# 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 11 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

2019

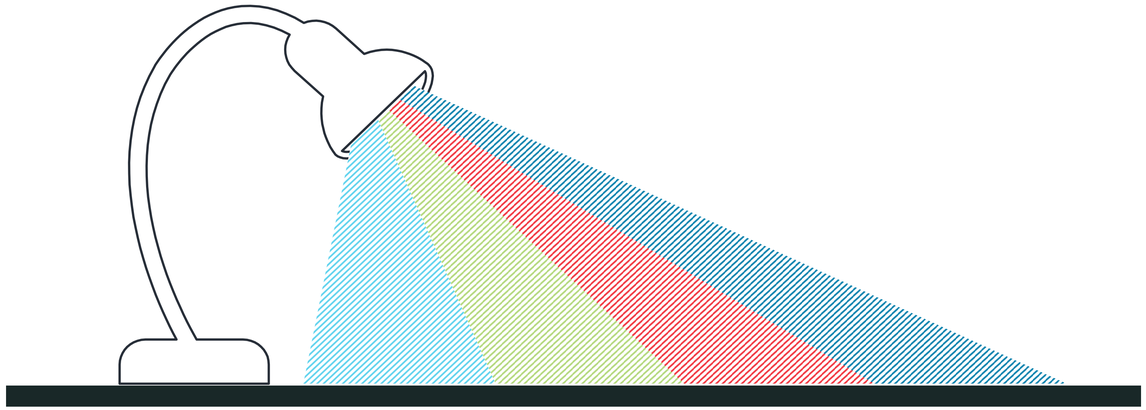
**From the beginning of establishment, we are firmly committed to this:**

**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<br>~~FDA~~<br>~~CE~~ | No<br>~~Drug Biologicals~~<br>~~Cosmetics~~<br>~~Health products~~<br>~~Special food~~ | No<br>~~Domestic~~<br>~~Class I,~~<br>~~Class II~~ | No<br>~~FinancingAg~~<br>~~ent~~<br>~~DistributerR~~<br>~~ent,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 of a large number of 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 10 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 38,000 people
- The coverage rate of the top 100 MD enterprises in the world is more than 35%
- Operation of customer satisfaction management system

**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 $1000^{+}$ of the Class III of declaration items
- The cumulative declaration item of the project is over 92%

**2018**

- An online service platform specially developed for Chinese device compliance personnel - Compliance tool On line
- Service specification and quality control system IT nization

# Our Customers


- 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.

- 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.

# Our Characteristics

01 **Cumulative 11 years, all declaration service (including registration, clinical trial, CER) success rate is 92%，Class III projects are over 80%.**

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

- We have 43 databases,22 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.

# 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

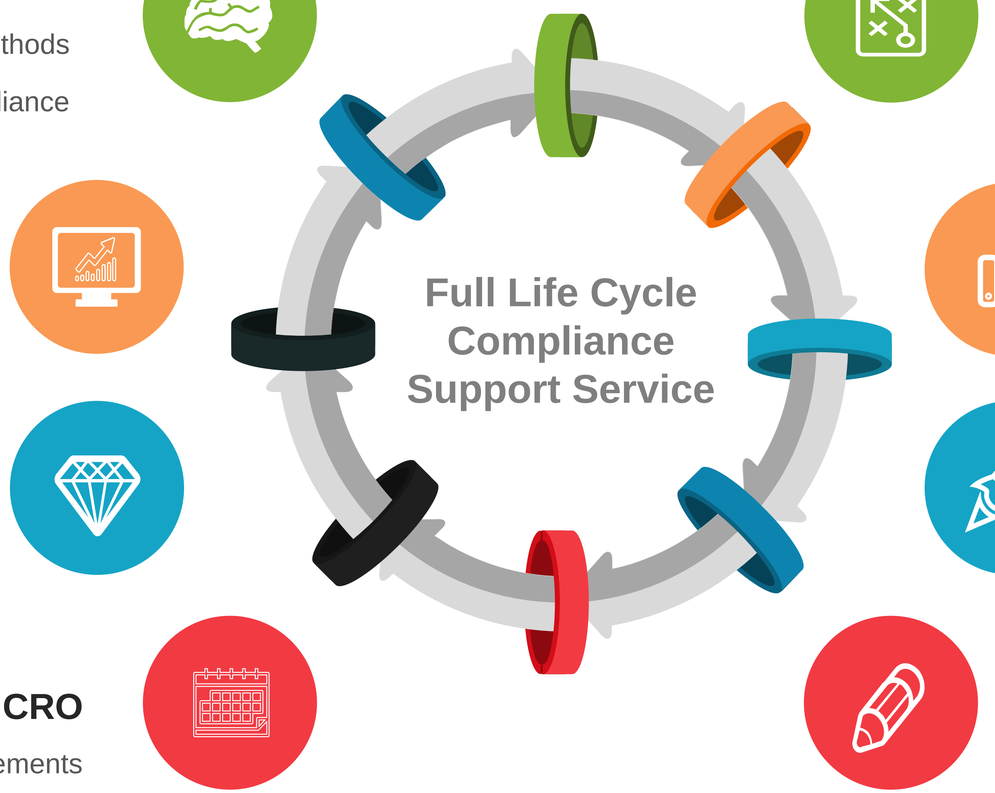
Support the final challenge with professional technology and successful experience

## 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

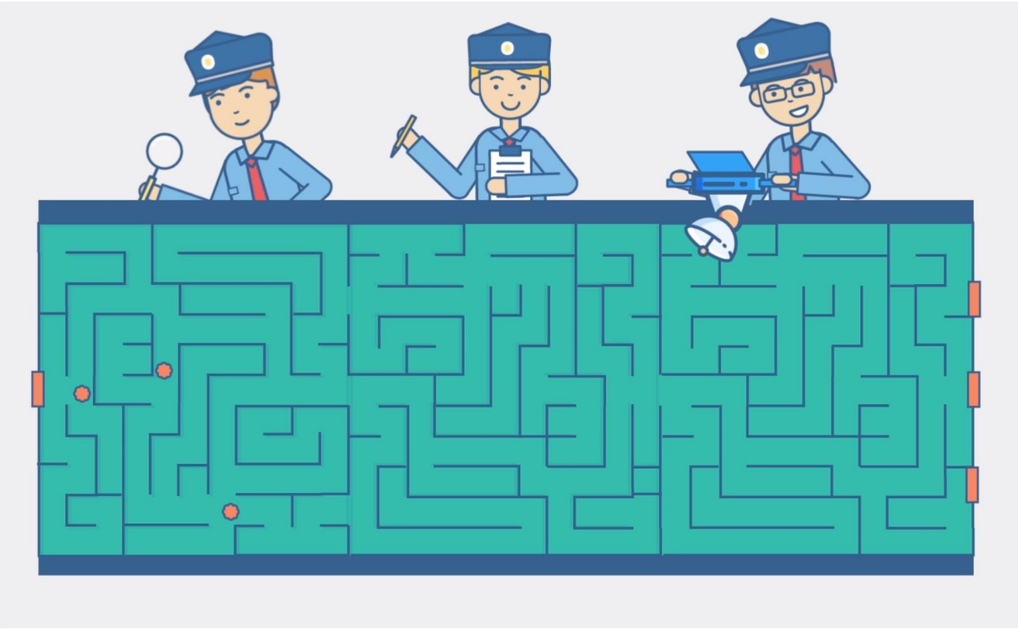
Process science risk prediction

Professional and technical services

# Our Services — Declaration Support on Product Registration

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

## Does it worry you?



We use：

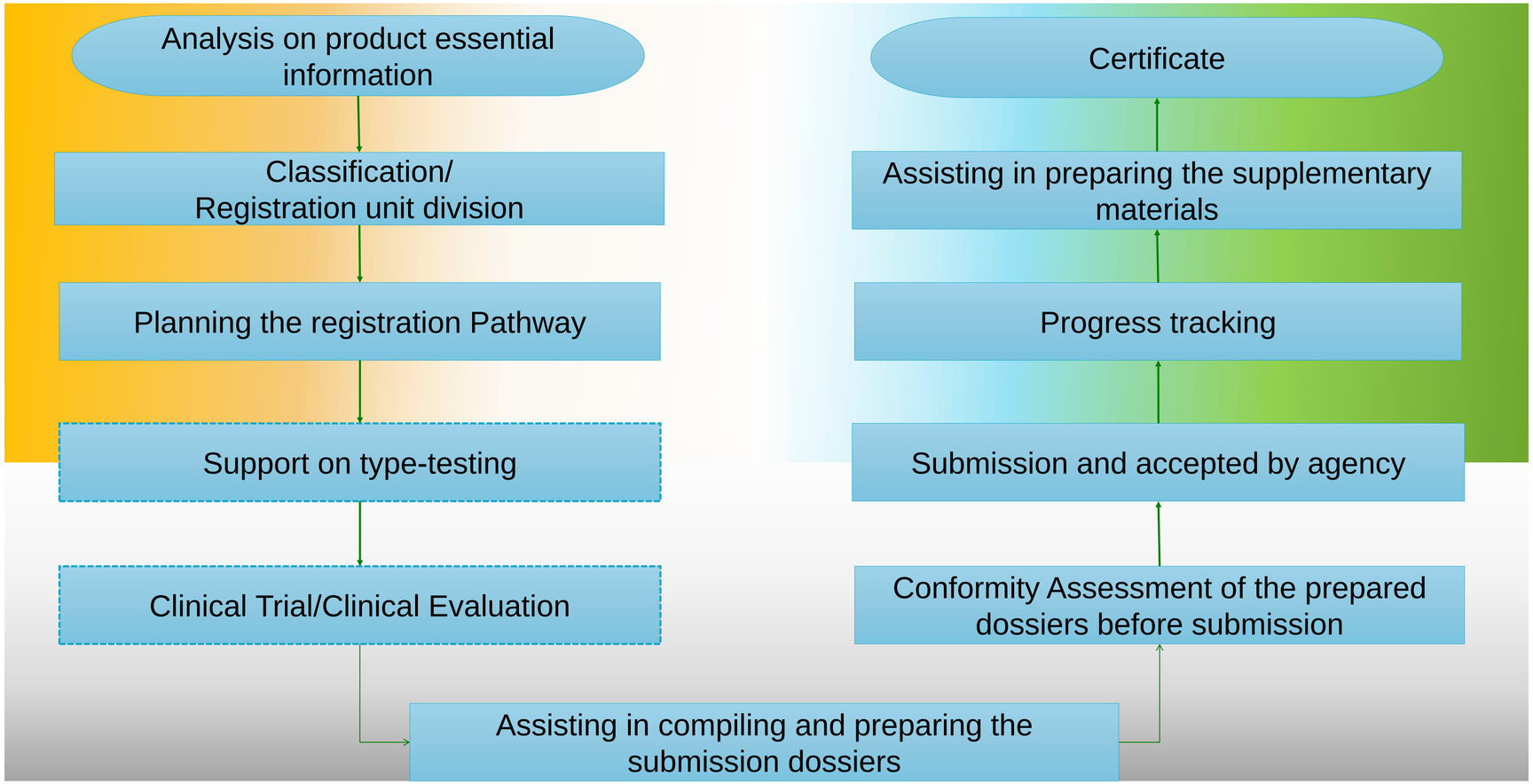
- Reliable knowledge and data, pragmatic experience support
- Standardized service and quality control ensure
- Accompanied by comprehensive and meticulous support services

## 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

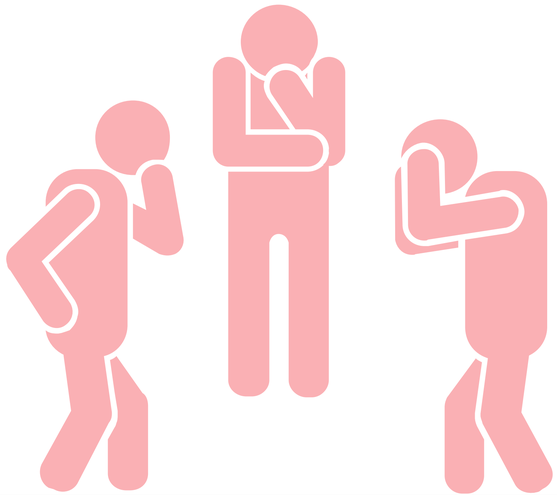
# Our Services — Clinical Trial Support

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**

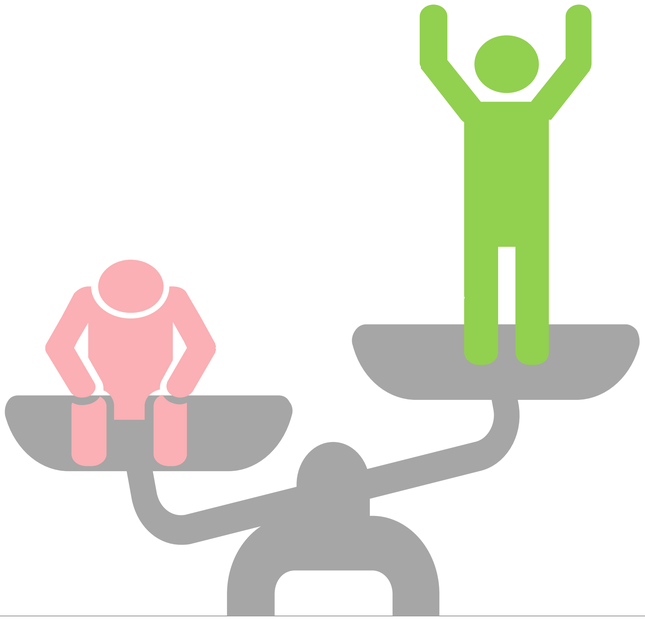
- **Provide Clinical trial Management and GCP Control system Construction for Global Top 30 Enterprises**
- **ISO9001-2015 Quality System Certification of SGS**
- **Special person to evaluate NMPA regulations update**

## 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 8-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 eight years,

**400+ Supplementary documents 9000+ 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 CFDE 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

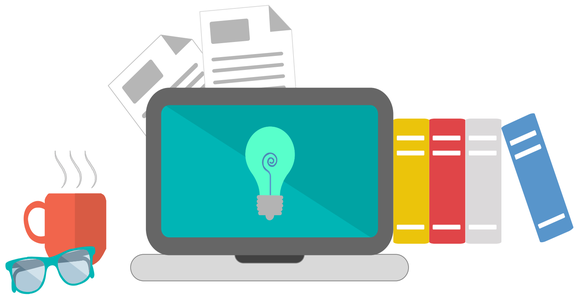
www. normalline. com

**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

## Click & Video overview

**Scan**

**Easy Journey to Your work**


### Utility tool library

**43 professional databases**

**22 unique databases**

Support your professional query and comprehensive application!

### Library of existing regulations

Monitor more than 130 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!**

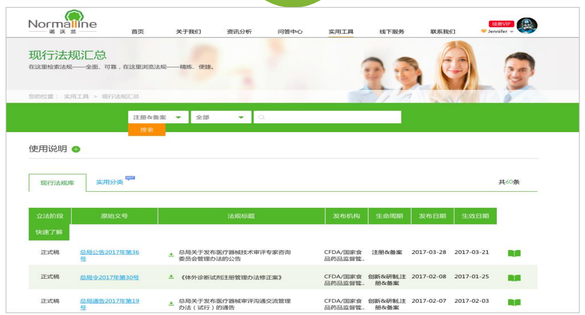
### Application Practice Guide

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**

800+Summary and analysis of regulations、40+application information templates、nearly 20 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！

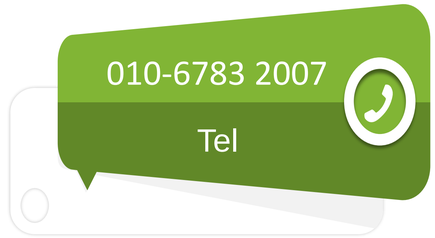
# Our Services — Online RA Box


## Free Subscription Account CMDRA

**Scan，Regulatory analysis information for more than 1900 days；**

**Focus on CMDRA,**

**You can see what RA in China have been concerned.**




## 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 1900 days；**

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

**You can see what RA in China have been concerned.**