberation council
  - Central pharmaceutical affairs review committee
  - Medical device committee
  - Committee for the safety control of the dietary life of children
  - Committee for the safety evaluation on the data of genetic recombination food, etc.

We protect **national health**
through the prevention, response and
support for food and pharmaceutical safety.

Promising Future 2020
for a safer/healthier life for the people

Vision To secure the highest level of public health by ensuring the safety of food, drugs, medical devices and cosmetics

Mission Prevention, action, support for the enhancement and protection of national healthcare, and securing of food and drug safety

↓

Global Top 5 by 2020

Core values

Knowledge	Abundant expert **knowledge**
Foresight	View for the **future**
Desire & Innovation	**Passion** for the best
Association	**Cooperation** by through communication

Purpose

Sufficient Protection
Sufficient prevention through elimination of risk factors in advance and enhancement of vulnerability

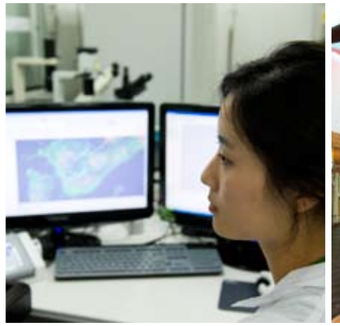
Smart Support
Smart support and cooperation for the establishment of the best food and pharmaceutical safety basis

Speedy Response
Speedy response and appropriate risk management to reduce and recover accidents regarding food and pharmaceutical safety

Era of Osong,

Promising Future 2020

for Korea's healthy tomorrow



Osong Health Technology Administration Complex

- Gangoe-myeon, Cheongwon-gun, Chungcheongbuk-do, 4,634,000㎡ scale
- The first high tech bio industry cluster in Korea collaborated with industries, academia, laboratories, and government of Korea
- Industries(59), Venture companies(70), 6 national project institutions have moved in

Size of the government office building

· **Size of the new government office building :** 67,309㎡(20,361Pyeong)

· **Buildings :** administration building, toxicity test building, test building, animal test facility

Facility, Equipment

· **Various analysis test lab:** Enhancement of test features as well as size of test labs Accuracy and professionalism of test and inspection Nurture biological engineering as a key strategic industry for next the generation

· **Animal test building :** Establishment of a high tech central control system which can control each animal that has been raised in the building. The transfer of 1,243 test animals and 7,500 frozen reproduction cell was completed.

· **National Center for Lot Release :** total 6,966㎡ scale, 25 specialized laboratories such as aseptic laboratory, human hazard level 3 laboratory, etc. are being operated. Strict control of facility standards such as difference of pressure and cleanliness, as well as temperature and humidity

The No.1 scale in Asia

365, More Immediate Responses

Operation of a system through step by step management, The first step to build a safer Korea.

We envision the food and pharmaceutical safety through an immediate response such as eliminating risk factors in advance and enhancement of vulnerabilities Immediate Response

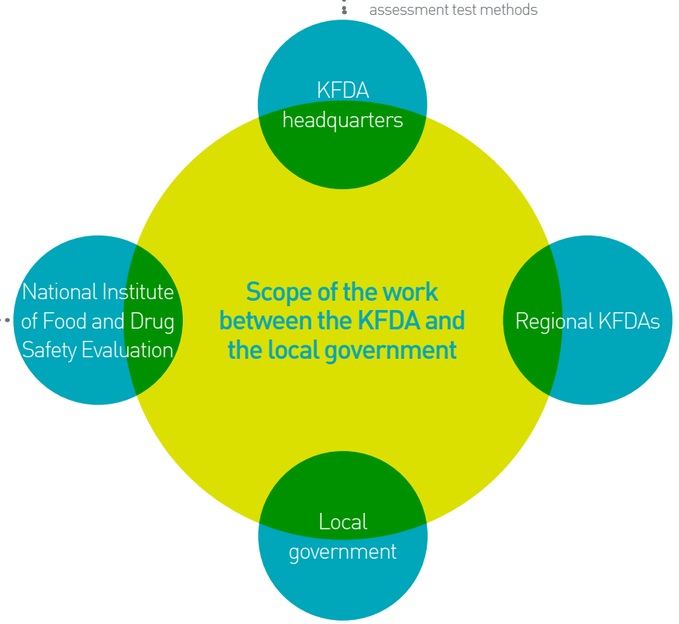
Areas to manage and current status of the industry

18 Functional structures of the KFDA and the local government 19 Size of Industries for areas in KFDA

Functional system of KFDA and the local government

Development of policy

- Safety control of food/health functional food
- Safety control of pharmaceuticals/bio pharmaceuticals
- Safety control of medical device/ cosmetics
- Development of researches and risk assessment test methods
- Development of policy for food and pharmaceutical safety control
- Development of policy for quality control
- Pre and post marketing monitoring of food and pharmaceuticals
- Investigation of hazardous illegal act on food and pharmaceuticals



Scientific research evaluation

- Risk assessment
- Test analysis
- Development of test
- Development of approval review technique
- Investigation/research such as monitoring, etc.

Execution of policy

- Safety control of imported foods
- Monitoring of hazardous materials
- Quality management of manufactures
- Support for the inspection of hazardous illegal act on food and pharmaceuticals

Approval/Instruction and inspection

- Approval (registration) of food, etc.
- Follow-up control such as instructing, monitoring, etc.
- Collecting/test of the distributed food
- Basic sanitation management in local areas

Related Laws and Acts

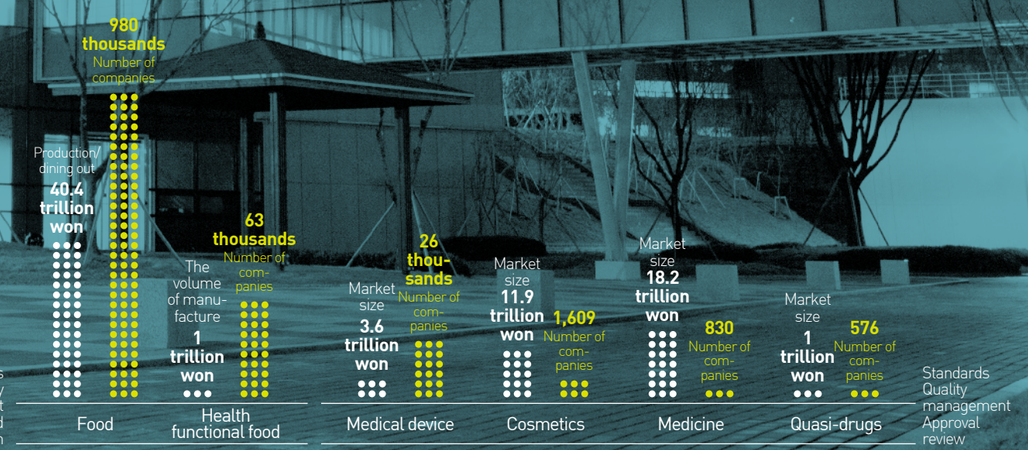
- **Acts on food :** Food Sanitation Act, Act on Health Functional Food, Management of Dietary lives for Children, Food Safety Basic Law
- **Acts on Pharmaceuticals :** The Pharmaceutical Affairs Law, Act on Cosmetics, Narcotics Control Act, Act on Human Tissue Safety and Control, etc.
- **Acts on medical device :** Act on Medical device
- **Acts on test animals :** Act on Laboratory Animals

We will secure safer food and pharmaceuticals through the **cooperation** with the local government and enhancement of industrial competitiveness.

Size of industry

About 75.1 trillion won(2010, 7.4% of Korean GDP 1,023 trillion and 9,380 billion won)
Number of companies : about 1.1 million

We perform quality management, crackdown, and approval review in order to secure safety and promote industrial competitiveness, enhancing national healthcare and protection.



※ Source : White paper of food and drug safety, 2010, Statistical annals on food and drug, 2010

365, More Perfect Prevention

We will establish a more reliable KFDA through safer and more accurate preventive measures.

We will achieve advanced safety on food and pharmaceuticals in the country through the protection and enhancement of national healthcare

We promise food and pharmaceutical safety
through the establishment of standards and
the step by step management.

The concept of safety

'safe condition'means the condition that there is no risk factor, or that there is a measure based on the prediction of potential dangers and that the people can still be protected from danger even with the presence of a risk factor.

(freedom of unacceptable risk, ISO 14971 : 2007).

Safety Control

- Actions or activities performed for the prevention of disasters or accidents
- Every action or activity of KFDA such as the establishment of standards, approval/reviewing, instruction/inspection, test, risk assessment, research/development, education/public relations, etc.

Safety control system

- Food, pharmaceuticals, medical device shall pass through the development → approval → manufacturing → (marketing) → distribution → consumption steps.
- Steps before marketing are called 'pre-marketing control', steps after marketing are called 'post-marketing control'
- There are advanced safety control systems according to the international standards for each steps, from the development to the final consumption of the product.

Pre-marketing control

Development step	Approval step	Manufacturing step
GLP/GCP Clinical(non-clinical) test	CTD/GRP/DMF Pre-marketing approval(PMA)	HACCP/GMP National validation/ access test

Post-marketing control

Distribution step	Consumption step
Collection test	GVP Post-marketing investigation(PMS)

365, More Active Support

Efforts for food and pharmaceutical safety in the country leading to the national healthcare and competitiveness of Korea.

We lead the food and pharmaceutical safety through further active researches and support, and establishment of stronger networks.

We **direct** the food and pharmaceutical field through scientific research and development and operation of research institutes.

Research and development

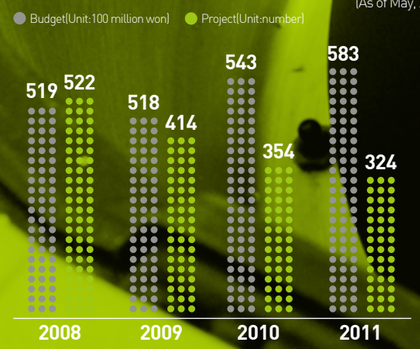
Secure a scientific basis on the safety control policies on food, pharmaceuticals, etc. and provide reliability of political performances

- Scientific risk assessment and test analysis

- Researches to establish standards and systems
- Researches for the risk assessment, monitoring, and toxicity data
- Researches for the development of an evaluation technique for quality, safety, and efficacy
- Researches to establish systems for promotion and development of training contents.

Current status on research and development

(As of May, 2011)



Research institutes

2008 / Total budget 3 billion won (6%)

Food safety control for children, research on the advancement of pharmaceutical review and evaluation

2009 / Total budget 8.3 billion won (17%)

National research on the safety control of insecticide residues, research on technical and scientific approach of re-evaluation for herbal medicines, research on the monitoring of pharmaceuticals, basic research on pharmaceutical metabolism

2010 / Total budget 16.2 billion won (30%)

Research on the food safety control corresponding to climate change, basic research on the general exposure evaluation for hazardous material safety control, basic research on review and evaluation of stem cell pharmaceuticals, research on the development of high tech toxicity evaluation techniques based on green growth, basic research on the safety evaluation for nano materials

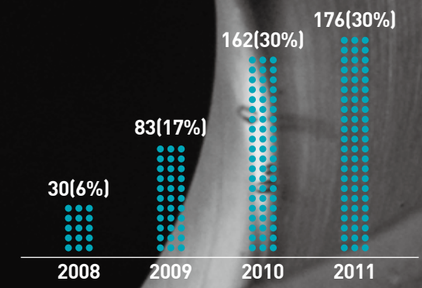
2011 / Total budget 17.6 billion won (30%)

Safety control of food for children, National safety control for insecticide residues, scientific approach of evaluation technique for herbal medicines, pharmaceutical monitoring, basic research on pharmaceutical metabolism, food safety control corresponding to climate change, basic research on the general exposure evaluation for hazardous material safety control, basic research on the review and evaluation of stem cell pharmaceuticals, research on the development of high tech toxicity evaluation techniques based on green growth, basic research on the safety evaluation for nano materials

※ ( ) is a research fund of research agencies compared to total research funds

Current status on research institutes

(Unit:100 million won)



Support for the development of high tech products

We provide customized services such as safety consultations, approval and review guidelines, etc. through the active participation from research to manufacturing in order to energize the high tech industry.

• Consultation on the manufacturing technique

- Consultations on the approval of BT, chemical pharmaceuticals, natural material pharmaceuticals, manufactured nano materials, etc.
- 'On-line consultation program for R&D of new drugs' which analyzes, diagnoses R&D of new drugs in the view of pharmaceutical approval.
- Visiting consultation services for local cluster, venture town, etc. nationwide

Submit an application for consultation → Designation of consultants (1 person of department in charge) → Organization of the expert consultation team → Election of the senior consultant (1 person in the consultation team)

→ Progress of consultation → Conclusion of consultation and sending consultation results to the person in charge → Posting the result on the consultation programs. Applicants can access

• Training and technical support

- Development of the training program and training materials regarding pharmaceutical approval
- Introduction and operation of GLP, GMP, GCP and basic technical support
- Technical support for international approval in promoting exports

• Provision of information and technical cooperation

- Provision of information such as acts domestic and foreign approval, regulation related Acts and guidelines, etc.: Publication of planning report, Question and Answer, newsletter, and provision of general information on support for public health biological venture/small and medium sized businesses promotion, etc.
- Operating 'Bridging Counter' to perform manufacturing cooperation
- Establishment of a cooperation basis for manufacturing through industries, academia, laboratories, government

Establishment of global expert network

• APEC harmonization center

- Performing main role of international harmonization on safety control system of manufacturing, distribution, quality of pharmaceuticals and medical devices
- Officially authorized training organization to develop excellent regulatory harmonization program

• The Chair Country of antibiotic tolerance special committee of Codex Alimentarius Commission (CODEX)

- Leading country of subcommittees on the establishment of a nutrition baseline contributing the globalization

• Leading international cooperation with WHO, OECD, etc.

- Quality assessment tests, training and education for quality inspectors and clinical reviewers entrusted by WHO
- Participation of the joint research of OECD on endocrine disruptor test, local establishment of alternative test, and establishment of verification/ evaluation basis
- Expansion of an international network to secure safety control of food and drug through task agreements with the European risk assessment expert institution (BfR), the European directorate for the quality of drugs (EDQM).

Global Top.5 KFDA

Efforts to achieve one of the global top 5 national healthcare and safety countries

The KFDA is challenging to the global leading country through the advanced safety control and systematical prevention and reveiw, in order to achieve a brighter and healthy life for the people

Food

Main Tasks

Food safety control

- Establishment and promotion of standards and policies regarding food safety
- Revision and establishment of food related laws and notifications
- Safety control on food under distribution in the market, imported food, alcohols, etc.

Establishment of all-time prevention system of food poisoning

- Strengthening comprehensive and systematic prevention management in the intergovernmental level
- Establishment of prompt response system and reinforcement of investigation and inspection of group feeding facilities
- Tracing food poisoning pathogens and reinforcement of training and public relations

Nutrition safety control on food for children

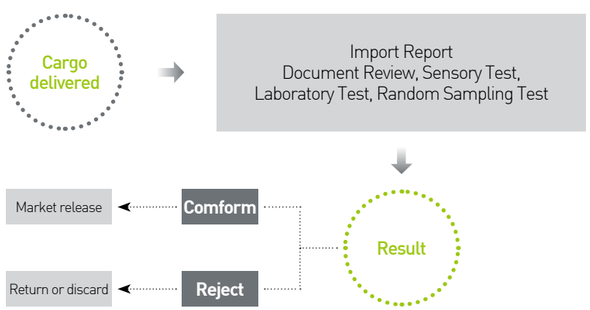
- Reduction of possible hazard nutrition such as sugar, sodium, etc.
- Nutrition labeling of food service industries
- Designation and management of food safety area for children (Green Food Zone)
- Control on children's' favorite food

Certification of functionality and authorization control

- HACCP system (Hazard analysis and critical control point)
- GMP (Manufacturing standards for the best health functional food)

Safety control on imported foods

- Inspection of imported food: possibility to use raw materials, compliance with standards for use of food additives and labeling in Korean, and GMO mark, etc.
- Thorough inspection such as laboratory test (physical, chemical, microbiological inspection) on products imported first, random sampling test and so on for products imported after the first import based on risk information and frequency of non-compliances, etc.



Pharmaceuticals

Main Tasks

Pharmaceutical safety control

- Development of policies and establishment of comprehensive plans on the pharmaceutical safety control
- Establishment and revision of the laws and notifications on drugs
- Provision of information on the proper use of pharmaceuticals
- Post-marketing safety control
- Re-evaluation of the safety and efficacy of human placenta based pharmaceuticals
- Introduction of Plasma Master File (PMF) system for plasma derivatives reinforcement of a management standard for imported blood plasma
- Establishment of guidelines on an excellent management standard for human tissues (GTP) and management of tissue bank

Pharmaceutical quality control

- Establishment of planning on management standards for Good Manufacturing Practices (GMP)
- GMP inspection and evaluation for domestic and imported drugs
- Introduction of GMP system for herbal medicines

Safety control on Narcotics

- Review of narcotics related acts and systems
- Establishment/adjustment of basic plan for narcotics control, and management of statistics
- Approval of the manufacturing, import and export of narcotics

Pharmaceutical approval and review

- Pharmaceutical manufacturing and import approval
- Reviewing and approval of herbal medicines and Korean traditional medicines
- Operation of management system for pharmaceutical approval and application
- Establishment and operation of pharmaceutical standards such as the Korean Pharmacopoeia, etc.
- Reviewing of the quality, safety, and efficacy of pharmaceuticals
- Reviewing of protocols
- Reviewing of the bioequivalence test protocols, result report, re-evaluation, etc.
- Approval of shipping bio pharmaceuticals based on the national verification system

Establishment of basis for nurture and support

- Supporting policies for new bio pharmaceuticals based on selection of growth engine industry
- Establishment of evaluation system for safety and efficacy of high tech fusion technology pharmaceuticals
- Simplification of licensing/approval of bio pharmaceutical area
- Establishment of the approval and review standards for bio-similar

Medical device

Main Tasks

Establishment and revision of standards, specifications, notifications, and acts on medical device

· Establishment of standard for medical device and promoting international harmonization
· Reinforcement of Good Manufacturing Practices (GMP) for medical device in view of the risk management

Secure safety by enhancing the pre and post management of medical device

· Notification of information on medical device
· Improvement of consistency and predictability of approval and review
· Establishment of MaPPs to enhance the management of approval review

Operation of the advanced GMP system to establish supply basis of safe medical devices

· Technical support for GMP review and risk management
· Expansion of GMP on-site inspection on foreign manufacturers to secure quality of imported medical device

Reinforcement of safety control system for medical devices distributed in the market to secure its quality

· Re-evaluation of safety and efficacy of medical devices
· Reinforcement of adverse reactions management for medical devices
· Introduction of Good Supply Practice (GSP) for medical devices

Reinforcement of support for industrial competitiveness of medical devices to contribute expansion of national profits

· Abolition of administrative or procedural regulations not related to safety
· Support commercialization of new tech medical devices by enacting pre-consultation and vitalizing approval consultant
· Support for the development of high growth medical devices such as BT·IT·NT fusion and complex, new tech, etc.

Cosmetics and quasi-drugs

Main Tasks

Establishment of basis for a safe and proper use

· Advancement of standards and specifications on raw materials of cosmetics, etc.
· Establishment of guidelines for cosmetics containing organic and nano materials
· Reinforcement of management for hazardous materials of cosmetics
· Revisions of GMP (Good Manufacturing Practices) for the production of cosmetics, and expansion of its application
· Reinforcement of management by expanding designation of quasi-drug ranges

Reinforcement of safety control of manufacturing, import, distribution, etc.

· Notification (Labeling) of entire ingredients of cosmetics and its expiration date
· Improvement of self-regulating inspection of the cosmetic manufacturers
· Collection and inspection of cosmetics distributed in the market

Management of approval and review

· Inspection of functional cosmetics and new materials
· Approval and review of quasi-drugs

※ Types of functional cosmetics

· Whitening cosmetics
· Wrinkle care cosmetics
· Sunscreens