Current Cellular Therapy in Korea

Oct 2010

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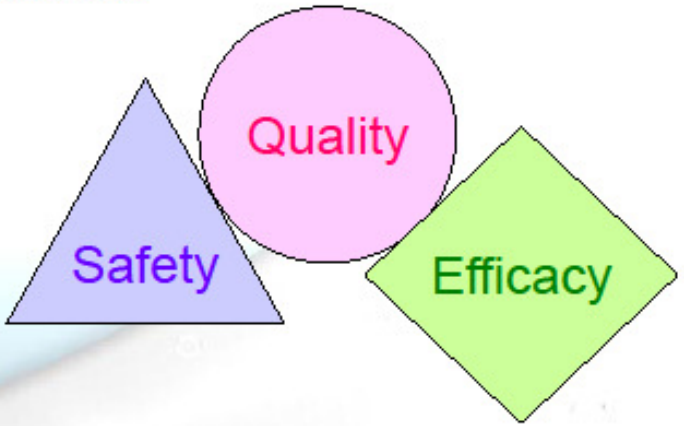
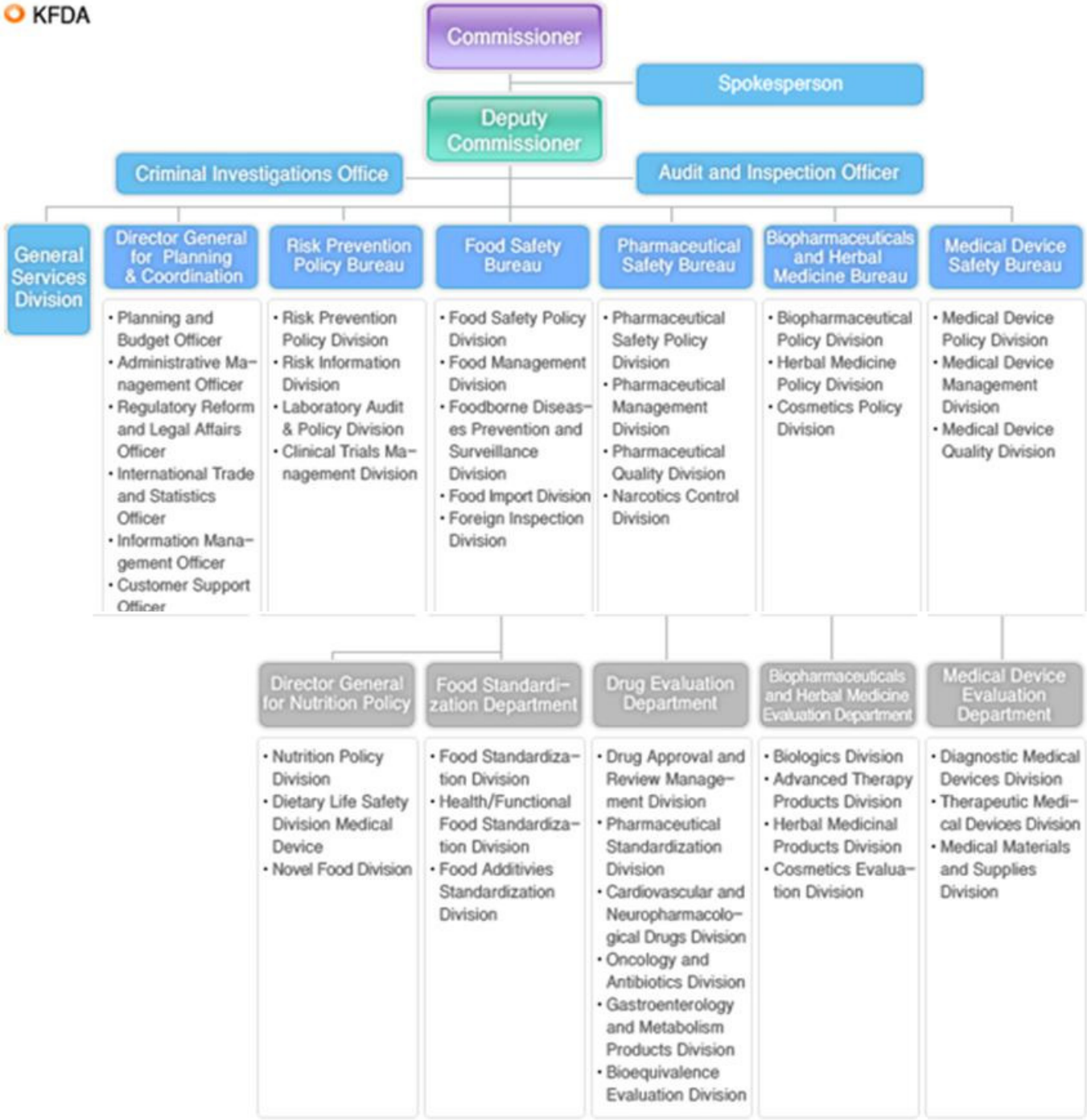
KFDA is ...

The government agency committed to protecting consumers and promoting the public health.

KFDA's mission is to promote the public health by ensuring the safety and efficacy of foods, pharmaceuticals, medical devices and cosmetics, and supporting the development of the food and pharmaceutical industries.



KFDA


Commissioner
Spokesperson
Deputy Commissioner
Criminal Investigations Office
Audit and Inspection Officer
General Services Division
Director General for Planning & Coordination
Risk Prevention Policy Bureau
Food Safety Bureau
Pharmaceutical Safety Bureau
Biopharmaceuticals and Herbal Medicine Bureau
Medical Device Safety Bureau
• Planning and Budget Officer
• Administrative Management Officer
• Regulatory Reform and Legal Affairs Officer
• International Trade and Statistics Officer
• Information Management Officer
• Customer Support Officer
• Risk Prevention Policy Division
• Risk Information Division
• Laboratory Audit & Policy Division
• Clinical Trials Management Division
• Food Safety Policy Division
• Food Management Division
• Foodborne Diseases Prevention and Surveillance Division
• Food Import Division
• Foreign Inspection Division
• Pharmaceutical Safety Policy Division
• Pharmaceutical Management Division
• Pharmaceutical Quality Division
• Narcotics Control Division
• Biopharmaceutical Policy Division
• Herbal Medicine Policy Division
• Cosmetics Policy Division
• Medical Device Policy Division
• Medical Device Management Division
• Medical Device Quality Division
Director General for Nutrition Policy
Food Standardization Department
Drug Evaluation Department
Biopharmaceuticals and Herbal Medicine Evaluation Department
Medical Device Evaluation Department
• Nutrition Policy Division
• Dietary Life Safety Division Medical Device
• Nowel Food Division
• Food Standardization Division
• Health/Functional Food Standardization Division
• Food Additivies Standardization Division
• Drug Approval and Review Management Division
• Pharmaceutical Standardization Division
• Cardiovascular and Neuropharmacological Drugs Division
• Oncology and Antibiotics Division
• Gastroenterology and Metabolism Products Division
• Bioequivalence Evaluation Division
• Biologics Division
• Advanced Therapy Products Division
• Herbal Medicinal Products Division
• Cosmetics Evaluation Division
• Diagnostic Medical Devices Division
• Therapeutic Medical Devices Division
• Medical Materials and Supplies Division

Definition of Cell Therapy Products

The KFDA defines a cell therapy product as below in accordance with the Regulation on Approval and Evaluation of Biological Pharmaceuticals (KFDA Notification No. 2010-50).

< Regulation on Approval and Evaluation of Biological Pharmaceuticals (KFDA Notification No. 2010-50 (amended on June 29, 2010))>

Article 2 (Definition) Terms used herein are defined as follows:

1. "Innovative Drugs" mean complex pharmaceuticals referred to in Article 2-8 of Pharmaceutical Affairs Law which contain innovative pharmaceutical or substances as effective contents that are totally different from locally permitted pharmaceuticals in their chemical structure or composition.
2. "Pharmaceuticals Requiring Submission of Materials" means non-innovative pharmaceuticals that need the review of safety and efficacy hereunder.
3. "Testing Reference" means materials about results of clinical tests conducted at home and abroad which provide information on pharmacokinetics, pharmacodynamics, dose response, and safety and efficacy of pharmaceuticals..
4. "Overseas Clinical Data" means data on tests of foreign countries provided in the Testing Reference.
5. "Bridging Data" means data on tests of Koreans residing in Korea and abroad that are extracted or selected from the Testing Reference or obtained from a bridging test.
6. "Bridging Tests" mean tests that are conducted on Koreans in Korea to obtain a bridging data in case where it is difficult to apply data of overseas tests as they are due to ethnical differences in the safety and efficacy of pharmaceuticals.
7. "Ethnical Differences" mean factors that make a difference in the safety and efficacy of pharmaceuticals among ethnic groups, consisting of internal factors such as genetic and physiological sub-factors and external ones such as culture and environment.
8. "Domestic Application of Overseas Clinical Data" means replacement of overseas clinical data by the data of the safety and efficacy of pharmaceuticals for Koreans.
9. **"Biopharmaceuticals" mean pharmaceuticals made of materials from humans or other organisms that require special care in terms of sanitation and public health, such as biologics, genetically manipulated pharmaceuticals, cell culture pharmaceuticals, cell therapy products, gene therapy products, and others approved by the KFDA Commissioner.**
10. "Biosimilars" mean biopharmaceuticals that have an manufacturing and import permit with proven quality and nonclinical and clinical comparability.

11. “Biologics” mean pharmaceuticals containing materials from organism or those made of organism such as vaccines, plasma derivatives and antitoxin of which efficacy and safety cannot be assessed through physical and chemical tests alone.

12. “Genetically Manipulated Pharmaceuticals (“Genetically Manipulated Pharmaceuticals”)” mean pharmaceuticals that contain peptides or proteins made with gene engineering technology as effective contents.

13. “Cell Culture Pharmaceuticals”)” mean pharmaceuticals that contain peptides or proteins made with cell culture technology as effective contents.

14. “Cell Therapy Products” mean pharmaceuticals manipulated physically, chemically, and biologically by culturing or propagating living autologus, allogenic and xenogenic cells ex vivo , unless a doctor of the medical institution conducts a safe minimal manipulation of autologus or allogenic cells (e.g. separation, washing, freezing, and thawing, while the biological characteristics are not changed).

15. “Gene Therapy Products” mean genetic substances administered into a human body for the purpose of curing diseases pharmaceuticals containing hose genetic substances.

16. “Scarce Pharmaceuticals” mean pharmaceuticals designated by the Commissioner of the KFDA of which introduction is urgent as their applications are rare and there are no alternatives.

17. “Pharmaceutical Additives” mean materials included in the package of the product which are necessary to use the product, such as pharmaceuticals and non-medical supplies in accordance with the Pharmaceutical Affairs Law as well as other medical devices in accordance with the Medical Device Law .

18. “Effective Contents” mean main content as a substance or a group of substances that is expected to make the pharmaceutical effective directly or indirectly by inherent Pharmacological Evaluation.

19. “Complex Pharmaceuticals” mean pharmaceuticals containing two or more main contents.

20. “Actual Measurements” mean measurements that are used for actual statistical analysis that removes abnormal values.

21. “Actual Statistical Values” mean results of a statistical analysis based on actual measurements.

22. “Samples” mean samples obtained in a reasonable manner such as random sampling.

23. “Undiluted Solutions” mean solutions containing main contents prior to formulation.

24. “Final Solutions” mean solutions made in the same container that can be divided directly with a uniform properties and quality.

25. “Evaluation by Unit“ means evaluation of data on toxicity, pharmacology, clinical practice, and quality (including standards and testing methods) that are necessary for approval of pharmaceuticals by the Commissioner of the KFDA separately, in case where those data are submitted prior to the application for the approval by unit of manufacturers of pharmaceuticals, entrusted maker-sellers, and importer self-evaluation.

26. “Evaluation Unit” means a unit of data as part of materials to be submitted before the application for an approval of a pharmaceutical which can be used to determine independently whether those materials are appropriate, as set forth in the regulation on the Materials to be submitted in Article 33.

Definition of Cell Therapy

In relation to the use of fat stem cells for cosmetic purposes at dermatology and plastic surgery clinics, the KFDA gave a notification of the scope of minimal manipulation of cell therapy products in May 2009 and since then has defined any manipulation exceeding the scope and those conducted in a setting other than a medical institution as a cell therapy product\ that requires a K

<The Scope of Minimal Manipulation>

○ **Definition**

Manipulation which does not change relevant biological characteristics of cells

○ **Scope (Example)**

1) Separation

Physical separation such as density-gradient separation using Ficoll or centrifugation

2) Enzyme treatment to separate cells

- The process of treating collagenase to separate fat cells from fat tissues
- Completely safe, as used under the control of a doctor at a medical facility

※ Wash thoroughly after enzyme treatment.

3) Selection

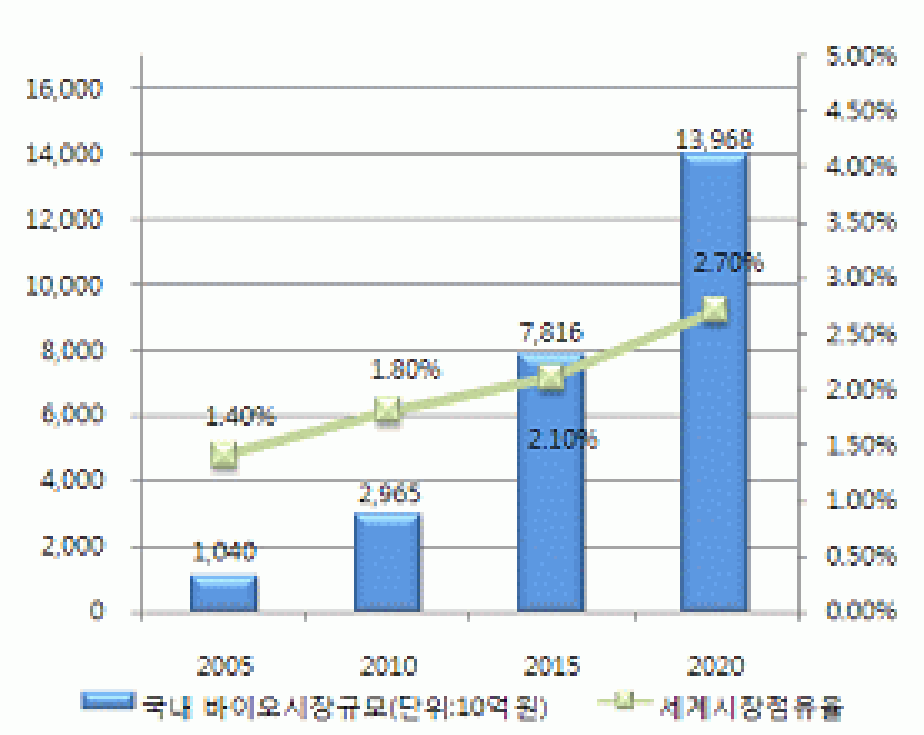
- The process of selecting CD34 benign cells from marrow
- Selectively removing B cells, T cells, red blood cells, and platelets from blood.

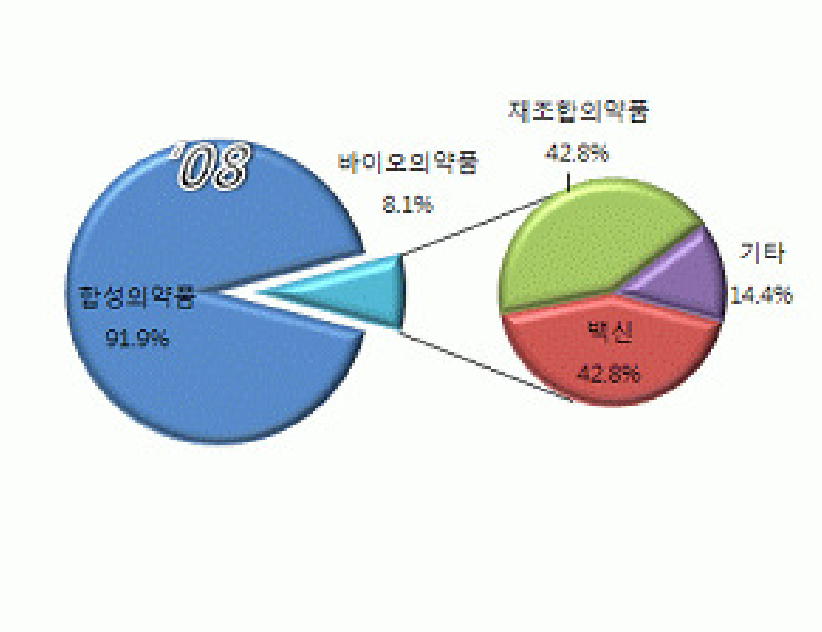
4) Freezing, cryopreservation, thawing, washing, etc.

※ Propagation of cells through intentional culture, activation of cells using growth factors, and gene transfection are excluded from “minimal manipulation.”

Korean Bio-industry Market

Sharply growing year after year, the bio-industry market is predicted to account for 8.1%(2008) of Korea's pharmaceutical market.
Although its global market share stood at 1.4% in 2005, the figure is expected to increase to 2.7% in 2020.





Source : The 2020 Vision & Strategies of the Biopharmaceutical Industry, Korea Institute for Industrial Economics and Trade (2007.6)

What are Cell Therapy Products(CTPs)?

Pharmaceuticals of
autologous, allogeneic, or xenogeneic living cells
manufactured by
physical, chemical, and/or biological manipulation
such as *ex vivo* expansion and selection.
However, excepted are the cases where medical doctors
minimally manipulate autologous or allogeneic cells
and use them in the same surgical or treatment procedure
within a hospital.

(Regulation on Review and Marketing Approval of Biologics)

Development Process of CTPs

1. Studies on the candidate cell
2. Counseling at KFDA
   - CMC
   - Nonclinical study
   - Clinical trial

3. Nonclinical Study
4. IND
5. Clinical trial (phase 1/2/3)
6. CMC review
   Safety & Efficacy review

7. NDA
8. Marketing approval

Civil Affairs Counseling

- Pre-IND meeting:
  All (quality, nonclinical, clinical) reviewers are together.
  Discussions are recorded.

- Civil Affairs Bureau meeting:

  1) Follow-up meeting with an individual reviewer after pre-IND meeting.
  Discussions are recorded.

  2) Pre-pre-IND meeting is available irrespective of pre-IND meeting.
  It is considered as a guideline.

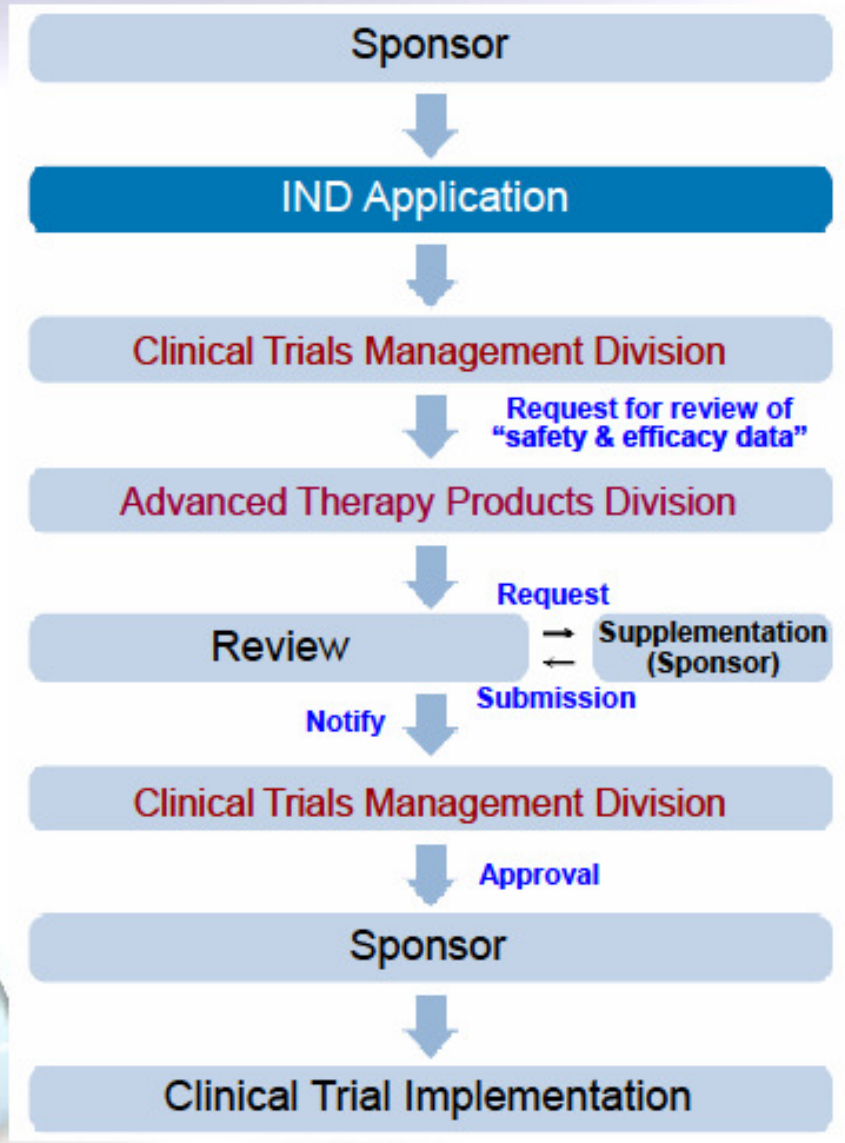
- Phone or E-mail counseling: For simple check-up.
  Further discussion is available at Civil Affairs Bureau meeting.

IND

IND Review Process

IND Content

- ✓ Application form
- ✓ Protocols
- ✓ Documents on manufacturing facilities
- ✓ Manufacturer's specifications and analytical procedures
- ✓ Safety & efficacy data (the next slide)



Content for Safety & Efficacy Data Submission

1. Investigational plan
2. Introductory statement
3. Chemistry, manufacturing, and control (CMC) information
4. Nonclinical data
   - A. Pharmacology data
     - 1) Effectiveness, 2) Safety pharmacology or General pharmacology,
       3) Absorption, distribution, metabolism, excretion (ADME)
   - B. Toxicology data
     - 1) Single dose toxicity, 2) Repeated dose toxicity,
       3) Genotoxicity, 4) Tumorigenicity,
       5) Reproductive and developmental toxicity, 6) Other toxicities
5. Previous human experience with the investigational drug (If applicable)
6. Protocols
7. List of references
8. Investigator's brochure (IB)

(Guideline on Clinical Trial Protocol Approval of Drugs)

Protocols Content (I)

1. Name and phase of the clinical trial
2. Institution and its address
3. Name and title of principal investigator, subinvestigator, and coinvestigator
4. Name and title of the clinical trial pharmacists
5. Name and address of the sponsor
6. Purpose and background of the trial
7. Code name of the investigational drug, common name of its main component, its composition and formulation
8. Indication
9. Inclusion and exclusion criteria of subjects, and the number of subjects and its rationale
10. Clinical trial period

(Enforcement Regulations of the Pharmaceutical Affairs Act)

Protocols Content (II)

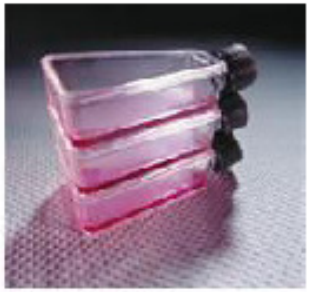
11. Dosage and administration
12. Clinical observation, lab tests, and observation/test methods
13. Expected adverse effects and use precautions
14. Withdrawal criteria
15. Criteria and methods for efficacy evaluation, and statistical analysis
16. Criteria and methods for safety evaluation, and reporting methods
17. Informed consent form
18. Compensation provision for subjects
19. Criteria of care & treatment for subjects after the trial
20. Safety and maintenance plan for subjects
21. Other provisions to ensure the safe and scientific acceptability of the trial process

(Enforcement Regulations of the Pharmaceutical Affairs Act)

Following Changes in Protocols Require KFDA Approval

- Change of composition of the investigational drugs
- Change of indication
- Change of inclusion & exclusion criteria
- Change of route of administration and duration of treatment
- Change of evaluation criteria of safety & efficacy
- Change of clinical tests & observation, test methods related to safety of subjects
- However, when principal investigator or institution is changed, it only need to be reported to KFDA.

NDA



NDA Submission Approach

There are two approaches for NDA submission.

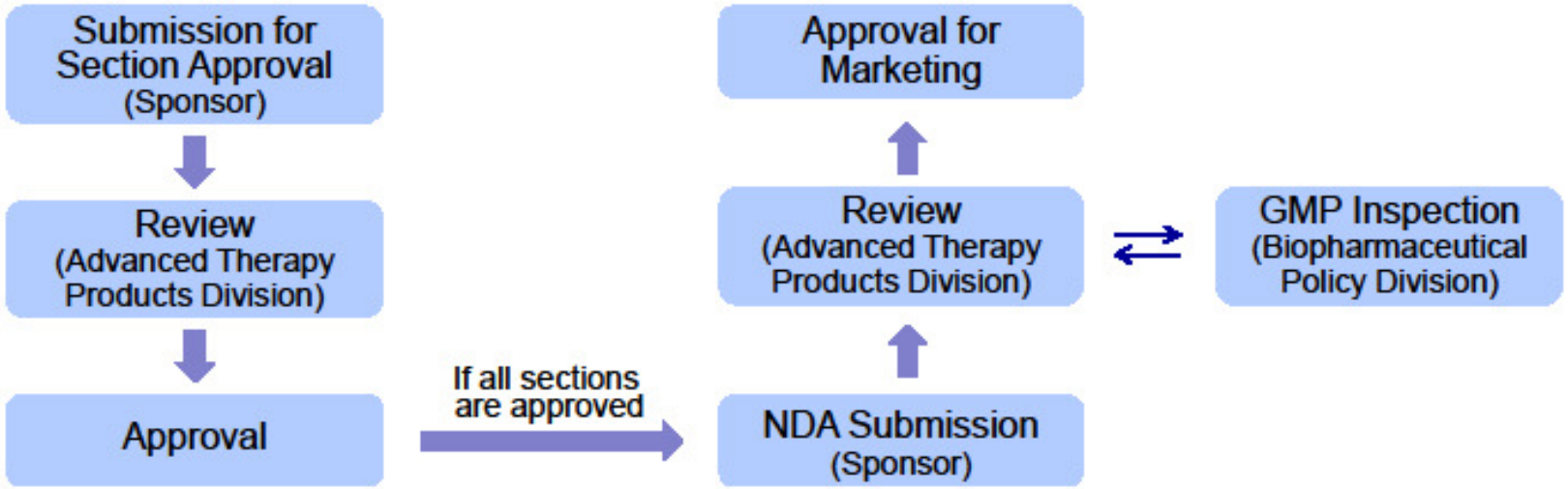
A. One-stop application

- General approach.
- All requirements are submitted simultaneously.

B. Rolling submission

- Applied to cell or gene therapy products.
- To support the development of industries.
- Requirements are sectioned and submitted on a 'first in, first out' basis.
- Scope
  1) Data of Quality(CMC) section.
  2) Data of Nonclinical section
  3) Data of Clinical section

NDA Review Process (rolling submission)



Submission Content for Section Approval

- ✓ Application form
- ✓ Development history
- ✓ Brief CMC information
- ✓ Plan for rolling submission
- ✓ Data of quality, nonclinical, and/or clinical section

NDA Submission Content

- ✓ Application form
- ✓ Approval letters for each section
- ✓ Documents on the facility

Quality Section Content (Module 3)

A. General Information
B. Manufacture
    1) Manufacturer(s)
    2) Description of Manufacturing Process and Process Controls
    3) Control of Materials
    4) Controls of Critical Steps and Intermediates
    5) Process Validation and/or Evaluation
    6) Manufacturing Process Development
C. Control of Product
    1) Specifications
    2) Analytical Procedures
    3) Validation of Analytical Procedures
    4) Results of Batch Analyses
    5) Characterization of Impurities
    6) Justification of Specifications
D. Reference Standards or Materials
E. Container Closure System
F. Stability

Specifications

- Name
- Description
- Sterility test
- Mycoplasma test
- Endotoxin test
- Adventitious virus test
- Total cell number
- Cell viability
- Identity
- Purity
- Potency

(Regulation on Review and Marketing Approval of Biologics)

Nonclinical Section Content (Module 4)

❑ Pharmacology Reports
- A. Pharmacodynamics (Effectiveness)
- B. Safety pharmacology (or General pharmacology)
- C. Pharmacodynamic drug interactions

❑ Pharmacokinetics Reports
- A. Analytical methods and validation reports
- B. Absorption, distribution, metabolism, and excretion
- C. Pharmacokinetic drug interactions
- D. Other pharmacokinetic studies

❑ Toxicology Reports
- A. Single dose toxicity
- B. Repeated dose toxicity
- C. Genotoxicity
- D. Tumorigenicity (← Carcinogenicity)
- E. Reproductive and developmental toxicity
- F. Local tolerance
- F. Other toxicity
  - Antigenicity, Immunotoxicity, Dependence etc.

(Regulation on Review and Marketing Approval of Biologics)

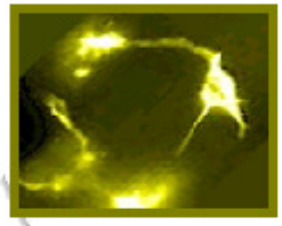
Clinical Section Content (Module 5)

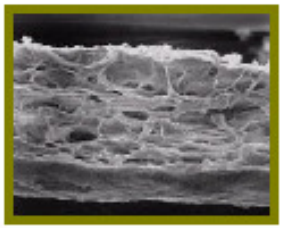
- Clinical Reports
  - A. Reports of biopharmaceutic studies
  - B. Reports of studies pertinent to pharmacokinetics using human biomaterials
  - C. Reports of human pharmacokinetic (PK) studies
  - D. Reports of human pharmacodynamic (PD) studies
  - E. Reports of efficacy and safety studies
  - F. Reports of post-marketing experience
  - G. Case report forms and individual patient listings
- Bridging Study Reports (if applicable)

(Regulation on Review and Marketing Approval of Biologics)

Approval Status of Cell Therapy Products (CTPs)







CTPs approved for marketing in Korea

Product (Company)	Cell Type	Indication	Date
Chondron (Cellontech)	Chondrocyte (auto)	Articular cartilage defects	2001. 2.
Holoderm (Tegoscience)	Keratinocyte (auto)	Burn wounds	2002. 12.
Kaloderm (Tegoscience)	Keratinocyte (allo)	Burn wounds	2005. 3.
Keraheal (MCTT)	Keratinocyte (auto)	Burn wounds	2006. 5. Conditioned
Innolak (Innomedisys)	Activated lymphocyte (auto)	Lung cancer	2007.5 Conditioned
Creavax-RCC (Creagene)	Dendritic cell (auto)	Kidney cancer	2007.5 Conditioned
Immuncell-LC (Innocell)	Activated lymphocyte (auto)	Liver cancer	2007.6 Conditioned

CTPs approved for marketing in Korea

Product (Company)	Cell Type	Indication	Date
Hyalgraft-3D (Chabio&tech)	Fibroblast (auto)	Diabetic foot ulcer	2007.7 Conditioned
Adipocel (Antrogen)	Adipocyte (auto)	Scar	2007.8
NKM (NKBio)	Activated lymphocyte (auto)	Lymphoma	2007.8 Conditioned
RMS ossron (Cellontech)	Osteoblast (auto)	Fracture	2009.8
Autostem (Chabio&tech)	Minimally manipulated Adipocyte (auto)	Scar	2010.2
Queencell (Antrogen)	Minimally manipulated Adipocyte (auto)	Scar	2010.3
Cureskin (S-Bio Medics)	Fibroblast (auto)	Pimple scar	2010.5

Clinical Trials of Cell Therapy Products

Since 2003, approval has been given to clinical tests for over 80 cell therapy products, which are underway currently. Among them, 13 items have been commercialized following clinical tests, and major clinical tests underway now are summarized as in the following table.

In addition, there are a number of researcher clinical tests for exploration in progress.

No.	Company	Product	Date of Approval	Clinical Development (target disease)	Commercialization
1	Bi-Nex	DCBACK-IR Ini (autologusdendritic cell)	2004.04.06	½ phase(colorectal cancer)	
2	Medipost	Cartistem (human cord blood mesenchymal stem cells)	2005.04.01	½ phase(cartilage loss)	
3	FCB-PHAMICELL	MSC1 (autologus mesenchymal stem cells)	2005.06.03	3 phase (acute cerebral infarction)	
4	FCB-PHAMICELL	MSC2 (autologus mesenchymal stem cells)	2006.04.17	2 phase (acute myocardial infarction)	Application for approval underway
5	CREAJENE	CreaVax-PC Inj (autologus dendritic cell	2006.07.04	1/2a phase (prostate cancer)	
6	Bio Heart Korea	MyoCell (autologusskeletal myoblast)	2006.09.29	2 phase (post-myocardial infarction congestive heart failure)	
7	Bi-Nex	DCBACK/EP-B injection (autologus dendritic cell)	2006.10.17	1/2a phase (breast cancer)	
8	Kolon Life Science	Tissue Gene-C	2006.12.13	1 phase (degenerative arthritis)	
9	Innocel	Immuncell-LC	2007.05.09	3 phase (glioblastoma)	Target disease added
10	INNOMEDISIS	INNOLOCK	2007.05.14	3 phase (non-small cell cancer)	Commercialized +3 phase underway
11	CREAJENE	CreaVax-RCC	2007.05.15	3 phase (renal cell carcinoma)	Commercialized +3 phase underway
12	Innocell	Immuncell-LC	2007.06.26	3 phase (Liver cancer)	Commercialized +3 phase underway
13	NK Bio	NKM Inj.	2007.08.03	3 phase (lymphoma)	Commercialized +3 phase underway

No.	Company	Product	Date of Approval	Clinical Development (target disease)	Commercialization
14	Bi-Nex	TK Cell injection	2007.09.04	2 phase(Gastrointestinal tract cancer)	
15	TEGOSCIENCE	kaloderm	2007.11.13	3 phase(Diabetic Foot Infection)	Target disease added
16	FCB-PHAMICELL	Cerecellgram-spine (autologus marrow stroma stem cell)	2007.12.10	2/3 phase(spinal damage)	
17	RNL Life Science	Vascostem	2007.12.18	1/2 phase(Buerger's disease)	
18	Medipost	Promostem (hematopoietic stem cell implant survival catalyst)	2008.03.05	1/2 phase(hematopoietic stem cell implant for luekemia, etc.)	
19	RNL Life Science	RNL-Jointstem	2008.05.13	1/2 phase(degenerative arthritis)	
20	Medipost	Cartistem	2008.07.23	3 phase(degenerative arthritis)	Application for approval underway
21	Bi-Nex	TK Cell injection	2008.08.20	1/2 phase(advanced gastric cancer)	
22	Bi-Nex	TK Cell injection	2008.08.20	1/2 phase(advanced colorectal cancer)	
23	Homeotherapy	Graft-versus-Host disease drug	2008.09.25	1/2a phase	
24	CREAJENE	CreaVax-HCC	2008.09.26	1/2a phase(liver cancer)	
25	Anterogen	Adipo Plus Inj.	2008.11.06	1 phase(Crohn's disease, anal fistula)	
26	Anterogen	Repaircell	2009.01.19	1 phase(cosmetic surgery, tissue reproduction)	
27	Kolon Life Science	Tissue Gene-C	2009.02.20	2a phase(degenerative arthritis)	
28	Bi-Nex	Oncovac (autologus dendritic cell)	2009.05.07	1/2 phase(non-small cell lung cancer)	
29	Green Cross	MG4101(homogenous natural killer cells)	2010.03.16	1 phase(malignant lymphoma & advanced, recurrent solid tumors)	

Manufacturers of Cell Therapy Products

The following table shows projects and commercialization data of 15 companies that play a leading role in the development and production of cell therapy products.

Company	Cell therapy related project	Commercialization & R&D	Rem
Innocell	Anticancer and immune cell therapy products Immuncell-LC(Liver cancer)	Immuncell-LC liver cancer drug approved in Aug. 2007	
	Immune cell bank, anticancer resistance test, cord blood bank	liver cancer, glioblastoma 3 phase trials underway since 2007	
NK Bio	Anticancer and immune cell therapy products NKM(malignant lymphoma)	NKM malignant lymphoma drug approved in Aug. 2007	
		malignant lymphoma 3 phase trials underway since 2007	
CREAGEN	dendritic cell therapy product CreaVax-RCC(Kidney cancer)	CreaVax-RCC Kidney cancer drug approved in May 2007	
	arthritis drug	dendritic cell therapy product for prostate cancer 1/2 phase underway	
	liver cancer drug development underway	dendritic cell therapy product for liver cancer 1/2 phase underway	
INNOMEDISIS	Anticancer and immune cell therapy products INNOLOCK(lung cancer)	lung cancer drug Innolock approved in Feb. 2007	
Bi-Nex	Anticancer and immune cell therapy products(TKcell, DCBACK)	,/2 phase trials of DCBACK lung cancer and colorectal cancer patients underway	
	Cell bank(ImTK: T Celll bank, ImOK: dendritic cell bank)	2 phase trials of DCBACK breast cancer patients underway	
		2 phase trials of DKCell Gastrointestinal tract cancer, gastric cancer, and colorectal cancer patients underway	
Cha Bio & DiosTech	Development of embryonic stem cell artificial blood production technology (USA)	Application for Clinical trials for embryonic stem cells retinal pigment epithelium cell therapy products underway	
	Development of embryonic stem cell cardiovascular cell therapy products		
	Development of embryonic stem cell Parkinsonism drug		
	Development of cord blood stem cell urinary incontinence cell therapy product		
	stem cell cosmetics, cord blood bank		
Medipost	cell therapy products Cartistem (cartilage reproductive stem cell therapy products)	3 phase trials of Cartistem completed, Application for approval underway	
	Promostem(hematopoietic stem cell survival-inducing stem cell therapy products)	Promostem 1/2 phase approved	
	Bonestem(skeletal kidney stem cell therapy products)	Bonestem researcher clinical trials underway	
	Neurostem(neuron reproductive stem cell therapy products)	Neurostem researcher clinical trials completed	

Company	Cell therapy related project	Commercialization & R&D	Remark
FCB Pharmicell	Development of stem cell therapy products	acute cerebral infarction stem cell therapy products 3 phase completed, approval process underway	
		Spinal disease drug 2/3 phase underway	
		Heart disease drug 2/3 phase underway	
	stem cell storage project (adult stem cell bank, cord blood bank, fat cell bank)	Lung disease drug clinical trials set to conduct	
		Liver disease drug pre-clinical trials completed	
Sewon Cellontech	Cartilage reproductive cell therapy products Condron	Condron cartilage loss drug approved in Jan. 2001	
	Bone reproructive cell therapy products Ossron		
	Skin reproductive cell therapy products Derman	Asron fracture, damage, loss drug approved in Aug. 2009	
	Biocollagen(cosmetics), cord blood bank		
TEGOSCIENCE	Autologus skin cell therapy products Holoderm	Holoderm skin burn treatment drug approved in Dec. 2002	
	Autologus skin cell therapy products kaloderm	kaloderm skin burn treatment drug approved in Mar. 2005	
	Artificial skin model for trials Neoderm	kaloderm Diabetic Foot Infection cell therapy product 3 phase trials underway	
	Skin cell bank		
RNL Bio	Fat stem cell therapy product	Buerger's disease ½ phase underway	
		degenerative arthritis 1/2 phase underway	
	Stem cell bank	Spinal damage 1 phase underway	
		Romberg disease researcher clinical trials underway	
	stem cell cosmetics	critical limb ischemia researcher clinical trials underway	
		urinary incontinence researcher clinical trials underway	
Anterogen	fat stem cell therapy products Adipocell	Adipocell substitution drug for skin dent approved in Aug. 2007	
	fat stem cell bank	Adipocell 1 phase for Crohn's disease, anal fistula underway	
		Xenogeneic fat cell therapy product Repaircell1 phase underway	

Company	Cell therapy related project	Commercialization & R&D	Remark
HENSON BIOTECH	Foot Infection cell therapy products HiR Graft3D	HiR Graft3D Diabetic Foot Infection cell therapy products approved in Sept. 2007	Acquired by Cha Bio & Diostech in 2009
	autologus keratinocyte drug LSK AutoGraft	Diabetic Foot Infection 3 phase underway since 2007	
	autologus dermal fibroblast cell cutaneous loss treatment	Autostem subcutaneous fat loss cell therapy product approved in Feb 2010	
		LSK AutoGraft for buns 3 phase underway in 2010	
MCTT	Burn cell therapy products KeraHeal	KeraHeal burn treatment product approved in May 2006	
	Development of tissue engineering products (artificial organs)	KeraHeal II(scar, skin color correction cell therapy products) clinical trials set to conduct	
		KeraHeal Allo (for deep dermal burn re-epithelization) clinical trials set to conduct	
S.BIOMEDICS	Skin reproductive cell therapy products CureSkin(scar)	CureSkin scar treatment product approved in May 2010	
	Synthetic cornea		
	Skin cell freezing and reproduction surgery		
	Diabetic Foot Infection cell therapy products		


Thanks for
Your Attention