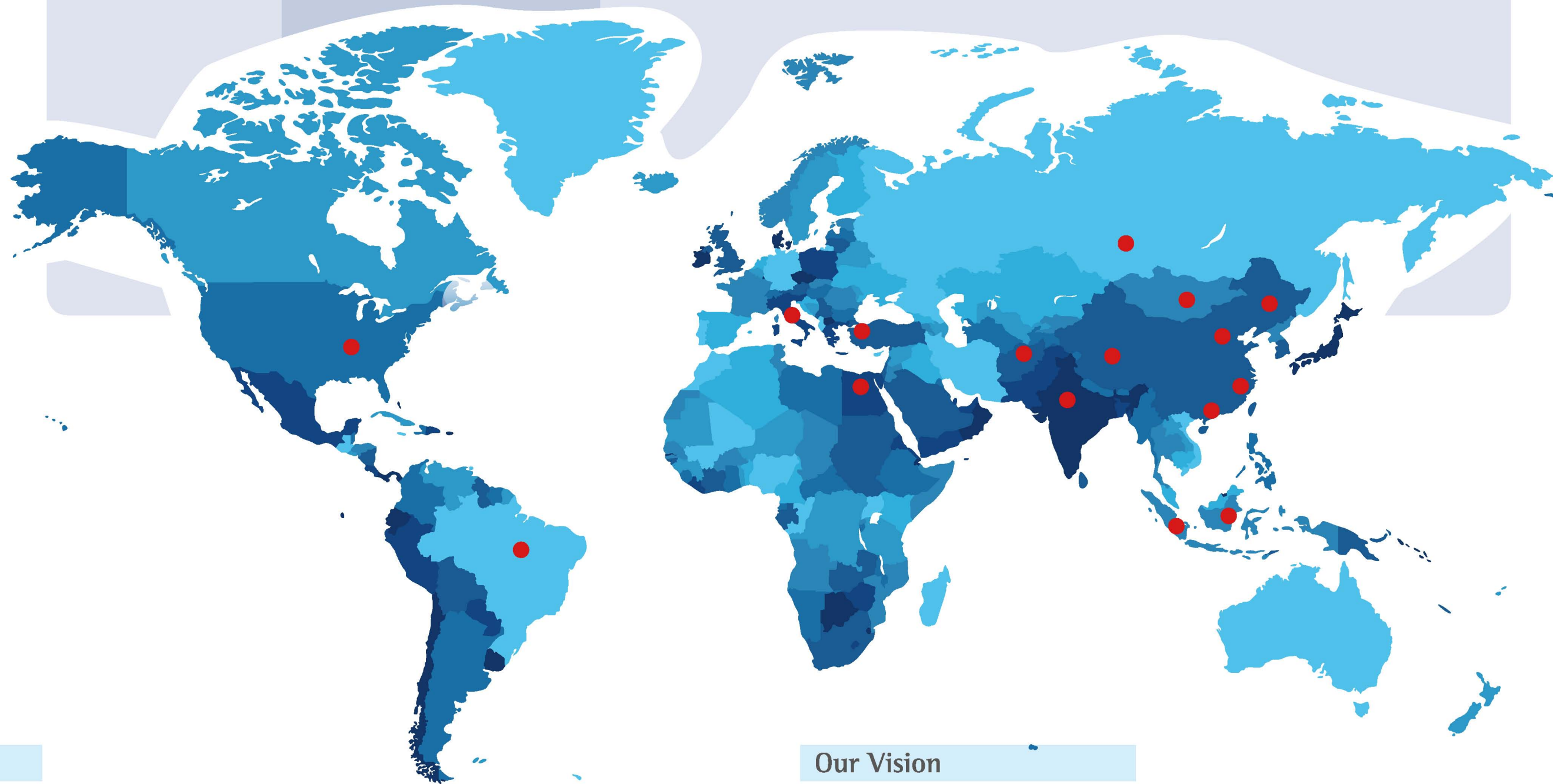




AUSTAR GMP Compliance & Quality
Management Consultancy

MISSION & VISION



Our Mission

Helping Chinese and the emerging countries' pharmaceutical enterprises to approach western developed level in validation and GxP implementation.

Our Vision

Becoming the most professional and excellent one-stop provider on GMP compliance and quality management consultancy services in pharmaceutical industry in China and other emerging countries.

– Providing validation consultancy and validation testing services to conform to US FDA/EU/WHO requirements

– Helping customers to establish a US FDA/EU/WHO standard quality management system

– Establishing a GEP/Construction Quality Management team in accordance with Chinese working environment and conforming to EU and US requirements

– Providing on-line and on-site training services



Brief Introduction to AUSTAR GMP Compliance and Quality Management Consultancy Service Department

Introduction

AUSTAR GMP Compliance and Quality Management Consultancy Service Department was established in 2000. Now we own a professional team with more than 200 , including world leading GxP experts both in domestic and overseas, and several senior international registration consultants.

We have provided professional GxP services for hundreds of pharmaceutical enterprises.

We are in close collaboration with many overseas consulting organizations . We aim to promote and improve the customers interests , provide worldwide resources to pharmaceutical enterprises through our professional services.

Service Positioning

Dedicating to provide professional and comprehensive GxP compliance consultancy services complying with of US FDA, EU, CFDA and WHO requirements

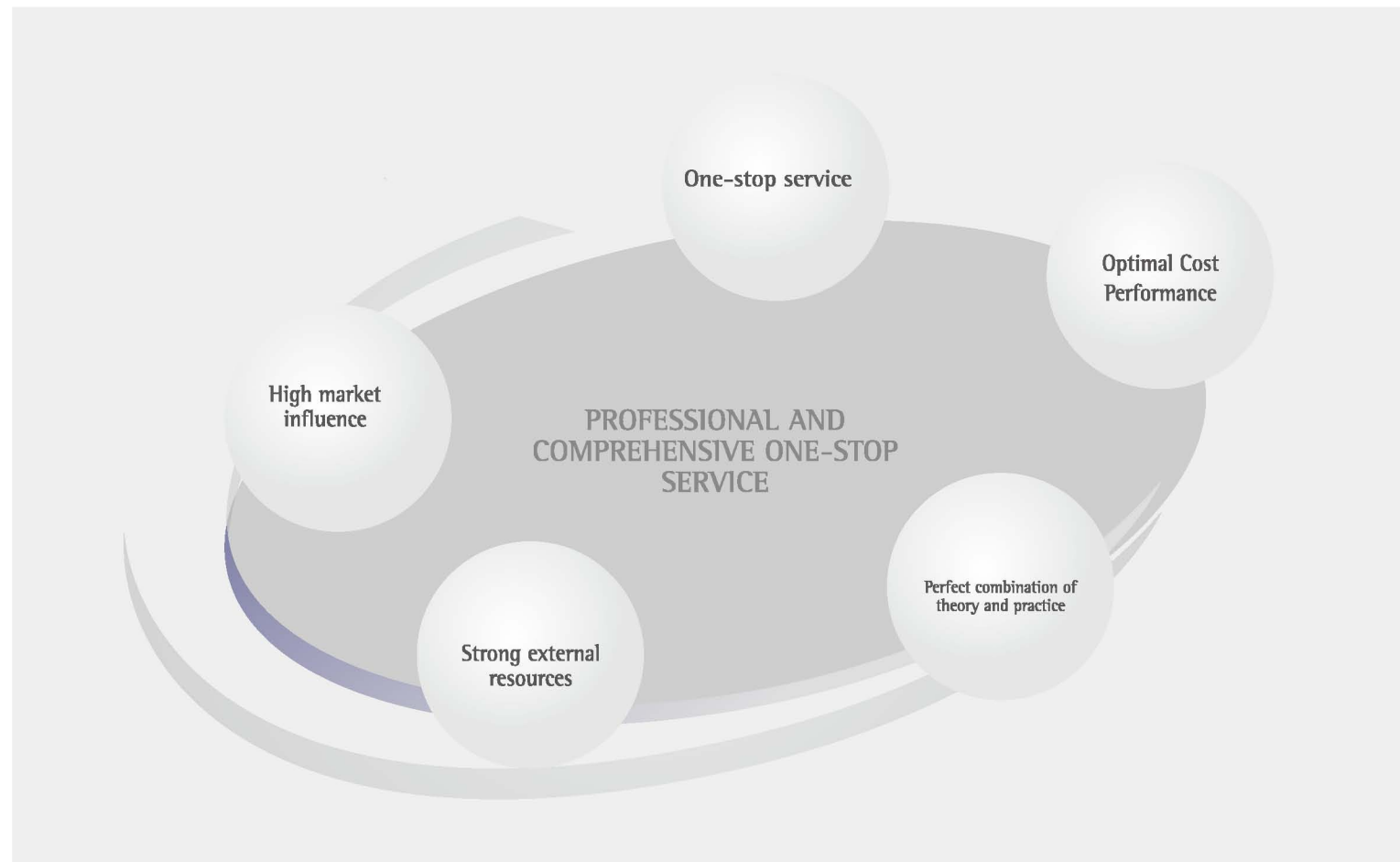


SERVICE ADVANTAGES

ADVANTAGE



We Can Provide Professional and Comprehensive One-Stop Service



Best Cost Performance

EU/US standard

- Full-time foreign consultant
- Part-time foreign consultant
- Whole set of original English documents
- All imported test instruments

Execution in China

- The largest execution team in China
- Completed functional departments such as QA and CSR.

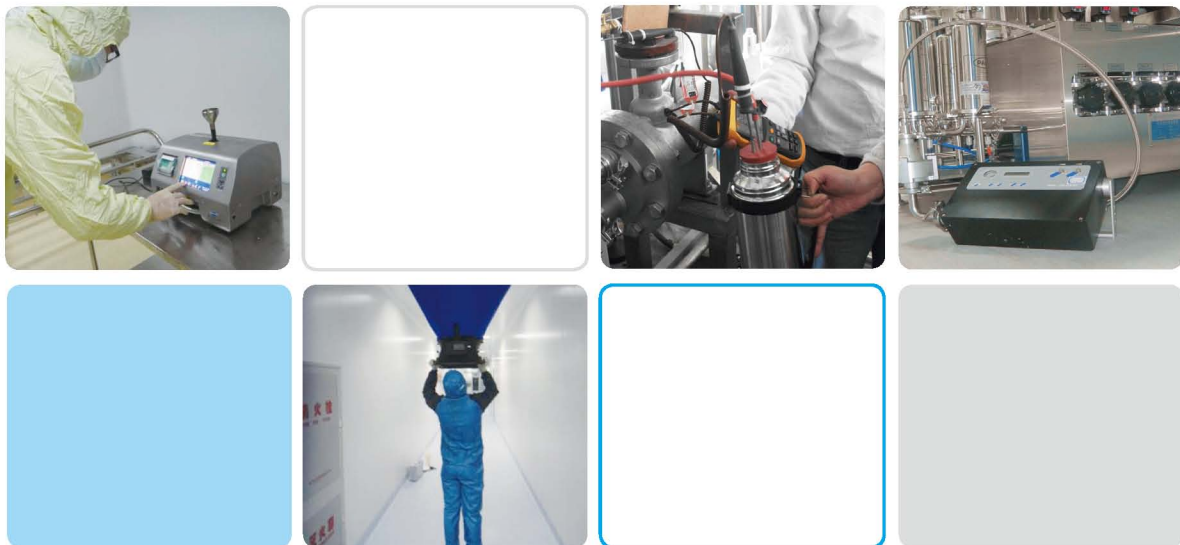


Perfect Combination of Theory and Practice

Capable of compiling whole set of engineering, validation and pharmaceutical quality system documents



Full validation testing services



External Resources



Influence Of Market Advantage



Pharmaceutical Water System

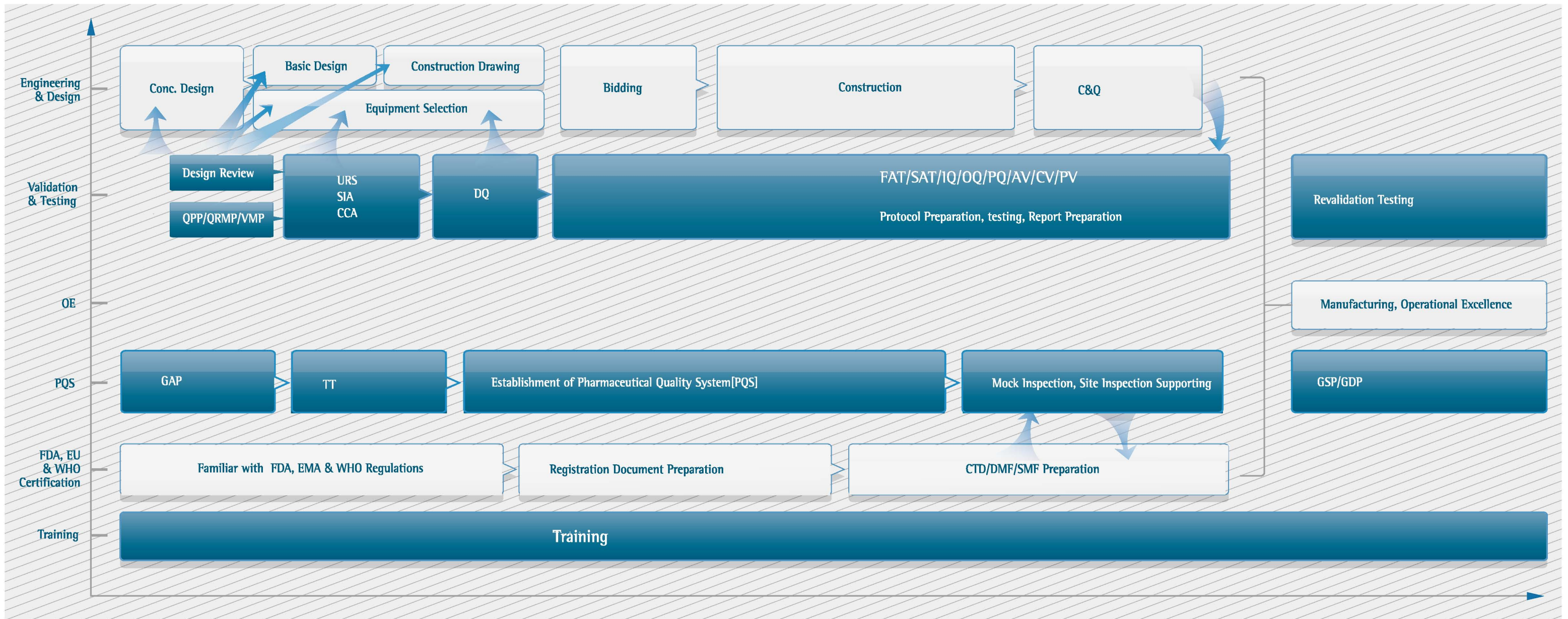
Pharmaceutical Validation Manual

Microbial Control in Pharmaceutical Cleanroom

Pharmaceutical Fluid Manual

SERVICE INTRODUCTION

INTRODUCTION



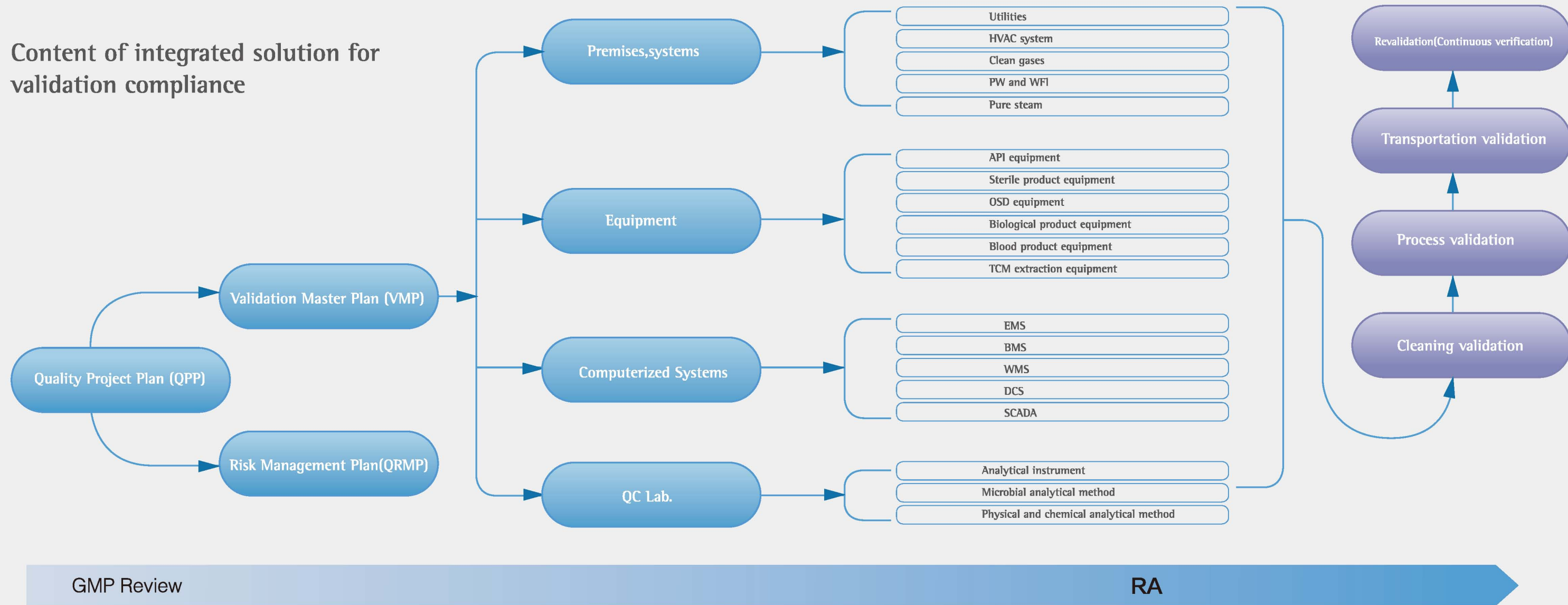


AUSTAR provides customers with integrated solutions for validation compliance covering the whole lifecycle of pharmaceuticals production.

We provides complete commissioning and validation services for the successful completion of the project to satisfy the customers requirements for such services as consultancy, commissioning, qualification, validation, re-qualification and re-validation at different stages, and help the project to meet the requirements of CFDA, US FDA, EU certification and WHO pre-qualification.



Content of integrated solution for validation compliance



02 Validation Testing Service

AUSTAR has a team of professional testing engineers. With our excellent validation testing instruments we can provide professional and highly efficient testing services that conform to EU/US standards.

Validation testing services of AUSTAR cover HVAC systems, clean piping systems and pharmaceutical equipment.

THE HVAC SYSTEM



Air volume/air exchange rate, differential pressure and air speed tests
HEPA leak test (PAO test)

HEPA leak test (PAO test)

Air flow pattern test
Airborne particle test
Recovery test
Settling microbe, airborne microbe and surface microbe tests
Central-station AHU commissioning test
... ..

CLEAN PIPING

Clean pipeline systems include PW/WFI/PS/Compressed air/clean nitrogen systems



Planktonic bacteria gas compression test

Clean gas dew point/water content test, oil content test, airborne particle test, and airborne microbe tests
Pure steam quality tests: non-condensable gases, dryness and super heat degree
PW pre-treatment system tests
Clean pipeline system tests
... ..

PHARMACEUTICAL EQUIPMENT

Pharmaceutical equipment includes steam sterilizers, dry-heat sterilizers, stopper washers, depyrogenation tunnel, lyophilizers, cold rooms, inoculators, incubator, etc.



Thermal mapping (wireless and wired thermometer)
Biological indicator challenge tests
Sterilization in Place
... ..

03 Pharmaceutical Quality System Consultancy Service



AUSTAR is devoted to providing pharmaceutical enterprises with all-round integrated quality system solutions throughout the whole lifecycle of a medicinal product, including quality system establishment, maintenance and training.

Content of Integrated Solution for PQS

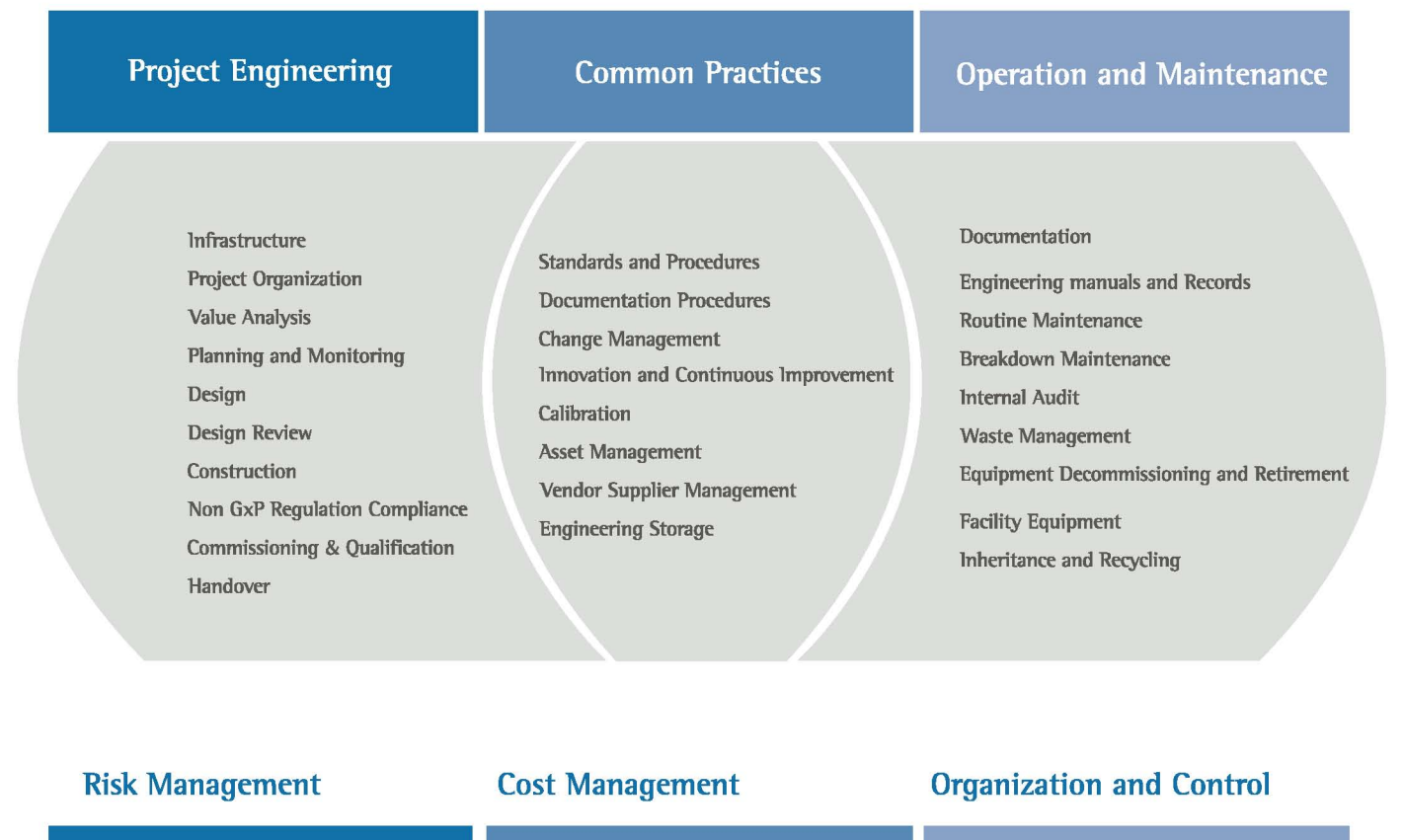
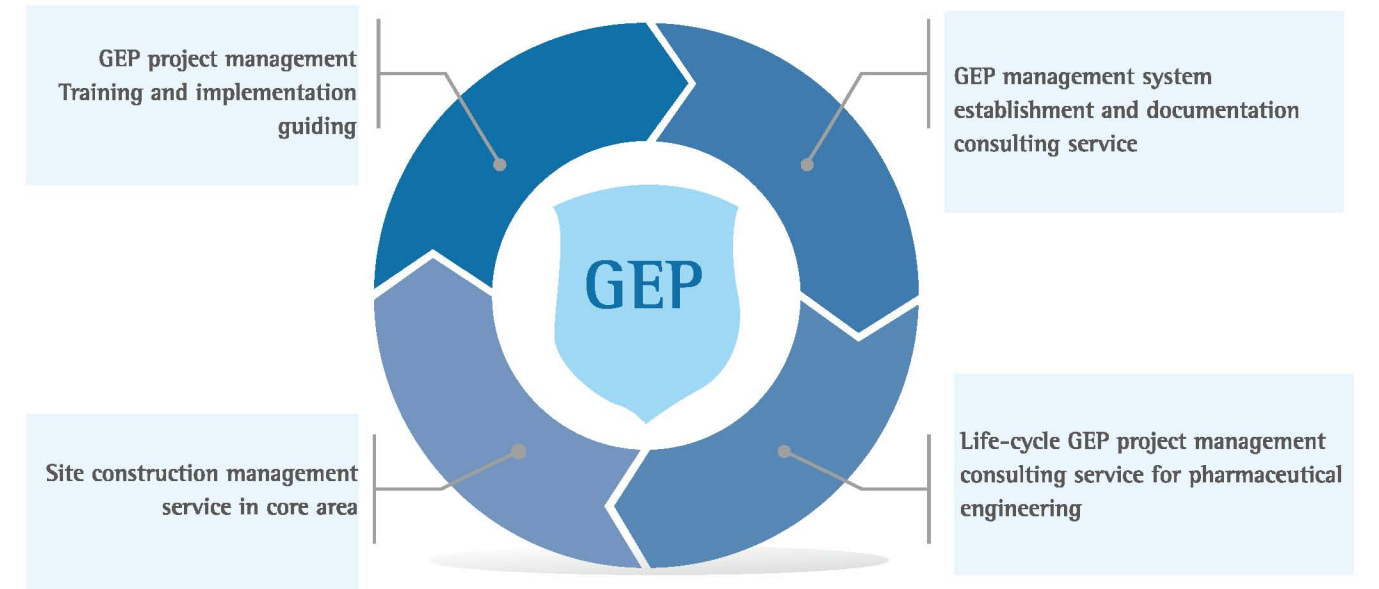
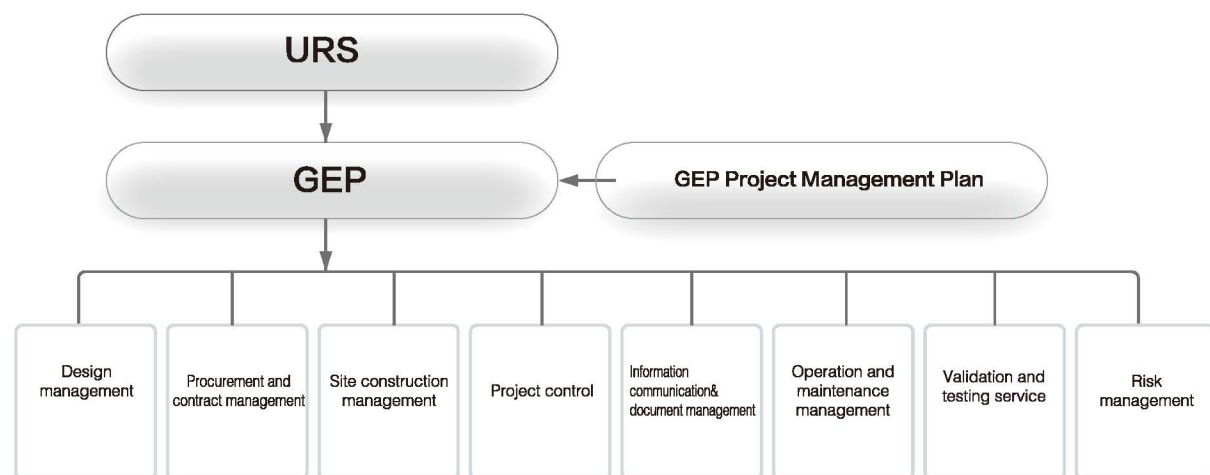


Integrated Solution for Pharmaceutical Engineering Quality Management



AUSTAR is dedicated to providing customers with specialized and standardized integrated GEP solutions throughout the whole lifecycle of a pharmaceutical engineering project. The project profit is maximized through overall arrangement, reasonable deployment and comprehensive allocation of project scope, time, cost, quality, human resources, communication, risk control and procurement during the project implementation phase.

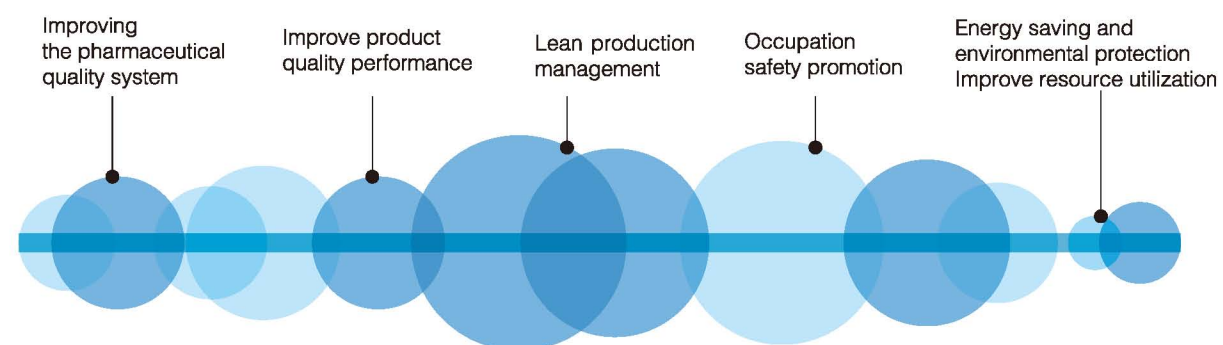
Content of GEP Solution



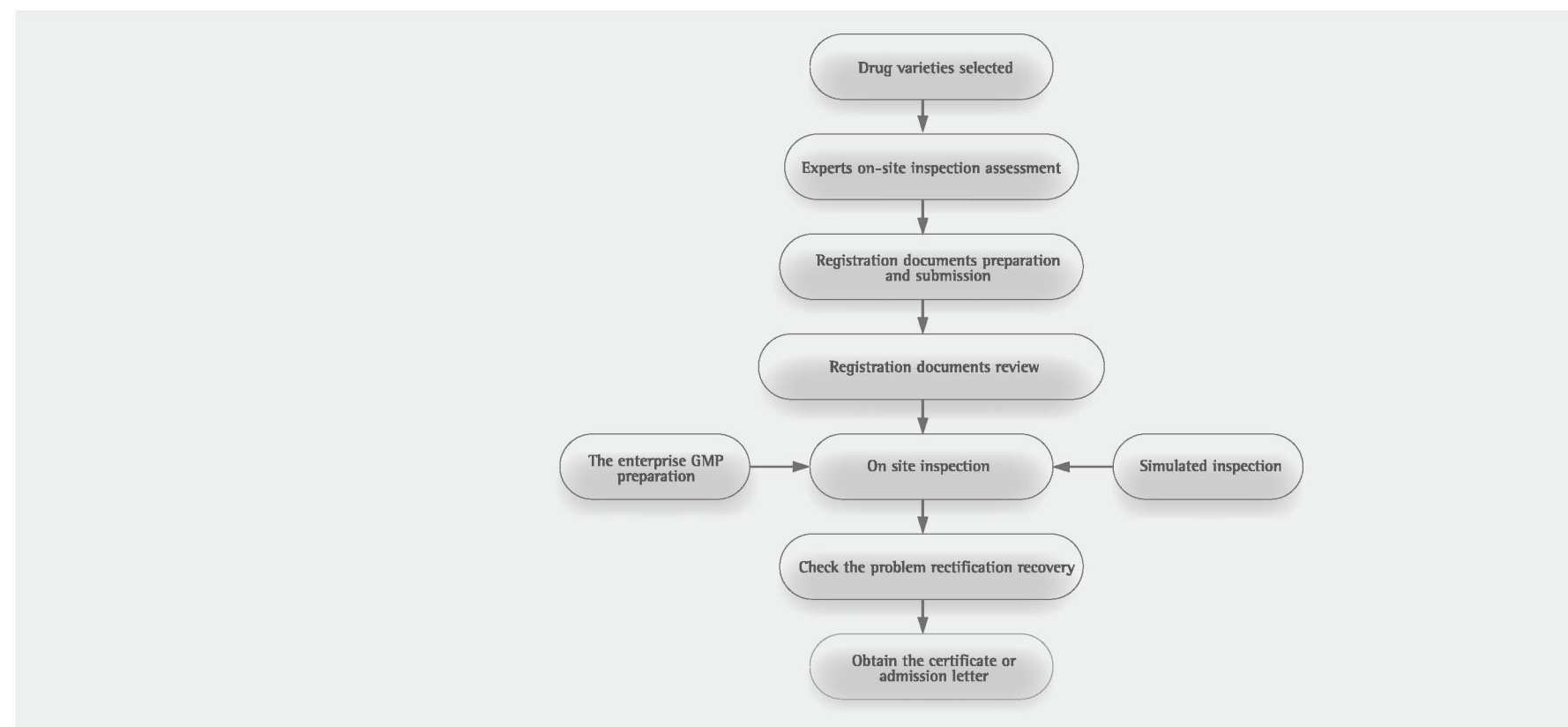
Operational Excellence Consulting Service - Content



Operational Excellence Consulting Service - Process



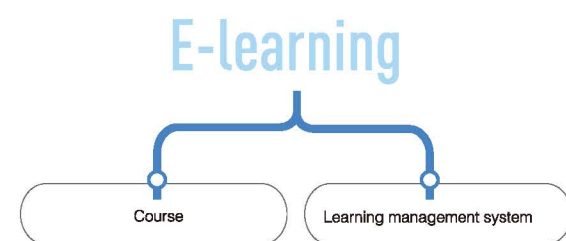
AUSTAR is dedicated to providing professional drug international registration services. We can perform registration gap analysis, registration training, registration document templates provision and application guidance, registration document writing and consultancy, registration related consultancy and guidance, and supports in registration site inspection to help our customers enter into FDA, EU and WHO markets.



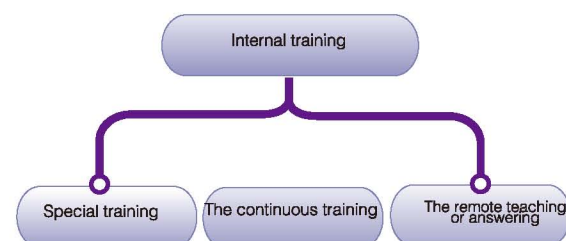


Austar has developed various kinds of training solutions, which include site training, remote training and E-learning system (E-learning platform establishment and E-learning courses).

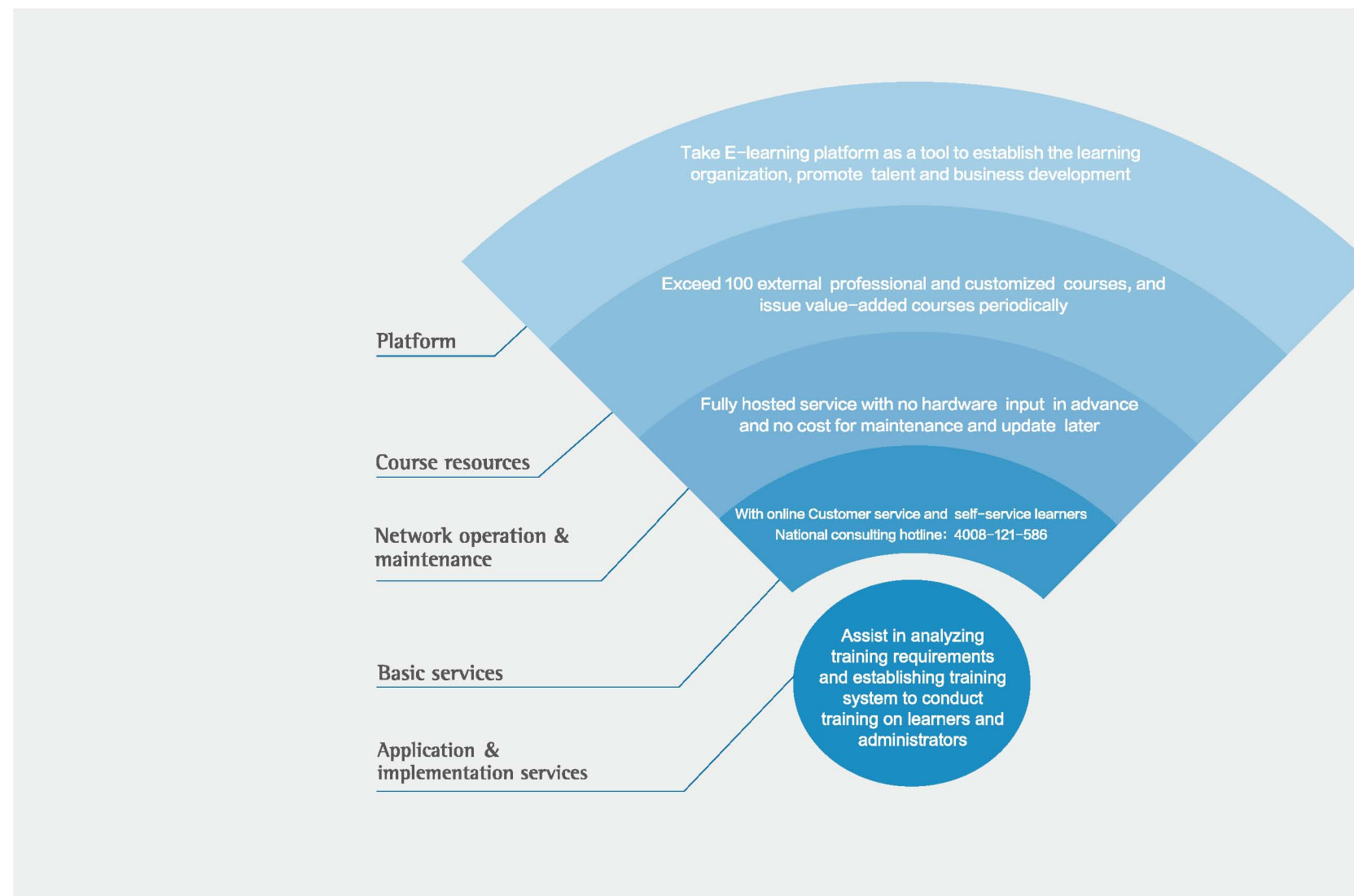
We can provide an internet-based customized learning platform for a pharmaceutical enterprise, which can provide training services on a 4A basis (Anyone, Anytime, Anywhere and Anything) for our customers.



Basic Package , Improve Package , Optional Package

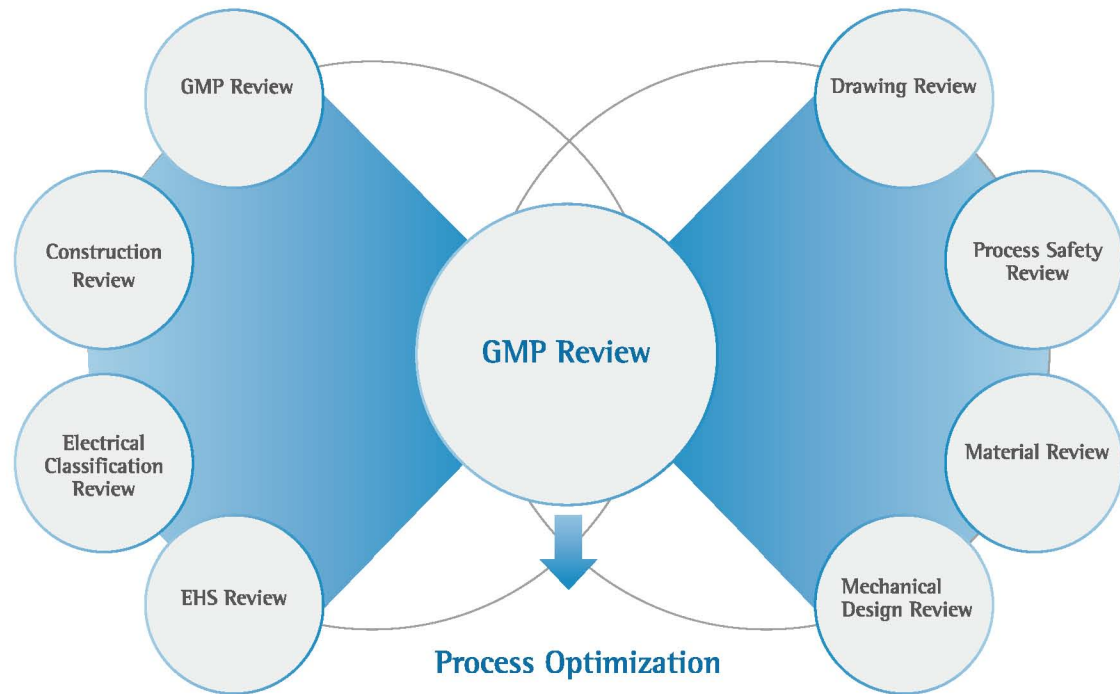


Category
Regulatory Guidelines
GEP
PQS
Validation
Pharmaceutical Technology and Knowledge



For more details and trial courses, please visit the website of AUSTAR training management system at www.austartraining.com.cn

GMP Review and Process Optimization



Non-compliance Report

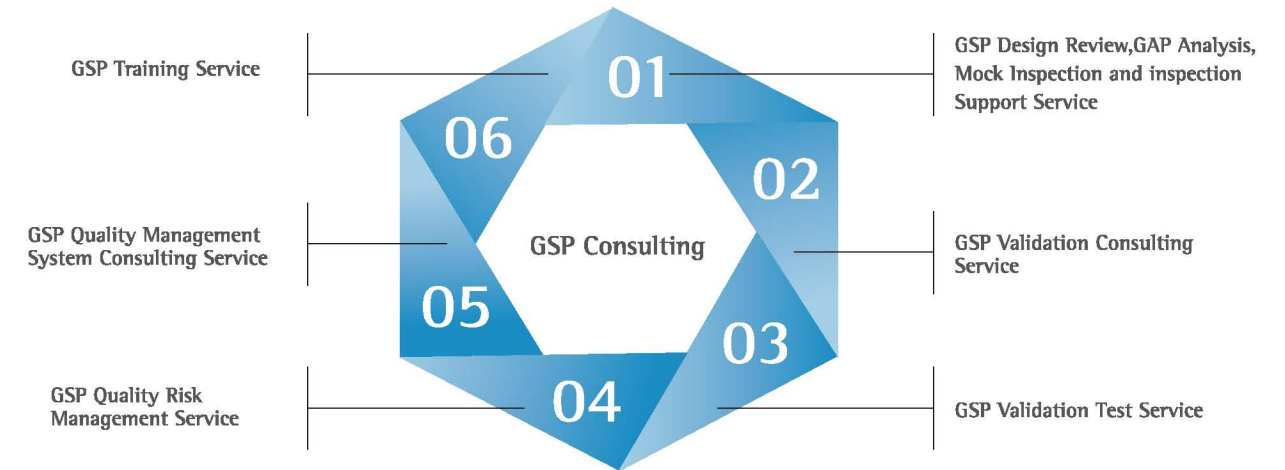
Gap Assessment

Review Report

Engineering Change Documents

Critical Aspect Handling & Final Confirmation of Acceptance Criteria

GSP Consulting



We still provide you with GMP Consulting Services for the follow industry

Medical Devices
Health Food
Food Additives
.....

OUR CUSTOMERS

CUSTOMERS



US FDA Standard

Beijing Novartis Pharmaceutical Co., Ltd
Zhejiang Yongning Pharmaceutical Co., Ltd
Shanghai Wyeth Nutritional Products Co. Ltd
Tianjian Smithkline & French Labs, Ltd
Shandong Freda Biochem Co., Ltd
Shijiazhuang Yiling Pharma Co., Ltd
Chengdu Kanghong Biotechnology Co., Ltd
OncoGenerix Biopharmaceutical Co., Ltd
Beijing Camphos Food Ingredient Co., Ltd
Beijing Sciecare Pharmaceutical Co., Ltd
Beijing Taide Pharmaceutical Co., Ltd
Hisun Pfizer Pharmaceutical Co., Ltd
GE (China) Research and Development Center Co., Ltd

EU Standard

Sichuan huiyu pharmaceutical Co., Ltd
Fonko Pharmaceutical Ltd Indonesia
Shenzhen GlaxoSmithKline Co., Ltd
Beijing Fresenius Kabi Pharmaceutical Co., Ltd
Shijiazhuang Pharma Group NBP Pharmaceutical Co., Ltd
Novozymes(China) Biopharma Co., Ltd
NCPC Hebei Huamin Pharmaceutical Co., Ltd
Novo Nordisk (Tianjin) Technology Co., LTD
Beijing BeiLu Pharmaceutical Co., Ltd
Harbin General Pharmaceutical Factory
AstraZeneca Pharmaceutical Co., Ltd
WuXi AppTec Co., Ltd (Wuxi)
Zhejiang Tianyuan Bio-Pharmaceutical Co., Ltd
Shenzhen Sanofi Pasteur biological product Co., Ltd
Suzhou Innovent Biologics Co., Ltd

WHO Standard

Chengdu Institute of Biological Products
Beijing Tiantan Biological Products Co., Ltd
Shanghai Institute of Biological Products
Changchun Institute of Biological Products
Changchun BCHT Biotechnology Co., Ltd

Other Standards (PIC/S&TGA, etc.)

Bright Future Pharmaceutical Laboratories Ltd
Chengdu Rongsheng Pharmaceuticals Co., Ltd
Shijiazhuang No.4 Pharmaceutical Co., Ltd
Serum Products
Abacus Parenteral Drugs
Monos Pharma Co Ltd
Goldmile Contracts Limited
Dentafill Plus
Pt Bentala Nusa Persada
Enkhiim Shuuder

CFDA Standard

Shandong Ruiyang Pharmaceutical Co., Ltd
Suzhou Dawnrays Pharmaceutical Co., Ltd
Chengdu Rongsheng Pharmaceuticals Co., Ltd
Langzhi Group Wanrong Pharmaceutical Co., Ltd
Jiangsu Hengrui Pharmaceutical Co., Ltd
Shanghai RAAS Blood product Co. Ltd
Sichuan Yuanda Shuyang Pharma Co., Ltd
Shijiazhuang No.4 Pharmaceutical Co., Ltd
Guangzhou Baiyunshan chemical pharmaceutical factory
Qingdao Huaren Taiyi Pharmaceutical Co., Ltd
Xiamen Bioway Biotech Co., Ltd
Wuhan Institute of Biological Products Co., Ltd



Offices and Factories

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