Company Introduction

2020

MediTip

Contents

Introduction of the company

1. Introduction

MEDITIP Co., Ltd guides you through the Korean and Global Healthcare market with intelligence, in-depth knowledge and experiences.

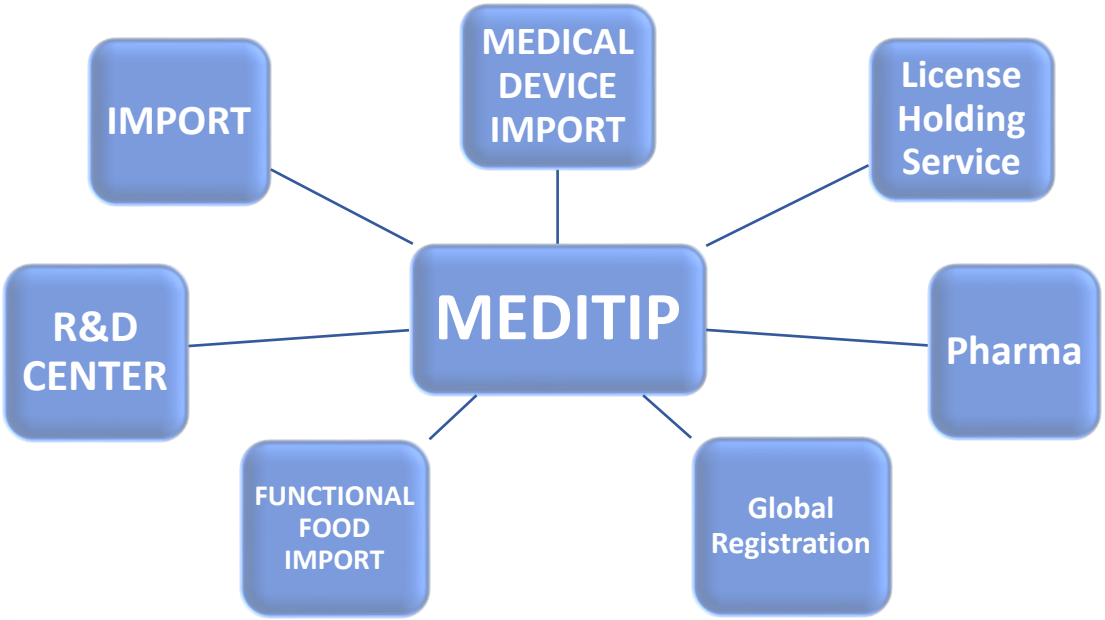
We have rich experiences in successfully collaborating with world class multinational medical technology suppliers in both Korean and Global market entry issues, pre-market regulatory affairs and post-market compliance affairs, reimbursement pricing, local distributor identification, market feasibility study, government relations and more. MEDITIP is well connected with key government authorities, local pharmaceutical companies and the industry decision makers; thereby providing the highest quality of intelligence that is crucial to your business success both in Korea and Globally.

We are glad to offer our consulting services for your great success

Global Healthcare Market Clearance Service

MediTip Gate to Healthcare Biz

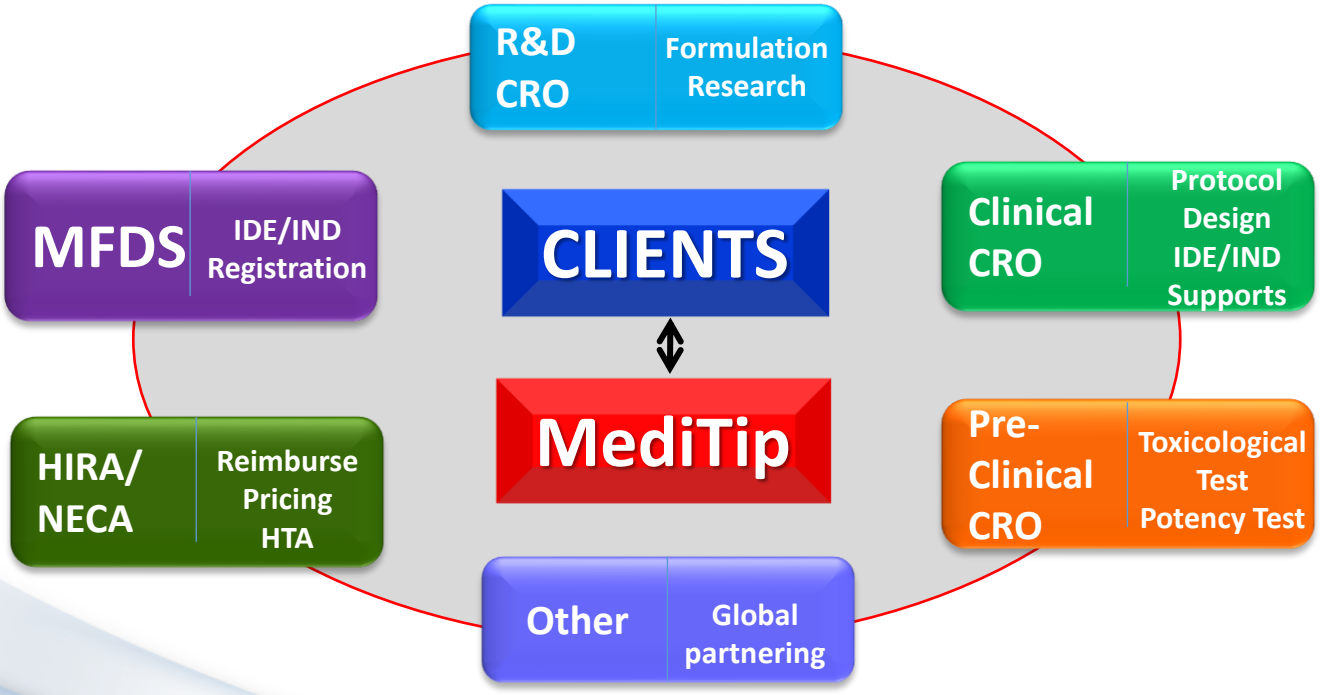
One Stop Total Service



2. Company Profile

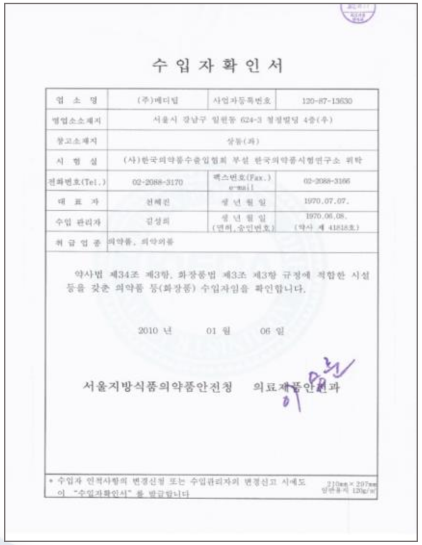
Company Name	MEDITIP Co., Ltd.
Country/ Territory	Korea
Registered Address	10th Floor, Gangnam Post Office B/D, 619 Gaepo-ro, Gangnam-gu, Seoul, Republic of Korea (Zip: 06336)
Services we offer	Medical Device and Pharmaceutical R&D, Registration, Reimbursement, Clinical trial supports, ICC Service and Marketing
Business Type	Regulatory Affairs Consulting
Buyer or Supplier	Pharmaceutical or Medical Device Company
No. of Employees	38 People
Year of Established	April 2007
Legal Representative	Yoo, JeoungHee

MediTip Work Flow



Healthcare Biz License

Pharma & Quasi-drug



수 입 자 확 인 서

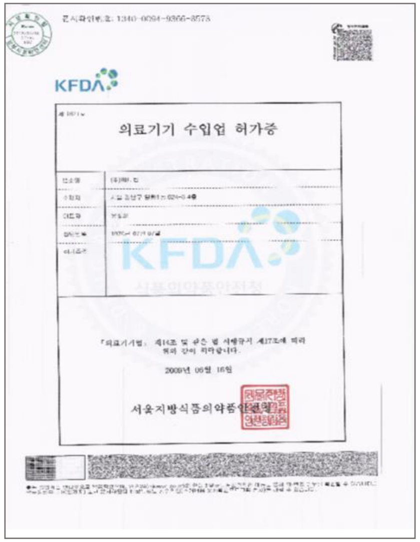
업 소 명	(주)메디팁	사업자등록번호	120-87-13630
전화번호(Tel.)	02-2088-3170	팩스번호(Fax.) e-mail	02-2088-3166
대 표 자		생 년 월 일	1970.07.07.
수입 관리자		생 년 월 일 (면허,승인번호)	1970.06.08.

약사법 제34조 제3항, 화장품법 제3조 제3항 규정에 적합한 시설 등을 갖춘 의약품 등(화장품) 수입자임을 확인합니다.

2010 년 01 월 06 일

서울지방식품의약품안전청 의료제품안전과

Medical Device



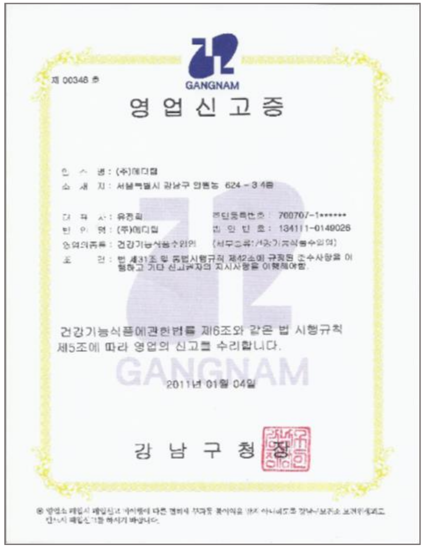
KFDA

의료기기 수입업 허가증

2009년 06월 16일

서울지방식품의약품안전청

Health Food



제 00348 호

GANGNAM

영 업 신 고 증

법 인 번 호 : 134111-0149026

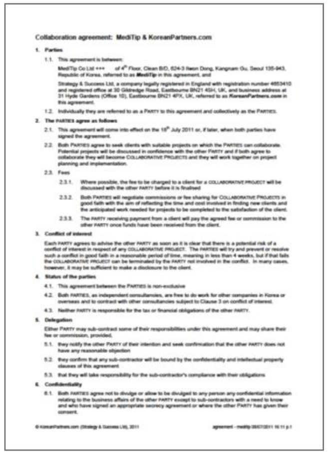
건강기능식품에관한법률 제6조와 같은 법 시행규칙 제5조에 따라 영업의 신고를 수리합니다.

2011년 01월 04일

강 남 구 청 장

Global Network

EU : UK



Collaboration agreement: MediTip & KoreanPartners.com

1. **Parties**
   1.1. This agreement is between:
   MediTip Co Ltd +++ of 4th Floor, Clean B/D, 624-3 Ilwon Dong, Kangnam Gu, Seoul 135-943, Republic of Korea, referred to as **MediTip** in this agreement, and
   Strategy & Success Ltd, a company legally registered in England with registration number 4853410 and registered office at 30 Gildredge Road, Eastbourne BN21 4SH, UK, and business address at 31 Hyde Gardens (Office 10), Eastbourne BN21 4PX, UK, referred to as **KoreanPartners.com** in this agreement.
   1.2. Individually they are referred to as a PARTY to this agreement and collectively as the PARTIES.
2. **The PARTIES agree as follows**
   2.1. This agreement will come into effect on the 18th July 2011 or, if later, when both parties have signed the agreement.
   2.2. Both PARTIES agree to seek clients with suitable projects on which the PARTIES can collaborate. Potential projects will be discussed in confidence with the other PARTY and if both agree to collaborate they will become COLLABORATIVE PROJECTS and they will work together on project planning and implementation.
   2.3. Fees
   2.3.1. Where possible, the fee to be charged to a client for a COLLABORATIVE PROJECT will be discussed with the other PARTY before it is finalised
   2.3.2. Both PARTIES will negotiate commissions or fee sharing for COLLABORATIVE PROJECTS in good faith with the aim of reflecting the time and cost involved in finding new clients and the anticipated work needed for projects to be completed to the satisfaction of the client.
   2.3.3. The PARTY receiving payment from a client will pay the agreed fee or commission to the other PARTY once funds have been received from the client.
3. **Conflict of interest**
   Each PARTY agrees to advise the other PARTY as soon as it is clear that there is a potential risk of a conflict of interest in respect of any COLLABORATIVE PROJECT. The PARTIES will try and prevent or resolve such a conflict in good faith in a reasonable period of time, meaning in less than 4 weeks, but if that fails the COLLABORATIVE PROJECT can be terminated by the PARTY not involved in the conflict. In many cases, however, it may be sufficient to make a disclosure to the client.
4. **Status of the parties**
   4.1. This agreement between the PARTIES is non-exclusive
   4.2. Both PARTIES, as independent consultancies, are free to do work for other companies in Korea or overseas and to contract with other consultancies subject to Clause 3 on conflict of interest.
   4.3. Neither PARTY is responsible for the tax or financial obligations of the other PARTY.
5. **Delegation**
   Either PARTY may sub-contract some of their responsibilities under this agreement and may share their fee or commission, provided,
   5.1. they notify the other PARTY of their intention and seek confirmation that the other PARTY does not have any reasonable objection
   5.2. they confirm that any sub-contractor will be bound by the confidentiality and intellectual property clauses of this agreement
   5.3. that they will take responsibility for the sub-contractor's compliance with their obligations
6. **Confidentiality**
   6.1. Both PARTIES agree not to divulge or allow to be divulged to any person any confidential information relating to the business affairs of the other PARTY except to sub-contractors with a need to know and who have signed an appropriate secrecy agreement or where the other PARTY has given their consent.

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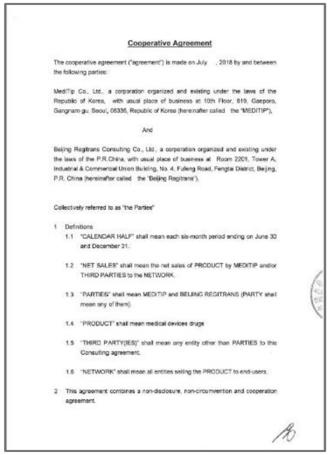
CHINA



Cooperative Agreement

The cooperative agreement ("agreement") is made on July , 2018 by and between the following parties:

MediTip Co., Ltd., a corporation organized and existing under the laws of the Republic of Korea, with usual place of business at 10th Floor, 819, Gaeporo, Gangnam-gu, Seoul, 06336, Republic of Korea (hereinafter called the "MEDITIP"),

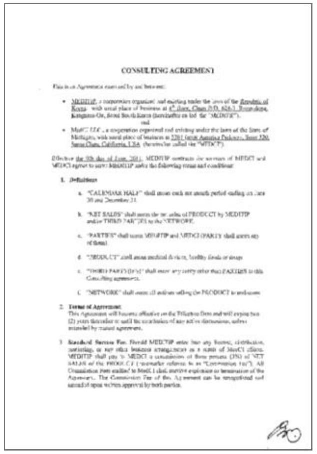
And

Beijing Regitrans Consulting Co., Ltd., a corporation organized and existing under the laws of the P.R.China, with usual place of business at Room 2201, Tower A, Industrial & Commercial Union Building, No. 4, Fuleng Road, Fengtai District, Beijing, P.R. China (hereinafter called the "Beijing Regitrans").

Collectively referred to as "the Parties"

1 Definitions
   1.1 "CALENDAR HALF" shall mean each six-month period ending on June 30 and December 31.
   1.2 "NET SALES" shall mean the net sales of PRODUCT by MEDITIP and/or THIRD PARTIES to the NETWORK.
   1.3 "PARTIES" shall mean MEDITIP and BEIJING REGITRANS (PARTY shall mean any of them).
   1.4 "PRODUCT" shall mean medical devices drugs
   1.5 "THIRD PARTY(IES)" shall mean any entity other than PARTIES to this Consulting agreement.
   1.6 "NETWORK" shall mean all entities selling the PRODUCT to end-users.
2 This agreement combines a non-disclosure, non-circumvention and cooperation agreement.

US



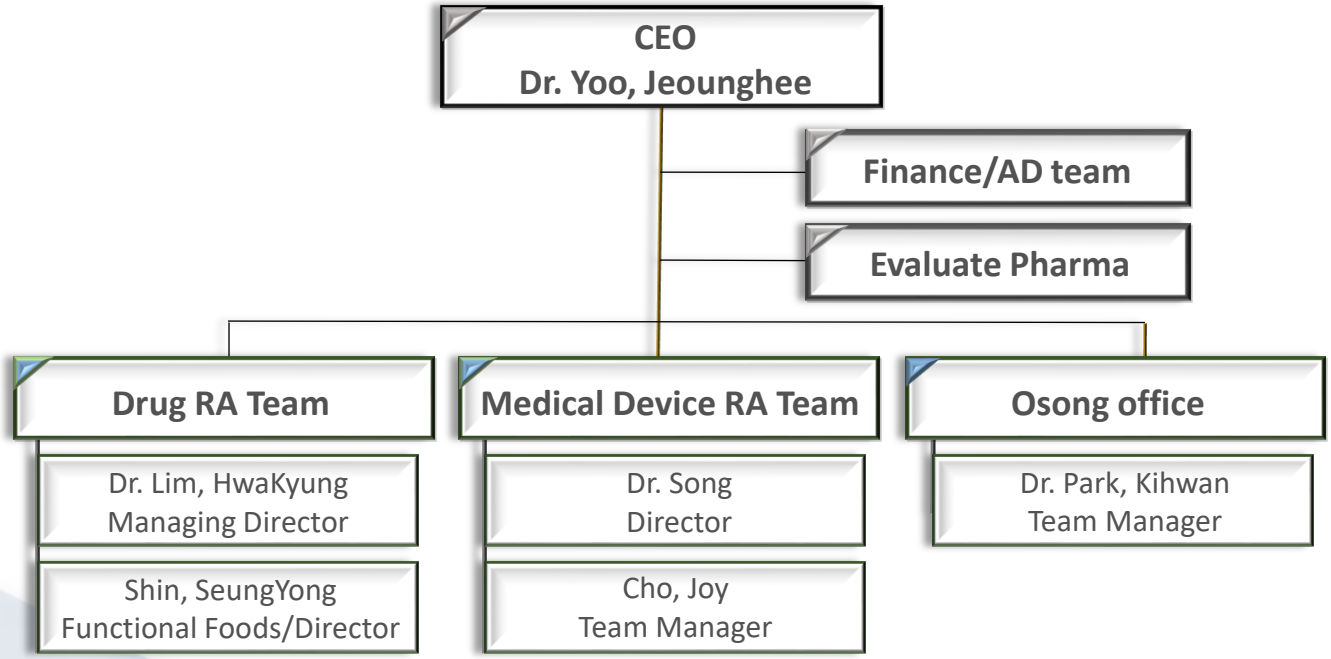
CONSULTING AGREEMENT

clinivation

Master Services Agreement for Meditip Co., Ltd.

State of Massachusetts

3. Organization



4. CV of Consultants

- Dr. Yoo, JeoungHee :

  CEO and Head consultant, Ph.D, Pharmacist / jhyoo@meditip.co.kr

  - Regulatory Affairs of Drug and Medical Device: 23 years
  - Health insurance & Price management: 17 years
  - Feasibility study and Evaluation of new product development: 20 years
  - Commercial Formulation study in industry: 5 years
  - Pharmaco-Econominc study: 1 year
  - Marketing and Promotion: 3 years
  - Clinical trial research: 2 years
  - Worked at : B.Braun Korea, Daewoong Pharm, Pacific Pharm

CV of Consultants

- Dr. Lim, HwaKyung :

  Director and Principal Consultant, Pharmacist, Ph.D of Pharmacy / hklim@meditip.co.kr

  - Regulatory affairs and evaluation of Drugs over 19 years
  - Deputy director at Ministry of Food and Drug Safety (MFDS) over 13 years
  - RA and development consulting of pharmaceutical product
  - Adjunct Prof., School of Pharmacy, CHUNGBUK National Univ.

  ➢ Main Scope

  - Consultation of non-clinical and clinical data of Pharmaceuticals (drugs, herbal drug product and biologics) and quasi-drugs.
  - Development of NME and IMD (Fixed dose combinations, new dosage forms)
  - Bridging strategy for extrapolation of foreign clinical data

CV of Consultants

- Ms. JiSun Kim:

  Senior Consultant/ Pharmacist / jskim@meditip.co.kr

  - Drug development and approval: 14 years
  - Main scope:
  - Consultation of drug development and approval, NDA, IND
    - Small molecule drug
    - Herbal medicine
    - New drug
    - Generic drug, etc.
  - Maintenance of approved products, Re-evaluation, etc.
  - Drug manufacturing and importing approval
  - Worked at : KUKJEPHARMA Co Ltd.

CV of Consultants

- Ms. JiHye Yun:

  Senior Consultant/ M.S / jhyun@meditip.co.kr

  - Clinical planning : 13 years
  - Main scope:
  - Developing clinical study design(Phase I-IV)

    - New drug

    - generic drug

    - biologics and etc.
  - Medical writing
  - Implementation of clinical programs
  - Worked at : CROs and CELLTRION Inc.

CV of Consultants

- Mr. SeungYong Shin:

  Director and Senior Consultant, Food Scientist / syshin@meditip.co.kr

  - Regulatory Affairs of Food and Health Food : 22 years
  - Regulatory Affairs of Cosmetics : 3 years
  - Commercial Formulation study in industry: 6 years
  - Master's degree in Food Science
  - Main scope :
  - Food, Functional health food and cosmetic development
  - New ingredient approval(Product-specific authorization for functional health foods, temporary standard and

    specification
  - for food and food additives, functional cosmetics
  - Importation consulting
  - Worked at : Daewoong Pharm, Globalhealthcare Co.

CV of Consultants

- Dr. Chiwon, Song:

  Director and Principal Consultant, DVM, Ph.D of Veterinary Medicine/ cwsong@meditip.co.kr

  - Regulatory affairs and evaluation for Medical Device etc over 18 years
  - Deputy director at Ministry of Food and Drug Safety (MFDS) over 17 years
  - RA and development consulting of Medical Device(Cardiovascular Devices) and Biopharmaceutical product (Recombinant product).

  [Main Scope]

  - Consulting for non-clinical and clinical data for Medical Device and Recombinant product.
  - Registration of combination product such as DES etc.

CV of Consultants

- Ms. Cho, Joy:

  Senior Consultant / joy@meditip.co.kr

  - Regulatory Affairs of Medical Device: 10 years
  - Medical Device Reimbursement and Health Technology Assessment : 10 years
  - Main scope :
  - Registration of combination product such as dermal filler, DES, etc. IDE approval and development of new technology
  - CE Marking
  - Health Technology Assessment

5. Committee Activities

Participated in policy research projects in pharmaceutical parts of Ministry of Food and Drug Safety(KFDA) (Human body health care products)2017

Was selected as a participant of CRO projects for Medi-Bio business under Ministry of SMEs and Startups (Licensing business support for global advancement/entry)2017

A member of the KFDA innovation facilitators group in 2008,2009

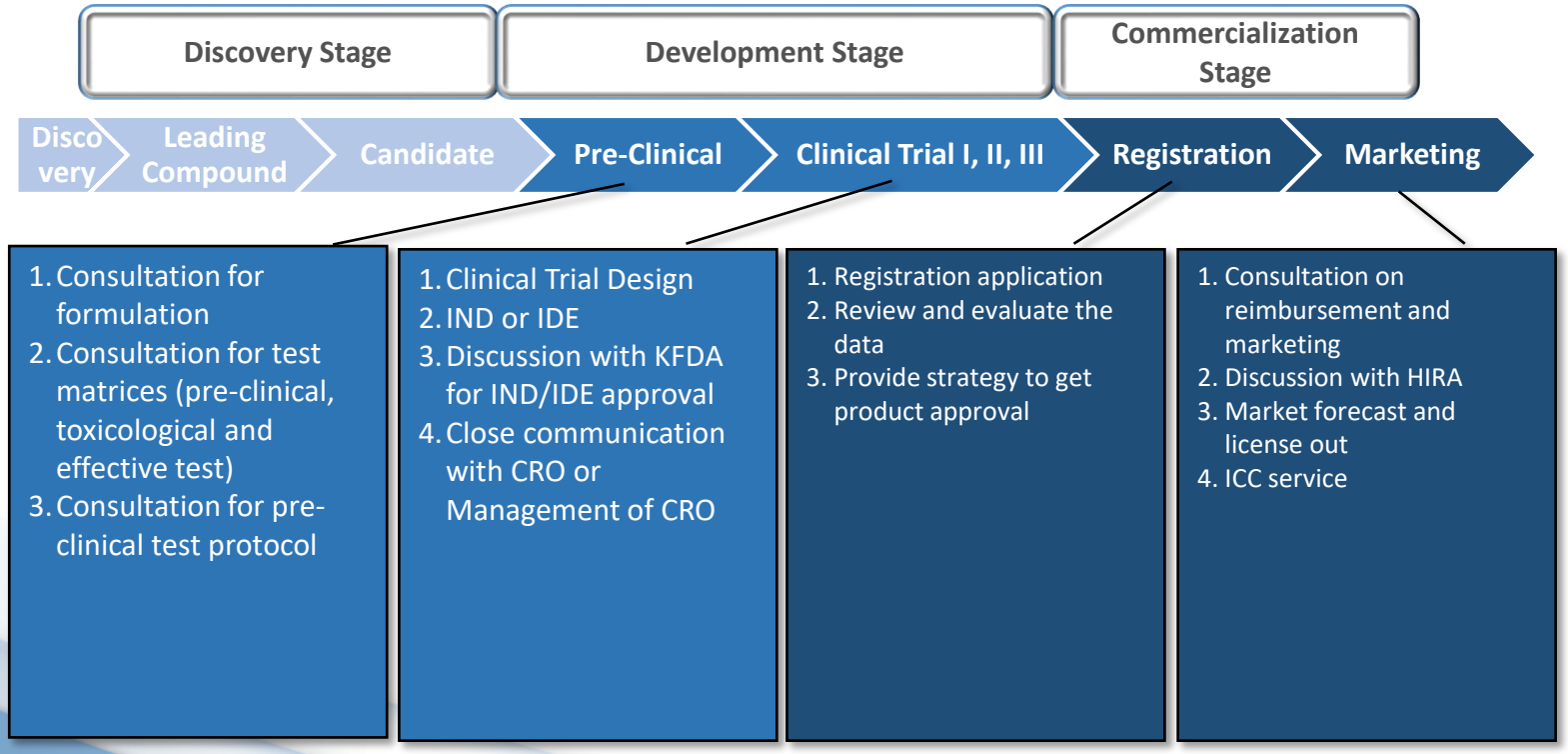
A member of the Health Insurance Committee of the Korea Medical Device Association in 2007, 2010

A member of the Enforcing Notification of KFDA in the Medical Device Law Committee of KFDA in 2007 to 2009

Other : Invited Participant as the Representative of consulting company in Korea for Health industry Exhibition in Denmark (30th, May to 1st June, 2007 in Denmark)

Biz Scope

1. Consulting Scopes



2. Registration Scope

Product Registration

- **Pharmaceuticals / Herbal Medicines**
- Drug :
  - New drug(NME and IMD etc.) and generic
  - Safety, efficacy and quality consulting
  - DMF and GMP
  - CTD writing and development
  - Pre-review consulting
- **Biologics /Cell Therapy**
- Cell therapy development and licensing consulting
- Recombinant drug RA consulting
- BLA/IND consulting
- Vaccine/Plasma derivatives/Antitoxin RA consulting
- Biosimilar development and licensing consulting

Registration Scope

Product Registration

- **Quasi-drug /Health functional food**
- Quasi-drugs approval consulting
- Functional health food and Cosmetics consulting
- Newly developed medical devices / Hybrid medical devices
- Consulting on licensing, development/clinical study of newly developed medical devices
- Hybrid product : DES, DEB, antibacterial wound care products and others
- Surgical Supplies, Coronary stent, Balloon Catheter, Human tissue&organ substitute, Dermal Filler, Orthopedic materials, Suture, Probe, Puncturing, Abrasion, Tube & Catheter for medical use, etc.

Registration Scope

- Product Registration

  - **IVD (In Vitro Diagnostics) – medical devices/pharmaceuticals**
  - **IVD reagent (Class II, III, IV)**
  - **IVD –Medical device (Class II,III,IV)**
  - **HIV, HBV, HCV, HTLV, ABO, Rh(D)**
  - **Diagnosis, Disease progress and treatment determination for IVD reagents. (including PCR reagents)**
  - **Self-monitoring in vitro diagnostic reagents**

Registration Scope

- Medical Devices Registration

  - **Hybrid product**
    - ✓ DES, DEB, antibacterial wound care products and others

  - **Active Medical Devices :**
    - ✓ Infant Incubator/Warmer, Patient Monitor, Ventilator, Defibrillator, Phototherapy, PCR, etc.

  - **Non Active Medical Devices :**
    - ✓ Surgical Supplies, Coronary stent, Balloon Catheter,
    - ✓ Human tissue & organ substitute, Dermal Filler, Orthopedic materials,
    - ✓ Suture, Probe, Puncturing, Abrasion, Tube & Catheter for medical use, etc.

3. Health Insurance Scope

- Health Technology Assessment
  - **Systematic review**
  - **Safety and efficacy evaluation**
  - **Cost-effectiveness evaluation**
- Procedural Terminology Review
  - **Cost effectiveness evaluation**
  - **Evaluation of impact to Health insurance budget**
- Medical Device Pricing Review
- Pharmaco-economic Evaluation

4. ICC Service Scope

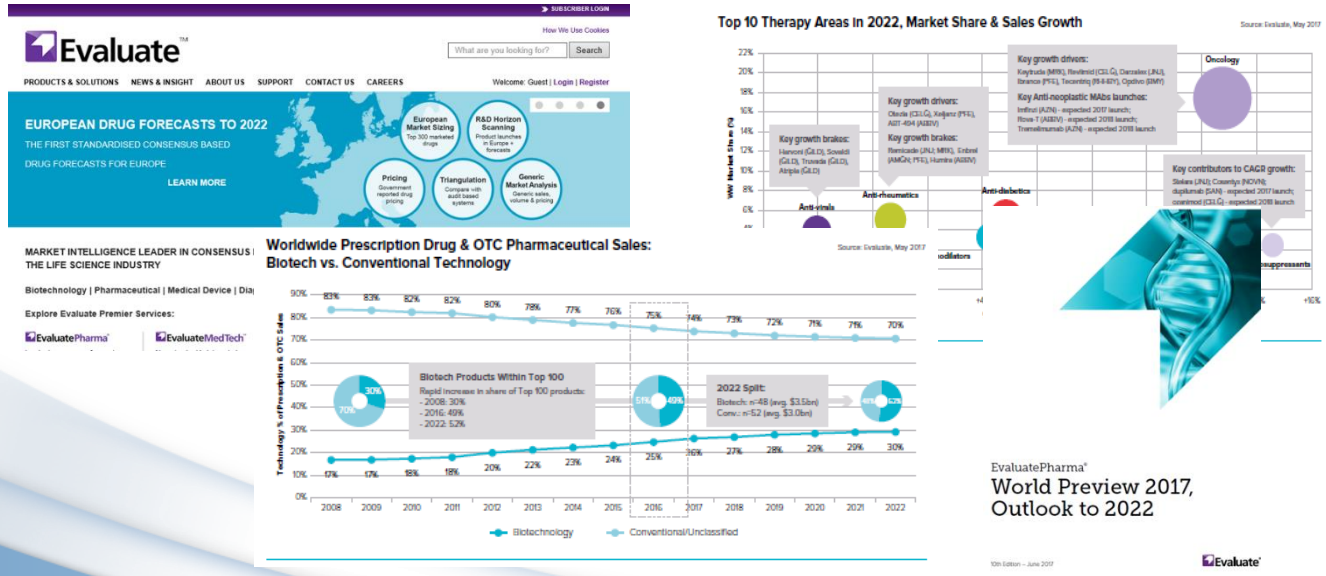
We offer “In-country Caretaker Service” for medical importers to Korea seeking direct control over their product licenses and reimbursement coverage decision process with local authorities rather than relying on local distributors, so you can secure long-term stability in product supply to local customers. The essence of our In-country Caretaker Service is that we act as your local third-party consultant to obtain and hold import licenses and to host reimbursement pricing. For assistance in this service, you are very welcome to contact MEDITIP Consulting (Korea).

- Host regulatory approvals
- Host reimbursement price
- Post market Follow-ups and government correspondences

5. Evaluate Pharma

EvaluatePharma incorporates all the data required to fully analyze,

understand and derive values from the pharmaceutical and Biotechnology industry.



6. Major Customers

Why Meditip and Meditip Experiences

- Service area for Regulatory Affairs (MFDS)

1. **Strategic consulting**

   Service area :

   - Establish RA strategy

   - Develop Synopsis of Clinical trial and Bridging study

   - Communication and/or Getting Opinion of MFDS

   - Review and Evaluation of IND/NDA and CTD (CMC, Safety and Efficacy).

   - Feasibility study according to the Client's need

   Service outcome : Total over 50 projects and 5-15 projects/year

2. **Preparation of Application doc.**

   Service area :

   - Analysis and review of Related data.

   - Preparation of submission package for MFDS Application

   - Follow-up after application, if needed.

   Service outcome : Total over 100 projects and 10-15 projects/year

Why Meditip and Meditip Experiences

- Meditip experiences - MFDS.

1. **Hanmi Korea : Strategic Consulting**
   Product : Hypertension
   Project : Clinical study design and RA strategy for triple combination FDC
   Period : 6 months
   Outcome : 1) Providing study design of all possibility ways.
   2) Meeting and debate with MFDS
   3) Giving special recommendation for inside decision of ways

2. **Dainichi Sankyo Korea : Strategic Consulting and Preparing doc.**
   Product : Edoxaban, New Oral Anticoagulant drugs(NOAC)
   Project : Evaluation and Interpretation of bridging data and development strategy
   Period : 5 months
   Outcome : 1) Interpretation of the bridging data and foreign clinical data
   2) Strategy for bridging evaluation
   3) development of bridging report

Why Meditip and Meditip Experiences

- Meditip experiences -MFDS.

3. **DongWha : Strategic Consulting and RA activity Consulting**
   Product : Antibiotics
   Project : CTD preparation and NDA Follow-up
   Period : 12 months
   Outcome : 1) All Strategic consulting .
   2) Preparation of CTD
   3) Meeting and Follow-up with MFDS and Clients
4. **Shinpoong : Strategic Consulting and Preparing doc.**
   Product : SP : Stroke
   Project : IND preparation and Follow-up
   Period : 12 months
   Outcome : 1) All Strategic consulting .
   2) Preparation of IND
   3) Meeting and Follow-up with MFDS and Clients

Why Meditip and Meditip Experiences

- Meditip experiences -MFDS.

5. **ONO Pharma : Strategic Consulting and RA activity Consulting**
   Product : Nivolumab (Opdivo)
   Project : CTD preparation and NDA approval
   Period : I year (2016. April)
   Outcome : 1) All Strategic consulting
   2) Preparation of CTD (NDA)
   3) Meeting and Follow-up with MFDS and Clients
6. **Ildong : Strategic Consulting and Preparing doc.**
   Product : NME and IMD
   Project : NDA CTD development
   Period : 6 months
   Outcome : 1) All Strategic consulting .
   2) Preparation of NDA CTD

Why Meditip and Meditip Experiences

- Meditip experiences -MFDS.

8. N-N Pharma: Strategic Consulting and RA activity Consulting

Product : Antiviral (NCE)

Project : IND approval

Period : 8 months

Outcome : 1) All Strategic consulting .

2) Preparation of IND

3) Meeting and Follow-up with MFDS and Clients

Others :

IND filing (phase 1, 2 and 3) : over 30 projects

NDA filing : over 60 projects

Why Meditip and Meditip Experiences

- Service area for Health Insurance.

1. **Strategic consulting**

   Service area :

   - Estimation of Price and reimbursement range

   - Interview and/or Getting Opinion of Health Insurance authorities

   - Re-evaluation of PE or Non-direct comparison data.

   - Other feasibility study according to the Client's need

   Service outcome : Total over 15 projects and 3-5 projects/year

2. **Preparation of Application doc.**

   Service area :

   - Analysis and review of Related data.

   - Preparation of Application form and related data.

   - Follow-up after application, if needed.

   Service outcome : Total over 6 projects and 1-2 projects/year

2018 Completed registration in MFDS Korea

2019. 1. 1. Standard

RA type	In process	Completed	Total
ANDA	1		1
NDA/BLA	3	5	8
sNDA	1	6	7
DMF	1	3	4
IND	2	18	20
IND amendment		1	1
ODD		1	1
Pre-review	1	10	11
License holder change		1	1
Pre-meeting		2	2
Registration of exipient	1		1
Renewal	1		1
Total	10	48	58

Thank you