

MARIS GROUP

Beijing Maris (CRO)

Beijing Shanpeng (SMO)

Maris Group Korea Co., Ltd

迈瑞生集团

北京迈瑞生 (CRO)

北京善芄 (SMO)

(株) 迈瑞生韩国

MARIS GROUP

迈瑞生集团

注册 · 咨询 · 服务
器械 · 医美 · 特医

写在前面的话：

Preface:

我们是一群志同道合的人...

We are the team members have a common goal.

我们是一群 80 后 90 后的创业者...

We are entrepreneurs in 80s and 90s.

我们是一群热情有活力的年轻人...

We are a group of vigorous young people passions .

我们希望通过自己的辛勤工作帮助您产品进入中国...

We hope your products can launch into Chinese market through our productive works.

我们希望通过自己的技术专长帮助您突破法规壁垒...

We hope to help you break if the barriers of regulations through our experienced techiques.

我们希望通过自己的沟通协调为您加速时间进程...

We hope to save time and cost for you through communication and coordination.

我们精通进口、国产医疗器械注册，IVD 产品注册，化妆品注册以及食品注册；

We are dedicated to the registration imported and domestic for the device, IVD product, cosmetics registration and FSMP.

我们擅长医疗器械临床实验和体外诊断试剂临床实验；

We are specialize in clinical trials of medical devices and IVD products.

我们可以做韩国、中国台湾、欧洲、美国医疗器械注册；

We can registrate medical devices for the client of Korea, Taiwan, Province of China, the United States,

Europe and so on.

随着我们的不断的学习和成长，我们能为您做更多...

As we get learning and growthing, continuously we can do much more for you...

从 2008 年的 2 个人，到现在的 100 多人，我们有理由相信，我们可以做的比说的更好...

Since two people in 2008, nowadays we have more than 100 employees, so that we have more confidence that we can do better than what we said.

we love maris !

专注 专心 专业

您身边的法规顾问

十余年法规积淀

成就好品质

ON MY WAY





"There are so much to do in life, and now we've chosen this one, let's insist on making it as a classic. "

“一生中要做的事很多，而现在我们选择了这一件，那就让我们把它做成经典。”

——Steve Jobs（史蒂夫·乔布斯）

ABOUT MARIS:



Maris Group members consist of Beijing Maris Medical Technology Co., Ltd(CRO), Beijing Maris Trading, Beijing Shanpeng (SMO), Maris Group Korea Com.Ltd, .Maris Group Suzhou is dedicated to Regulatory Affairs consulting and registration business related to NMPA (National Medical Products), formerly CFDA. Maris Group was founded in 2008 and its main business scope is focused on medical devices registration, medical devices clinical trials which also

include SMO service and cosmetics registration and FSMP. The key members of the firm have excellent personal capabilities, rich experiences in registration who are familiar with the NMPA regulatory system and application procedure. Besides, Maris has a fully mature and professional quality system (ISO9001&ISO13485) for registration task, which demonstrates more productive and efficient among the RA field.

北京迈瑞生医药科技有限公司、北京迈瑞思商贸有限公司、北京善梵科技发展有限公司、(株)迈瑞生韩国、苏州瀚洋隶属于 Maris 集团。Maris 集团专业从事 NMPA(国家市场监督管理总局, 原 CFDA 已合并划归)相关的法规咨询以及相关产品的注册业务。Maris 集团创立于 2008 年, 业务主要发展方向为医疗器械注册、医疗器械临床试验、化妆品注册、特医食品注册。团队主要成员个人能力优异, 注册经验丰富, 熟知 NMPA 法规体系及申报流程。Maris 具有十分成熟, 专业的注册工作体系, 并已取得 ISO9001 和 ISO13485 质量管理体系证书, 与同行业中其它公司相比, 更具规模与实力。



公司发展历程

2008 年 成立北京迈瑞生医药科技有限公司 (CRO)

2012 年 成立化妆品事务部

2013 年 成立临床事务部

2014 年 成立北京迈瑞思商贸有限公司

2015 年 成立迈瑞生集团韩国支社

2017 年 成立北京善苾科技发展有限公司 (SMO)

2018 年 成立迈瑞生集团台湾办事处

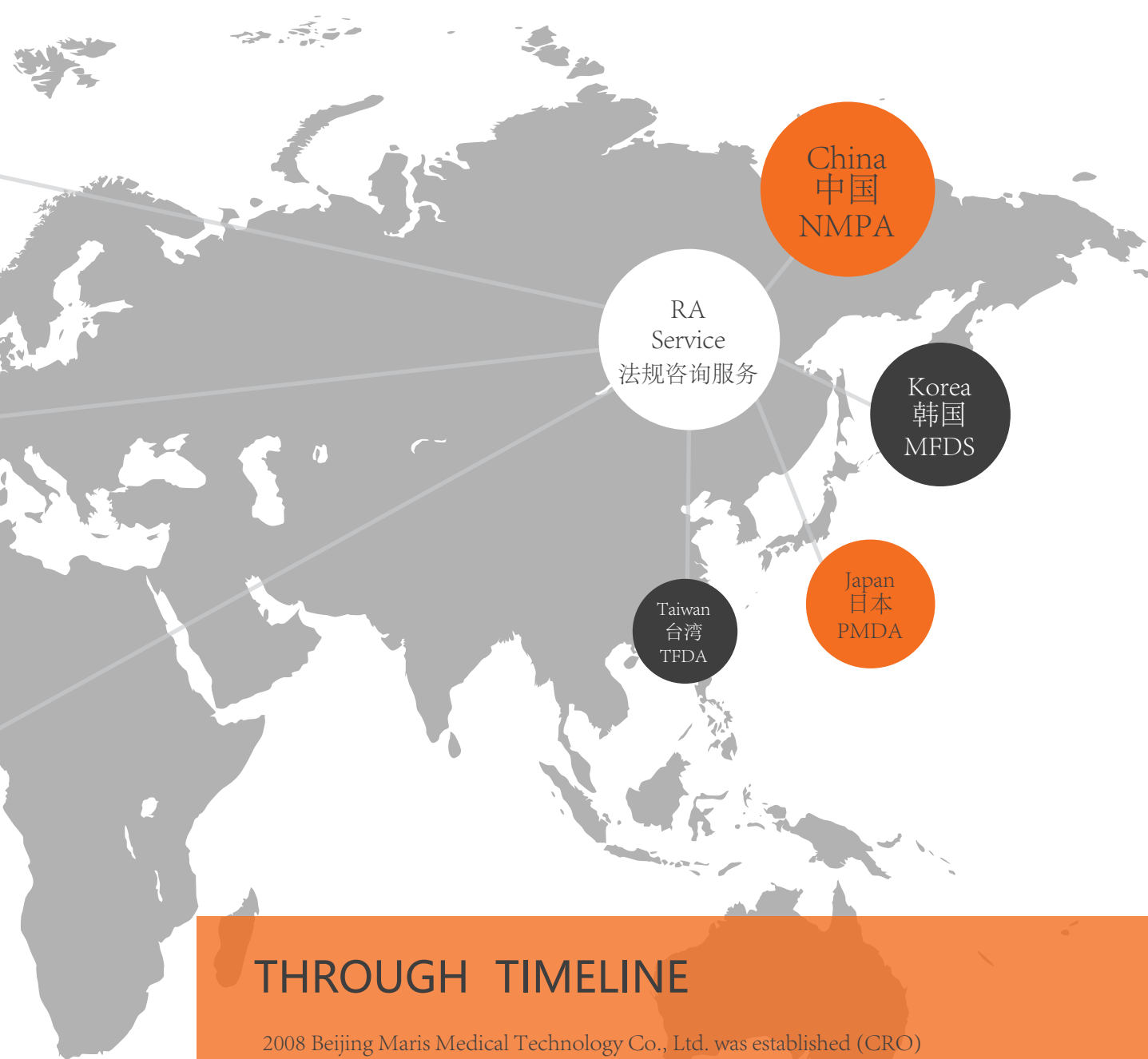
2019 年 成立苏州子公司

2021 年 成立江西南昌子公司

China 中国分支机构 (含港澳台地区)

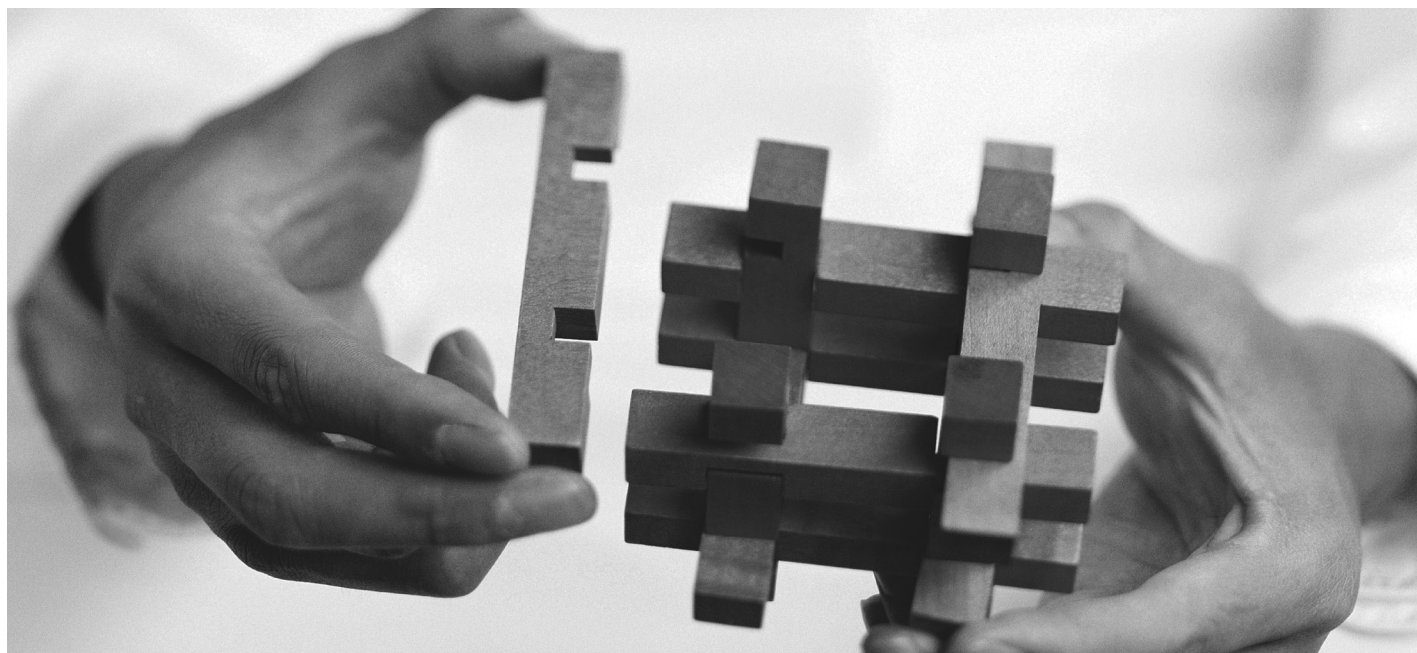
- 北京总公司
- 台湾办事处
- 上海办事处
- 河北办事处
- 东北办事处

Korea 韩国子公司



THROUGH TIMELINE

- 2008 Beijing Maris Medical Technology Co., Ltd. was established (CRO)
- 2012 Cosmetics Department was established
- 2012 Clinical Affair Department was established
- 2014 Maris (Hong Kong) Technology Limited was established
- 2014 Maris Commerce Co.,Ltd.was established
- 2015 Maris Group-Korea branch office was established
- 2017 Beijing Shanpeng Technology Development Co., Ltd. was established (SMO)
- 2018 Maris Group-Taiwan branch office was established
- 2019 Maris Group-Suzhou branch was established.
- 2021 Maris Group-Nanchang branch was established.



Medical Devices Registration

Imported/Domestic

Active medical Device/Non-Active medical Device

The Whole Category Registration Services

医疗器械注册

进口 / 国产器械

有源 / 无源器械

全品类注册服务

Clinical Trial/Clinical Evaluation

Clinical Trial Exemption Evaluation

Clinical Protocol Drafting

CRO&SMO

Audit services

临床试验、临床评估

临床豁免评估

临床方案设计

CRO&SMO

稽查服务

Cosmetics Registration

Cosmetics Registration & Filing Service

Cosmetics Marketing Approval Evaluation Service

Cosmetics Chinese Responsible Officer Service

Cosmetics Customs Clearance Service

Cosmetics Trademark Registration Service

Cosmetics Customized Production Service

Cosmetics marketing services

化妆品注册

化妆品注册备案服务、

化妆品上市风险评估服务

化妆品中国责任人服务

化妆品海关通关服务

化妆品商标注册服务

化妆品生产定制服务

化妆品市场推广服务

FSMP Registration

New product approval and Market Research

Product formula, production process, technical requirements,
enterprise standards, testing methods

Pilot scale production

Inspection plan drafting

New product registration

Charges and renewal of registration

Health food technology transfer

特医食品注册申报

新产品立项及市场调研

产品配方、生产工艺、技术要求、企业标准、检测方法研究

产品中试放大生产

注册检验试验方案

新产品注册申报

变更与延期注册

保健食品技术转让



OUR SERVICE

Maris Group mainly provides services such as regulatory affairs, testing clinic trial and registration for medical devices cosmetics and FSMP. Our company has established a good and stable cooperation relationship with a number of testing institutions, and has become a reliable RA partner for a large amount of imported and domestic manufacturers of medical device and cosmetics, assisted in launching products into Chinese market

迈瑞生集团主要提供医疗器械、化妆品的注册、检测、临床试验、特医食品注册等服务。公司已与多个检测机构建立了良好、稳定的合作关系，并成为国内外众多医疗器械、化妆品厂商企业固定的注册合作伙伴，为其打开中国市场奠定了良好的基础。



精

Experts: Top experts in the industry work together to think out the perfect solutions.

精锐部队，团队全部来自行业内顶尖公司的人才，汇聚在一起迸发出新的智慧。

细

十余年，积累 1000 余项目的操作经验，总结出一套成熟完备的运营和管理体系，对于进口和国产医疗器械注册、临床试验有着独到的管理和执行经验，辅助以公司严格的质控 SOP，从而能够保证项目优质高效的完成。同时是行业内为数不多的拥有自己 SMO 服务的 CRO 公司，为客户注册备案提供一站式服务。

Detail-oriented: In the past 10 years, we have accumulated more than 1000 project experiences, and summarized a set of excellent and perfect quality system for operating and managing. We have unique management and execution experience for imported and domestic medical devices registration , clinical trials, and assisted with the our strict quality control SOP, in order to ensure the high quality and high efficiency for completing the projects. It is also one of the only CRO companys who has its own SMO in order to provide one-stop service to customers in the inidustry.

企业理念

Corporate philosophy

十余年专注、精耕细作、优质高效、使命必达

A decade of focusing on consultation of CFDA regulations with high quality and high efficiency. Experts can solve problem frequently. And we won't stop until reach the goal.



耕

Ploughing: Focus on high efficiency. In the industry, it has been established a good cooperative relationship with supervision department, laboratory, and a large amount clinical trial sites, which can effectively prejudge, avoid and solve problems that may occur during the product testing, registering, conducting clinical trial and other process.

唯有专注，才能高效。在行业内，与行业监管部门、检验机构、以及众多临床试验机构建立了良好的合作关系，可以有效预判、规避和解决产品检测、注册、临床等各个环节可能出现的问题。

作

深刻理解法律法规，在严格执行各类条款的同时，对于行业发展趋势有宏观的预判、能够结合产品的实际情况，帮助企业整体规划设计，指定最精准、最优化、最高效的注册方案。

Implement: Based on precise understanding of regulation and executing it, at the meantime according to the trend and the diversity of products of the industry, combined with the strategic design for enterprises, we can offer the most accurate, optimized and efficient registration and clinical proposal.

MARIS CRO

Beijing Maris Medical Technology Co., Ltd. is a complex of professional CRAO (Contract Regulatory Affairs Organization) and CRO (Contract Research Organization).

Maris has from the production system, registration, and detect the clinical evaluation, clinical trials and SMO whole process service, committed to medicine, food, cosmetics and other areas of the whole process technical advisory services, to provide customers with comprehensive, professional technical advisory services, for the research and development, listed in front of the laws and regulations to guide enterprises to provide professional, perfecting laws and regulations knowledge, don't read the advanced experience To be the most professional regulation consultant for you and your enterprise

After R&D-Pre IRO

Production system

Product testing

Registration services

Clinical evaluation

Clinical trials

SMO service

Clinical audit

Post marketing clinical

Domestic agent

Product Research Report

Patent services

Training services

MARIS —注册咨询顾问

北京迈瑞生医药科技有限公司是专业 CRAO（是“Contract Regulatory Affairs Organization”的缩写，即合同注册组织，指专业从事各种医药法规符合事务的服务机构）与 CRO 合同研究组织（CRO，Contract Research Organization）的综合体。

迈瑞生拥有从生产体系，注册，检测到临床评价，临床试验以及 SMO 全流程服务，致力于医疗，食品，化妆品等多领域全流程的技术咨询服务，为客户提供全面，专业的技术顾问服务，为研发后，上市前的企业提供专业的法规指导，不断完善法规知识，不断积累先进经验，成为您与您企业最专业的法规顾问。

研发后—上市前

生产体系

产品检测

注册服务

临床评价

临床试验

SMO 服务

临床稽查

上市后临床

境内代理人

产品调研报告

专利服务

培训服务

SMO COMPANY INTRODUCTION

SMO 公司介绍

The SMO (Site Management Organization) Operating Department of Beijing Shanpeng Technology Development Co., Ltd. was formally established in June 2017. It is dedicated to introduce the advanced international clinical trial management system and assisting researchers and research institutes in non-medical judgment affairs by providing high quality and efficient services for the growing number of clinical trials from clients around the world, improve the quality and promote the standardization process of clinical trials. Main Business: Responsible for the management of clinical CRC personnel throughout the country, providing coordination services for clinical trials and research, hospital research reports, questionnaires and other services. The Shanpeng SMO is dedicated to provide the best CRC service with a professional, solid and honest attitude.

北京善芴 SMO (site management organization) 公司是 2017 年正式成立，致力于引进国际先进的临床试验管理体系，通过提供临床试验相关的专业服务，协助研究者和研究机构临床中非医学判断类的事务性工作，为日益增长的、来自全球的临床试验提供优质高效的服务，提高临床试验质量和进度，推动临床试验规范化进程。主要业务：负责全国临床 CRC 人员管理，提供临床试验研究协调服务、医院调研报告、问卷调查等服务。

北京善芴 SMO 服务以客户利益为先，本着对客户负责的态度，专业、扎实、诚信做项目，为每位客户的每个项目负责，致力于提供最好的 CRC 进行中心驻地管理服务。



Comprehensive——Comprehensive coverage of 24 provinces and cities.

Professional——To nursing, medicine, pharmacy, biotechnology.

Experienced——Rich working experience and good command of English.

Excellent——Familiar with the process, have passed the national GCP certification.

Familiar with blood sample transportation and laboratory requirements; Familiar with the use of various devices, have rich experience in clinical trials, are high-quality professional CRC.

CRC PERSONNEL QUALIFICATIONS

CRC 人员专业素质

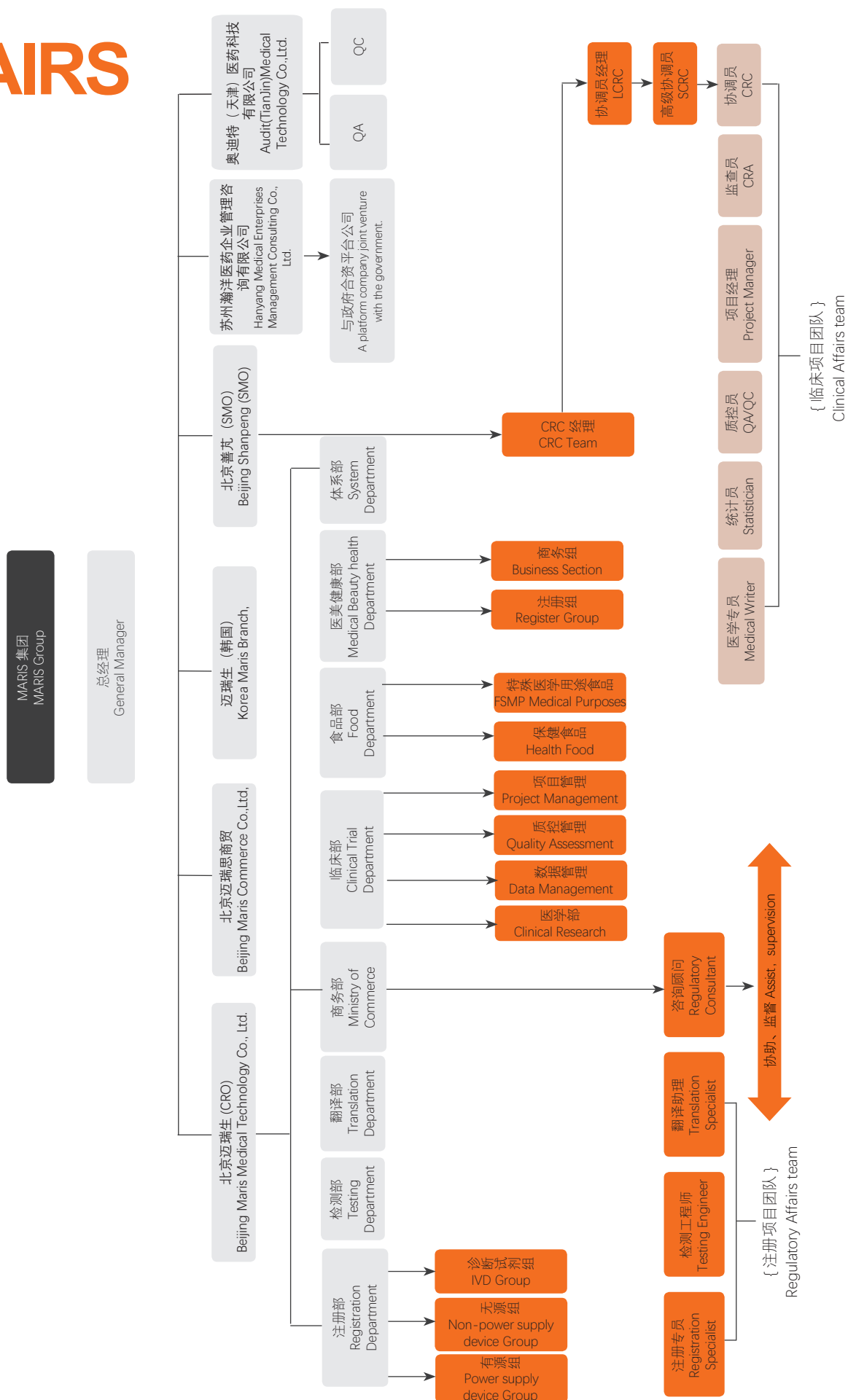


MARIS CRC 驻地
陆续扩增中

- 全**—— 全面覆盖 24 个省市；
- 专**—— 以护理，医学，药学，生物技术；
- 深**—— 工作经验丰富，良好的英语水平；
- 精**—— 熟悉流程，均通过国家 GCP 认证；
熟悉血液等标本的运送及实验室的要求；熟
悉各种器械的使用，有较为丰富的器械临床
试验经验，均为高素质的专业 CRC。

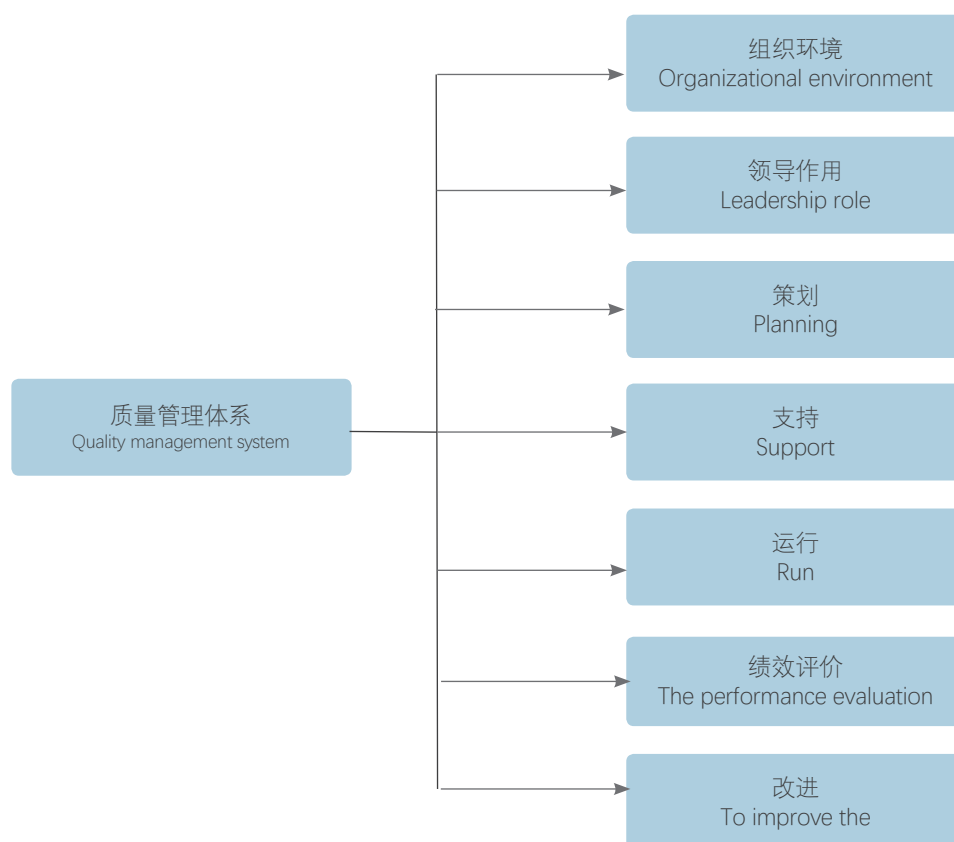
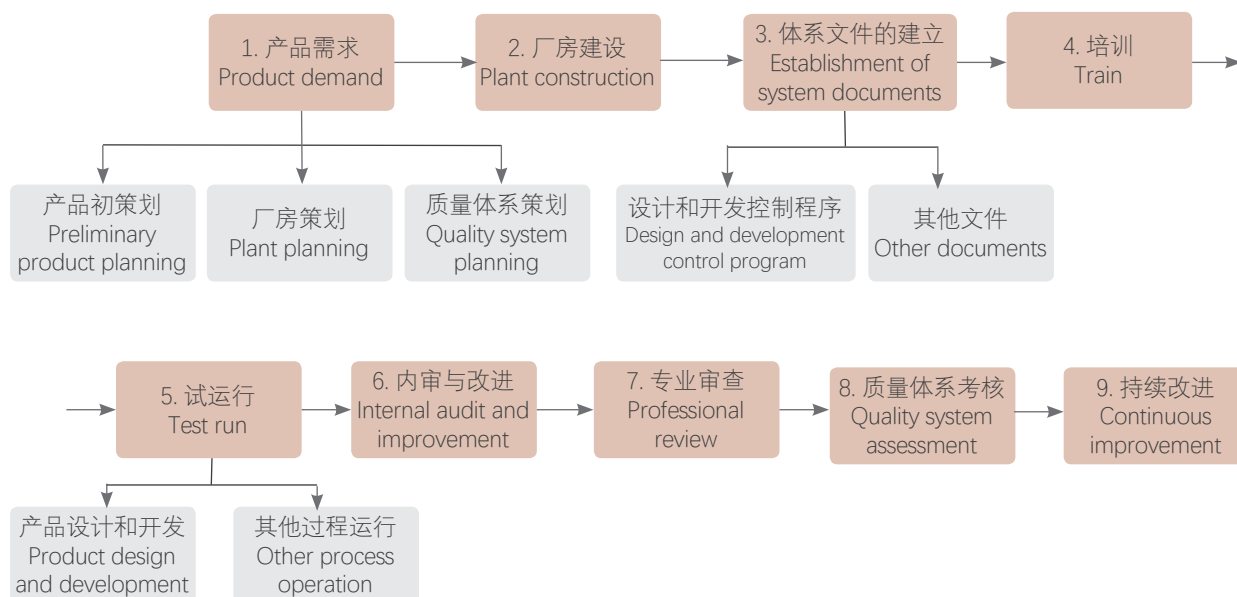
MAIRS

组织架构



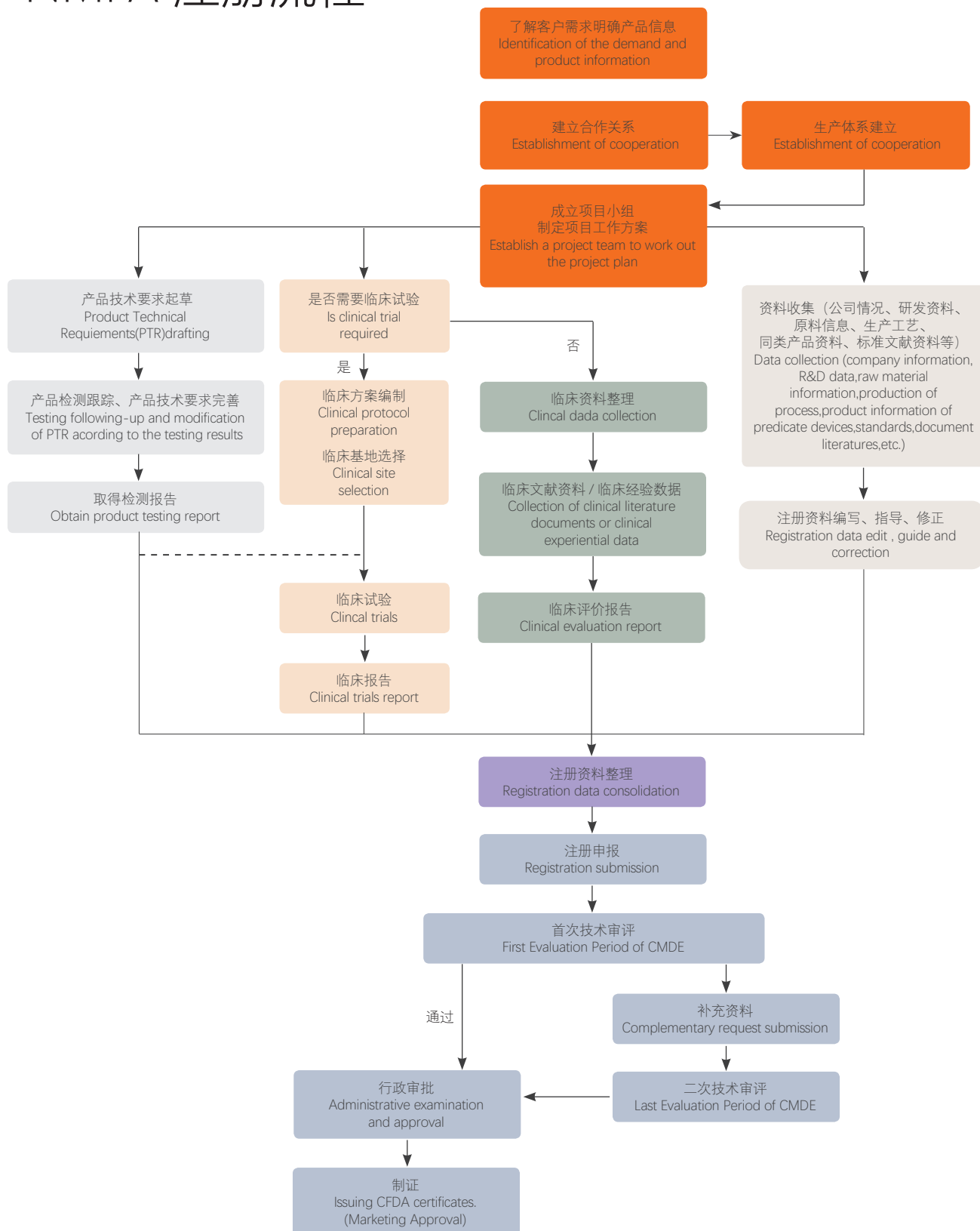
PRODUCTION SYSTEM FLOW

生产体系流程



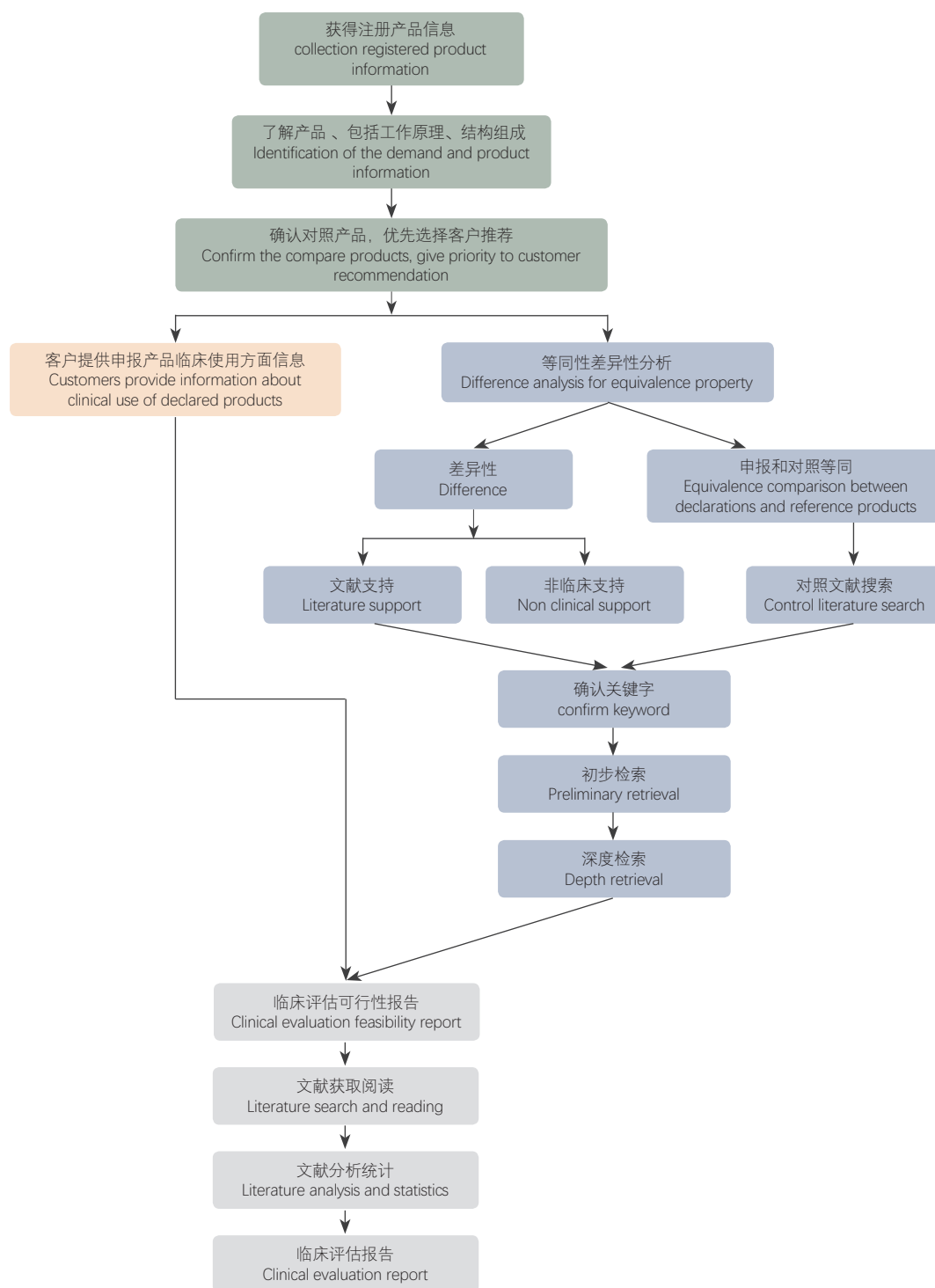
NMPA REGISTRATION WORKFLOW

NMPA 注册流程



CLINICAL ASSESSMENT PROCESS

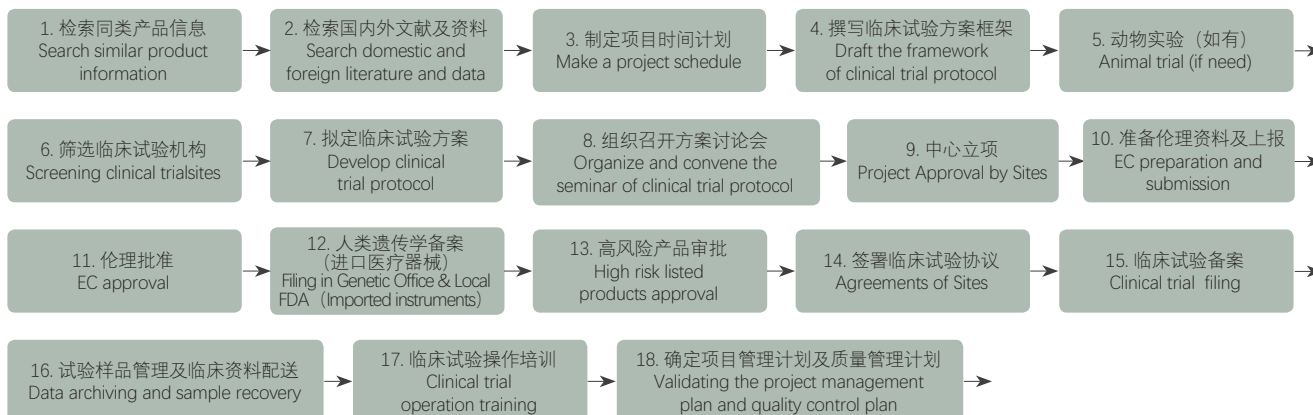
临床评估流程



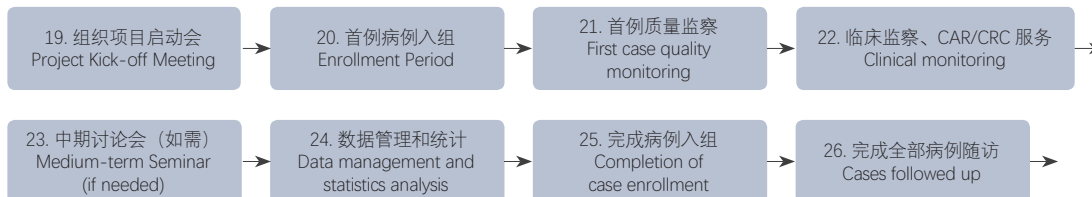
CLINICAL TRIAL PROCESS

临床试验流程

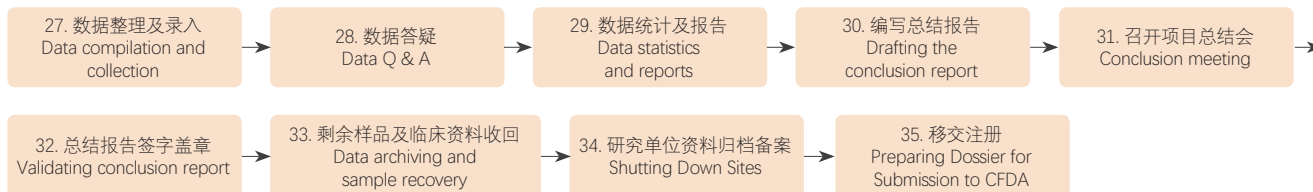
试验准备 clinical trial preparation



试验启动 start-up clinical trial



试验关闭 Close clinical trial



FSMP DEPARTMENT INTRODUCTION

特医食品部门介绍

具有丰富申报经验的团队，深刻理解相关法规和审评原则，精通申报的各个环节；

坚实可靠的专家资源，从立项到审评，全程技术支持，规避申报风险；

具有良好合作关系的检测机构，能够确保产品顺利检测，省时省力；

具有经验丰富的检测分析人员，确保注册检验过程及时、高效！

特医食品项目经验

FSMP project experience

| | |
|---|------------------|
| Whole nutrition formula food for FSMP | 特殊医学用途全营养配方食品 |
| Amino acid metabolism disorders formula products | 氨基酸代谢障碍配方产品 |
| Electrolyte formula | 电解质配方 |
| Carbohydrate components | 碳水化合物组件 |
| Protein component | 蛋白质组件 |
| Tumor whole nutrition formula food for special medical purposes | 特殊医学用途肿瘤全营养配方食品 |
| Other types of FSMP (pre-development stage) | 其他类别特医食品（前期开发阶段） |

特定全营养配方食品分类（13 种）

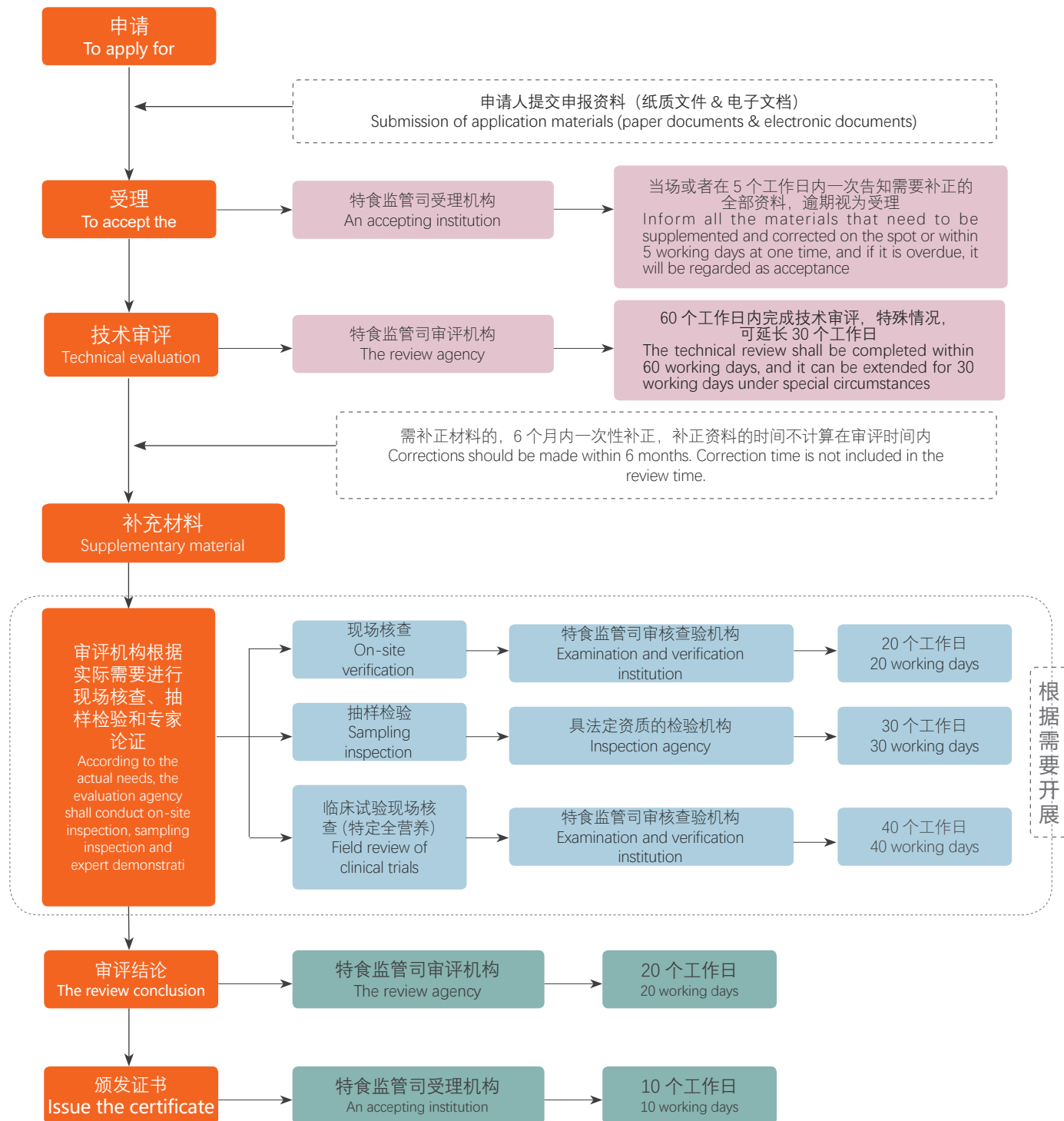
Classification of specific total nutrition formula (13 kinds)

- 1、糖尿病全营养配方食品 /Whole nutrition formula food for diabetes
- 2、呼吸系统疾病全营养配方食品 /Whole nutrition formula food for respiratory diseases
- 3、肾病全营养配方食品 /Whole nutrition formula food for kidney disease
- 4、肿瘤全营养配方食品 /Whole nutrition formula for cancer
- 5、肝病全营养配方食品 ※/Whole nutrition formula for liver disease※
- 6、肌肉衰减综合征全营养配方食品 ※/Muscle decay syndrome whole nutrition formula food※
- 7、创伤、感染、手术及其他应激状态全营养配方食品 ※/Whole nutrition formula for trauma, infection, surgery and other stress conditions※
- 8、炎症肠病全营养配方食品 /Inflammatory bowel disease whole nutrition formula food
- 9、食物蛋白过敏全营养配方食品 /Food protein allergy whole nutrition formula food
- 10、难治性癫痫全营养配方食品 /Whole nutrition formula food for refractory epilepsy
- 11、胃肠道吸收障碍、胰腺炎全营养配方食品 ※/Whole nutrition formula food for gastrointestinal malabsorption and pancreatitis※
- 12、脂肪酸代谢异常全营养配方食品 ※/Abnormal fatty acid metabolism whole nutrition formula food ※
- 13、肥胖、减脂手术全营养配方食品 /Whole nutrition formula food for obesity and fat reduction surgery

注 ※ 的五种特定全营养配方营养素调整证据尚不充分，法规暂未规定其营养素调整范围。

FSMP REGISTRATION WORKFLOW

特医食品注册流程



备注：对于不予注册的，申请人 20 个工作日内可提出复审申请，审评机构 30 个工作日内作出复审决定。

COSMETICS DEPARTMENT

化妆品部门介绍

The Aesthetic Medicine & Health Division of MARIS Group was established in 2012. Since the establishment, the Division has established a perfect ecological industrial closed-loop in the cosmetics field through long-term intensive cultivation, and is capable of providing domestic and foreign customers with multi-dimensional services including Registration and filing for import and domestic cosmetics, new raw materials Registration and filing and toothpaste filing as the main service contents, product customization and customs clearance support as the supplement. We have established long-term and stable cooperative relations with relevant government departments and inspection institutions, and have successfully filed various cosmetics in China, the United States, Japan, Korea and the European Union. And we have rich online and offline resources.

迈瑞生集团医美健康事业部成立于 2012 年，原名化妆品注册部，2020 年 1 月因为公司战略调整正式更名为医美健康事业部，部门成立来，通过 9 年多的深耕细作，建立了完善的化妆品领域生态产业闭环，能够为国内外化妆品客户提供以注册备案为主，产品定制、通关支持为辅的多维度服务。与相关政府部门、检测机构等建立了长期稳定的合作关系，线上、线下资源丰富。

业务范围

Scope of business

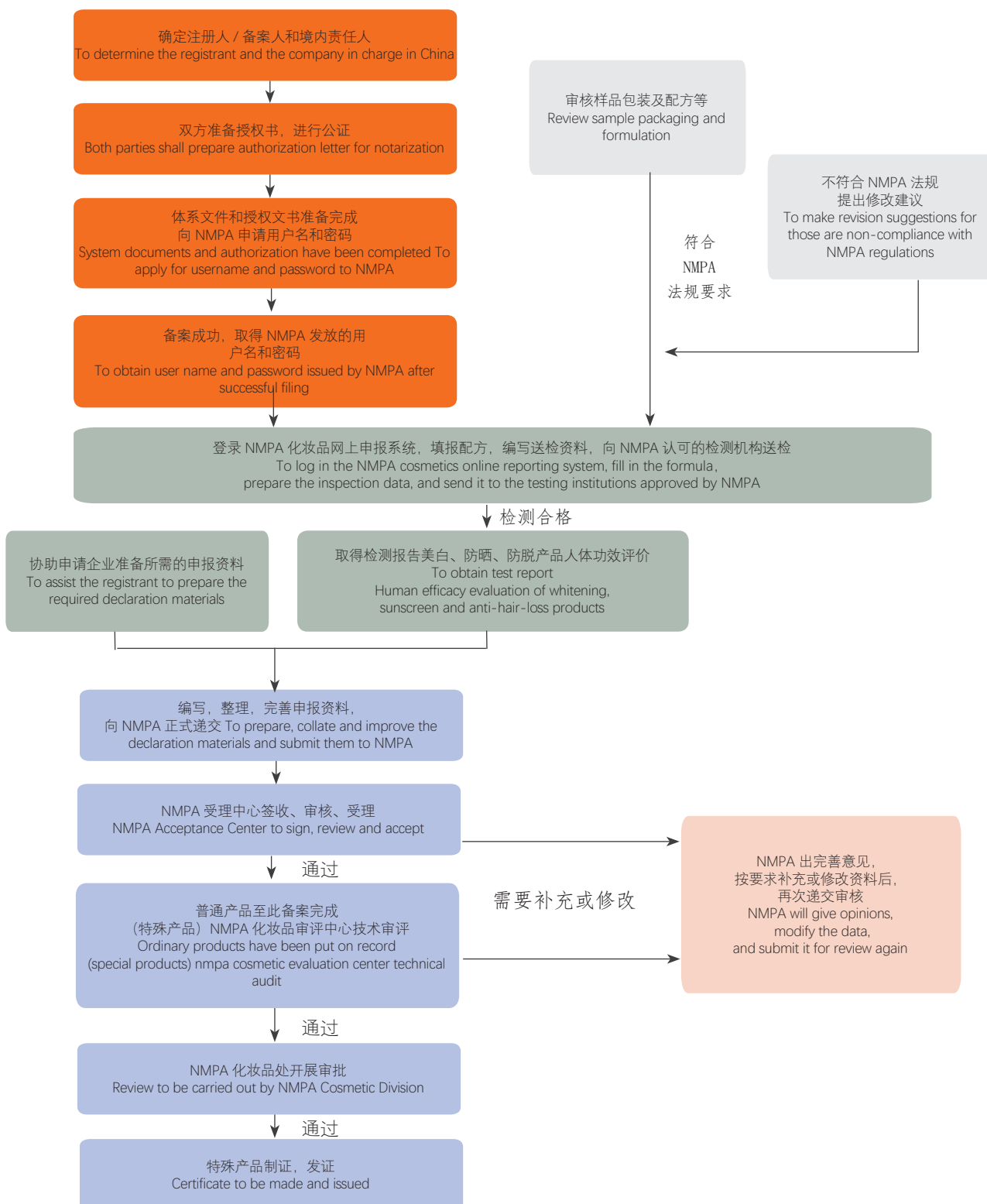


化妆品分类

| 特殊 化妆品 | 染发、烫发、祛斑美白、防晒、防脱发的化妆品以及宣称新功效的化妆品。 | | | | |
|-----------|-----------------------------------|------------------------|-----------------------|--------------------------|------------------------|
| 普通 化妆品 | 发用类 | 护肤类 | 彩妆类 | 指（趾）甲类 | 芳香类 |
| | 例如： 洗发液 护发素 发膜 | 例如： 洗面奶 乳液 面膜 | 例如： 胭脂 口红 眼影 | 例如： 洗甲水 指甲油 护甲霜 | 例如： 香水 古龙水 精油 |

COSMETIC REGISTRATION PROCESS

化妆品申报注册 / 备案基本流程



CLIENTS

部分服务客户

长期合作客户

欧美
Europe
and
America

stryker

natus

 **CareFusion**

BIO-RAD

 **STERIS**

 **NONIN**

 **Ortho Clinical Diagnostics**

B|BRAUN
SHARING EXPERTISE

**HAMILTON
MEDICAL**
Intelligent Ventilation since 1983

DynaMesh®

GRIFOLS

 **BioSystems**

 **TERUMO**
泰尔茂

 **MITSUBISHI**

 **SAKURA**

phcbi

 **GOODMAN**

alfresa

Allm SHAPING
HEALTHCARE

KYOWA KIRIN

韩国
Korea

selvas
Healthcare

OSSTEM®
IMPLANT

 **PharmaResearch**

 **RF MEDICAL**

 **Creative BioSolutions**

Jeisys

 **WONTECH**

Genewel
a Dongsung Company

 **HDX WILL**

 **PointNix**

CYBER1ED

 **philosys**

中国台湾
Taiwan, China

 **瑞光生醫**
科技股份有限公司

CHOICE

htc

 **T-PLUS**
Dental Implant

BIONIME

 **BAVI SPINE**
BAVI Biotechnology

 **中央醫療器材股份有限公司**

CGH

中国
China

 **MicroPort**
微创优通医疗

AEOMED 谊安
产品可靠 服务贴心

 **Cingular Biotech**
欣吉特生物科技

 **奥朋医疗**
Online Vascular Operation

 **PUYI**

SHINVA 新华医疗

LIRCON®
西尔康

DRAGON CROWN

 **CANWELL**
科惠

 **欣汶**
Xinwen Medical

TUORen

 **JINGJING**
京精医疗设备

 **INNOVEX**

 **ANOROAD**
安诺优达

 **GENOME**
安诺基因

 **事生医械**
SHENG MEDICAL

 **厚凯医疗**
Hocor Medical



CLIENTS

部分服务客户

长期合作客户

韩国化妆品
Korea

Cellromax Store

Cledbel

Dr.FORHAIR

JAYJUN

MEDI-PEEL

Coréana

LISANGE

EVER

DRESKIN | MOMELI

CHAMOS

FAU

MOOLDA
One Moolda One Kill

VITACOS Corporation

Anua

DMCK

iCure 아이큐어(주)
Pharmaceuticals & Cosmetics

Wyatt a kakao company

WELLAGE

CLIO
PROFESSIONAL

CELRANICO

特医食品注册申报案例

FSMP registration and declaration cases

项目类别
Project Category

| | |
|---|----------------------|
| 特殊医学用途全营养配方食品 Full nutritional food for special medical purposes | 数量：7 个 Quantity:7 |
| 氨基酸代谢障碍配方食品 Amino acid metabolic disorder formula | 数量：2 个 Quantity:2 |
| 电解质配方 Electrolyte formula | 数量：3 个 Quantity:3 |
| 碳水化合物组件 Carbohydrate component | 数量：2 个 Quantity:2 |
| 蛋白质组件 Protein component | 数量：3 个 Quantity:3 |

专业的团队
高效的沟通
优质的服务

We are Maris!

Contact Us

MARIS Beijing



TEL: +86-10-67166800

FAX: +86-10-64125512



WWW.MARIS-REG.COM

bd@maris-reg.com



北京市东城区广渠门内大街
90 号楼新裕商务大厦 A 座 9 层

MARIS Group Korea Co,Ltd



TEL: +82-02-6264-1737

FAX: +82-02-6008-7747



WWW.MARIS-REG.KR

mariskorea@maris-reg.com



No. 715, The Sky Valley 2, HausD,
1142, Beoman-ro, Geumcheon-gu,
Seoul, Republic of Korea

MARIS Taiwan Branch



TEL: (02) 7703-0559

FAX: (02) 8809-8993



中國台灣 25170 新北市淡水區中正
東路二段 27-10 號 10 樓

迈瑞生微信
官方公众号

