

CCSB



Brief Introduction

Chunghwa Chemical Synthesis & Biotech Co., Ltd.

Brief History of CCSB



➤ **Founded in 1964**

- First registered and one of the largest active pharmaceutical ingredient manufacturers in Taiwan
- First US FDA approved plant in Taiwan (1984)

➤ **Affiliated Formulation Companies**

- China Chemical & Pharmaceutical Co., Ltd. in Taiwan (cGMP certified by TFDA)
- Suzhou Chung-Hwa Chemical & Pharmaceutical Industrial Co., Ltd. in China (cGMP certified by SFDA)

➤ **Publicly listed on December 20, 2010.**

Turning Points (1997)

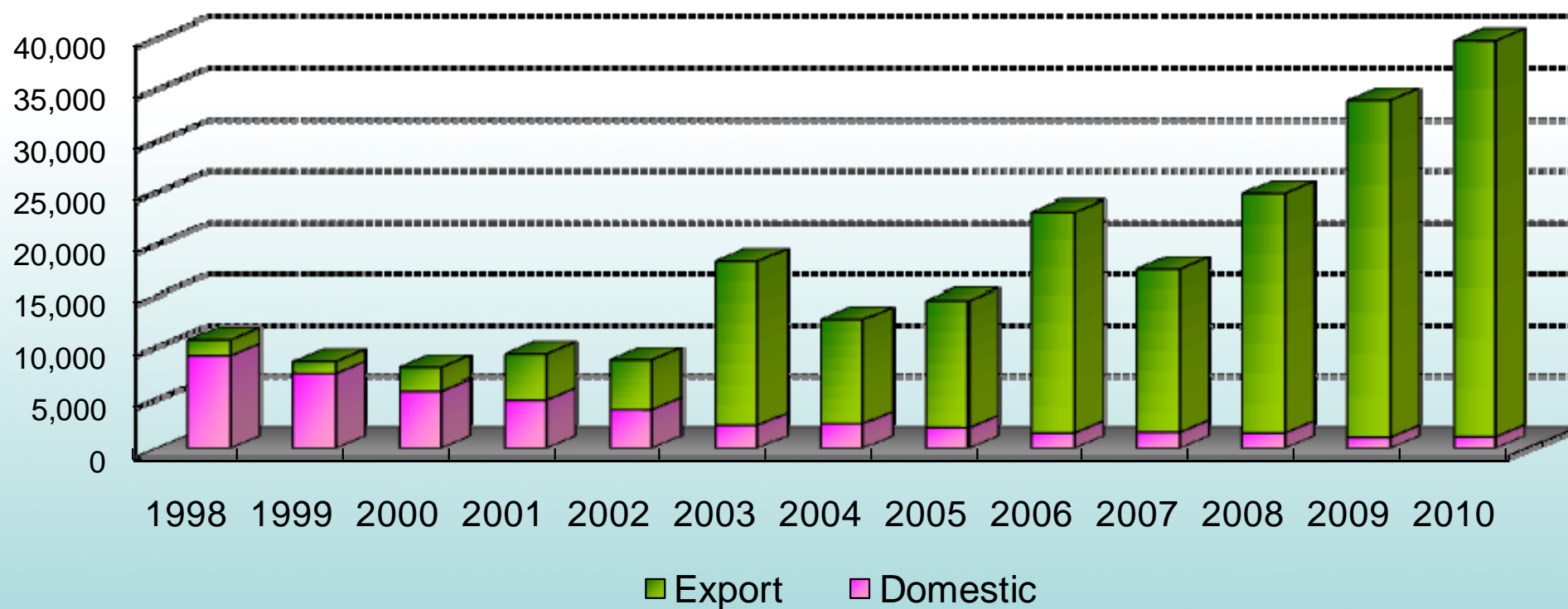


- **Established the New Management Team**
- **Invested US\$ 20 million to construct**
 - 4 cGMP Plants for Synthetic Products
 - 2 cGMP Plants for Biotechnology Products
- **Set up US Sales Office-Pharmaports in 2000**
- **Products**
 - Developing both synthetic & biotech products (microbial fermentation)
 - Participating new drug development and contract manufacturing
- **Global Market Oriented with Emphasis on**
 - U.S.A.
 - Europe
 - Japan

Sales from 1998 to 2010



USD Thousands

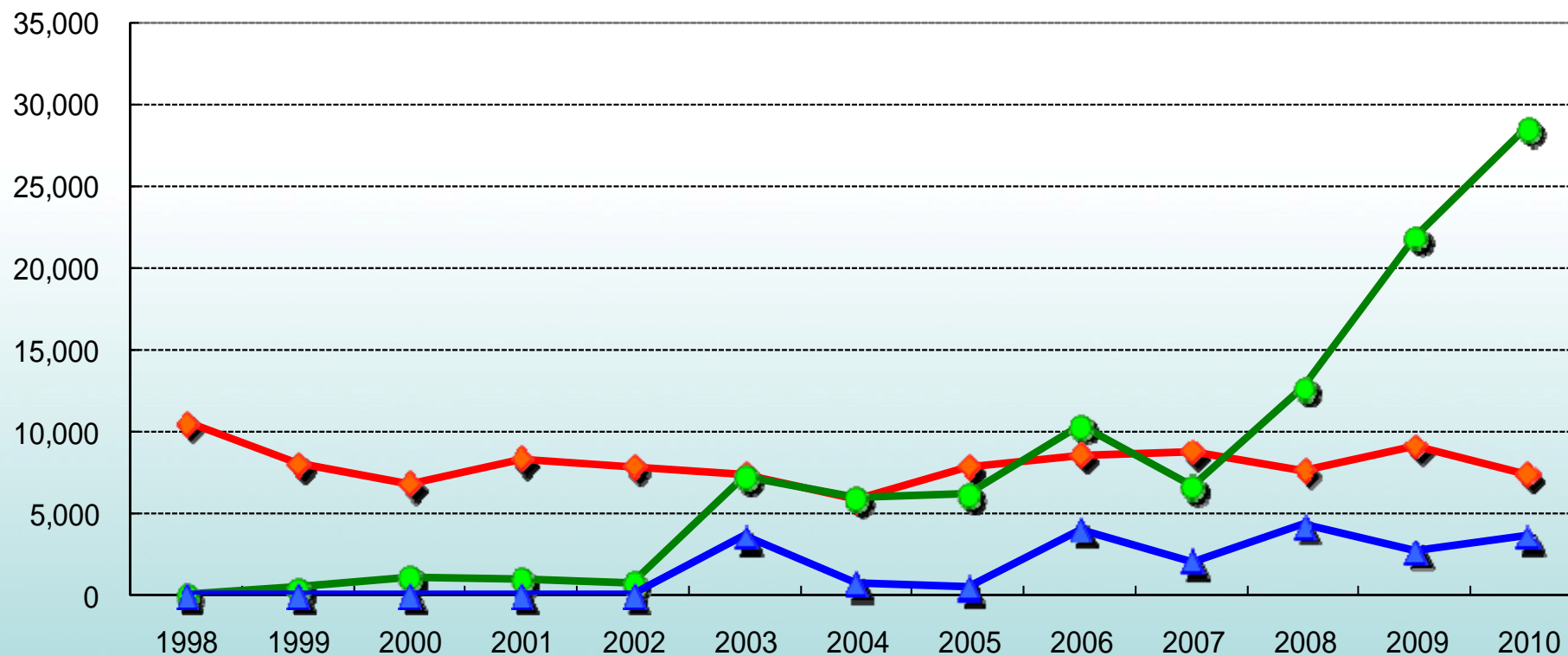


Sales from 1998 to 2010

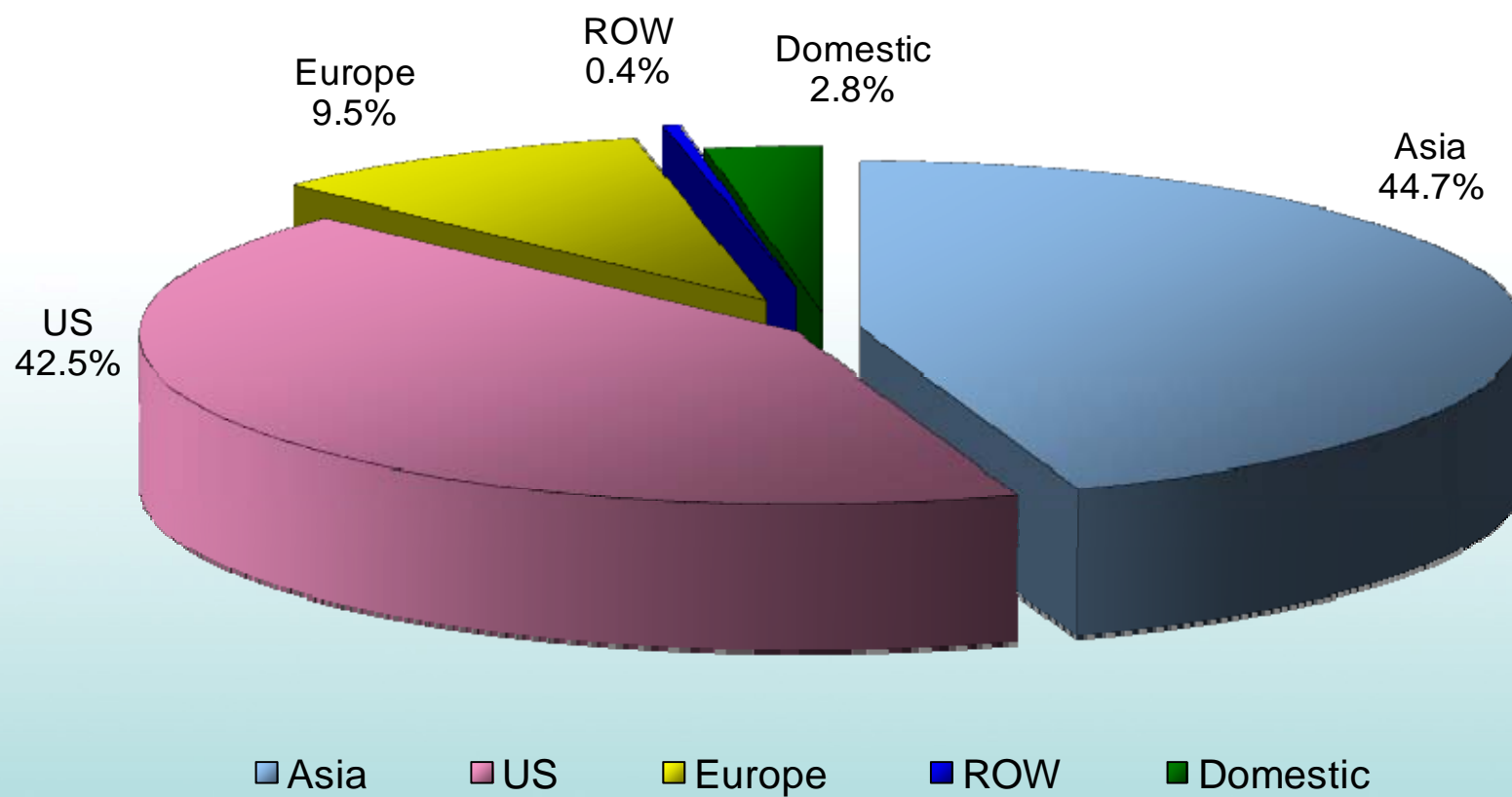


USD Thousands

◆ Synthetic Products ● Biotech Products ▲ Contract Manufacturing



Sales Area in 2010



Management Team



➤ **President – Dr. Steve Chang**

- D.Sc. Chemistry, Univ. Texas at Arlington
- Abbott Laboratories, Abbott Parks, IL, 1989-1998
- QA/QC Manager, CCSB 1999-2002
- VP of Operation 2002-2004

➤ **Chief Operation Officer, Pharmaports – Dr. Jack Yen**

- Ph.D., Chemistry, Drexel University
- Johnson & Johnson Pharmaceutical R&D 1996-2007
- Glaxo SmithKline Pharmaceutical R&D 1988-1996
- Wyeth Laboratories Pharmaceutical R&D 1986-1988

Management Team (cont.)



➤ VP of Business Management - Mr. Denry Huang

- Deputy Plant Manager
- Marketing & Sales Manager
- General Manager, Shaoguan City Fermentec Co., China

➤ Plant Manager – Mr. K.H. Tseng

- B.E. in Chemical Engineering
- Pharmaceutical Manufacturing since 1976

Management Team (cont.)

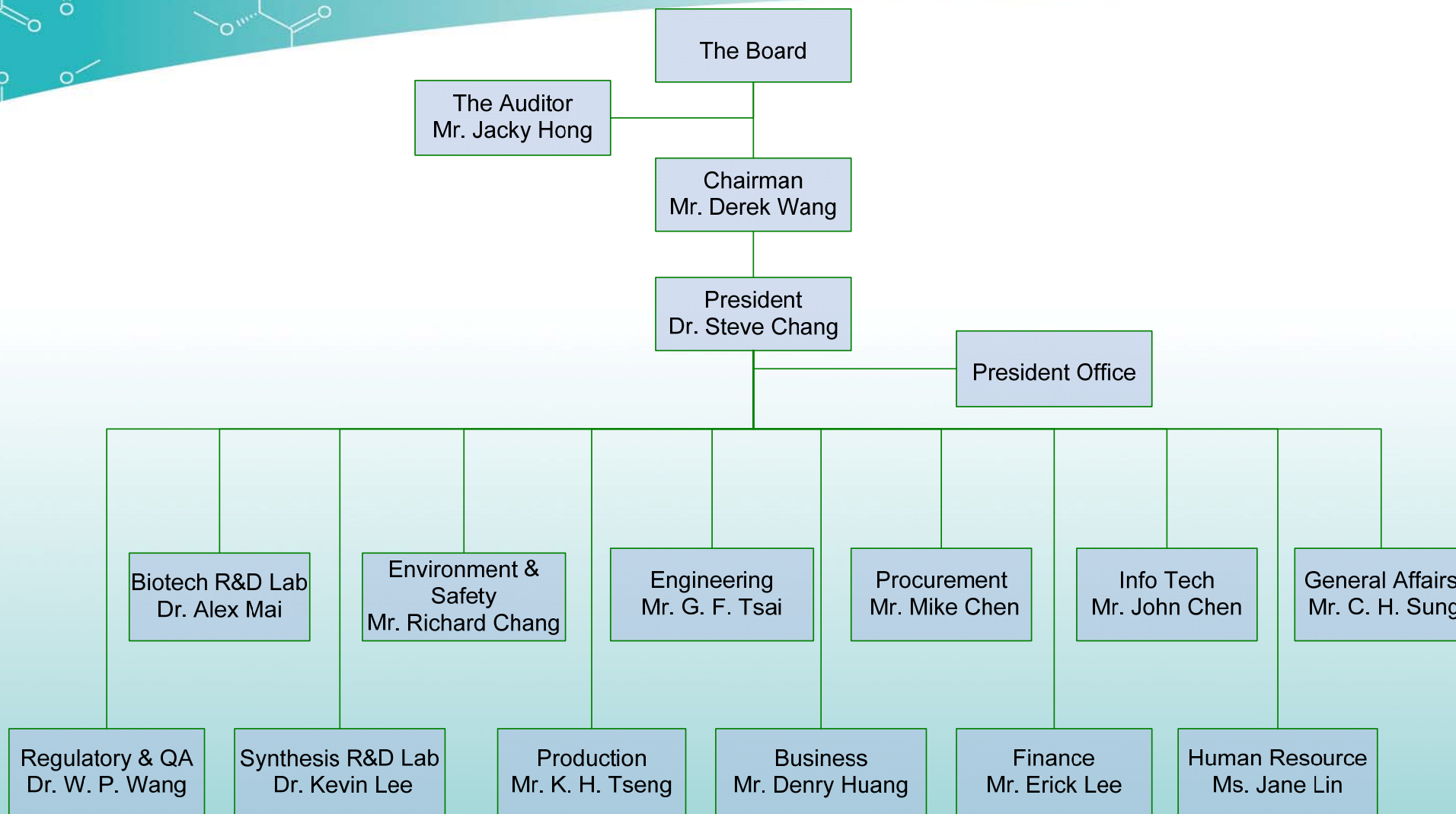


- **Regulatory & QA Manager – Dr. W.P. Wang**
 - Ph.D. Ch.E., University of Massachusetts
 - Experienced in API R&D, Production and QA/QC since 1995

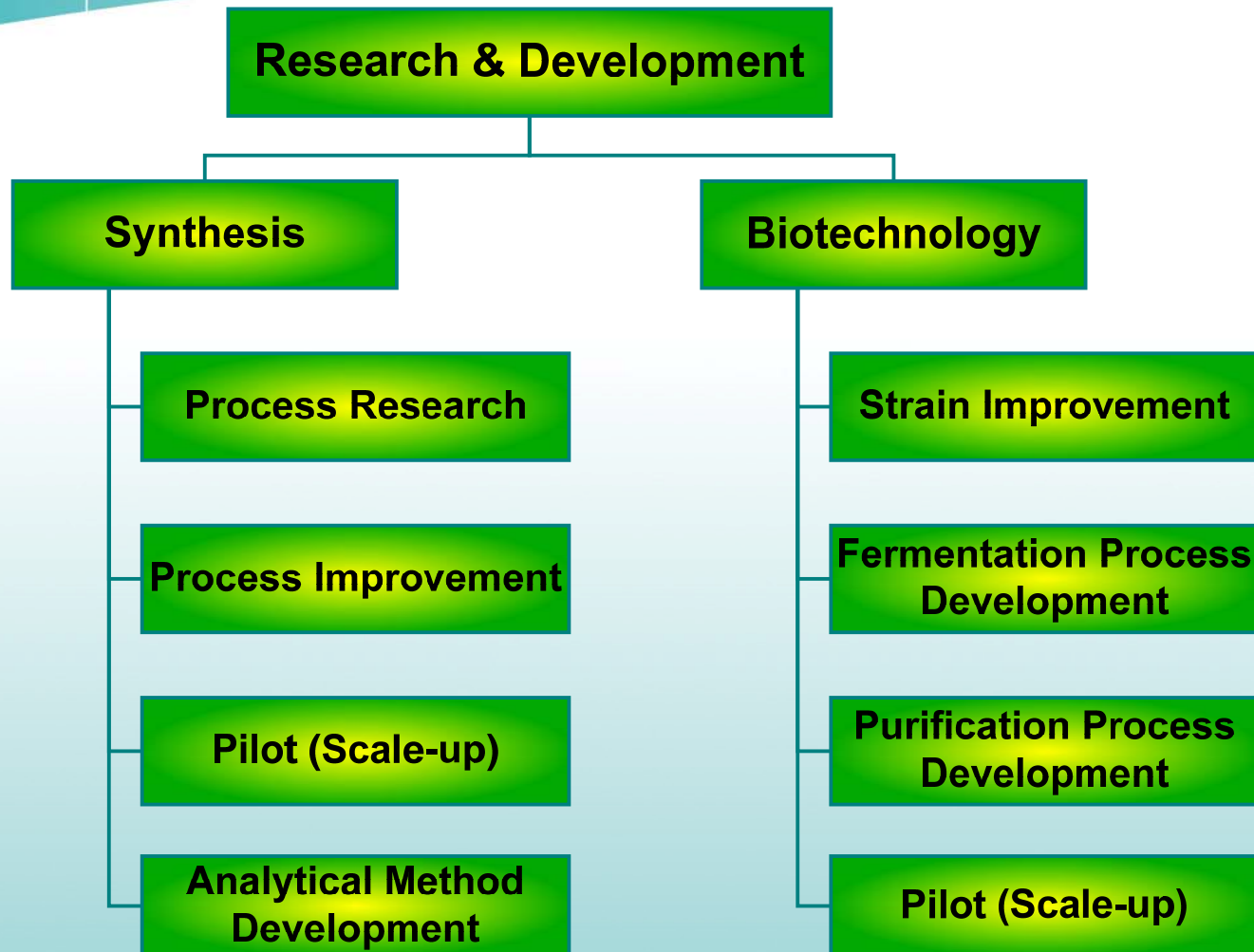
- **Synthesis R&D Director – Dr. Kevin Lee**
 - Ph.D. Chemistry, National Tsing Hua University
 - API R&D since 1994

- **Biotech R&D Director – Dr. Alex Mai**
 - Ph.D. Chemistry, National Taiwan University
 - API R&D since 1994

CCSB Organization Chart



Research and Development



R & D Manpower



	Synthesis	Biotech	Total	%
Ph.D.	4	3	7	21.2%
Master	5	9	14	42.4%
Bachelor	7	3	10	30.3%
Others	0	2	2	6.1%
Total	16	17	33	

Biotech Capabilities



➤ Strain Improvement

Obtain high producer strain through screening and mutation

➤ Fermentation Process Development & Commercialization

Pravastatin Sodium; Rapamycin (Sirolimus);
Mycophenolate Mofetil; Tacrolimus(FK506);
Caspofungin; Micafungin; Anidulafungin;
Temisirolimus; Everolimus; Biolimus; Zotarolimus

Contract Research & Development



➤ **Antiarrhythmia Drug**

- Collaborated with National Science Council & National Taiwan University in Taiwan

➤ **Blood Substitute, Antioxidant Drugs**

- Collaborated with SynZyme in U.S. funded by DOD & NIH

➤ **Antiradiation Drugs**

- Collaborated with SynZyme in U.S.

➤ **Macrolide**

- Collaborated with a U.S. Biotech company

➤ **COX II Inhibitor**

- Collaborated with a German company

Official cGMP Inspections



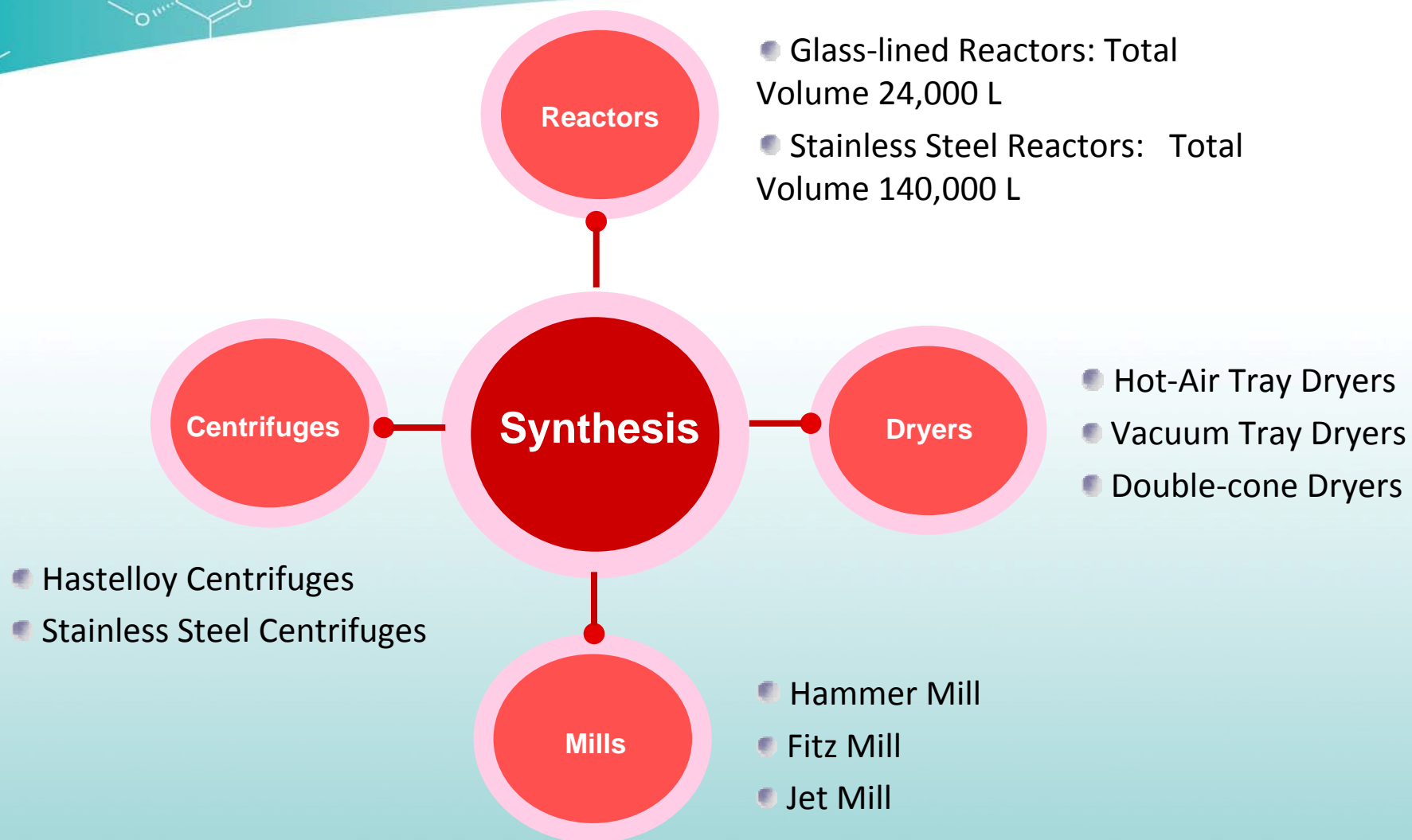
Year	Official	Nation	Product
2002	FDA	US	Methocarbamol
2005	FDA	US	Pravastatin
2006	TFDA	Taiwan	Perindopril
2007	KFDA	Korea	Methocarbamol
2008	NIP	Hungary	Perindopril
2008	TFDA	Taiwan	Trandolapril
2009	Koln	Germany	Pravastatin
2009	TFDA	Taiwan	GMP Systems
2011	FDA	US	Dexb; MMF; Tacrolimus

Active US DMF List

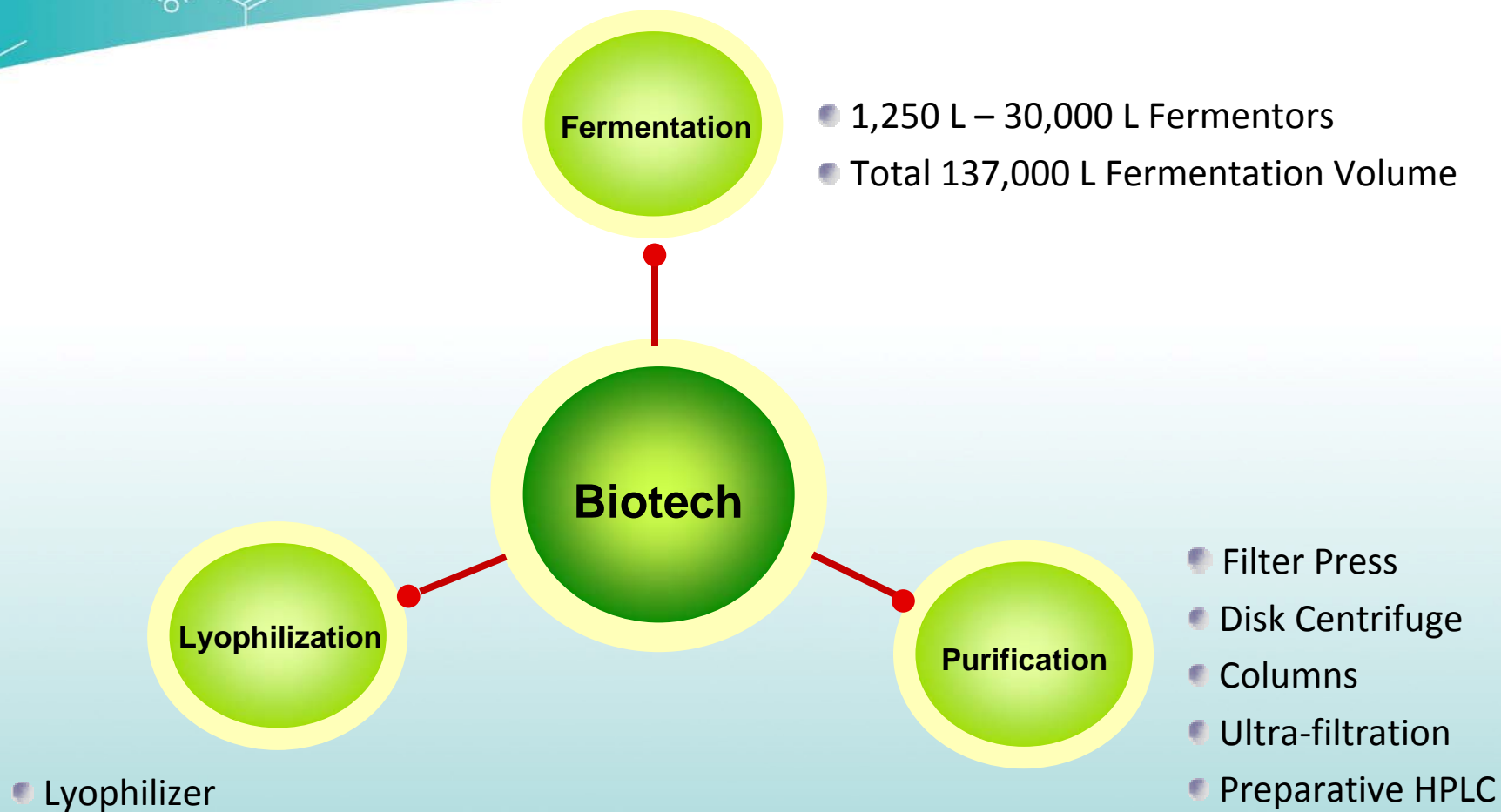


- **DMF 8625**
Dexbrompheniramine Maleate
- **DMF 13080**
Methocarbamol
- **DMF 14234**
Guaifenesin
- **DMF 14235**
Pravastatin Sodium
- **DMF 17399**
Rapamycin
- **DMF 17573**
Trandolapril
- **DMF 18494**
Mycophenolate Mofetil
- **DMF 18985**
Tacrolimus
- **DMF 22430**
Olopatadine
- **DMF 23434**
Metaxalone
- **DMF 23435**
Mycophenolate Sodium
- **DMF 24372**
Myophenolate Motefil HCl

Equipment for Synthesis



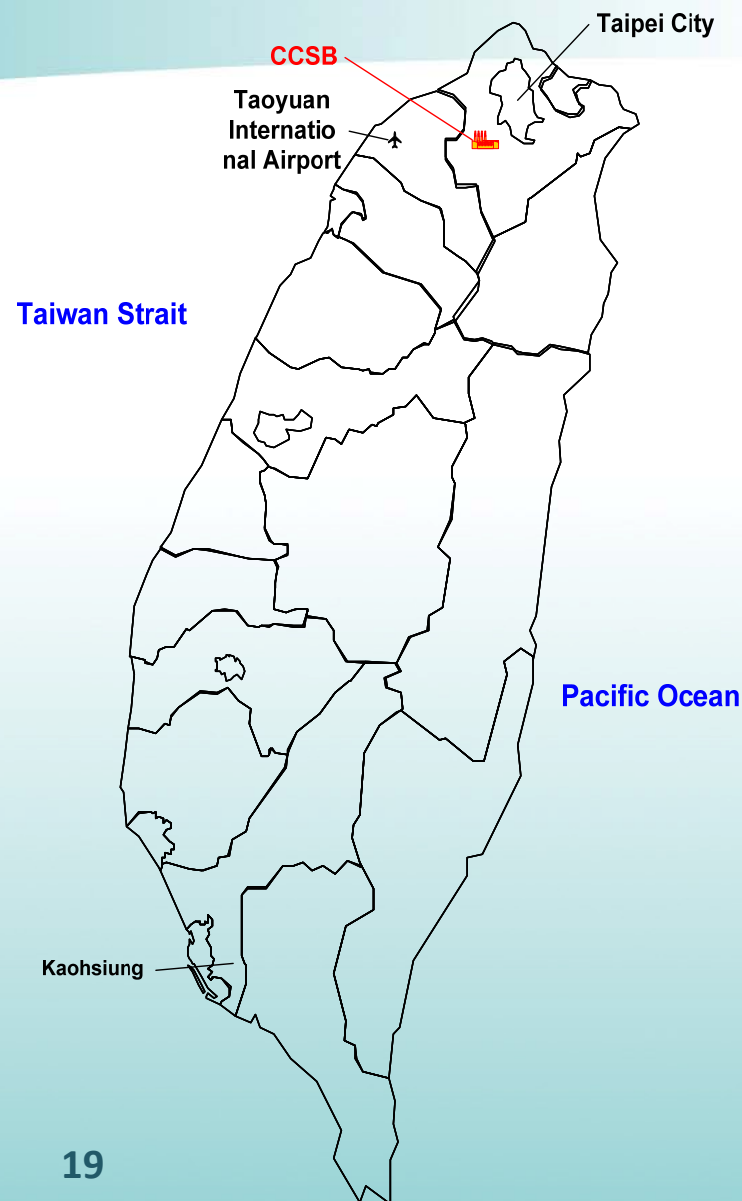
Equipment for Biotech



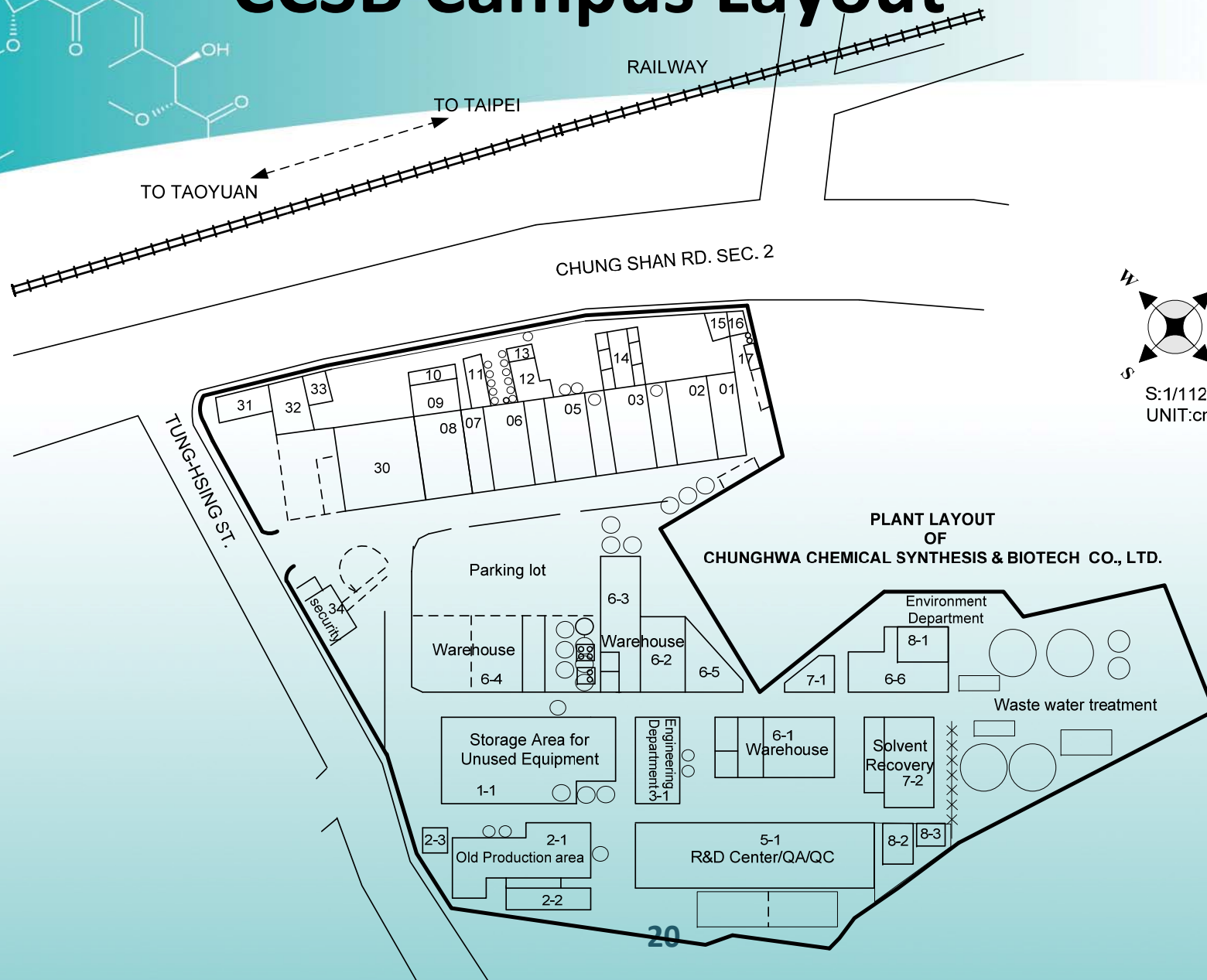
Location & Buildings



- Located in Shu-Lin, New Taipei City
- 20 km South of Taipei
- 34,000 m²
- 197 Employees



CCSB Campus Layout



Chunghwa Chemical Synthesis & Biotech



cGMP Commercial Plants



cGMP Plants
22

Whole Drug Life Cycle Support



Pre-clinical

Phase I/II

Phase III/Launch

Drug Life Time

grams

kilograms

tons/multi-tons

Summary of CCSB



- **Over 45 years of API manufacturing experience**
- **FDA and Health Authorities approved cGMP facilities for synthesis & 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**