



台耀化學股份有限公司

## *Company Introduction*

*Jul 2015*





## Milestones – 1995 ~ 2015

- Dec 1995    Founded by Dr. C. Y. Cheng as a contract research laboratory.
- Apr 2000    Started cGMP production of API's.
- May 2001    Filed EU DMF of Alfacalcidol and Calcitriol.  
(Total 14 API's filed, 7 out of 14 are now used in EU formulations.)
- Jun 2002    Filed US DMF of Leflunomide. (Total 34 API's filed, 10 out of 34 are now used in US formulations.)
- Nov 2002    Signed supply agreement with Roche Vitamins for the production and supply of UV filters.
- Nov 2002    Inspected by TFDA.  
(GMP certificates on 29 products have been granted.)
- Oct 2004    Passed 1st PAI by US FDA for Leflunomide API.
- Mar 2006    Passed 2nd PAI by USD FDA for Avobenzone.
- Nov 2007    Passed 1st GMP inspection by BSG of Hamburg, Germany.
- Jul 2008    Merged with LC United Chemical Corporation.
- Jul 2008    Filed Japan DMF (JMF) of Gadodiamide hydrate.  
(Total 7 on file now; 6 out of 7 are now used in JP formulations.)



### Milestones – 1995~2015

- Apr 2009 Passed 1st PAI for Gadodiamide by PMDA of Japan.
- Jun 2009 Passed 3rd PAI by US FDA for 7 APIs (2 NDAs and 5 ANDAs).
- Aug 2009 Obtained COS certificate of Calcipotriol Anhydrous. ( Total 4 CEP certificates)
- Oct 2009 Commissioning of facilities for high-potent APIs.
- Jul 2010 Incorporated brand new RD, QC & QA facilities, including an automated warehouse.
- Nov 2010 Passed 1st PAI for Mycophenolate Mofetil by COFEPRIS of Mexico.
- Mar 2011 Successful IPO launch. Currently listed in Taiwan Stock Exchange (stock code: 4746).
- May 2012 Passed the 4th US FDA inspection, the general GMP inspection.
- Mar 2013 Passed joint GMP inspection by EDQM and BGV Hamburg.
- Aug 2013 Passed 2nd PAI for TS-1 (Gimeracil, Oteracil, Tegafur ) by PMDA of Japan.
- Oct 2013 Passed 2nd PAI by COFEPRIS of Mexico for 11 APIs.
- Mar 2014 An IND (118719) for MPT0E028 has been approved to US FDA which is co-developed with TMU.
- Jul 2014 Obtained ISO14001, OHSAS18001, and CNS15506 certificates
- Jan 2015 Passed the 5th US FDA inspection, a general GMP inspection.



## Location



•Address: 36, Hoping Street, Louchu, Taoyuan 33842, Taiwan R.O.C.  
+25° 5' 33.83", +121° 16' 36.06"



### An aerial view of our site in Taoyuan

- Capital: USD 28.1 mil
- # of Employees : 587
- Area: 45,508 M<sup>2</sup>

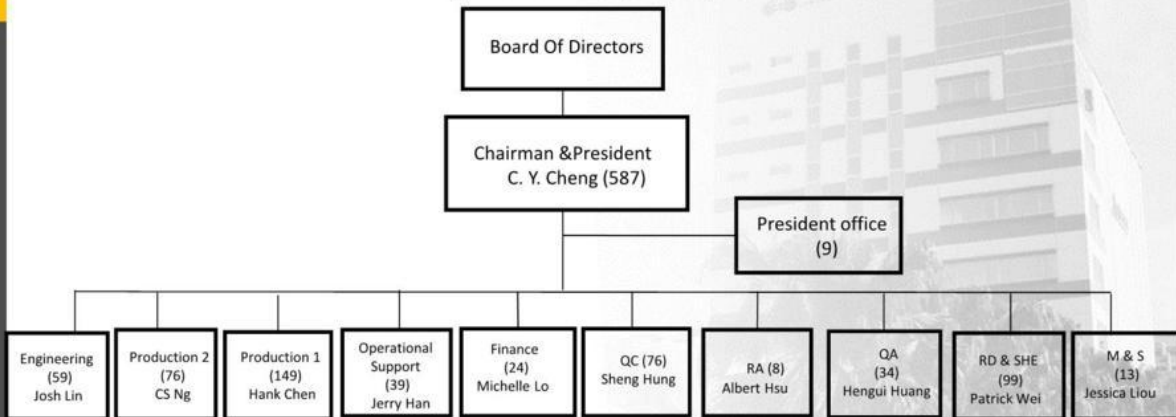




## Organization Chart

Updated: 07/272015

### Formosa Laboratories, Inc. Organization Chart (HC=587)





## Management Team

### **Dr. C.Y. Cheng / Chairman & President**

Ph.D. in Medicinal Chemistry, UC, San Francisco, postdoctoral research at MIT, Professor at National Taiwan University, has over 30 years pharmaceutical industrial experience including 3.5 years at DuPont, Delaware, USA.

### **Dr. Patrick C. P. Wei / Vice President of R&D & SHE**

Ph. D. in Organic Chemistry, National Tsing-Hua University , Hsinchu , Taiwan , has more than 20 years research experience in pharmaceutical industry, including 5 years at Siegfried Chemicals, Taiwan

### **Ms. Jessica Liou / Vice President of Marketing & Sales**

M. S. in Organic Chemistry, Providence University, Taichung, Taiwan, worked as research chemist, deputy supervisor of QC, and Deputy Supervisor of Research for 10 years at Siegfried Chemicals, Taiwan, has over 25 years experience in pharmaceutical industry.

### **Mr. Josh Lin / Vice President of Engineering**

B.S. in Chemical Engineering, Thunghai University, has over 20 years pharmaceutical industrial experience .

### **Ms. Michelle Lo / Vice President of Finance**

B.S. in Accounting, Ming Chuan University, Taipei, Taiwan, has more than 25 years accounting and financial experience. Prior to joining Formosa, Ms. Lo was financial VP of LCU.



## Management Team

### **Mr. Hank Chen/ Assistant Vice President of Production**

B.S. in Chemistry, Chung Yuan Christian University, Taiwan, has more than 25 years pharmaceutical industrial experience including 7 years at Siegfried Chemicals, Taiwan.

### **Mr. C. S. NG/ Assistant Vice President of Production**

B.S. and M.S. in Food Science and Biotechnology, National Chung Hsing University, Taiwan, has over 10 years pharmaceutical industrial experience in HAPI production at Formosa.

### **Mr. Hengui Huang/ Assistant Vice President of QA**

M.S. in Science/Biochemistry & Molecule Biology, National Taiwan University, Taipei, Taiwan; has over 15 years pharmaceutical industrial experience including 14 years at ScinoPharm.

### **Mr. Albert Hsu / Manager of RA**

B.S. in Chemical Engineering, Tamkang University, Taipei, Taiwan; has over 20 years pharmaceutical industrial experience including 10 years at GSK Taiwan.

### **Mr. Sheng Hung / Assistant Manager of QC**

M.S. in Applied Chemistry, Chaoyang University of Technology, Taichung, Taiwan; has 8 years pharmaceutical industrial experience at Formosa.





## Products

### API's

#### Anticancers

Imatinib (TW)  
Ixabepilone (US, TW)  
Lapatinib (US, TW)  
Pazopanib (US(6/15)\*, TW(12/15)\*)  
Temozolomide (US, RU, TW, CN, EU, KR, AU, CA, SG)  
TS-1(Gimeracil, Oteracil, Tegafur) (TW, JMF, KR)

#### Anti-inflammatory and Analgesic Agents

Balsalazide (US, TW, IN, KR)  
Capsaicin (US, EU, TW, IN)

#### MRI Enhancing Agents

Gadodiamide (JP, TW, EU, RU, TR)

#### Cholesterol and Phosphate Binders

Calcium Acetate (US, TW)  
Colesevelam HCl (US, TW)  
Sevelamer HCl (US, TW, CA)  
Sevelamer Carbonate (US, EU, TW, CA, CN)

#### CNS Agents

Fludiazepam (TW)  
Flupentixol (TW, CN, IN)  
Melitracen (CN, TW)  
Taltirelin (JP)

#### Immunomodulators

Leflunomide (US, CEP, RU, TW, CA, EU)  
Mycophenolate Mofetil (US, TW, EU, RU)

#### Respiratory Agents

Benzonatate (US, TW, CN)  
Montelukast Sodium (US, EU, TW, CN)

#### Steroids

Levonorgestrel (US, TW, ZA, EU)  
Mifepristone (US, TW)

#### Vit. D Derivatives

Alfacalcidol (EU, TW, CN, SA)  
Calcipotriol Anhydrous (US, CEP, CN, CA, IN, TW, EU)  
Calcitriol (US, CEP, TW, CA, KR, EU)  
Doxercalciferol (US, TW)  
Ergocalciferol(US)  
Maxacalcitol (JP)  
Paricalcitol (US, EU, TW, CN, KR)

#### Others

Fondaparinux Sodium (US)  
Linezolid (US, EU, JP, CA, AU)  
Orlistat (US, EU, TW)

\* Expected filing date

Notice: Please be reminded that some products listed above are still patented and can only be made available for R & D use as permitted under 35 USC § 271 (e) (1), Article 69, Paragraph 1 of the Patent Act of Japan, Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, or Article 69 (4) of the Patent Law of People Republic of China. We will not be responsible if the use of any of the above products infringes on any patent in your country.



## Products

### UV filters (for Sunscreens and Cosmetics)

Avobenzene  
Octyl p-Methoxycinnamate  
Octocrylene  
4-Methylbenzylidene Camphor  
Phenylbenzimidazole Sulfonic Acid  
Octyl Salicylate  
Homosalate

### Custom synthesis/ Contract manufacturing

Custom synthesis service is offered under strict confidentiality from lab scale to commercial production, with full documentation support.





## Kilo Lab Equipment

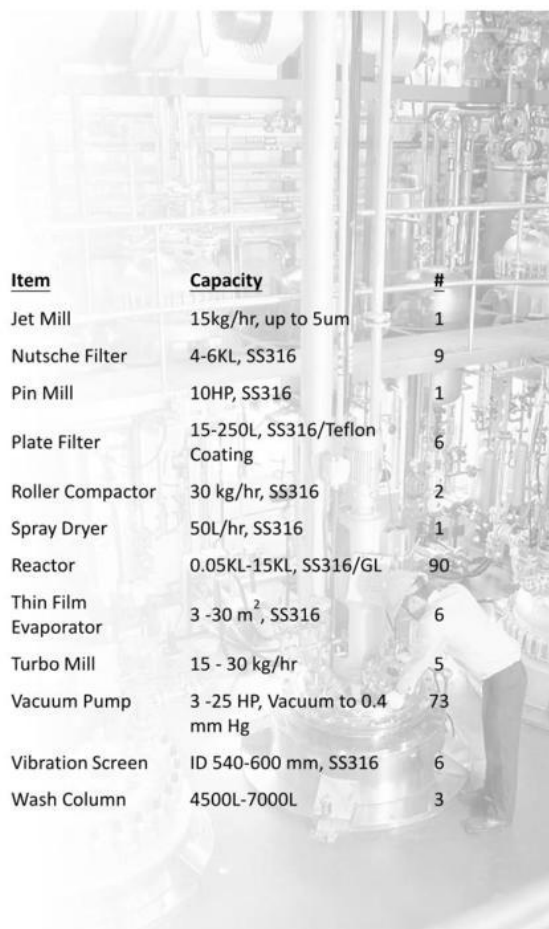
<b>Item</b>	<b>Capacity</b>	<b>#</b>
Centrifuge	15-16", SS316/Hastelloy C/PTFE	5
Chromatography Column	50-80 L	2
Cone Dryer	70L, SS316/GL	2
Spray Dryer	3 kg/hr	1
Cartridge Filter	10" SS316/PP	15
Plate Filter	15-250L SS316/GL	5
Reactor	50-100L, SS/GL	6
Jet Mill	10g/hr, up to 5um	1
Vacuum Pump	3-7 HP , Vacuum to 0.5 mm Hg	3





## Production Equipment

<u>Item</u>	<u>Capacity</u>	<u>#</u>	<u>Item</u>	<u>Capacity</u>	<u>#</u>
Autoclave	1 m <sup>3</sup> , up to 20 kg/cm <sup>2</sup> G	2	Jet Mill	15kg/hr, up to 5um	1
Cartridge Filter	10" SS316/PP	79	Nutsche Filter	4-6KL, SS316	9
Centrifuge	25-52", SS316/Hastelloy C /Teflon Coating	21	Pin Mill	10HP, SS316	1
Chromatography Column	150-500L	3	Plate Filter	15-250L, SS316/Teflon Coating	6
Cone Dryer	70- 500 L, SS316/GL	11	Roller Compactor	30 kg/hr, SS316	2
Distillation Column	5-20KL, 13 plates-20 plates	10	Spray Dryer	50L/hr, SS316	1
Dryer	500-3650L, SS304/ SS316	9	Reactor	0.05KL-15KL, SS316/GL	90
Filter	10-100L, SS304/SS316	35	Thin Film Evaporator	3 -30 m <sup>2</sup> , SS316	6
Filter Dryer	4-6 m <sup>3</sup> , SS	3	Turbo Mill	15 - 30 kg/hr	5
Filter Press	4.3 -30 m <sup>2</sup> , PP	6	Vacuum Pump	3 -25 HP, Vacuum to 0.4 mm Hg	73
Fitz Mill	5HP, SS316	4	Vibration Screen	ID 540-600 mm, SS316	6
Fluidized Bed Dryer	Φ1654-14800, SS316	5	Wash Column	4500L-7000L	3
Freeze Dryer (Lyophilizer)	20L, SS316	1			

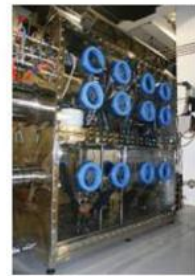




## Facilities for High-potent APIs

### General Description

- 4-floor building:  
3rd and 4th floor, Vit D derivatives  
2nd floor, Steroids  
1st floor, Cytotoxics
- Independent entrances and exits
- Equipment under total containment
- Clean-in-place system
- Target OEL up to  $< 0.1 \mu\text{g}/\text{m}^3$
- Batch size: mgs to kilos



## Facilities for High-potent APIs

3<sup>rd</sup> Floor (Vit D Derivatives )

Batch Size: up to 500 gram

<u>Item</u>	<u>Capacity</u>	<u>#</u>
Lab-scale equipment	0.5 L - 12 L	400
Reactor	0.5 L - 1000 L, GL/SS	54
Chromatography Column	50 L-1000 L	8
Prep-HPLC system	50 × 250 mm / XBridge™ Prep C18, 5µm, OBD™	2
MPLC system	100 × 460 mm	1
Isolator (glove box)		6
Plate Filter	12 L -110 L	4
Falling Film Evaporator	280 L	1
Oven	60 L	1





## Facilities for High-potent APIs

**2<sup>nd</sup> Floor (Steroids)      Batch Size: 65 Kg**

<u>Item</u>	<u>Capacity</u>	<u>#</u>
Reactor	1 L - 1000 L, GL/SS	6
Filter Dryer	30 L-300 L	2
SS Column	1000 L	1
Plate Filter	32 L	1
Jet Mill	100 mm(ID), 2Kg/day	2
Isolator		3



## Facilities for High-potent APIs

1<sup>st</sup> Floor (Cytotoxics)      Batch size: 20 Kg

<u>Item</u>	<u>Capacity</u>	<u>#</u>
Reactor	1 L - 1000 L, GL/SS	13
SS column	20 L	1
Filter Dryer	50 L	1
Plate Filter	10 L~200 L	3
Jet Mill	100 mm(ID), 2Kg/day	1
Isolator		5
Oven	60 L	1
Freeze Dryer (lyophilizer)	15 L	1







### Analytical Instrument

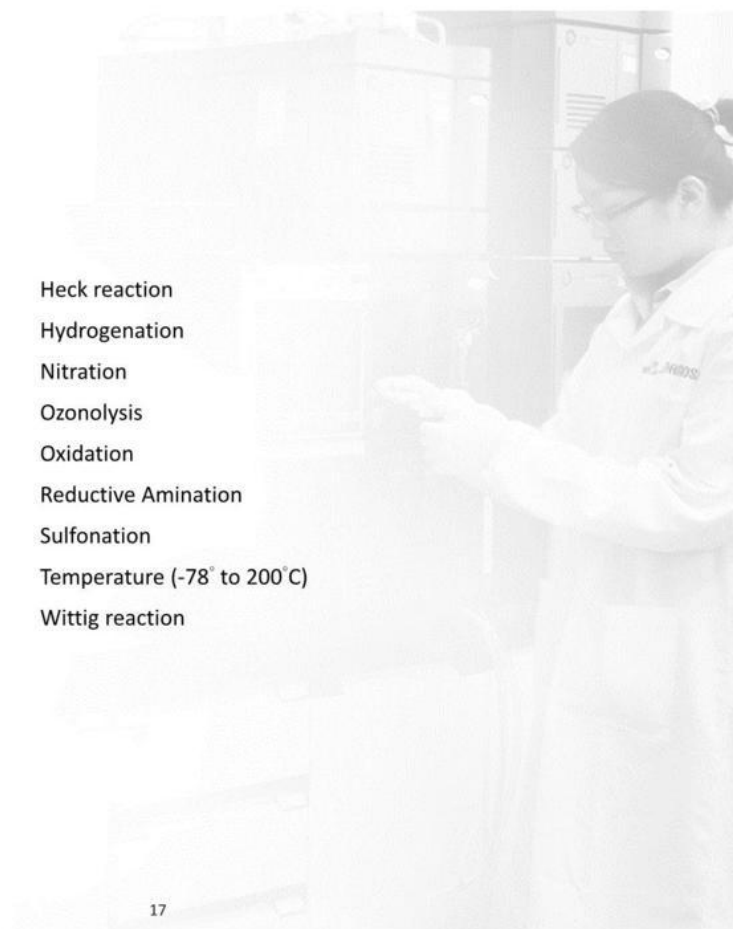
<u>Item</u>	<u>#</u>	<u>Item</u>	<u>#</u>
Auto-Titrator	5	pH Meter	5
Analytical Balance	16	Polarimeter	2
Conductivity Meter	3	Tapped Density Tester	2
Coulometer	1	Ultra-Low Temp. Freezer	1
FT-IR Spectrometer	1	UPLC	17
GC	35	UPLC-MS	2
GC-MS	2	UV Spectroscopy	2
HPLC	29	Vacuum Oven	4
Ion Chromatography	3	CE	1
Karl Fisher Titrator	3	TGA	1
Laser Particle Sizer (Malvern type)	2	iIC	3
Melting Point Detection Apparatus	3	iICP-MS	1
Microscope	1	ICP-OES	1
Moisture Analyzer	4	Microwave Disester	1
Muffle Furnace	3	X-ray diffraction	1
Sonic Sifter	1		

**A well equipped Microbial Analytical Lab is up and running at Formosa Labs.**



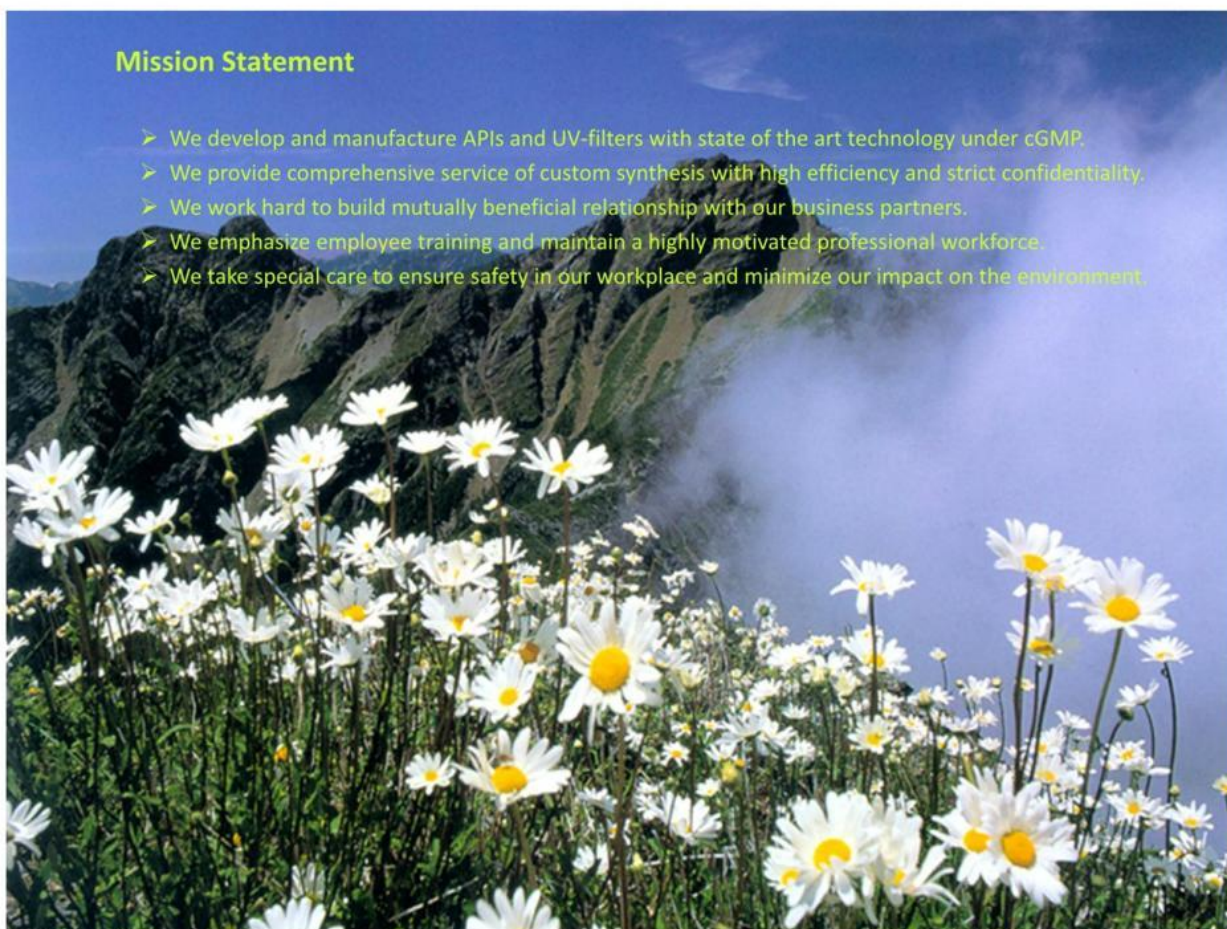
## Reaction Capabilities

Alkylation	Heck reaction
Amidation	Hydrogenation
Bromination	Nitration
Chiral Resolution	Ozonolysis
Condensation	Oxidation
Dehydrohalogenation	Reductive Amination
Diazotization	Sulfonation
Esterification	Temperature (-78° to 200°C)
Friedel Crafts Reaction	Wittig reaction
Grignard reaction	



## Mission Statement

- We develop and manufacture APIs and UV-filters with state of the art technology under cGMP.
- We provide comprehensive service of custom synthesis with high efficiency and strict confidentiality.
- We work hard to build mutually beneficial relationship with our business partners.
- We emphasize employee training and maintain a highly motivated professional workforce.
- We take special care to ensure safety in our workplace and minimize our impact on the environment.





[www.formosalab.com](http://www.formosalab.com)