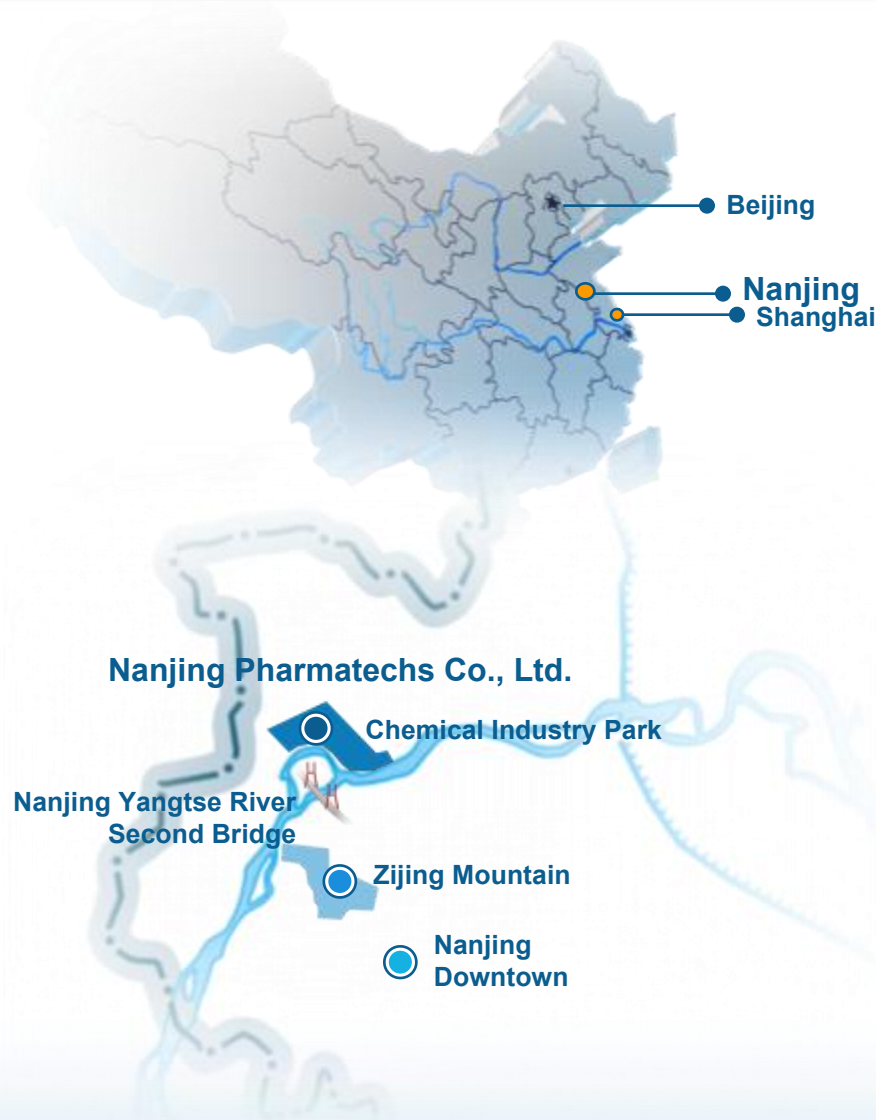


Nanjing Pharmatechs Co., Ltd. Presentation



9 East Fangshui Road, Chemical Industry Park
Liuhe, Nanjing, China 210047
Phone: 86 25 58392668; Fax: 86 25 583922998
Email: info@nanjingpharma.com
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Our Location



Geographic

Nanjing

190 miles from Shanghai

750 miles from Beijing

Area

2548 sq. miles

Population

8.3 million

Language

Mandarin

Nanjing Chemical Industry Park
(Government owned Chemical Industry Parks)
19 miles from downtown Nanjing
36 miles from Nanjing International Airport

Our History



Analytical Chemistry Services

- **Method development and validation;**
- **Quality control analysis;**
- **Compound identification and structure elucidation;**
- **Impurity isolation and characterisation;**
- **Stability studies.**

Process Development Services

- **Route selection & process development of scalable, robust and cost-effective chemical processes;**
- **Process optimization;**
- **Critical process parameter assessment;**
- **Process demonstration from multi-gram to multi-kilogram quantities;**
- **Synthesis of reference standards and impurities.**

Manufacturing Services

- **Manufacturing regulatory starting materials (RSM) under cGMP controls;**
- **Process scale-up from multi-kilogram to multi-ton quantities;**
- **Manufacturing for pre-clinical, clinical and commercial supply;**
- **Specialty chemicals production;**
- **Quality assurance and quality control;**
- **Toll manufacturing.**

As a reliable CRO/CDMO, we have over 10 years experiences supporting the process development and production of regulatory starting materials (RSMs) and APIs from pre-clinical support to clinical trials I/II/III and commercialization.

Technical abilities:

- **Completed more than 50 projects to support all phases of clinical studies of APIs;**
- **Developed the processes to the advanced intermediates and APIs up to 15 steps;**
- **Developed and validated analytical methods to support the process development and production.**

Western style management:

- **Every project is executed under full confidentiality;**
- **All documentation including weekly updates, campaign reports, research summaries, batch records, and analytical documents will be provided to the customers in English;**
- **Transparent communication with the customers by email, tele-conference, and customer visit.**

Production under cGMP controls:

- **Produced RSMs for 2 APIs from Phase I clinical study to commercialization;**
- **Produced RSMs for more than 5 APIs from Phase I to Phase III clinical studies;**
- **Produced RSMs for more than 10 APIs from Phase I to Phase II clinical studies;**
- **Produced RSMs and the starting materials to RSMs to support preclinical studies of APIs and pre-clinical candidates.**

Our Core Technology

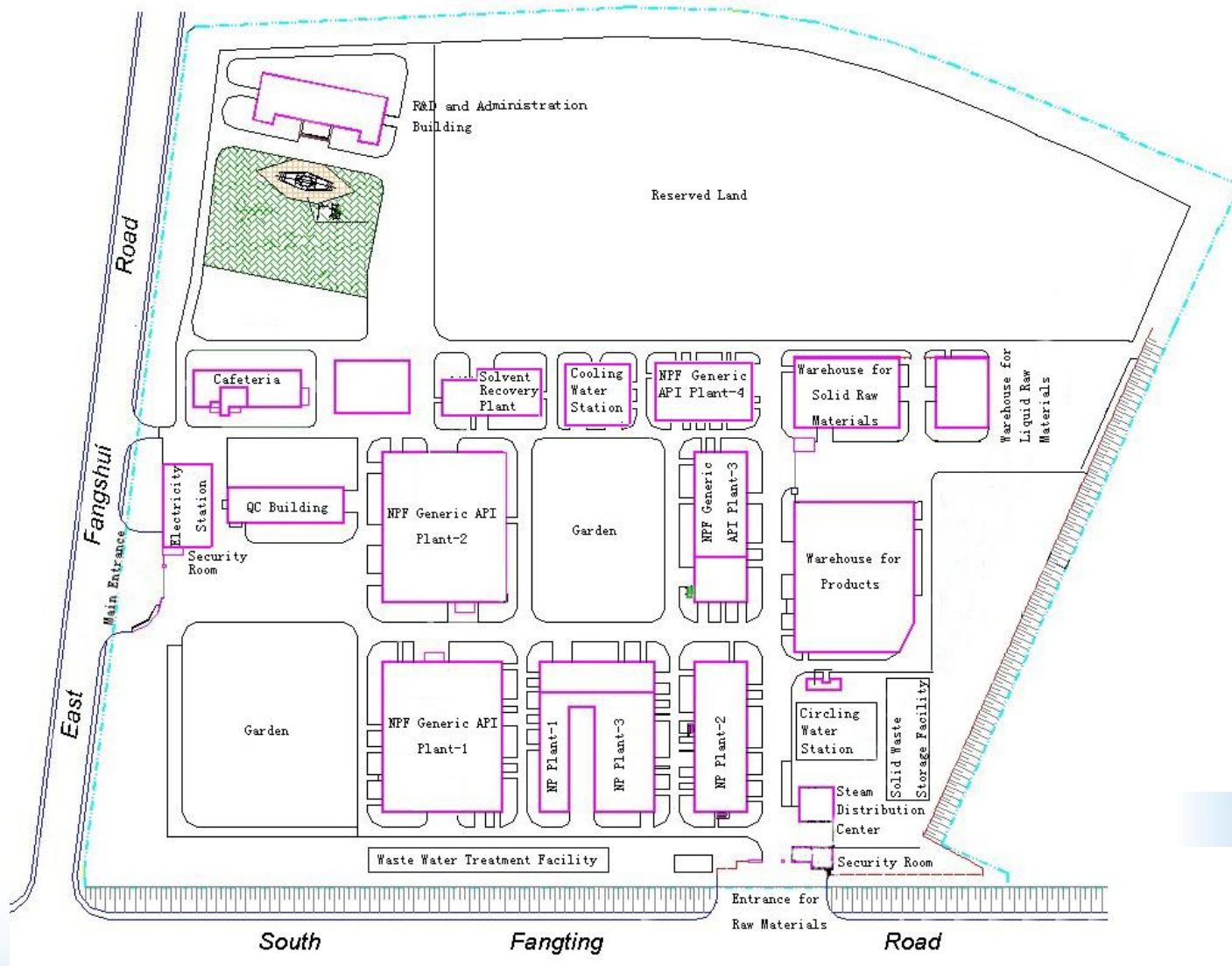
The following reactions have been scaled up both in the Laboratory and in production:

Name of Reaction	Lab Scale	Production Scale
Amidation	Yes	Yes
Alkylation	Yes	Yes
Chiral resolution	Yes	Yes
Cross coupling reactions (Suzuki, Negishi, Sonogashira coupling reactions)	Yes	Yes
Decarboxylation	Yes	Yes
Diazotization	Yes	Yes
Esterification	Yes	Yes
Friedel-Crafts reactions	Yes	Yes
Grignard reaction	Yes	Yes
Halogenation (Chlorination, Bromination, Iodization)	Yes	Yes
High pressure reactions	Yes	Yes
Hydrogenation	Yes	Yes
Low temperature reactions	Yes	Yes
Nitration	Yes	Yes
Oxidation	Yes	Yes
Radical reactions	Yes	Yes
Rearrangement (Curtis, Beckmann, Hofmann rearrangements)	Yes	Yes
Reduction	Yes	Yes

Area Map



Site Plot



Total Area

50 Acres

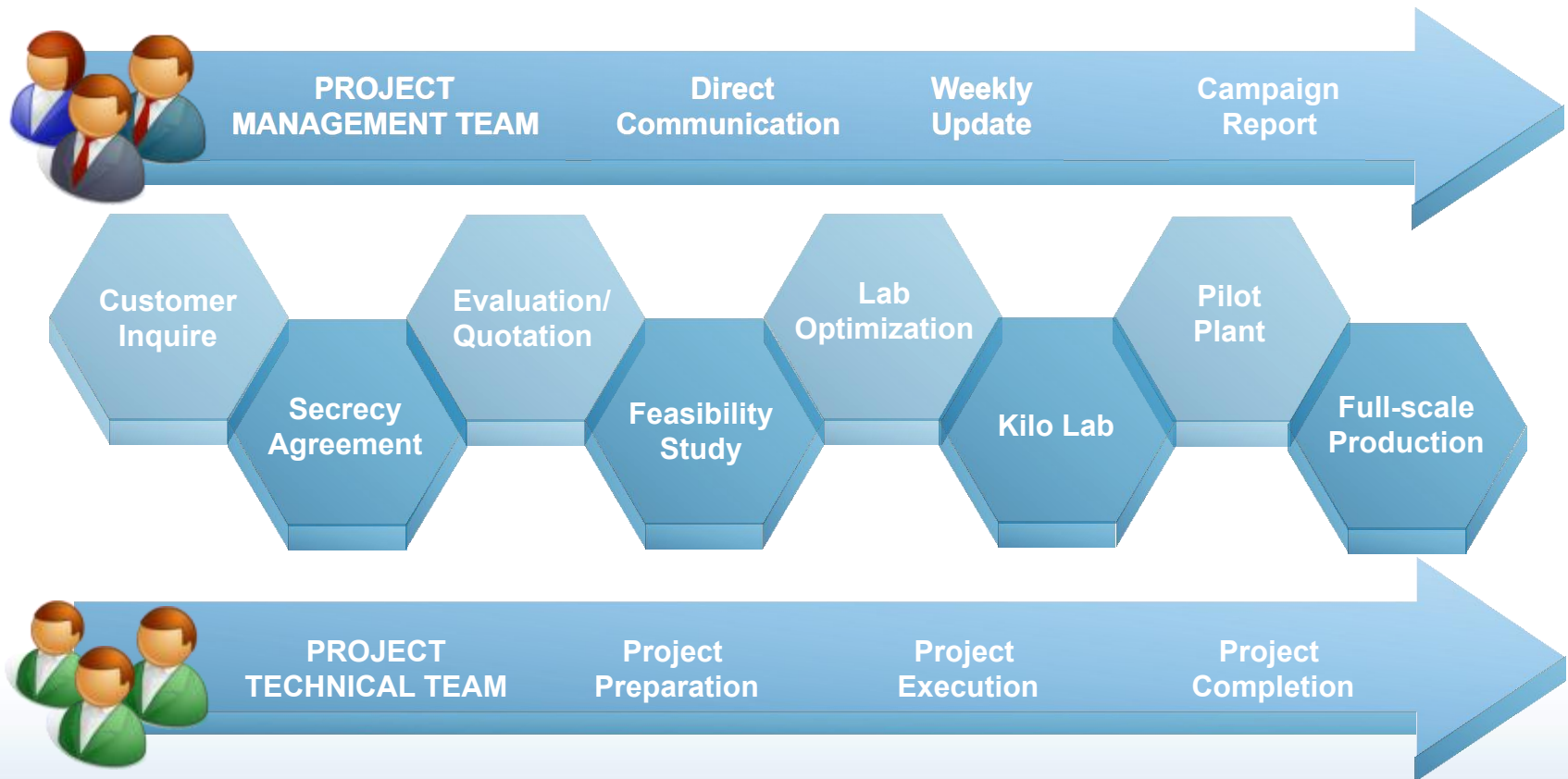
Project Management

Project Management Team:

- To keep the customers constantly informed with regular updates and meetings on the progress of the projects.

Project Technical Team:

- To complete the projects with agreed specifications, milestones, and deliverables.



R&D and Kilo Lab

R&D Facility	3250 sq. ft.
Kilo Lab Facility	1150 sq. ft.
R&D Laboratories	4 (36 fume hoods)
Kilo Lab Suites	2
Laboratory Glassware	1mL to 20L
Kilo Lab Jacketed Glass Reactors	20L to 100L
High Pressure SS Hydrogenators	0.5L to 10L
Rotary Evaporators	1L, 5L, 20L and 50L
Temperature Range	-78°C to 200°C



Analytical Support

Analytical Laboratories

1300 sq. ft.

Analytical Equipments

Agilent HPLC 1100, 1260

10

Shimadzu HPLC 2010

2

Shimadzu GC 2010

3

Shimadzu FT-IR 8300

3

Shimadzu UV-Vis 2450

1

Mettler KF Titrator DL-38

1

Malvern Mastersizer 2000

1

**Access to NMR, MS, LC-MS, GC-MS, DSC,
TGA, ICP, XRPD**



Pilot Plant

Pilot Plants	3
50L to 1000L Glass-lined Reactors	30
50L to 1000L SS Reactors	2
2000L SS Hydrogenators (Up to 100 bar)	2
1000L Glass-lined Hydrogenator (Up to 15 bar)	1
Dryers	4
Centrifuges	5 (SS and PE Coated)
Mills	2
Temperature	-20°C to 140°C
Pressure	Up to 100 bar



Commercial Production

Commercial Plants

500L to 5000L Glass-lined Reactors

500L to 5000L SS Reactors

Centrifuges

Driers

Mills

Temperature

Pressure

3

45

18

6 (Vertical in SS304, SS316)

6

3

-20°C to 140°C

Up to 100 bar



Quality Assurance (QA):

- Nanjing Pharmatechs has achieved ISO9001 certification since January 28, 2011;
- Nanjing Pharmatechs has successfully inspected by more than 50 customers including the big pharma companies, Johnson & Johnson, AstraZeneca, and Roche Pharmaceuticals;
- The US FDA inspected the facility on September 12-15, 2017.

Quality Control (QC):

- Qualitative Tests: UV-VIS, FTIR, ¹HNMR, ¹³CNMR, ³¹PNMR, ¹⁹FNMR, Mass Spectroscopy (MS), LC-MS, GC-MS, Melting Point, X-ray Crystallography, DSC, TGA;
- Quantitative Tests: HPLC, GC, Quantitative ¹HNMR, Titration, Loss on Drying (LOD), Residue on Ignition (ROI), Metal Analysis (ICP), Water Content (KF), Specific Rotation, Residue Solvent (GC); Elemental Analysis, Particle Size Analysis.



The company is compliant with Chinese laws, regulations and company EH&S policy.

Environmental:

- Waste water is collected and discharged to the waste water treatment center owned and operated by Chemical Industry Park;
- Acidic and basic off-gases are neutralized using wet scrubbers; Off-gases with organics are captured by activated charcoal absorber units;
- Non-hazardous wastes are shipped to a sanitary landfill by certified waste disposal vender;
- Hazardous wastes are incinerated by contracting with the vender certified for the disposal of hazardous wastes.

Health & Safety:

- Personal protective equipments such as safety glasses, gloves, safety shoes and hardhats are provided to all R&D and production personnel;
- Physical examination is mandatory to all employees every two years.



THANKS



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