Raffles PharmaTech Company Overview

(May 2017)

莱佛士制药技术有限公司

Raffles PharmaTech Pte Ltd

About Us

- Established in August 2011 with a foundation in innovative organo-catalysts. Raffles expanded into a comprehensive and product and service provider for pharmaceutical industry.

- Utilizing our experience within major global pharmaceutical companies, we develop and manufacture small molecule key raw materials, specialty reagents, intermediates and APIs for the pharmaceutical industry.

Our Business

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What we Have

Small molecule R&D and manufacturing capabilities and facilities

Who we Serve

Pharma Companies

CMOs

What we Deliver

- Development of API stages
- Intermediates
- Specialty materials and reagents

- Difficult to Source Materials
- Specialty materials and reagents

Staff Composition

Total 67 people: PhD(6), MSc (12), BSc(37)

- R&D (38)
  - 30 synthetic chemists (Across 4 Teams)
  - 8 analytical development chemists
- Manufacturing (17)
  - 10 Operations (Ops + Production Manager)
  - 2 Production Chemists
  - 2 QA, 3 QC
  - 1 RA
  - 2 Purchasing and Logistics
- Commercial and Supporting (12)
  - 6 Sales and business development
  - 6 Supporting

Core Team

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CEO, Dr Weiping Ye

2003 BSc, Chemistry, Peking University
2003 Minor, Economics, Peking University
2006 PhD, National University of Singapore
2006-2010 GlaxoSmithKline, Senior/Chemist
2008-2010 GlaxoSmithKline, Lead Chemist for NCE Retigabine
2009-2010 GSK-Singapore Green and Sustainable Manufacture Fund, Project Manager, S$33 millions.
2010-2011 Pfizer, Manager – API Global External Supply Asia
Sept 2011-now, CEO and Co-Founder of Raffles PharmaTech

- Published 10 international paper and filed 14 patents
- Awarded GSK "**Excellence Recognition Award**" **3** times;
- Led/ worked on 8 commercial products and 2 NCE's were approved
- Managed Pfizer's strategic API suppliers in Asia with total annual spend of more than US$200 millions.
- Led the registration of 2 Pfizer API projects in more than 180 countries
- Strong and proven track record of API process development, international project management, and commercialization.

Core Team

- **VP of BD, Andrew Phillis PhD**

2000 BSc, Chemistry University of Waikato, New Zealand
2002 MSc(Hons), University of Waikato, New Zealand
2006 PhD, Australian National University
2007- 2010 GlaxoSmithKline, Chemist (R&D Pilot Plant)
2010- 2011 GSK, Senior Chemist (Commercial Production)
2011- 2012 GSK, Project Manager
2011- Mar 2014 GSK, Senior Process Chemist (2nd Generation API Group)
Apr 2014-June 2016, R&D Director, Raffles PharmaTech
June 2016 – Now: VP of BD

- Led/worked on 9 products, out of which 6 were successfully commercialized;
- Awarded GSK "**Excellence Recognition Award**" **2** times;
- Strong experience in both R&D and commercial product;
- Proven track record in developing green second generation processes that lead to significant cost and environmental benefits

Core Team

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- **Deputy GM, Dr Junye Xu**

2003 BSc, Suzhou University
2008 PhD, National University of Singapore
2007-2008 Teaching Assistant, National University of Singapore
2009-2011 Codexis (NSDQ: CDX), Staff Scientist
Sept 2011-now, Co-Founder and Deputy GM of Raffles PharmaTech

- Awarded US "**2012 Presidential Green Chemistry Challenge Award**" for the excellent work on Simvastatin enzymatic process development
- 4 US Patents on enzymatic process development: US20110111468A1, US20120244582A1, US20130260426A1, US20130130351A1.
- Successful enzymatic process development of more than 8 products, including Simvastatin, Esomerprazole, Armodafinil, etc.
- One successful technology transfer of enzymatic process to a major MNC pharma for commercialization

Core Team

- **R&D Director, Dr. Tom Zhou**

2003 B.Sc. Chemistry, Nankai University
2009 Ph.D. Organic chemistry, Nankai University
2009-2011 Guangdong Hec pharma., group leader
2011-Jan 2016 Lonza, senior chemist
2016-now, R&D Director of Raffles PharmaTech

- Published 5 international papers
- Awarded Lonza "**Operation Excellence Award**" **2** times;
- Widely experiences in pharmacy industry including: development of new drugs, development of generics, contract development and manufacturing business.
- Led more than 20 projects in 7 years work experiences.
- Capable in from mg to 100 tons scales.
- Experienced and innovative.

Core Team

- **Scientific Advisor, Prof. Choon-Hong Tan**

1996 Honors(First Class), National University of Singapore
1999 PhD, Cambridge University
1999-2003 Post-doc, RF, Harvard University
2003-2012 Assoc Professor, National Univ. of Singapore
2012-2015 Associate Professor, Nanyang Technological Univ.
2016-Now Full professor, Nanyang Technological Univ.
2011-now Scientific Advisor, Raffles PharmaTech

- World renowned scientist in organo catalysis
- Published more than 100 international paper and 4 patents.
- Developed series of novel organo catalysts that see wider and wider application in pharmaceutical synthesis.
- Received multiple international awards, such as

  - Asia Core Program Lectureship Award from Taiwan (2013)
  - GSK-SNIC Organic Chemistry Award (2011)
  - Young Chemist Award (2009)
  - Young Scientist Award (2009)
  - CRISP award (2009)
  - UK-Singapore Partners In Science Collaboration Development Awards (2008)

R&D Capabilities

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Process Development

Our team has many years of experience in developing and installing synthetic processes for the pharmaceutical industry.

Chemical Synthesis

- The heart of a small molecules business
- Design of Experiments (DoE) for support of screening, optimization and robustness studies.

Our core competencies include:

- Route scouting: Routes selected for safety, quality and cost.
- Optimization: High quality, low cost, and robust.
- Impurity studies: Scope of studies based on of ICH guidelines
- Scale-up and industrialization or Tech-Transfer:
  - Scale-dependence and robustness.
  - PARs established
  - CPPs designated

R&D Capabilities

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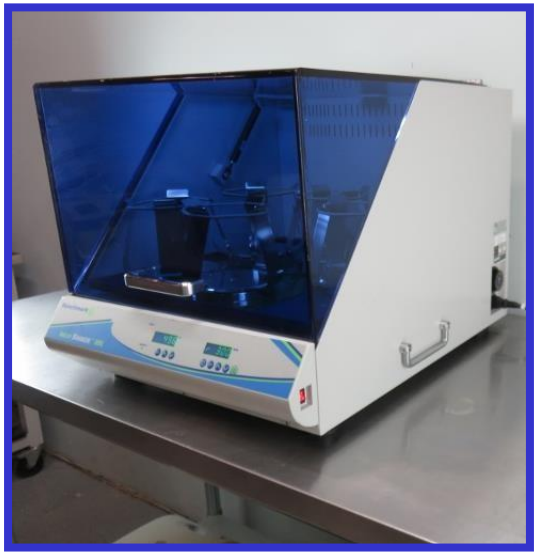
Catalysts screening services

- Parallel screening and fast-LC analysis
- Biocatalysts (enzymes)
- Organocatalysts
  - Holder of Codexis enzyme screening kits (NSDQ: CDX) in China
  - Codexis is the global leader in enzyme evolution and application in the pharma industry.



CODEXIS®

WE ARE BIOCATALYSIS®

www.codexis.com

R&D Capabilities

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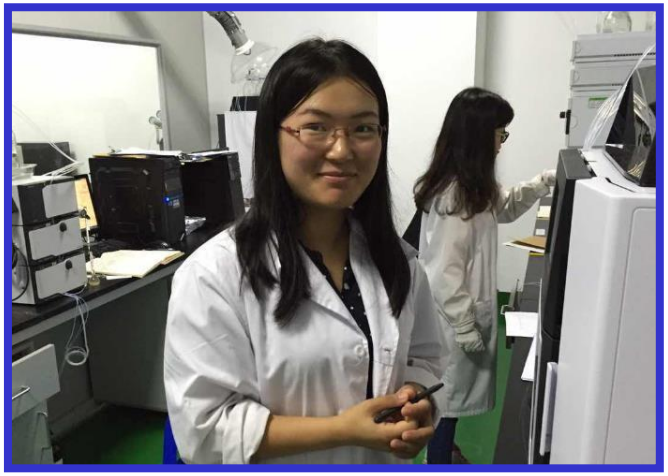
Analytical Methods Development

- We have analytical labs staffed by highly experienced teams located with our development sites.
- Analytical methods development.
- Method validation for IPM, IPC and product release testing.
- Methods development for chiral products.

R&D Facilities

- Shenzhen R&D Site: 1800 m^2
- 7 labs
  - 4 Synthetic Chemistry
  - 1 Catalyst Screening Lab (Enzymes and organocatalysts)
  - 1 Analytical development
  - 1 IPM/IPC testing



R&D Equipment

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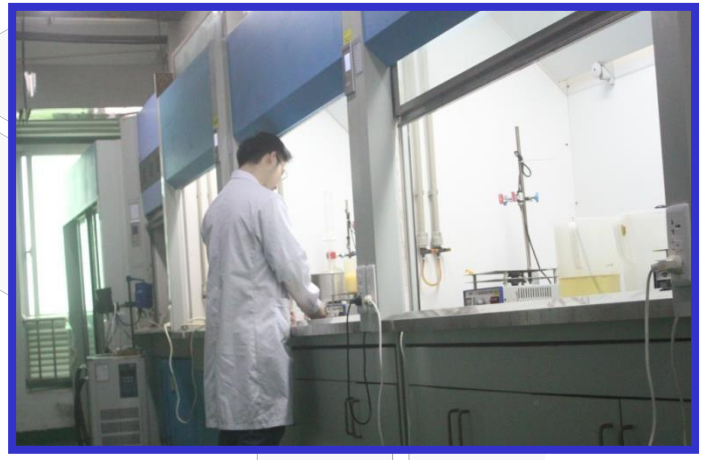
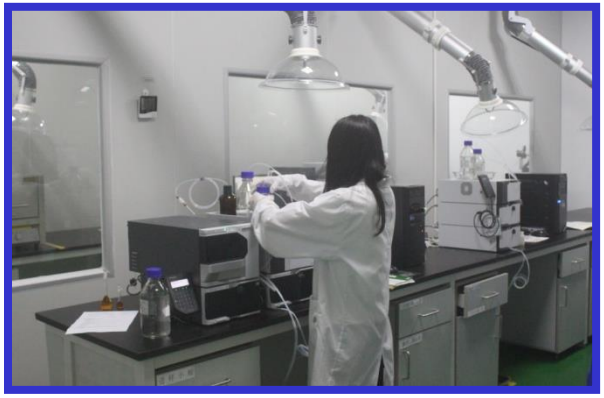


Synthetic Chemistry Lab

Kilo-Scale Lab

Analytical Development Lab



QC Testing Lab

Stability Chambers

Analytical Instruments

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HPLC
Agilent and Shimadzu

GC/HSGC

Muffle Furnace (ROI)

Polari meter

Karl Fischer
Titrator

Melting Point

Manufacturing

- Experienced Team from global pharma and contract organizations
- **3 facilities at 2 sites**
  - **Kilo-scale facility**: Dayawan
  - **Pilot plant**: Dayawan
  - **Large scale manufacturing facility**: Mu dan Jiang

- Capacity from grams to tons.
- Robust quality system.
- Full regulatory support is available with CMC documentation
- High quality, occupational health and safety standards
- Certified ISO9001 compliant quality system.

By partnering with us for development and manufacturing, you can stay focused on accelerating your product development, and simplify your supply chain.

Manufacturing

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Quality and Compliance

- Our commitment to high quality products translates into our services business.
  - Robust process design.
  - Comprehensive analytical testing.
  - ISO9001 certified quality system.
  - Mudan jiang plant is GMP certified
- Physical and chemical definition and analysis
- Impurity tracking
- Stability testing for various ICH recommended climatic zones

Dayawan Site

- 2000 m^2
- ISO 9001:2008 Certified
- Kilo scale facility.
  - In operation since Q3 2015
  - 4 x 50L Reactors
  - 50L Double Cone Drier
  - 8 Vacuum Tray Driers
  - 100 L chromatography column
  - 30 L Rotary evaporator
- QC testing
- Stability monitoring
- Product Warehouse

Dayawan Site

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- Pilot Scale facility.
  - 2 x 200 L Glass lined reactors
  - 1 x 200 L 316 SS reactor
  - 20kg per cycle centrifuge
  - 100 L Double cone drier
  - Highly Configurable

Dayawan Site

- Environmental protection controls.

Above ground Waste Storage Tanks

Easily inspected and emptied

- Spray scrubber
- Cooling tower
- Fume hood vapour extraction system

Mu Dan Jiang Site

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- Raffles is a significant shareholder
- CFDA inspected and approved.
- GMP certified.
- Clean room
- 16 Reactors (50 - 3000 L)
- Purified water system

Future Dayawan Site

- Raffles is planning to secure a block of land ~20,000 m2 in 2017.
- Located in Dayawan, near to the current Dayawan site which houses the current pilot facility and kilo scale lab.
- Our vision is to build a world-class, state of the art manufacturing facility for production of advanced intermediates and APIs.
- Targeting to break-ground in mid 2018, and start operations in early 2020.

Locations

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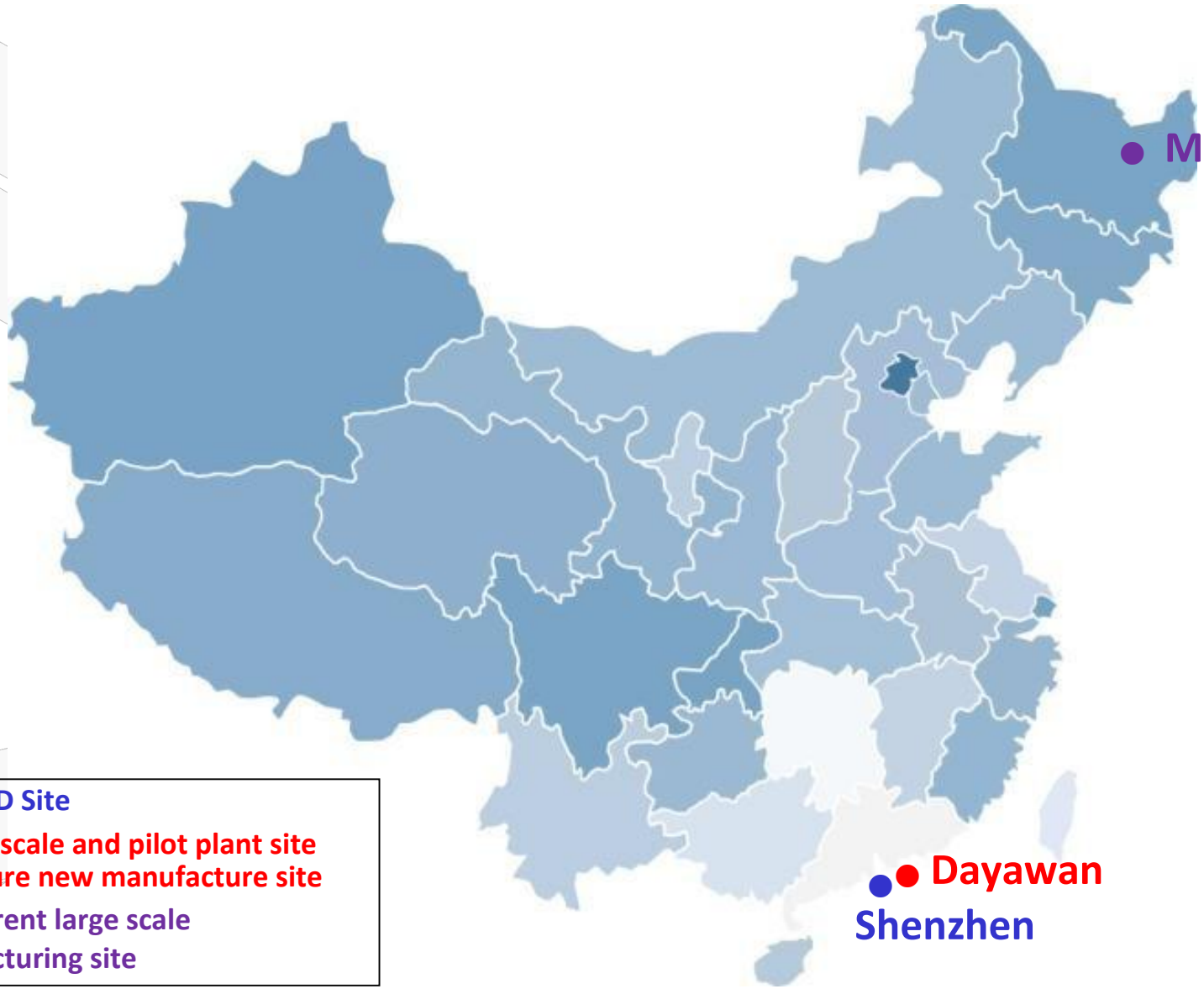

● = R&D Site

● = Kilo scale and pilot plant site
And future new manufacture site

● = Current large scale
Manufacturing site

Recognition

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★ Awarded multiple **Science and Technology Project Grants**
- **4** from Daya Bay Economic and Technology Development Zone
- **3** from the Huizhou City
- **2** from Guangdong Provincial government
- **2** from Central Government.

★ **17** Chinese patent applications（**6 granted**) and **3** PCT international applications (**1 granted**).

★ Our Organic Phase Transfer catalyst was awarded **"2012 Guangdong High-Tech Product**" certification.

★ Our project on "Novel Asymmetric Phase Transfer Catalyst" (Code: 20134400012) was awarded grant support from the **Chinese State Administration of Foreign Experts Affairs in 2013**.

★ Certified as **State High-Tech Enterprise in 2015**.

★ Andrew Phillis, PhD awarded, "**Leading Talent**" title from Huizhou Government.

ISO 9001 Certification

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SGS

Certificate CN16/30227

The management system of

Huizhou Raffles Pharma Tech Pte Ltd.

Level 5 & 7, Accelerator Building, No 3, Binhai 10th Road North,
Shihua Dadao Middle, Xiachong, Daya Bay,
Huizhou City, Guangdong Province, P.R. China

Unified Social Credit Code 91441300581363263 1

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

Research and development on Active Pharmaceutical Ingredients (including Vilanterol, Celecoxib); Manufacturing of chemical intermediates (including 5'-chloro-2'-hydroxy-[1,1'-Biphenyl]-3-carboxylic acid; 5'-chloro-3'-nitro-2'-hydroxy-[1,1'-Biphenyl]-3-carboxylic acid; 3'-amino-2'-hydroxy-[1,1'-Biphenyl]-3-carboxylic acid; 3-Methyl-1-(3,4-dimethylphenyl)-2-pyrazolin-5-one)

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization

This certificate is valid from 26 January 2016 until 15 September 2018
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 1. Certified since 26 January 2016

Authorized by

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com
The certification information can be verified on the web site of Certification and Accreditation Administration of the People's Republic of China www.cnca.gov.cn

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UKAS MANAGEMENT SYSTEMS 0005

Honors and Awards

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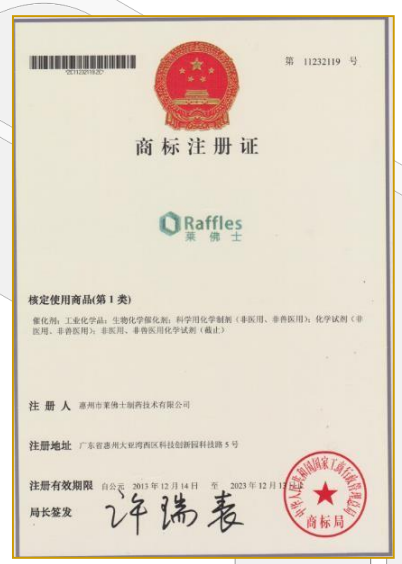

Academic Partners

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Nanyang Technological University

Singapore Polytechnic

South China Normal University

Huizhou Research Institute of Sun Yat-Sen University

Shenzhen Institute of Advanced Technologies, Chinese Academy of Science

Henan University

Thank you !

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Business Enquiries : sales@rafflespt.com
Website : www.rafflespt.com