Normalline

Company and Service Introduction

Your reliable regulatory consultant concerning medical devices in China

About Us

Normalline， Founded in Beijing in 2008

Always focus on **the field of medical devices in China(MD & IVD)**

Provide online and offline omni-directional—— **Compliance support and management consulting services**

In the past 13 years, Normalline has worked with more than 100 well-known and innovative enterprises at domestic and abroad to provide reliable and high-quality service for customers at all stages of the product life cycle.

In particular, in the high-difficulty Class III of medical device segmentation market approved by NMPA, Normalline is in the leading position.

Invariable Original Intention

Normal

Regulation, standard, criteria

Line

Demarcation line

Normalline-Compliance Services

Normalline

Translate into normal，

The shortest distance from an off-line point to a straight line，

Reflecting compliance also requires efficiency and economy

Greening tree-Customer Business Development

Greening tree is like customer, representing our service to support the expansion and development of the customer's business

2008

2021

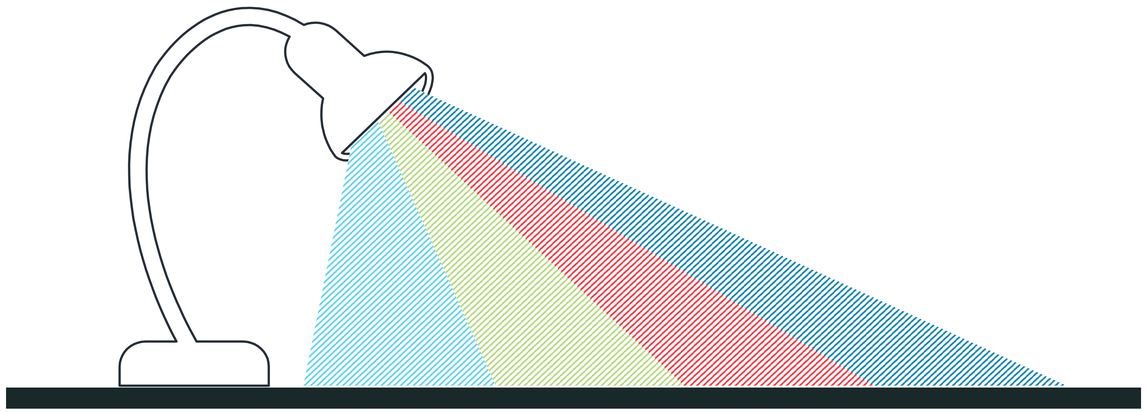
From the beginning of establishment, we are firmly committed to this:

Fixed position： In the field of medical devices in China, compliance support services are provided.

Vision： With professional, high-quality, efficient service, support and escort the smooth development of customer business! **Promise：** Strictly abide by the boundaries of laws and regulations to provide valuable services

Become your reliable regulatory consultant concerning medical devices in China

Concentration and Accumulation



China	MD&IVD	NMPA/High Risk	Compliance
No ~~FDA~~ ~~CE~~	No ~~Drug Biologicals~~ ~~Cosmetics~~ ~~Health products~~ ~~Special food~~	No ~~Domestic~~ ~~Class I,~~ ~~Class II~~	No ~~FinancingAgent~~ ~~DistributerRent,etc~~

Focus On

- NMPA(National Medical Products Administration)
- Field of MD and IVD
- NMPA approval items- High risk products
- Compliance support and management services

Accumulated.

- Convergence **Professional Team**
- Accumulation 920+ Class III high-difficulty projects **practical experience**
- High frequency contact，**Accurate close to regulatory cognition**
- Omnibearing specification of high-quality service，**With the support of** your requirements

Company Events

2009

The first On-line current regulations and libraries in China and Regulatory Tracking and Analysis Services Maintenance until now 12 years

2010

Take the lead in putting forward a new concept in the field - “Compliance is a management issue”. Change the traditional agent service model and create the Compliance and Management Service Model in an all-round way

2011

Around the core competencies
Launched the new service
“Emergency Support of Registration Supplementary”
"product registration strategic planning service"
“Expert consultation meeting support” etc.

2012

- Build and keep compacted service specification and quality assurance system
- Cumulative success rate of declared projects exceeds 90%
- The establishment of the service personnel’s capability model and the performance system

2015

- Create WeChat Subscription account, the Focus on the CMDRA over 70000 people
- The coverage rate of the top 100 MD enterprises in the world is more than 35%
- Operation of customer satisfaction management system

Company Events

2016

- Launch of Post-Market compliance services
- Good Supply Practice (GSP) plug-in IT service
- Opening a new service mode for compliant IT
- Annual customer satisfaction 95%

2017

- ISO9001:2015 certification of SGS for all-line service
- Expand the clinical trial service team and enhance the service scale
- Cumulative more than 1200+ of the Class III of declaration items
- The cumulative declaration item of the project is over 92%

2018

- A specially developed for compliance people full life cycle online service platform—Compliance tool On line
- Has 49 online databases

2019

Service specification and quality control system informatization
CER, real world data scaling
More than 50 medical device innovation projects
Establish a customer-centered three-dimensional service system

2020

Establish a service support knowledge base system
Service satisfaction 97%
The proportion of repeat customers exceeded 70%
More than 70 medical device innovation projects

Our Customers

- We provide reliable customization services for large enterprises at domestic and foreign companies for regulatory strategy compliance resolution, decision support and expert consultation;
- We provide medium - sized enterprises with high - quality flexible program portfolio, efficient and standardized professional services;
- We offer a series of companion support services for innovative products and start-ups.

- Main technical categories：
- **Passive device:**

Stent, Guide Wire and Catheter, Patch, Implantable Contact Lenses , Soft Contact Lens, Biodegradable materials, Drug-loaded Materials, etc.

- **IVD:**

Molecular Diagnosis, NGS, Companion Medicine Diagnosis, Blood type, Neonatal, microorganisms, etc.

- **Active device：**

Surgical Navigation System, Blood Dialysis, Endoscope, High Frequency Instruments, Monitoring Instrument, Software, etc.

Our Characteristics

01

Cumulative 13 years, all declaration service (including registration, clinical trial, CER) success rate is 92%，Class III projects are over 86%

02

Reliable data support, continuous accumulation and updating, better close to regulatory requirements.

- We have 49 databases, 26 owned databases, covering regulatory, guiding principles, standards and specification cases to ensure the most reliable information and requirements for customers.
- Focus on overseas and Class III Medical Device，We can communicate with regulators in high frequency, high density and in depth.， So as to more accurately interpret the requirements of the technical review.

03

Full life cycle service，help us stay close to our customers' multifaceted requirements. Provide a high-quality, all-round, efficient solution for our customer.

- Unique service：Emergency Support of registration supplementary , Development and Management of the Registration-oriented、Customized GSP Compliance plug-in IT Service.Compliance Decision Support Services, etc.

Management Certificate- SGS ISO 9001-2015

此为证书 CN18/10042 译本

下述组织

诺沃兰生物科技(北京)有限公司

注册地址: 中国北京市北京经济技术开发区荣华中路 19 号院 1 号楼 A 座 310 室

经营地址: 中国北京市北京经济技术开发区荣华中路 19 号院 1 号楼 A 座 310 室

统一社会信用代码 91110302680451739

的管理体系已经过审核，并被证明符合下述要求

ISO 9001:2015

所涉及的活动范围覆盖

提供医疗器械及体外诊断领域法规信息与分析、合规咨询及应对支持、申报支持与代理(包含产品注册、临床评价、临床试验、临床试验核查)、合规管理及辅助服务(医疗器械对应质量管理规范的建立与核查辅导)

该证书的有效期自 2021 年 01 月 29 日至 2024 年 01 月 28 日

组织必须定期接受监督审核并经审核合格此证书方继续有效

持续认证至少在证书失效前 60 天执行

版本号 2. 初始注册日期 2018 年 01 月 29 日

签署

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3 EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

本证书信息可在国家认证认可监督管理委员会官方网站www.cnca.gov.cn上查询

HC SGS 9001 2015 0118

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Certificate CN18/10042

The management system of

Normalline Biotechnology (Beijing) Co., Ltd.

Business Registration Address: Room 310, Tower A of Building 1, No. 19 Ronghua Middle Road, Beijing Economic -Technological Development Area, Beijing, P.R. China
Business Operation Address: Room 310, Tower A of Building 1, No. 19 Ronghua Middle Road, Beijing Economic -Technological Development Area, Beijing, P.R. China

Unified Social Credit Code 91110302680451739

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Provision of Regulatory Information and Analysis, Compliance Consulting and Solution, Submission Support and Agency (Premarket Approval, CER, CRO, Clinical Trial Audit), GXP (GCP, GMP, GSP, GUP) Compliance Management and Assistance Services in Medical Device and In Vitro Diagnostic Industry

This certificate is valid from 29 January 2021 until 28 January 2024 and remains valid subject to satisfactory surveillance audits. certification audit due a minimum of 60 days before the expiration date.
Issue 2. Certified since 29 January 2018

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com
The certification information can be verified on the web site of Certification and Accreditation Administration of the People's Republic of China www.cnca.gov.cn

HC SGS 9001 2015 0118

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- Provision of Regulatory Information and Analysis, Compliance Consulting and Solution, Submission Support and Agency (Premarket Approval, CER, CRO, Clinical Trial Audit) , GXP(GCP, GMP, GSP, GUP) Compliance Management and Assistance Services in Medical Device and In Vitro Diagnostic Industry.

0 Finding to pass the SGS supervisory audit for three consecutive years

The only service enterprise in the industry that covers the whole line of business

Our Services — Off Line

Compliance strategy consultation& Management service

Application of management methods

System guarantees continuous and effective compliance

Post-Market Compliance IT nization

GSP Compliance Plug-in IT Service

First-time management of qualification data, sharing and tracing

Emergency Support of Registration Supplementary

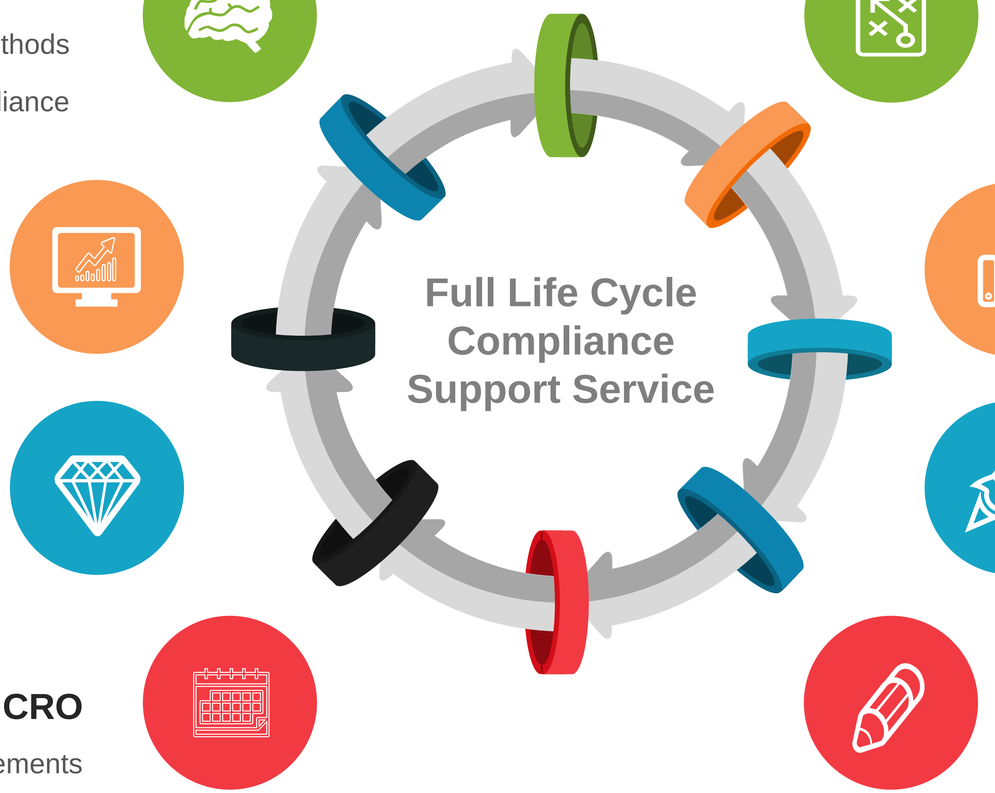
Support the final challenge with professional technology and successful experience

Clinical Trial Support CRO

Combined with product registration requirements

Focus on registration success

High-efficiency, standardize and economic implementation



Registration oriented development management

Integrating registration requirements into the development and management process

Innovation and Definition

Get the opportunity to communicate in advance

Accurate determination of starting point

Registration application support

Whole process risk control

Professional support success

CER / Real world data

Process science risk prediction

Professional and technical services

High success rate

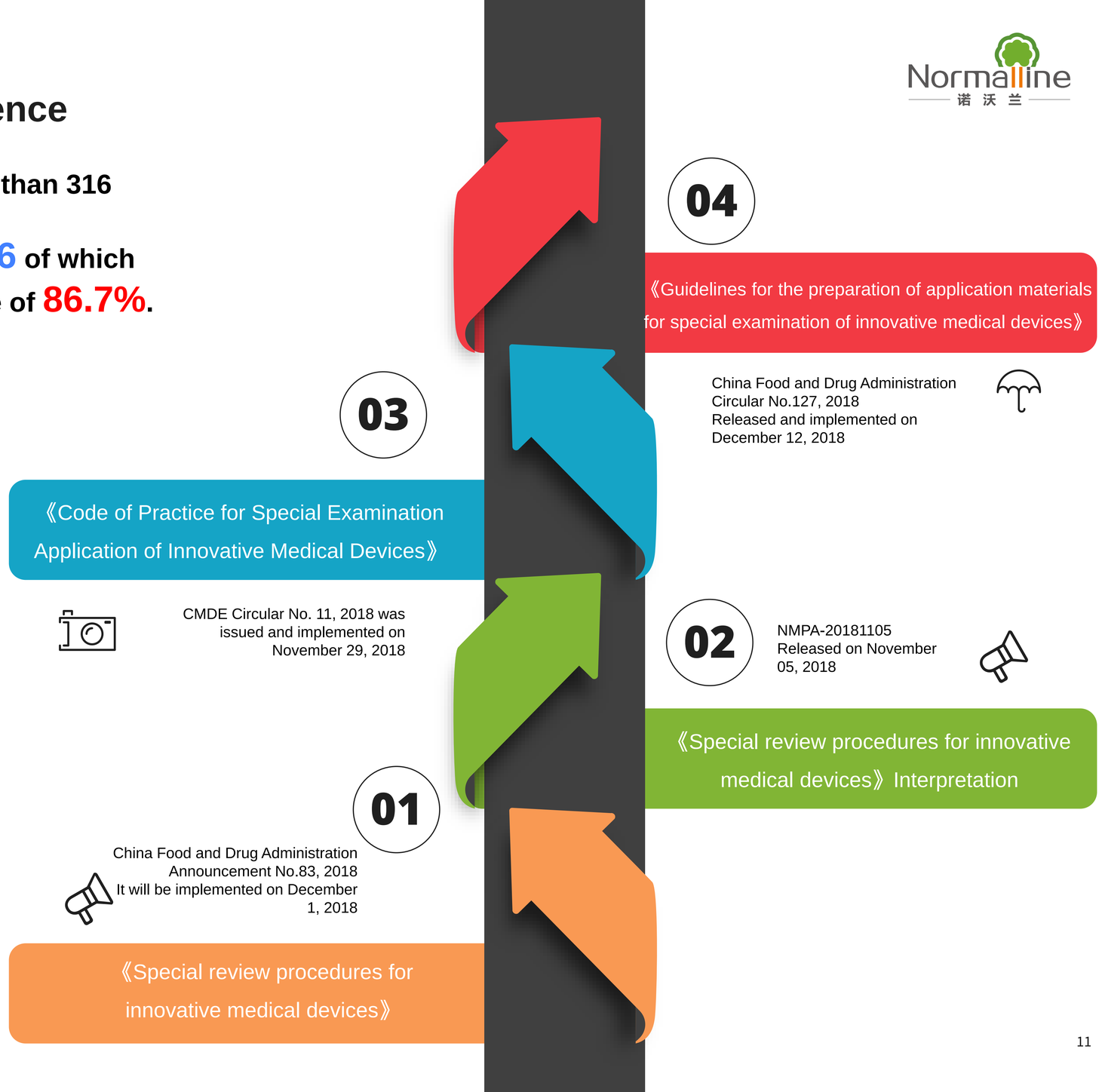
Submission on Innovation case experience

Since the "Innovation" channel opened in 2013, more than 316 products have been successfully approved,
Among them, we provide services for 53 products, 46 of which have been approved successfully, with a success rate of 86.7%.

The new Regulations of 2021 enhance the value of innovative Medical devices

Article 8 The State formulates plans and policies for the medical device industry, brings the innovation of medical devices into the focus of development, gives priority to the evaluation and approval of innovative medical devices, supports the clinical promotion and use of innovative medical devices, and promotes the high-quality development of the medical device industry. The drug regulatory department under the State Council shall cooperate with the relevant departments under the State Council to implement the national medical device industry planning and guidance policies.

Article 9 The State shall improve the innovation system of medical devices, support the basic research and applied research of medical devices, promote the popularization and application of new technologies of medical devices, and provide support in scientific and technological project approval, financing, credit, bidding and procurement, medical insurance and other aspects. Support enterprises to set up or jointly set up research and development institutions, encourage enterprises to cooperate with institutions of higher learning, scientific research institutes and medical institutions to carry out research and innovation of medical devices, strengthen protection of intellectual property rights of medical devices, and improve the ability of independent innovation of medical devices.



Our Services — Key Points of Innovation Value Declaration

- Communicate with the product reviewer face to face.
- It has a dedicated person in charge and a review team of more than three people to jointly support it.
- Unlimited formal communication and written confirmation is available.
- The communication content includes clinical trial scheme, major technical issues, determination of evaluation indexes, etc.
- Testing, system verification, review and approval are given priority.
- It can effectively speed up the time limit of review and approval.
- Promote the determination of the clinical application of the product.
- Share the risk of product registration.
- Learn product registration knowledge and accumulate product registration experience quickly.
- Industry reputation and influence.
- Small and micro enterprises are exempt from innovative product registration fees.
- …….

The best and most valuable green channel.

Escort your products for clinical trials, registration and marketing!

Process and Services for Submission Support on Innovation

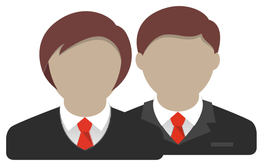
1. Submit Innovation Applications

2. Summary and compilation of innovation document

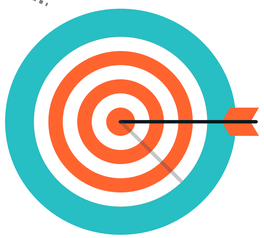
3. Submit to the provincial bureau for preliminary examination

- Imported products are submitted directly to NMPA

4. After passing the preliminary examination, it will be submitted to the State Bureau Acceptance Center



5. Setting up an Innovation Office
6. The Innovation Office organizes expert discuss



7. Publish the result

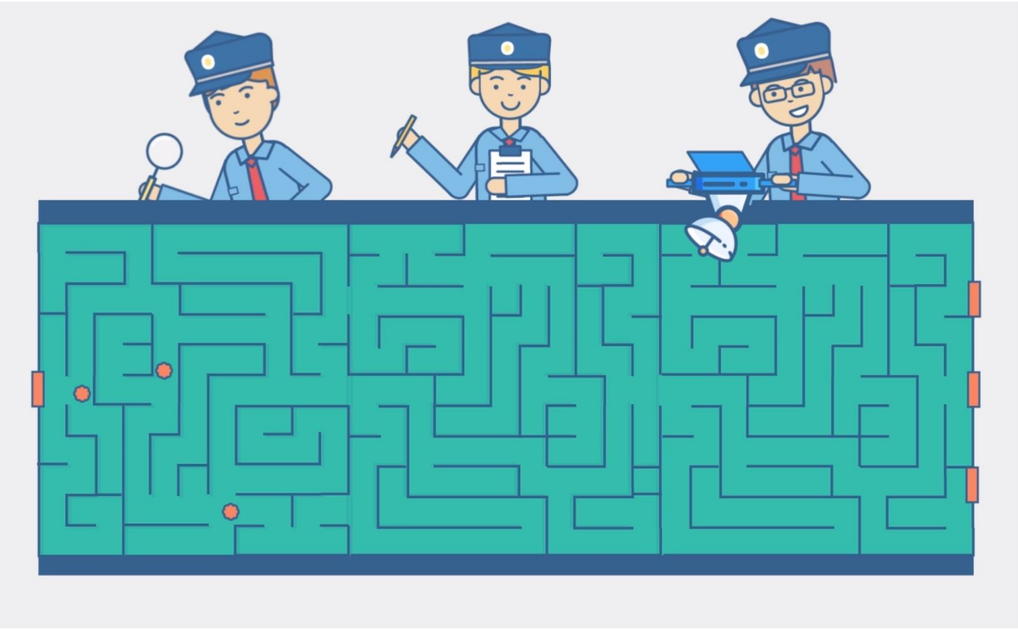
Normalline

1. Product core content evaluation
2. Clinical significant value demonstration
3. Viewpoint evidence support and discussion
   - PPT preparation
   - Deal with the expert meeting process
   - Forecast Expert Problem
   - Expert meeting drill guidance

Our Services — Declaration Support on Product Registration

Increasingly comprehensive, complex, changing and fine declaration and technical requirements

Does it worry you?



We use：

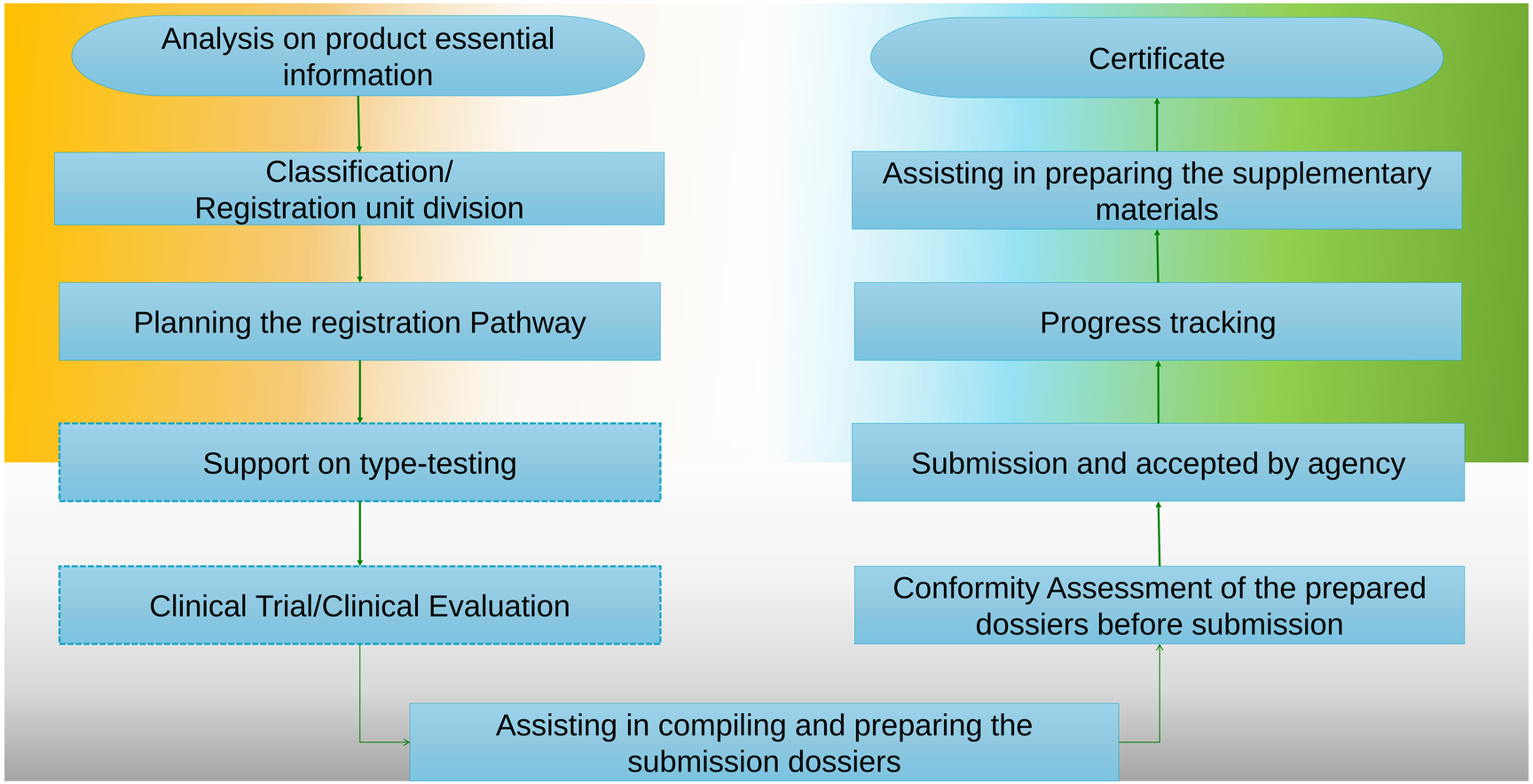
- Reliable knowledge and data, pragmatic experience support
- Standardized service and quality control ensure
- Accompanied by comprehensive and meticulous support services

To help you quickly, rest assured of the success of registration!

Registration declaration support service

- Registration strategy planning
- Full process registration support
- Registration variation support
- Qualification maintenance support

Registration Service Workflow



Service Assurance for Product Registration

Communication with NMPA (CMDE)

Accurately mastering the latest requirements/
Practically improving the success rate of registration

Professional team support

Supporting from several fields' professional team/Assisting in registering
with rich successful experiences

Project management

With the milestone node control, effectively supporting the project achieved in time

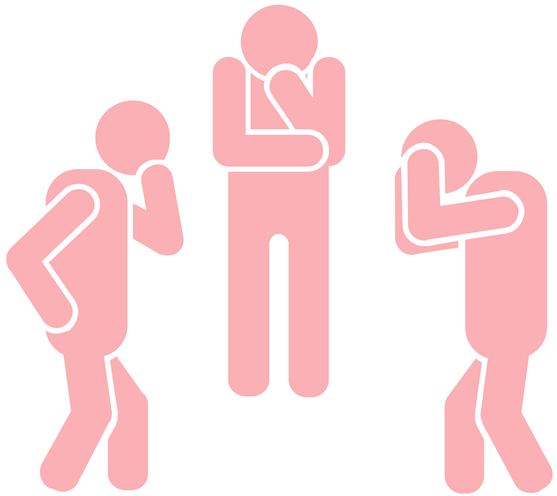
Our Services — Clinical Trial Support

High cost, can you ensure the success of registration?

For a long time, what if something goes wrong in the process?

What about the delay of the process and the change of personnel?

How to choose the right service provider?



CRO Providing registration services – The cornerstone of success

The final purpose of the clinical trial is to register the product, so consider the registration requirements

The protocol is particularly important, and the service provider should be able to ensure its reliability.

CRO With a management guarantee – Reliable guarantee

Team composition, project management, process progress, etc., the conventional requirements should be fixed and visible operational security. Coordinate the seamless docking of all parties, exception issues to deal with the plan.

CRO For MD&IVD – professions and attention

Instruments and reagents are different from drugs, registration clinic is also different from scientific research clinic, its GCP specification, scientific judgment, time cost are different.

Only choose the right one,
not the expensive one!

Our Services — Clinical Trial Support

- **Obtain clinical trial report**
- **Support for registration approval**

- **With customers**
- **With clinical trial site**
- **With investigator**
- **With statistics expert**

- **Project Management- Process management, risk management， Communication management, document management, etc.**
- **Clinical Trial Team- Senior consulting specialist, regulatory expert, project leader, Clinical specialist , CRA**

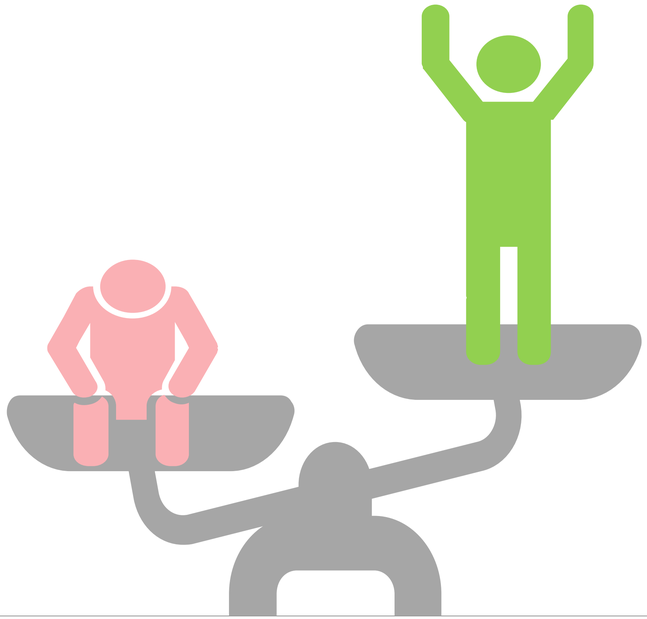
- **Provide Clinical trial Management and GCP Control system Construction for Global Top 50 Enterprises**
- **ISO9001-2015 Quality System Certification of SGS**
- **Special person to evaluate NMPA regulations update**

Clinical Trial Support Services CRO+

- Clinical protocol design and success rate analysis
- Site screening and ethical support
- Project management
- Standard and system Construction of Clinical Trials GCP
- Clinical trial monitoring CRA
- Data management and Statistical analysis
- Support for the writing of clinical trial reports
- Clinical adverse events monitoring and management support

Emergency Support on the Supplementary Submission —

Exclusive 11-year Service



Registration Supplementary, It is the "final battle" of registration.

Usually, it's not a set of templates, running errands, and asking questions that can be solved.

At this moment, what you need is special forces!

For eleven years,

800+ Supplementary documents 20000+ requests，Item-by-item analysis, point-by-point correspondence,

Into our—— **knowledge accumulation and delivery system**

Based on this, we provide you with the most effective emergency support services!

***Emergency Support of Registration Supplementary：** It refers to the "Notification of Supplementary Information for Medical Device Registration" document issued by the CMDE technical review center of the NMPA (Supplementary notice)，We assist you in the supplementary requirements analysis, the content organization, and the related services supported by the review and communication.

Online RA Box

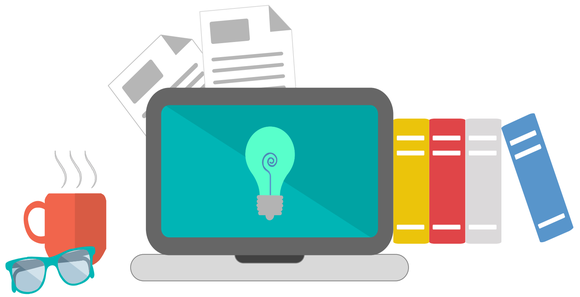
www. normalline. com

Designed for MD & IVD Compliance

24-hour maintenance and continuous updating and improvement

Online compliance support platform

Make your work easier and happier!



Our Services — Online RA Box

法规
信息库

Click & Video overview

Scan

Easy Journey to Your work

Utility tool library

49 professional databases

26 unique databases

Support your professional query and comprehensive application!

Library of existing regulations

Comprehensive information sources for 24 hours to monitor regulatory changes;

One-minute overview Keyword search

Full support for your regulatory application needs!

Inspection Case base

Summary of GXP inspection reports

Help you answer the regulatory scale!

Authoritative Q&A Center

Bring together authoritative answers from regulatory, corporate and third-party experts,

Compliance, own knowledge!

Application Practice Guide

From the step process, the actual operation diagram, the template download, To experience a reminder, at a glance, help you become an expert for a second!

Our Services — Online RA Box

One-stop

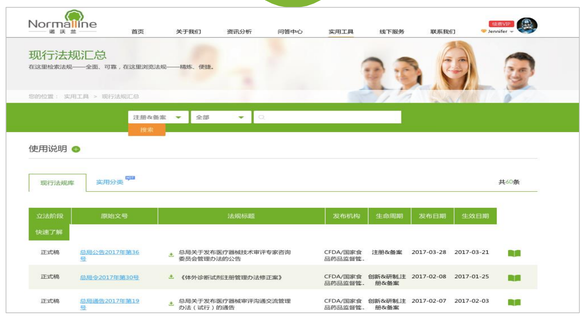
Comprehensive regulations, standards and regulatory information in the field of medical devices are a reliable and basic guarantee for you to run your business in China.

Professional and Comprehensive

1000+Summary and analysis of regulations、21 application information templates、nearly 49 searchable databases, for pilotage, navigation, and escort in advancing your business in China.

Unique

Only one Real-time update, structured, searchable medical device compliance database！



Our Services — Online RA Box

Free Subscription Account CMDRA

Scan，Regulatory analysis information for more than 2500 days；

Focus on CMDRA,

You can see what RA in China have been concerned.

010-6783 2007

Tel

Register Now, Free experience

Library of existing laws and regulations

Call us，

With your private compliance secretary,

24-hour personal support service.

GSP Software Service — Characteristics

Plug & Play

Product-based software services

Docking regulatory

Online and offline Inspection
in response to regulatory

System integration

Comprehensive Compliance Integration
of IT system

3D compliance

Process, system, data comprehensive
compliance solution

One stop solution for Supplying Compliance

GSP Software Service — Concept

Help customers to set up a IT system which can guarantee the continuous compliance operation of company, through the integration of GSP software and system compliance with the shortest time and lower cost and without changing the original business status.

01 Fully meet regulatory requirements;

02 Maintain the original state of the business;

03 Quickly put into use and serve as a portal and vehicle for corporate compliance;

04 Continuous focus on regulatory changes and industry demands and quick response;

05 Tailor-made plan according to customer demand.

Quick Understanding

One-stop compliance solution center

Membership, deep support

www.normalline.com

Tel: 010- 6783 2007

Accumulate with time,
Speak with facts!

Free Subscription Account

Scan，Regulatory analysis information for more than 2500 days；

Focus on CMDRA，You can see what we're doing every day；

You can see what RA in China have been concerned.