

CENRA+API Solutions

**Introduction of Chunghwa Chemical
Synthesis & Biotech Co., Ltd.**

Last updated on Aug. 2025



Embrace Life, Beyond Health

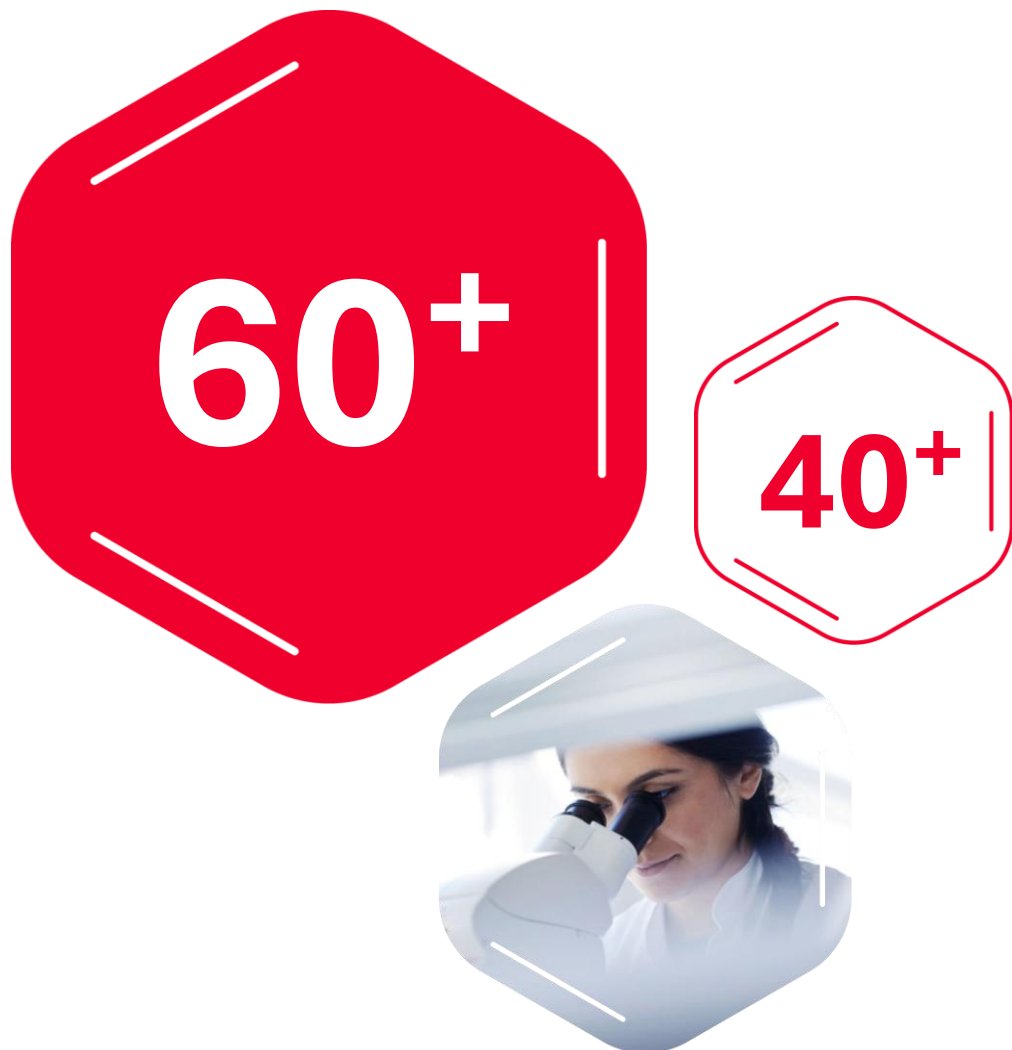




Safe Harbor Notice

- CAS's presentation contains forward-looking statements subject to significant risks and uncertainties. Actual results may differ materially from those contained in the forward-looking statements.
- The forward-looking statements in this release reflect the current belief of CAS as of the date of this release, we undertake no obligation to update these forward-looking statements for new information, future events or otherwise.





Brief History of CAS

Founded in 1964

First registered and one of the largest bulk pharmaceutical chemical manufacturers in Taiwan

First FDA approved plant in Taiwan (1984)

Turning Points in 1997

Formed the New Management Team in 1997

Invested US\$ 20 million to construct

4 cGMP Plants for Synthetic Products

2 cGMP Plants for Biotechnology Products

Established US Sales Office-Pharmaports in 2000

Products

Developing both synthetic & biotech products

Participate new drug development and contract manufacturing

Global Market Oriented with Emphasis on U.S.A., Europe, Japan

Initial public offering on December 20, 2010

Key Achievements of CAS

1964

First registered and largest bulk pharmaceutical chemical manufacturer in Taiwan

1997

Invested \$20M to establish:
• 4 cGMP synthetic product lines
• 2 cGMP biotech production lines

2015

Invested \$3M to establish one high-potency API production line

2018

US FDA GMP system

2020

Invested \$16M to establish 2 biotech production lines

2022

FDA, TFDA inspection

1984

First plant approved by US FDA in Taiwan

2000

Established US Sales Office – Pharmaports

2010

Initial public offering (IPO) on Taiwan Stock Exchange

2017

FDA, PMDA, TFDA inspection

2019

EU ANSM inspection

2021

FDA, TFDA inspection

2024

FDA, Münster PMDA inspection
Rebranded name: Cenra API Solutions

Location of CAS

- Located in Shu-Lin, New Taipei City
- 20 km from downtown Taipei city
- 30 km from Taoyuan International Airport
- Area of land is 36,800 m²
- 260+ Employees





Our Vision

The most trustworthy global APIs supplier.

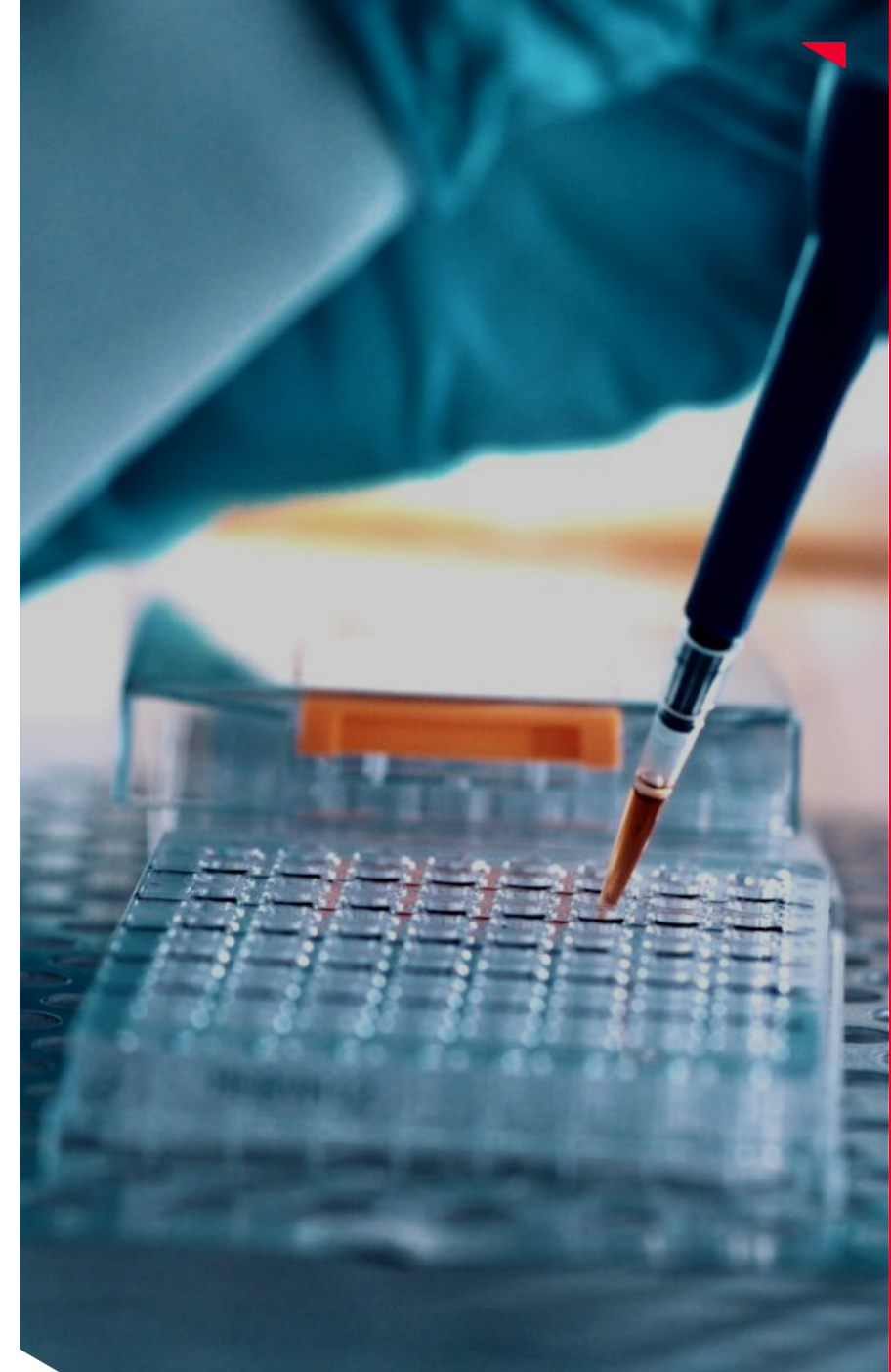
Mission Statement

Continuously pursue customer satisfaction, R&D excellence and quality products with competitive price.



Records of cGMP Inspections

Year	Authorities	Nation	Scope
2024	PMDA	Japan	Tacrolimus
2024	FDA	US	GMP system
2024	Münster	Germany	Tacrolimus
2022	FDA	US	MMF
2021	FDA	US	cGMP systems
2019	ANSM	EU	Methocarbamol
2018	FDA	US	cGMP systems
2017	PMDA	Japan	Rapamycin
2017	FDA	US	Ethyl Icosapentate
2015	COFEPRIS	Mexico	Caspofungin
2015	Köln	Germany	Pravastatin Sodium; Tacrolimus
2014	FDA	US	cGMP systems
2013	MFDS	Korea	Tacrolimus
2013	PMDA	Japan	Tacrolimus
2012	Köln	Germany	Pravastatin Sodium
2011	FDA	US	Dexb; MMF; Tacrolimus
2009	Koln	Germany	Pravastatin
2007	MFDS	Korea	Methocarbamol



Active US DMF List

8625 • DEXBROMPHENI RAMINE MALEATE	17399 • RAPAMYCIN	18494 • MYCOPHENOLAT E MOFETIL USP	18985 • TACROLIMUS	23213 • TACROLIMUS SD20	24372 • MYCOPHENOLAT E MOFETIL HCL ANHYDROUS
26271 • ETHYL ICOSAPENTATE	26819 • EVEROLIMUS PRE-MIX USP	27216 • EVEROLIMUS USP	27585 • CASPOFUNGIN ACETATE	31189 • RAPAMYCIN (SIROLIMUS)	33333 • MYCOPHENOLAT E MOFETIL USP (PROCESS B)
35848 • MYCOPHENOLAT E SODIUM USP	36030 • BARICITINIB	36174 • RIBOCICLIB SUCCINATE	36640 • MIDOSTAURIN	37532 • TOFACITINIB CITRATE	37586 • PALBOCICLIB
37597 • OZANIMOD HCL	38111 • EVEROLIMUS B02 USP	38310 • TACROLIMUS (PROCESS B)	38511 • DIFELIKEFALIN ACETATE	39312 • ESLICARBAZEPI NE ACETATE	40868 ELTROMBOPAG OLAMINE
41490 SETMELANOTIDE ACETATE	41491 BRIVARACETAM	41492 SELUMETINIB SULFATE	41493 PLECANATIDE	41494 TRILACICLIB 2HCL	

DMF filing support over 50 countries

Denmark, Poland The Netherlands, Sweden, Switzerland Bulgaria, Croatia, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Norway, Portugal, Romania, Spain, and United Kingdom



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



CDSO



MOH
Vietnam



Taiwan



CCSB



US office

OTTC





Business& Product Coverage

Synthetic/Nature API

- Abaloparatide
- Baricitinib
- Brivaracetam
- Difelikefalin Acetate
- Edoxaban Tosylate
- Eltrombopag Olamine
- Eslicarbazepine Acetate
- Etelcalcetide HCl
- Ethyl Icosapentate (EPA>98%)
- Imeglimin HCl
- Lanreotide Acetate
- Ozanimod HCl
- Palbociclib
- Plecanatide
- Ribociclib Succinate
- Ruxolitinib Phosphate
- Selumetinib Sulfate
- Setmelanotide Acetate
- Sugammadex Sodium[†]
- Tenapanor HCl
- Tofacitinib Citrate
- Trandolapril[†]
- Trilaciclib 2HCl

Biotech/Fermentation API

- Anidulafungin
- Caspofungin Acetate
- Dalbavancin HCl
- Everolimus
- Midostaurin
- Mycophenolate Mofetil
- Mycophenolate Mofetil HCl
- Mycophenolate Sodium
- Rapamycin (Sirolimus)
- Rezafungin Acetate
- Semaglutide
- Tacrolimus





Trusted Partner in APIs RD & MAG

With 60 years of expertise dedicated to APIs research and production in Fermentation, Synthesis and Peptide compounds, we safeguard your technical data as a trusted partner.

Our R&D capabilities

- Top tier R&D capability in research and optimizing process.
- Professional equipment enabling high-quality research.
- Stable pipeline with continuous improvement.



Core Technical Advantage

▲ Fermentation Capability

- Fermentation Strain Productivity Improvement
- Fermentation Process Development, Scale-up & Commercial Production
- Downstream Purification Process Development
- Recombinant Peptide/ Enzyme Production
- Enzymatic Reaction

▲ Chemical Synthesis Capability

- Synthesis Route Discovery
- Process Development, Optimization, Scale-up & Commercial Production
- Chemical Reaction Capability

Acetylation	Decarboxylation	Hydrazine chemistry
Acylation	Dehydrogenation	Hydrogenation
Alkylation	Diazotization	Hydrogenation, catalytic
Amidation	Diels-Alder Reactions	Nitration
Carbonylation	Esterification	Organometallic
Carboxylation	Etherification	chemistry
Chiral	Formylation	Reduction
Synthesis	Friedel-Crafts	Vilsmeier-Reactions
Condensation	Reactions	Peptide syntheses
Cyclization	Grignard-Reactions	
	Halide exchange	



CAS Production Capacity

Total 10 segregated cGMP production lines

■ 8 Chemical Synthesis GMP Production lines

- 2 pilot-scale production lines
- 6 commercial production lines
 - Glass-lined Reactors: Total Volume 24 kL
 - Stainless Steel Reactors: Total Volume 332 kL

■ 2 Fermentation GMP Production lines

- Size of fermenters from 1,250 L – 30,000 L
- Total Fermentation Capacity: 260 kL

Production Capacity overview

Pilot plant I/II

- **Batch size:** from 0.1 kg to 10 kg
- **Equipped with:**
Hastelloy, Glass-lined and Stainless Steel Reactors,
Glove Box and MPLC system

Commercial production line I

- **Batch size:** from 30 kg to 500 kg
- **Equipped with:**
Hastelloy, Glass-lined and Stainless Steel Reactors,
Glove Box and MPLC system

Commercial production line II

- **Batch size:** from 200 kg to 2000 kg
- **Equipped with:**
Hastelloy, Glass-lined and Stainless Steel Reactors,
Glove Box and MPLC system

CMO/CDMO Services Overview

Synthesis & Fermentation

- Extensive expertise in the production of pharmaceutical intermediates and active pharmaceutical ingredients (APIs) using both chemical synthesis and microbial fermentation technologies.

Process Development

- Proficient in process modification, optimization, scale-up, and validation to support robust and efficient manufacturing.

Analytical Services

- Comprehensive capabilities in the development and validation of analytical methods, as well as preparation and qualification of reference standards.

End-to-End Development Support

- Supply of intermediates and APIs across all development stages — from preclinical and clinical to commercial manufacturing.

Flexible Manufacturing Capacity

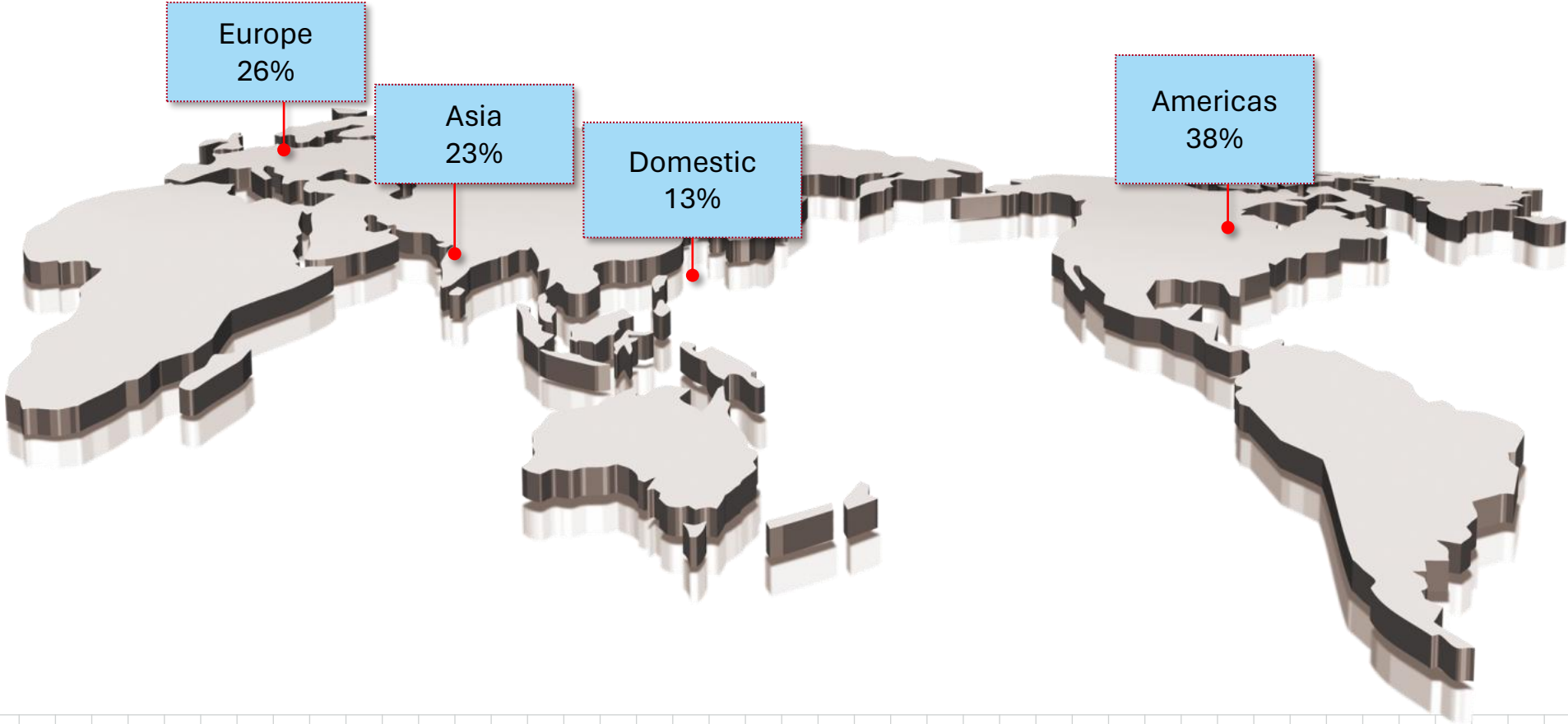
- Scalable production infrastructure supporting a wide range of quantities, from grams to metric tons.

Regulatory Support

- Strong experience in regulatory documentation, including complete Chemistry, Manufacturing and Controls (CMC) packages and global regulatory compliance assistance.



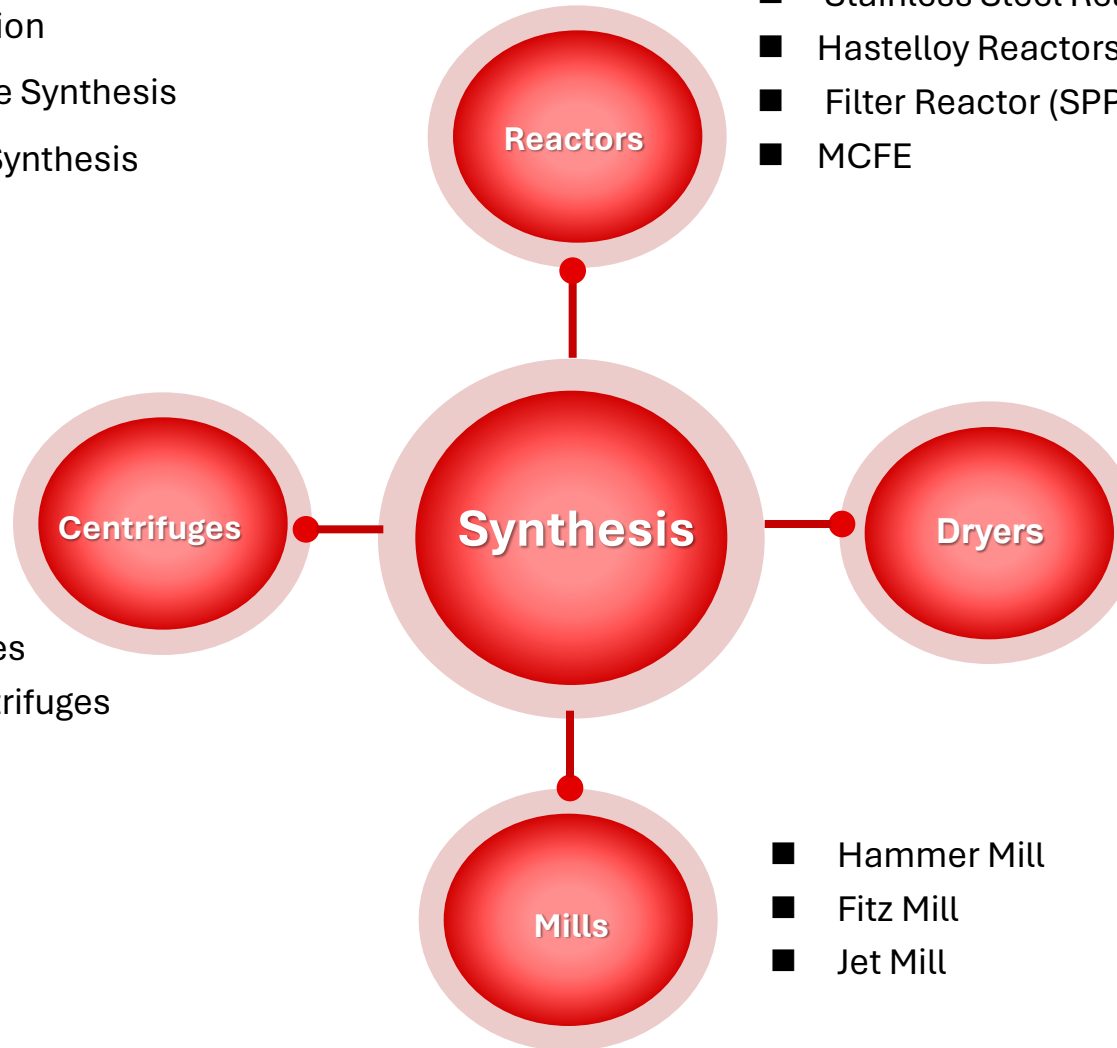
Sales Area in 2024



Equipment for Synthesis

- ▶ Catalytic Hydrogenation
- ▶ Liquide Phase Peptide Synthesis
- ▶ Solid Phase Peptide Synthesis

- Hastelloy Centrifuges
- Stainless Steel Centrifuges



- Glass-lined Reactors: Total Volume 31,000 L
- Stainless Steel Reactors: Total Volume 512,000 L
- Hastelloy Reactors: Total Volume 8,750 L
- Filter Reactor (SPPS): Total Volume 300 L
- MCFE

- Hot-Air Tray Dryers
- Vacuum Tray Dryers
- Double-cone Dryers

- Hammer Mill
- Fitz Mill
- Jet Mill



MCFE Reactor



3,000 L Glass Lined Reactors



5,000 L Glass-lined and Stainless Steel Reactors for Purification Process



75 L Stainless Steel Reactor



Stainless Steel Reactors



50 L Glass Lined Reactor



Freeze Dryers



6 inch MPLC system

Equipment For Synthesis

Reactors

Glass-lined reactors: Total volume 24,000 L

Stainless steel reactors : Total volume 333,500 L

Dryer

Hot-Air Tray Dryer

Vacuum Tray Dryer

Double-cone Dryer

Mills

Hammer Mill

Fitz Mill

Jet Mill

Centrifuges

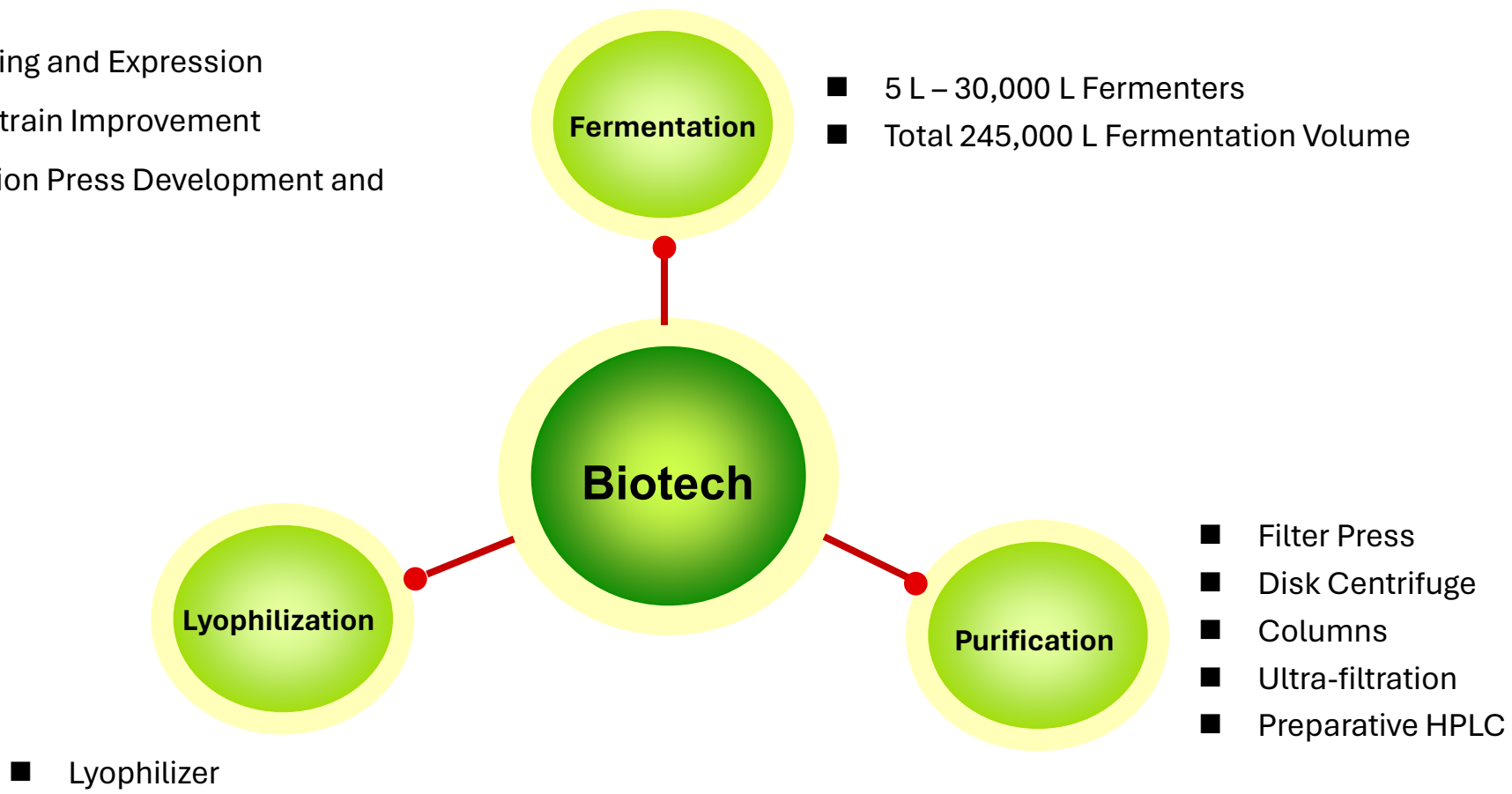
Hastelloy Centrifuges

Stainless Steel Centrifuges



Equipment for Biotech

- ▲ Gene Cloning and Expression
- ▲ Tradition Strain Improvement
- ▲ Fermentation Press Development and Scale-up





5 L Fermentor



22 L Fermentor



600 L Fermentor



20,000 L & 30,000 L Fermentors



ABEC 75L, 250L & 1250 L Bioreactors



Purification Equipment



Ultra Filtration



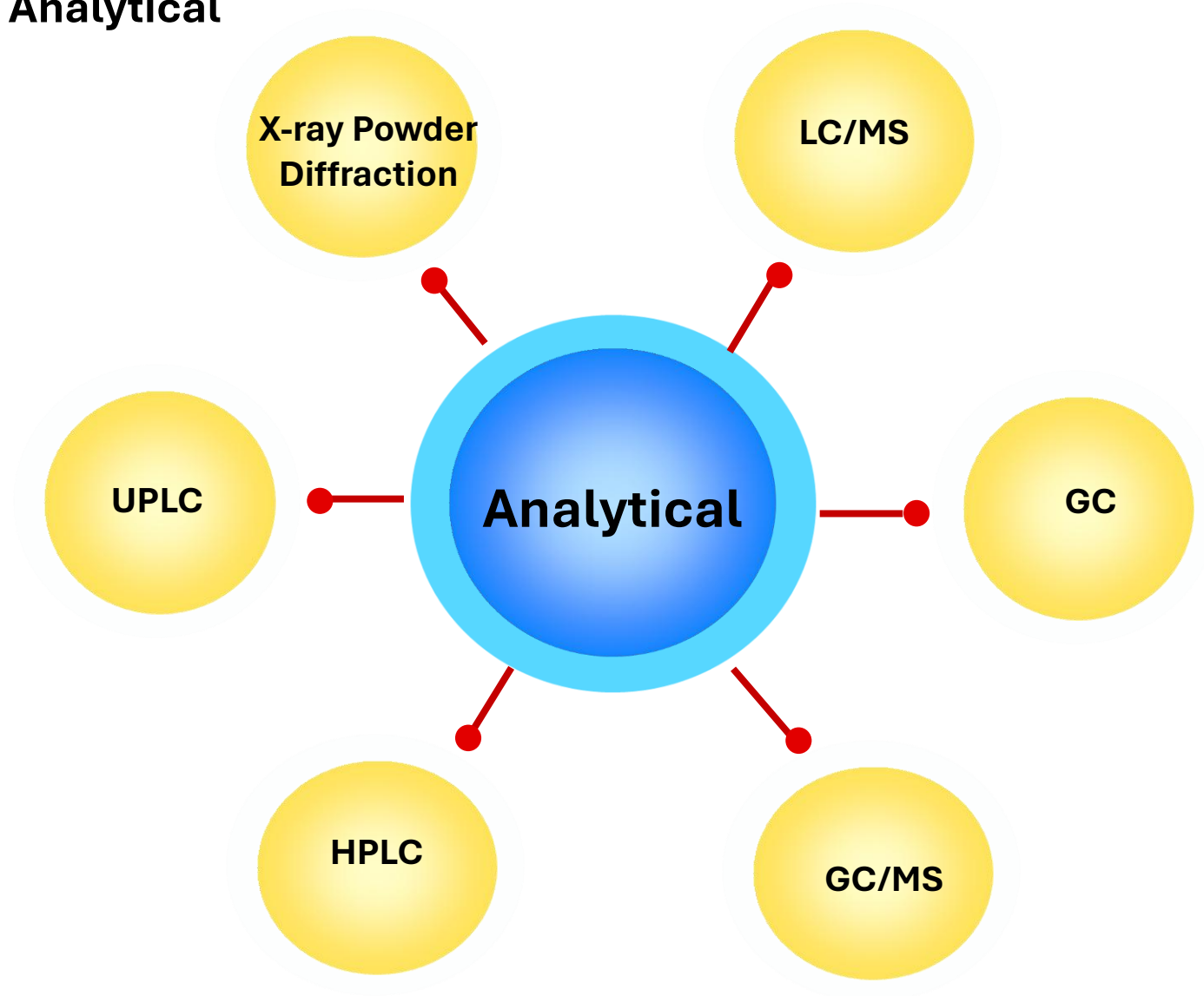
Pyros Kinetix Flex Automatic
Endotoxin Detection System

Equipment for Biotech

- ▶ Fermentation
 - Total 227,000 L Fermentation Volume
 - 1,250 – 30,000 L Fermentors
 - ABEC Bioreactor
- ▶ Purification
 - Filter Press
 - Disk Centrifuge
 - Ultra-filtration
 - MPLC: 15~45cm Diameter
- ▶ Lyophilization
 - Lyophilizer
- ▶ Others
 - Endotoxin Detection System
 - GEA Niro High Pressure Homogenizer



Equipment for Analytical





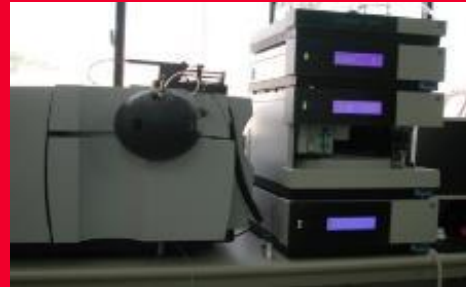
GC/MS



UPLC



GE AKTA Purifier UPC 100



LC Mass



BioTek Synergy H1 Hybrid Reader



KvickLab Cross Flow System

Equipment For Analysis

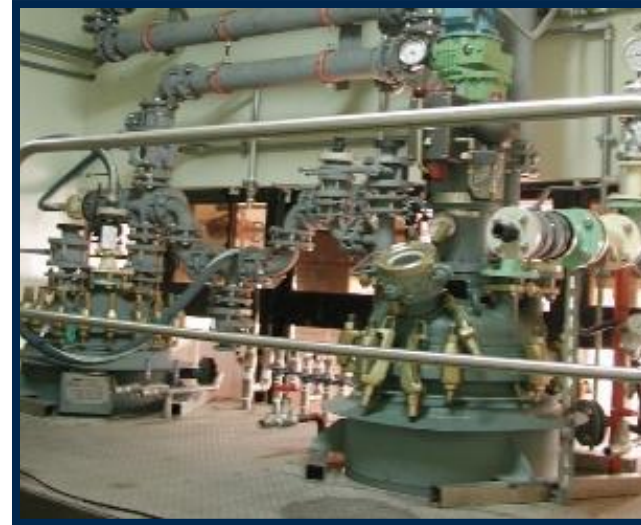
- ▲ X-ray Powder Diffraction
- ▲ LC/MS
- ▲ GC
- ▲ GC/MS
- ▲ HPLC
- ▲ UPLC

Synthetic Pilot Plant



75 L Stainless Steel Reactor

50 L Glass Lined Reactor



50 L Cone Dryer & 25" Centrifuge

Synthetic Pilot Plant (cont.)



Freeze Dryers



Synthetic Commercial Plants



3,000 L Glass Lined Reactors



Synthetic Commercial Plants (cont.)



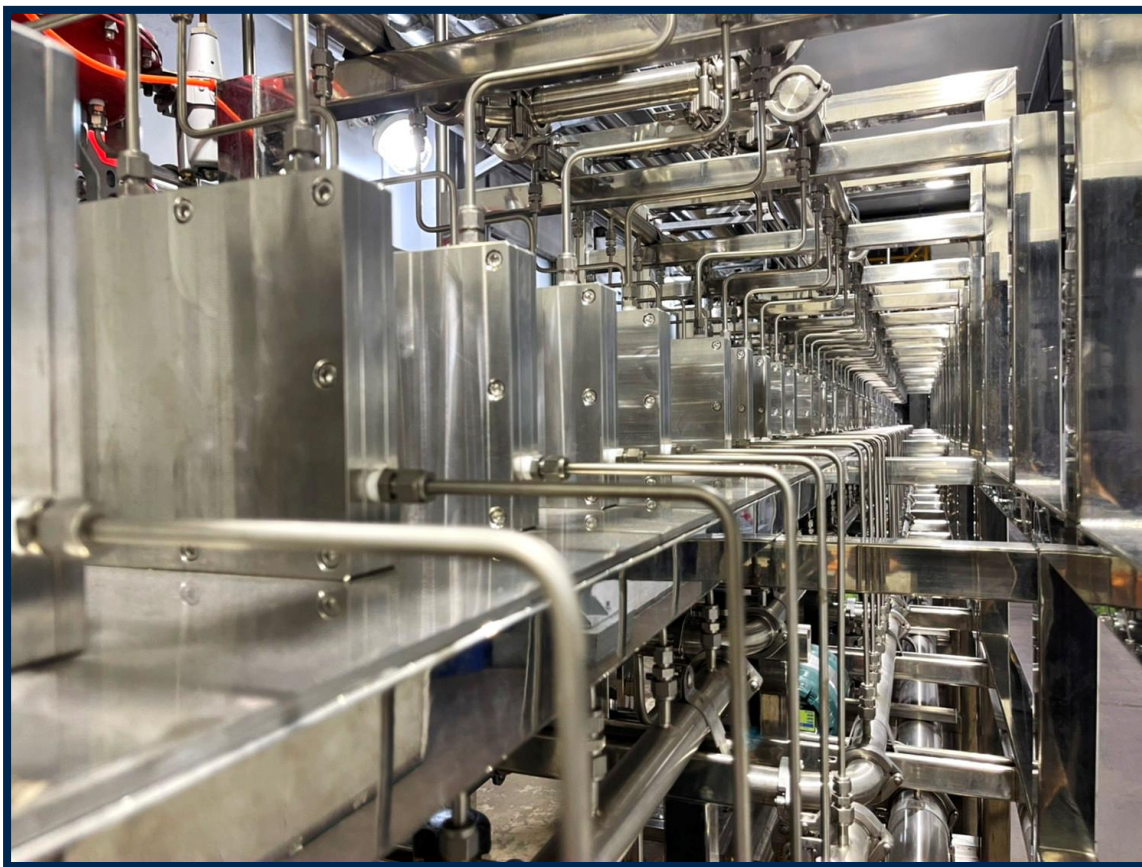
Stainless Steel Reactors

Cone Dryer in Controlled Room

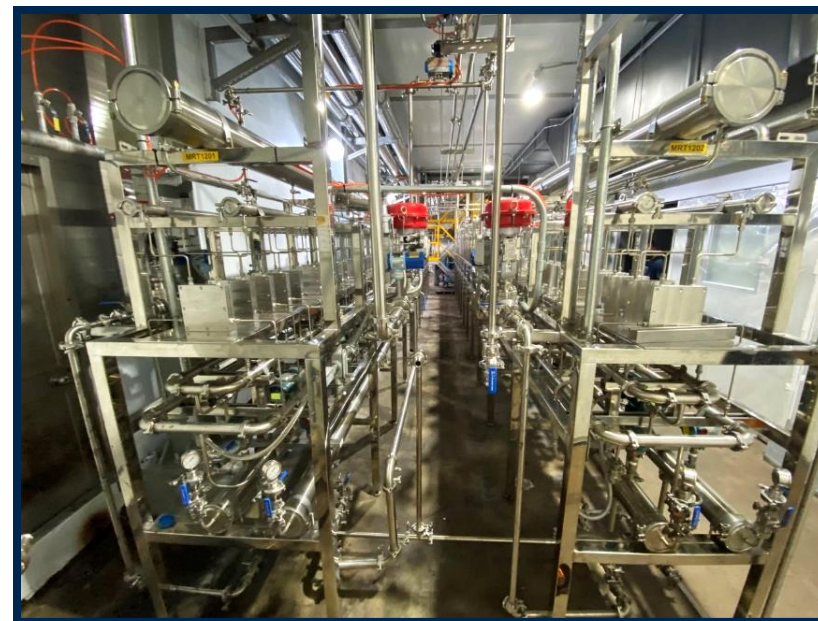




Synthetic Commercial Plants (cont.)



Microreactor Continuous Flow Equipment



Biotech Pilot Plant



5 L Fermentor



600 L Fermentor



22 L Fermentor



Biotech Commercial Plant



ABEC 75L, 250L & 1250 L Bioreactors



ABEC 250L Bioreactors





Biotech Commercial Plant (cont.)



Incubator & Shock Box



Biosafety Cabinet



Autoclave





Biotech Commercial Plant (cont.)



20,000 L & 30,000 L Fermentors





Biotech Commercial Plant (cont.)



**5,000 L Glass-lined and Stainless Steel
Reactors for Purification Process**





Biotech Commercial Plant (cont.)



Recovery & Purification Equipment



Ultra Filtration

Instrumentation (cont.)

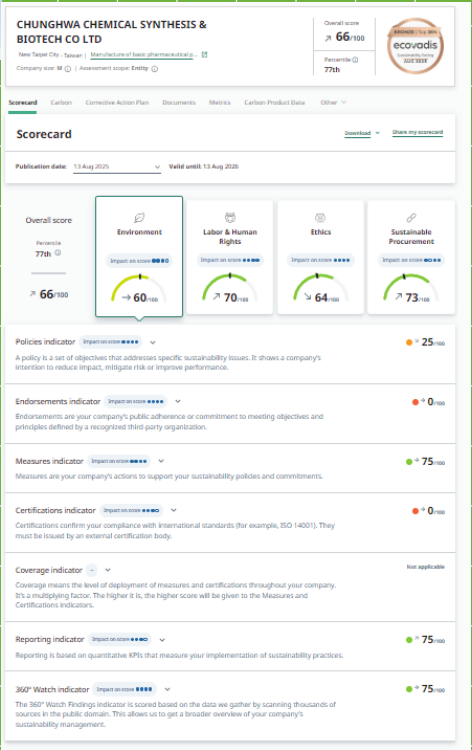


Mbraun Glove box

Type: UNILAB-B



Bio Rad ChemiDoc XRS+ Imaging System



Our ESG Commitment

CAS dedicates to pursue the goal of becoming the most trustworthy APIs supplier in the world.

ESG statement

We develop our corporate governance structure and practices to actively promote operational transparency and improve disclosure of financial and non-financial information in terms of quality and timeliness through upholding the integrity of our business philosophy, according to the Company Law, the Securities and Exchange Law and other relevant laws and regulations.

EcoVadis

Ethics: The top 35% of companies rated by EcoVadis in the Manufacture of basic pharmaceutical products and pharmaceutical preparations industry.





SUMMARIES OF CAS

- ▲ Over 60 years of API manufacturing experience.
- ▲ FDA and Health Authorities approved cGMP facilities for synthesis and biotech APIs.
- ▲ Fully cGMP trained and experienced personnel.
- ▲ Strong R&D support.
- ▲ Proven records for cost effective and on-time delivery of contract manufacturing from lab to commercial scales.
- ▲ Good communication skills & prompt response.

Thank You



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- Thanks for your attention

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