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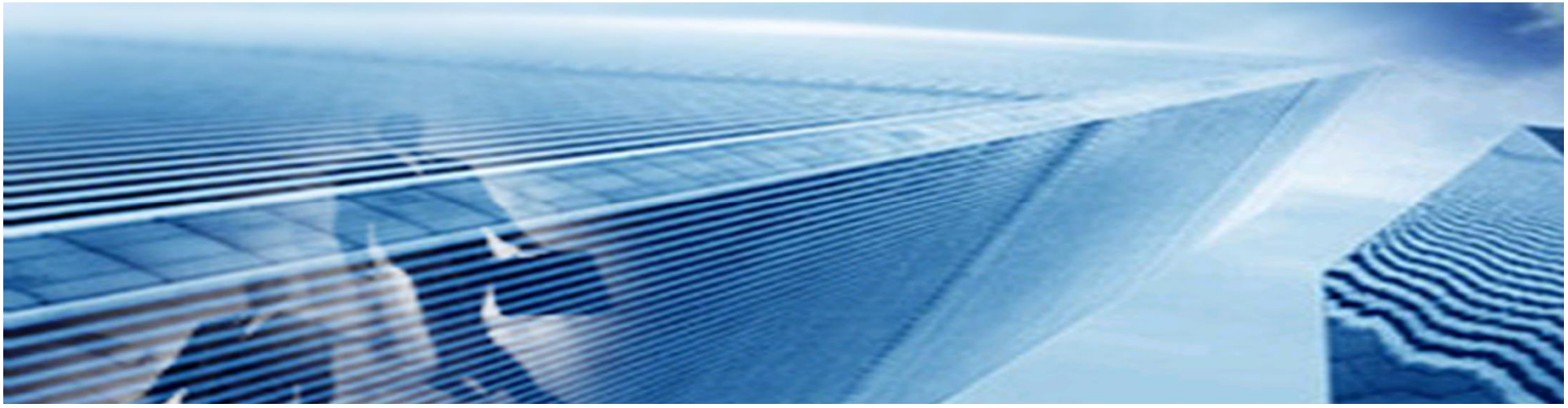
Introduction of

Beijing Regitrans Consulting Co., Ltd.



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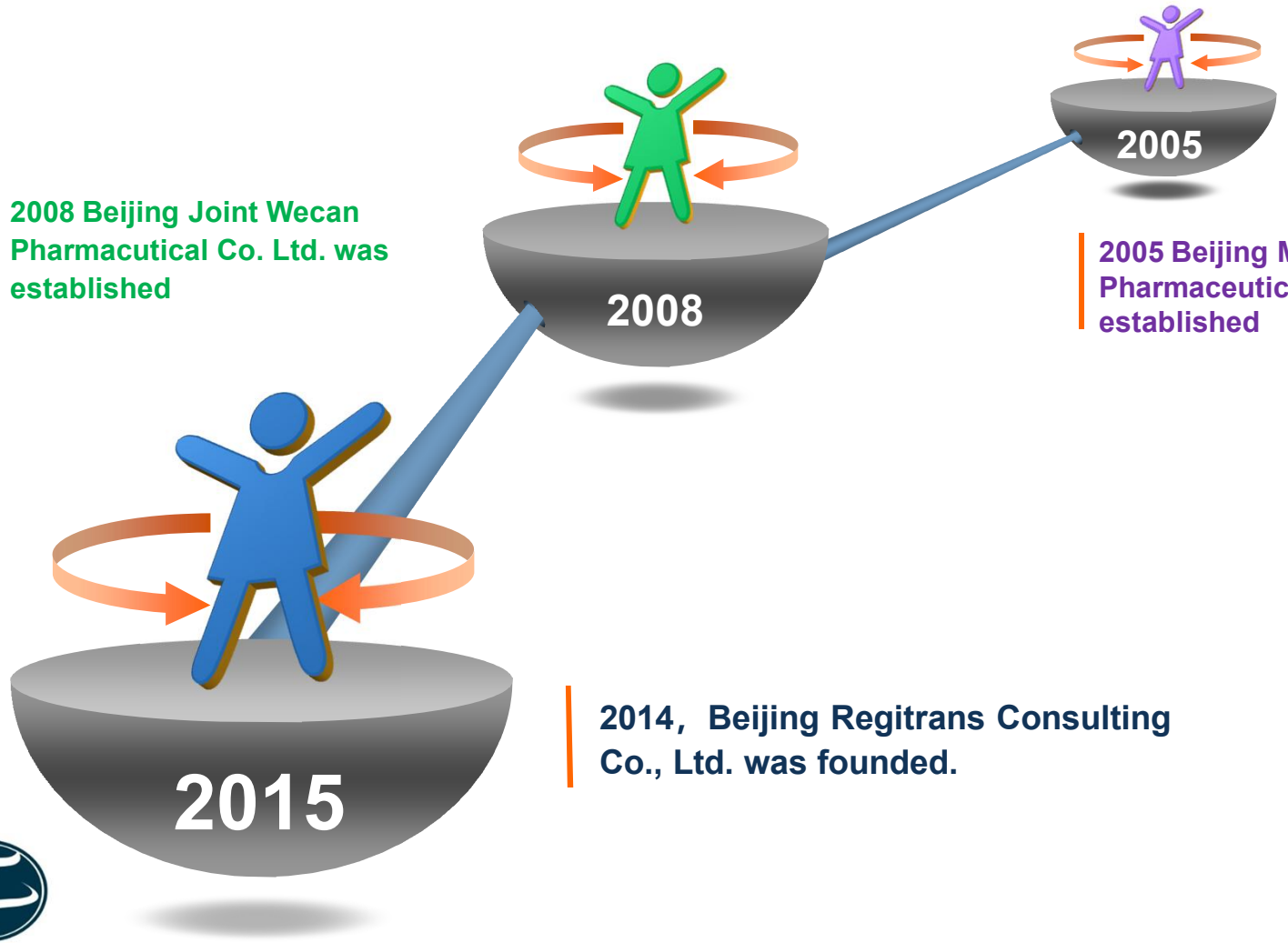
Company Profile



2005 Beijing Medi-Union Pharmaceutical Co., Ltd. was established

2008 Beijing Joint Wecan Pharmacutical Co. Ltd. was established

2014, Beijing Regitrans Consulting Co., Ltd. was founded.

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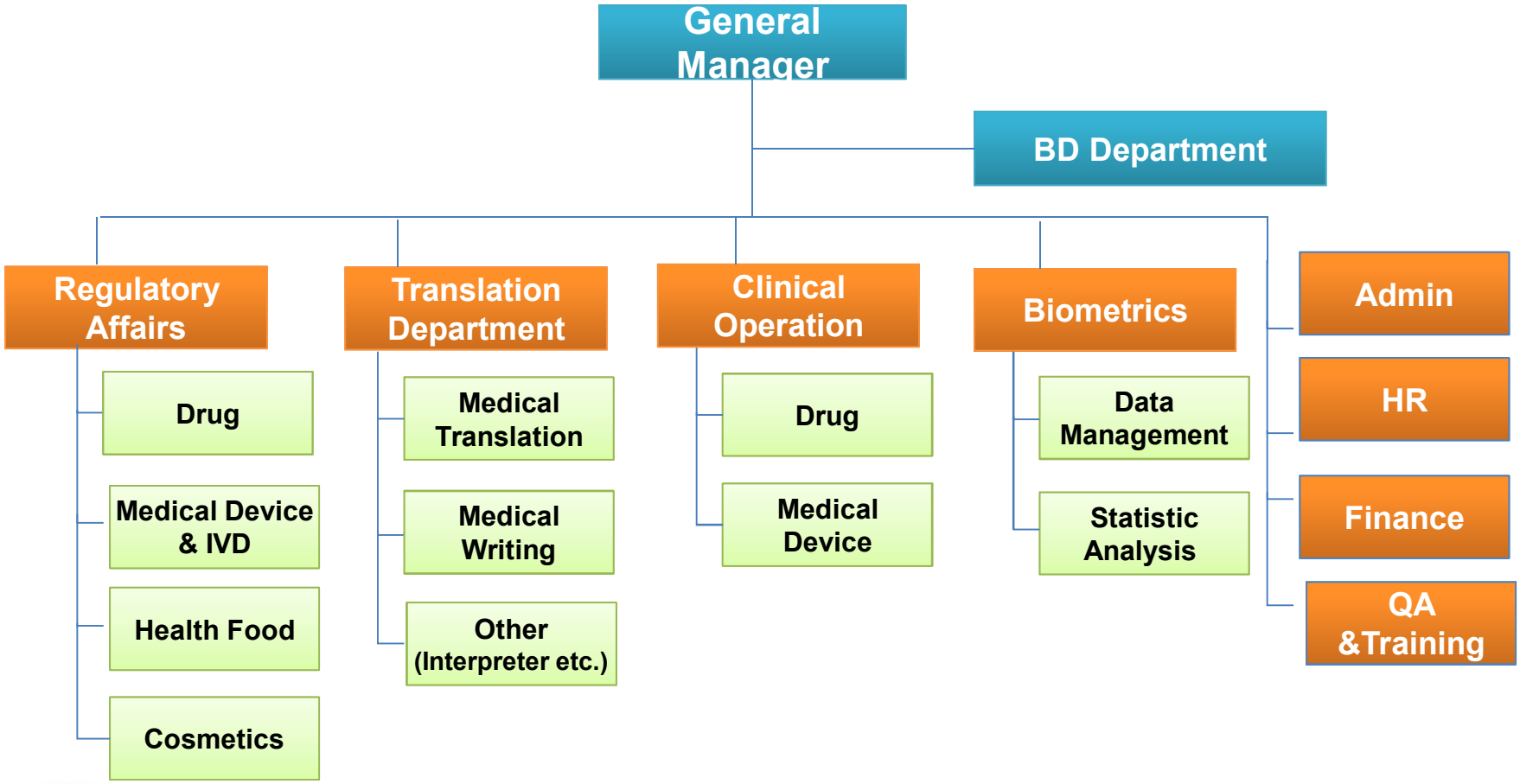
Organization chart



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Core Members

Zheng Li (Jack Lee), General Manager/ Sr. RA Director

- Graduated from Peking University Health Science Center (PUHSC) with master degree of Pharmacy.
- 10 years working experience on CMC sections in Center for Drug Evaluation of Beijing Municipal FDA as the CMC reviewer and inspector.
- Worked for CDE as CMC reviewer

Zhenghui Wang (Calvin Wang), RA Director

- Graduated from Peking University Health Science Center (PUHSC) with master degree of Pharmacy.
- Over 10 years' working experience in pharmaceutical industries and domestic leading CRO.
- Over 80 projects of drug registration, including chemical drugs and bio-products of import and domestic applications

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Core Members

Jack Wu, Head of Consumer Health Section

- 12+ years of regulatory experiences in multinational companies. Familiar with drug, MD, Cosmetics, and Health Food registration/regulations.
- Senior Regulatory Advisor at XinHuaNet Korean Channel
- Ever worked with Stryker, Galderma, and Mundipharma

Lian Liu(Eric Liu), Director of Clinical Operation

- **Graduated from Shenyang Pharmaceutical University with master degree of Pharmacy.**
- **2 years hospital work experience in hospital and 10 years operation experience on Phase I to IV and also post-market clinical study of pharmacy products and medical device.**
- **Over 40 successful clinical research projects which could cover department of Cardiovascular, Endocrinology, Gastroenterology, Neurology and Respiration.**
- **Good and long term cooperation with over 100 clinical research centers.**

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Core Members

Guozhi Yin (George Yin), Director of Business Development

- Graduated from Shenyang Pharmaceutical University with bachelor degree of Pharmacy.
- 10 years experience in two of China local biggest CRO companies (VPS CIINIC and Giant CRO)from 2004 ;
- Full process handling from R&D, GMP certification, product's registration , clinical research, marketing development.
- Good communication and personal relationship with clinical research centers and medical experts and also CDE authorities.

Prof. Xin Chen, Senior Consultant of medical technology

- Ph.D of Pharmacy from Peking University Health Science Center (PUHSC) .
- Worked for CDE as CMC reviewer

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Team Members

Rich experience on projects

Well educated Solid background

Execute Efficiently

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Professional Services

- **Regitrans can provide professional and flexible service to help launch your product in China.**

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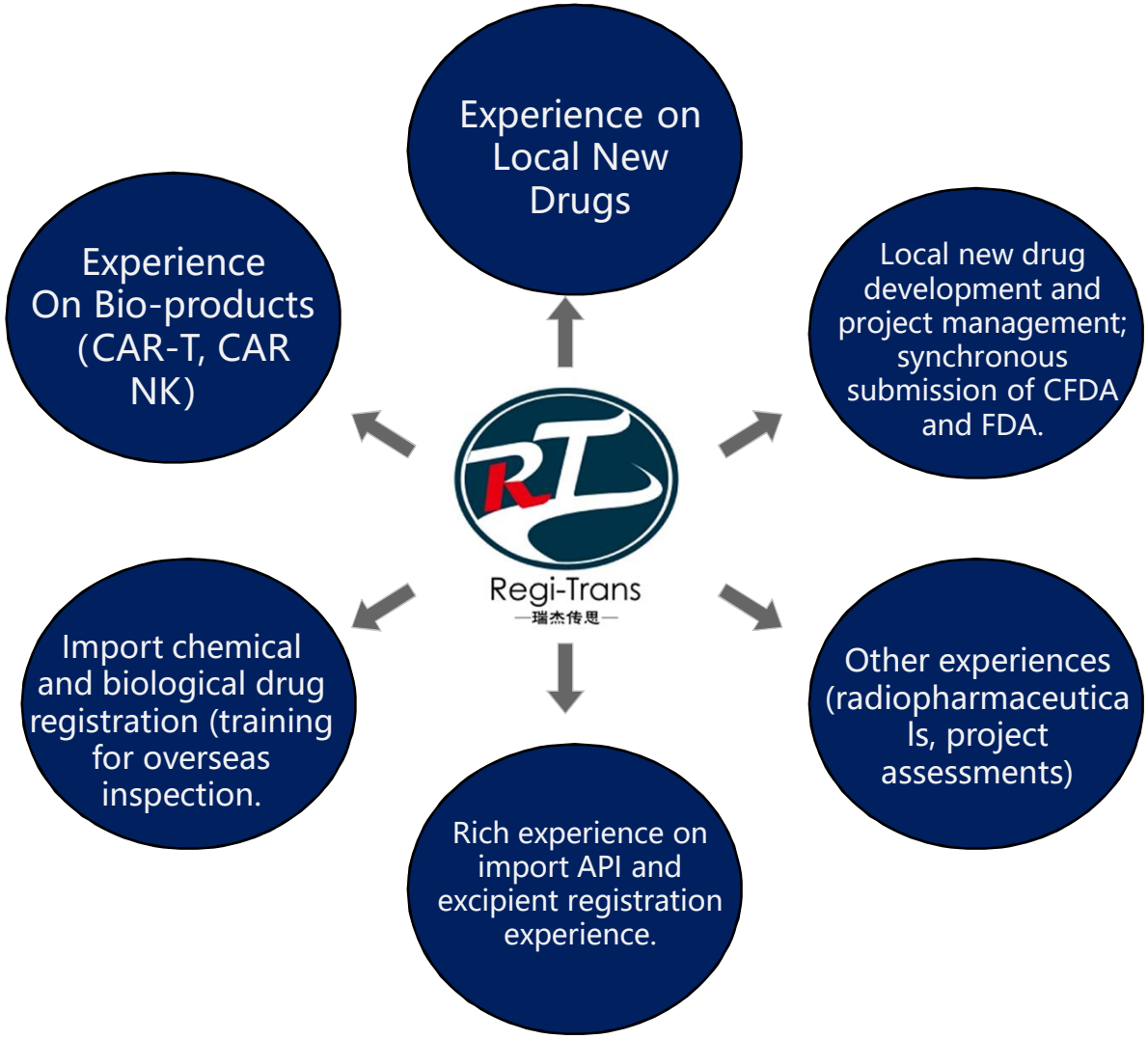
Drug Registration Service



Case examples:

- Dossier preparation and submission of many projects from an foreign manufacturer;
- Successfully prepared dossier of a reference drug for a import drug submission and get approval. It was the first batch of reference drugs listed by China;
- Completed many API success cased with IDL, approval or notification;
- Import new chemical and biological drug dossier preparation and successful submission;
- Saved an import RLD and generic drug by developing supplemental studies, solving problems during CFDA testing;
- Local new drug project management, registration consultant and Sino-America synchronous submission;
- Others

Import Regulatory Affairs Services

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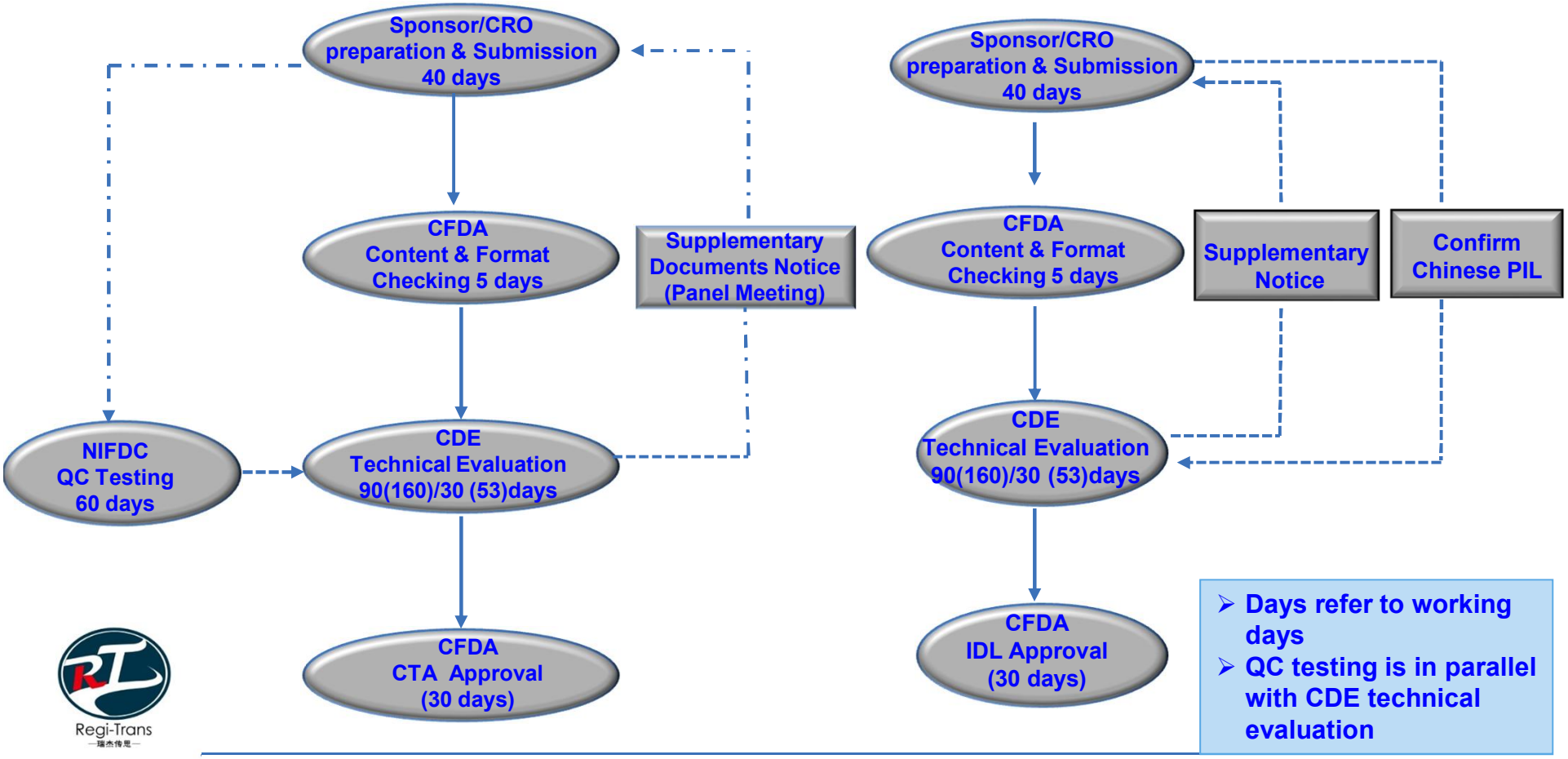
Import Regulatory Affairs Services



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Strategic Planning

- **What is your main objective of conducting clinical trials in China?**
  - ✓ Obtain marketing approval
  - ✓ To support global clinical development
  - ✓ To develop a concept proof trial
- **What is your timeline?**
- **Which is the best regulatory option?**
- **What we can do to achieve your objectives?**

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Clinical Study Service

- Clinical protocol, CRF design
- Screening for clinical trial sites
- Investigator's brochure
- Clinical study training
- Supervision and inspection of clinical study
- Adverse event monitor and report
- Data management and Statistical analysis
- Agreement providing CRA
- Subjects recruitment
- Blood sample and pathological specimen

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Third Party Inspection Service

Introduction

- Focusing on clinical trial, drug development and manufacring site inspection services, including quality control, training, consultation, as well as GMP development support; with rich experience on more than 30 cases related to GLP/GCP/GMP/cGMP/GPVP.
- The service team consists of more than 70 dedicated experts, with expertise covering clinical studies, product development, registration, and GMP development. There are also experts from who are previous CFDA inspection leaders, and senior overseas inspection experts. With rich experience in on-site inspection, we help manufactures accelerate the approval of new products.
- The company is a service entity helping manufacturers and MAH with expertise service covering the whole life cycle of a new product on clinical study, vendor selection, drug developments, pilot product study, manufacturing process and GMP validation.

Third Party Inspection Service

Services and Solutions

Part 1	Part 2
GLP/GCP/GMP/cGMP/GPVP	Quality control on whole process
Inspection service of drug development	OEM/Vendor selection
Inspection service of manufacturing site	Pre-assessment of dossier
Development site inspection of generic drugs	Risk control on IND/Pilot/manufacturing
Manufacturing site inspection of generic drugs	QA audit/appointed audit
GMP/cGMP site inspection	GMP audit
	Preparation prior to inspection and CAPA

Third Party Inspection Service

Consultation and Training service

- Development and maintenance of quality systems and SOPs.
- Drafting of quality system files
- Internal auditor training for MAH and manufacturer
- Assessment on registration, clinical study, and manufacturing for new drugs
- Solution for all problems before （PAI）

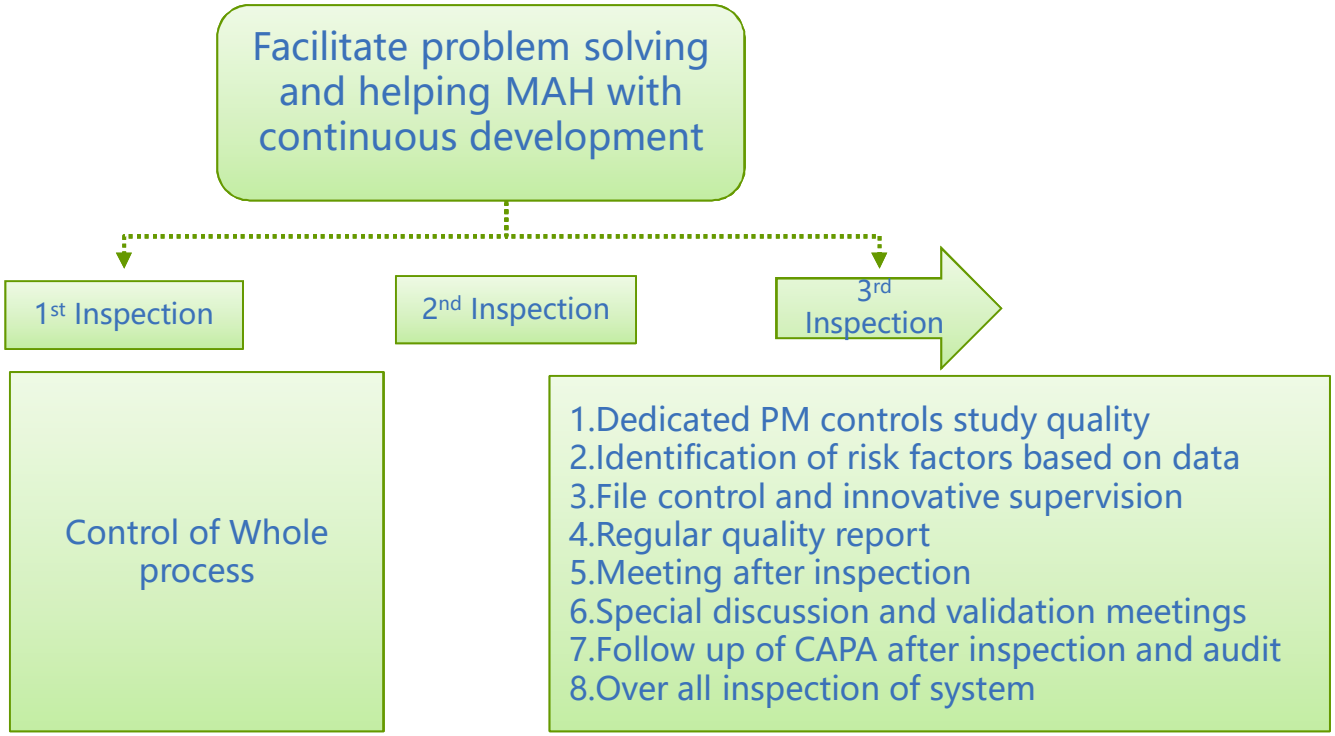
Third Party Inspection Service

What we offer for registration?

1. Whole project control, acceleration of speed and quality guarantee;
2. Process assessment, risk identification and solution for IND/Pilot/manufacturing;
3. Third party inspection reporting to guarantee the liability of development and manufacturing data;
4. Consultation service and solution for all problems in the quality system

Third Party Inspection Service

Quality Control of Drug Registration



Medical Device Registration

- Import Medical Device, Class II, III Registration
- Domestic Class II and III Registration
- Import and Domestic Class I Notification
- Medical Device Clinical Study
- Medical Device Clinical Evaluation
- Medical Device Classification
- Medical Device Testing Service
- Medical Device Production and Distribution Consulting Services.

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MD Registration—Experiences

Our registration service covering a wide product scope, including but not limited to:

Patient monitors, operating tables, HA dermal fillers, orthopedic implants and related products, medical disposals, wound dressing, lasers devices, HA fillers, needles, syringes, endoscopes, ultrasound devices, dental implants and devices, neurosurgical tools, wheeled chairs (active and non-active), etc.

CFDA

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MD Registration

Considerations for MD Registration in China:

- Classification?
- Country of origin approval and qualifications?
- Innovative product with Chinese Patient?
- Local Clinical Study?
- Clinical Trial application?
- Listed high risk products? OEM products?
- Could the management system meet Chinese requirement?
- Registration Cost? Timeline?

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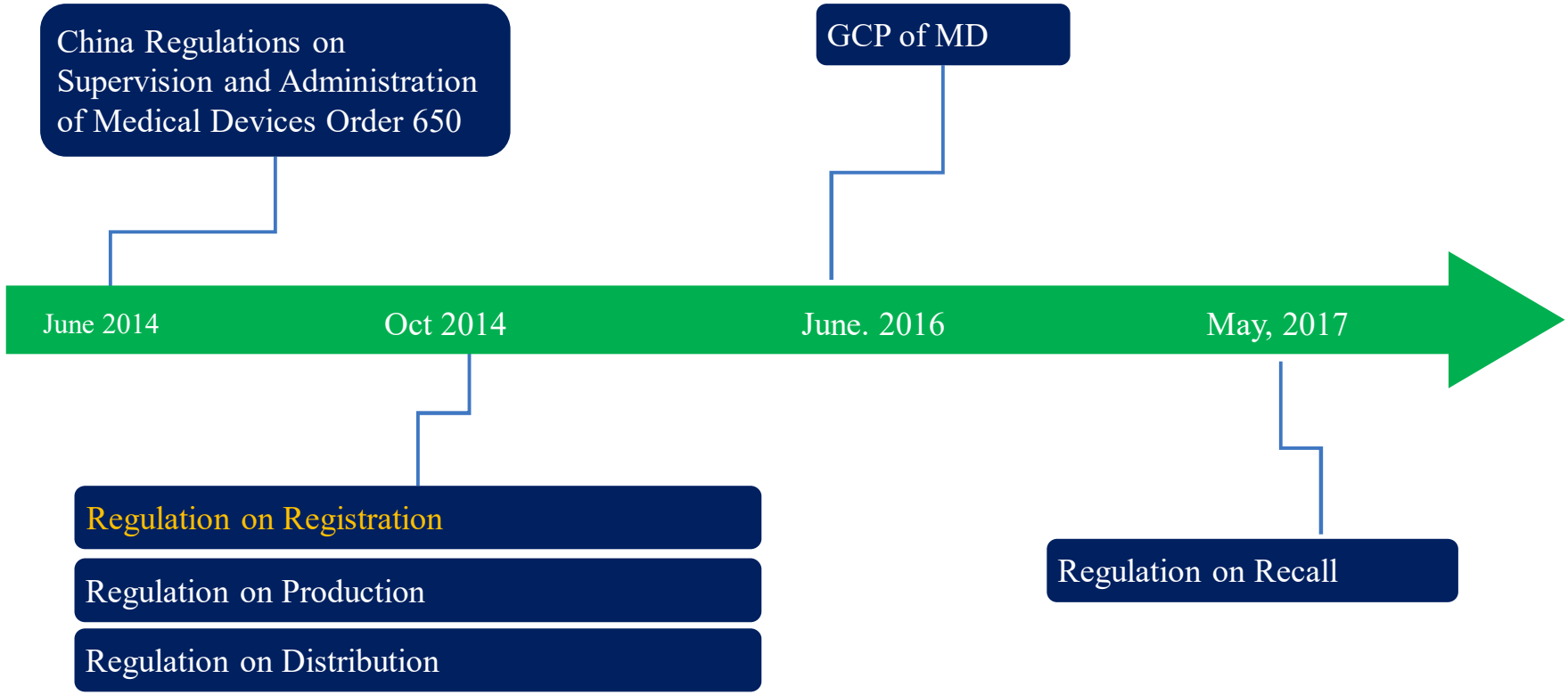
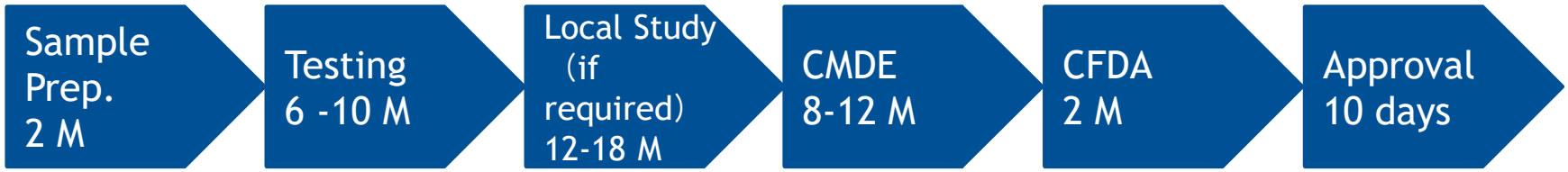
Medical Device Regulations



MD Registration Process



Timeline:

--- **30-44 Months** (with local study)

--- **18-26 Months** (without local study)

--- **6 Months** (license renewal)

Note: timeline sees the difference among different products.

Health Food Registration

Definition: Health food is defined as food that has specific health care functions, suitable to be taken by specific group of people. It can regulate the function of human body but not used for treating diseases. Health food includes vitamin and mineral supplements and functionality health food.

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Health Food--Classification

I. Mineral and Vitamin Supplements

Mineral and Vitamin supplements are not intended to provide energy. They are used as supplements to daily food to prevent possible relevant diseases.

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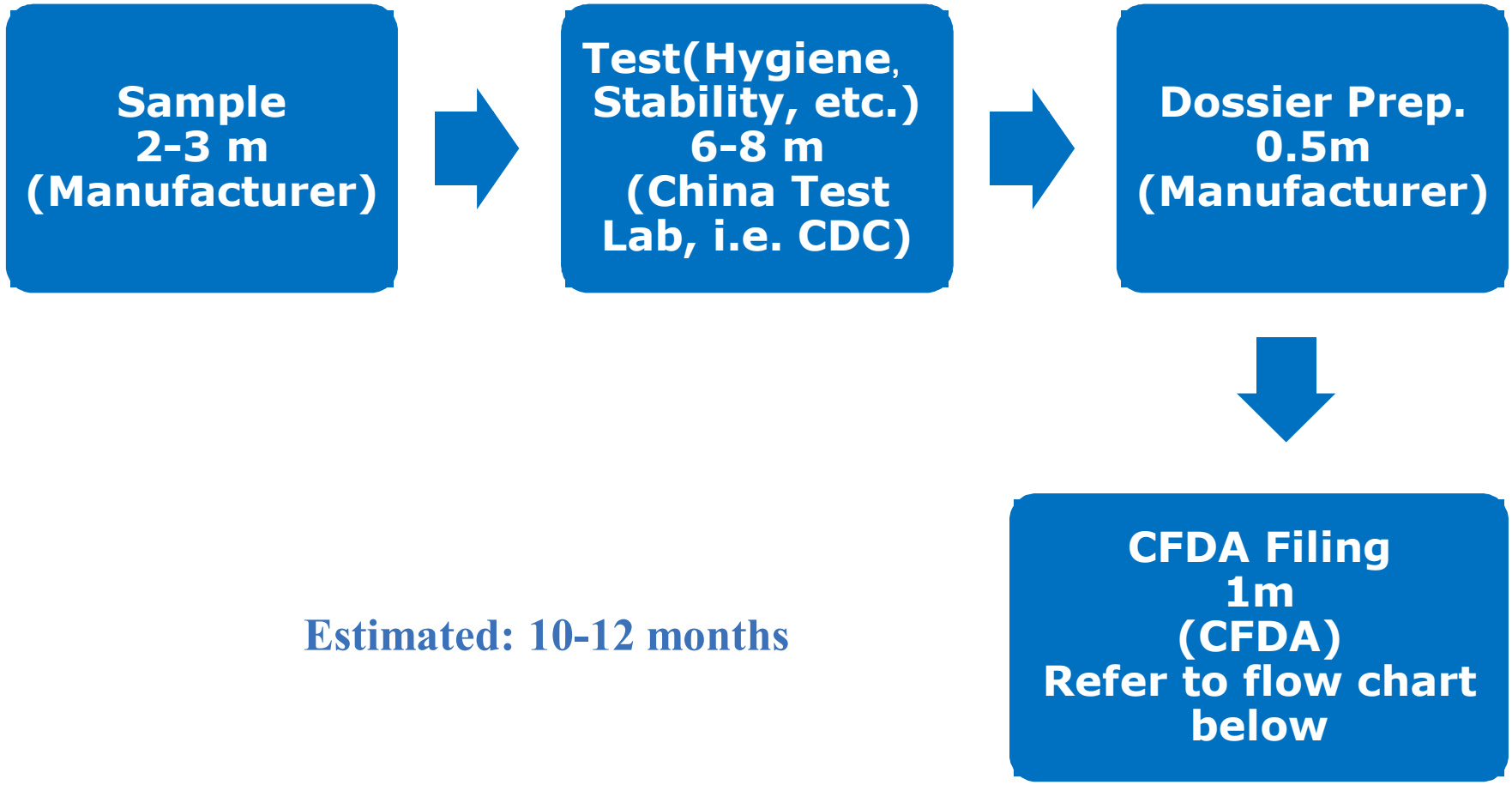
Health Food—Classification

II. Functional Health Foods—27 allowed claims

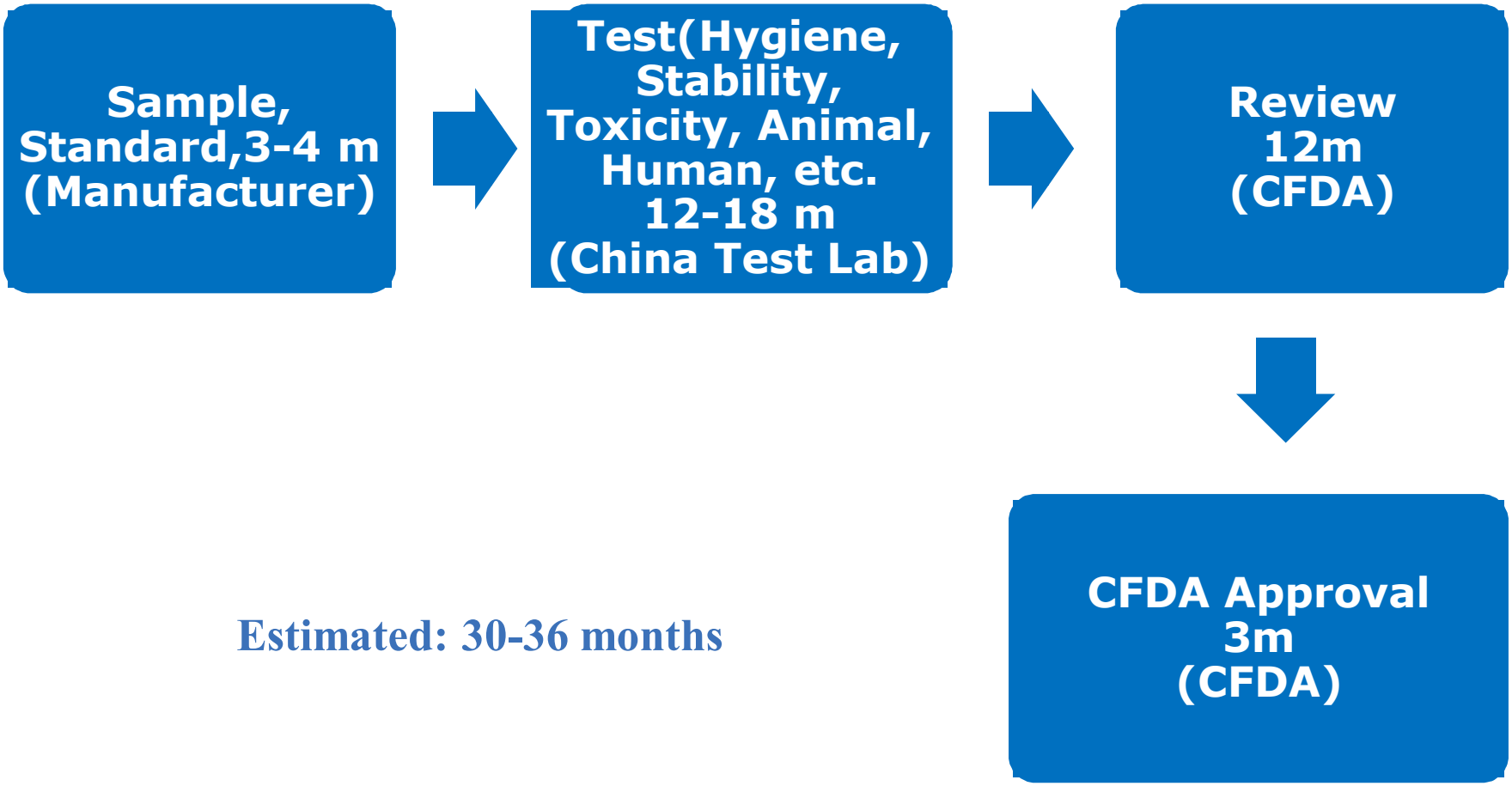
27 Allowed Claims for Health Food	
1 Enhancing immunity	15 Controlling obesity
2 Antioxidation	16 Improving growth and development
3 Assisting blood lipids reduction	17 Increasing bone density
4 Assisting blood sugar reduction	18 Improving nutritional anemia
5 Assisting blood pressure reduction	19 Assisting protection against chemical liver injury
6 Assisting memory improvement	20 Eliminating acne
7 Relieve Asthenopia	21 Eliminating yellow-brown spot
8 Facilitating lead excretion	22 Improving skin moisture
9 Moistening and cleaning throat	23 Improving skin oil content
10 Improving sleep	24 Regulating intestinal microflora
11 Increasing milk secretion	25 Facilitating digestion
12 Alleviating physical fatigue	26 Improving constipation
13 Improving endurance during anoxia	27 Assisting protection against gastric mucosa damage
14 Assisting protection against irradiation	

Health Food Timeline—Filing



Estimated: 10-12 months

Health Food Timeline-Registration



Estimated: 30-36 months

Cosmetics Registration

Cosmetics products refer to those daily chemical products applied to the skin of the body, through rubbing, spraying or similar methods, for the purpose of cleaning, eliminating odor, protecting skin, and facial makeup.

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Cosmetics Registration Process

Non – Functional: around 6 months

Functional: 12 months

Note: Specific timeline are dependable on specific testing items and cooperation from manufacturer

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Basic Requirements for Cosmetics

1. All ingredients in INCI name are listed in China and not banned ingredient is used.

2. Bio-microbial, chemical check, toxicity and human tests according to 2015 cosmetics technical requirements.

3. FSC from country of origin.

4. Validation: 4 years. Renewal must be submitted within 6 months before expire.

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Import Cosmetics Timeline

Non Functional:6m

Functional: 12m

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Experts Consulting

a. **Experts consulting provided by Regitrans regulatory affairs staff**

Regitrans regulatory Affairs staff may provide regulatory consulting services to SPONSOR on as-needed basis to support the applications in China, to make the regulatory strategies, as may be needed time to time.

b. **Regulatory consulting provided by Registrans external experts (former relevant officials)**

Regitrans may help sponsor obtain the regulatory consulting opinions from our external experts, who are former experienced regulatory officials. They have the insight to help sponsor properly meet CFDA requirement.

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Experts Consulting

c. GxP consulting provided by Registrans external experts(former relevant officials)

Regitrans may help sponsor obtain the China GxP compliance service from our external experts, who are former relevant officials.

d. Rehearse on-site inspection (former relevant officials)

To rehearse the CFDA on-site inspection for GxP compliance inspection.

Regitrans may also help sponsor rehearse the on-site inspection for R&D. (As more and more international biopharmaceutical companies would like to localize their products in China, they also have the demand to seek the expertise regarding the product localization).

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Translation & interpretation & simultaneous interpretation

- Last 10 years, Regitrans has been providing high quality professional medical translation services to over 100 clients for over 300 projects, totally about 130 million Chinese characters.
- We can handle inter-translations of Chinese, English , Japanese etc.
- Regitrans can provide the written translation, interpretation and simultaneous interpretation.

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Meeting Support & Logistics

- Regitrans may provide Meeting support and meeting logistics as-needed basis to help SPONSOR hold all kinds of formal or informal meetings (such as pre-IND meeting with CDE, CDE Panel Meeting).

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Regulatory Affairs Staff Outsourcing

- Regitrans may provide flexible outsourcing model of regulatory affairs staff to help the pharmaceutical company stay focused on core competencies when shortage of manpower.

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Our Strength

Why Choose Us ?

Professional Service

Focus on Import Registration and relevant Service

Good Relationship

Build good relationship with the Agency

High Quality Team

Energetic, stable excellent team.

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Commitment

- **Maintain your confidentiality**
  1. CDAs
  2. Internal Training System
  3. Internal SOPs
  4. Employees
  5. Others

- **Accomplish your projects without compromise of the quality and timeline.**
  - ➢ Comprehensive management by project manager
  - ➢ Close communication and keep the project progress posted in timely manner

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Our Clients

华润三九

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Thank You !