



XIANJU PHARMA



No.1, Xianyao Road, Xianju, Zhejiang, China, 317300

Xianju Pharma



Outline

I. Brief Introduction

II. Quality Unit

III. Production System

IV. EHS System



I. Brief Introduction

Zhejiang Xianju Pharmaceutical Co., Ltd.

- **A professional manufacturer of steroids and hormone products with largest scale and maximum varieties in China.**
- **A state-designated manufacturer of contraceptive drugs in China.**



Company Milestones



Jan 1972

Foundation of company

May 1997

Incorporated into Zhejiang Medicine Co., Ltd

Oct. 1999

Listed in Shanghai Stock Market

Jun. 2000

Reorganized into Xianju Pharmaceutical Co., Ltd

Dec. 2001

Reformed to Zhejiang Xianju Pharmaceutical Co., Ltd

Jan. 2010

listed in Shenzhen Stock Market

Location of Xianju



There are six airports around Xianju, which makes us easily accessible for our partners.

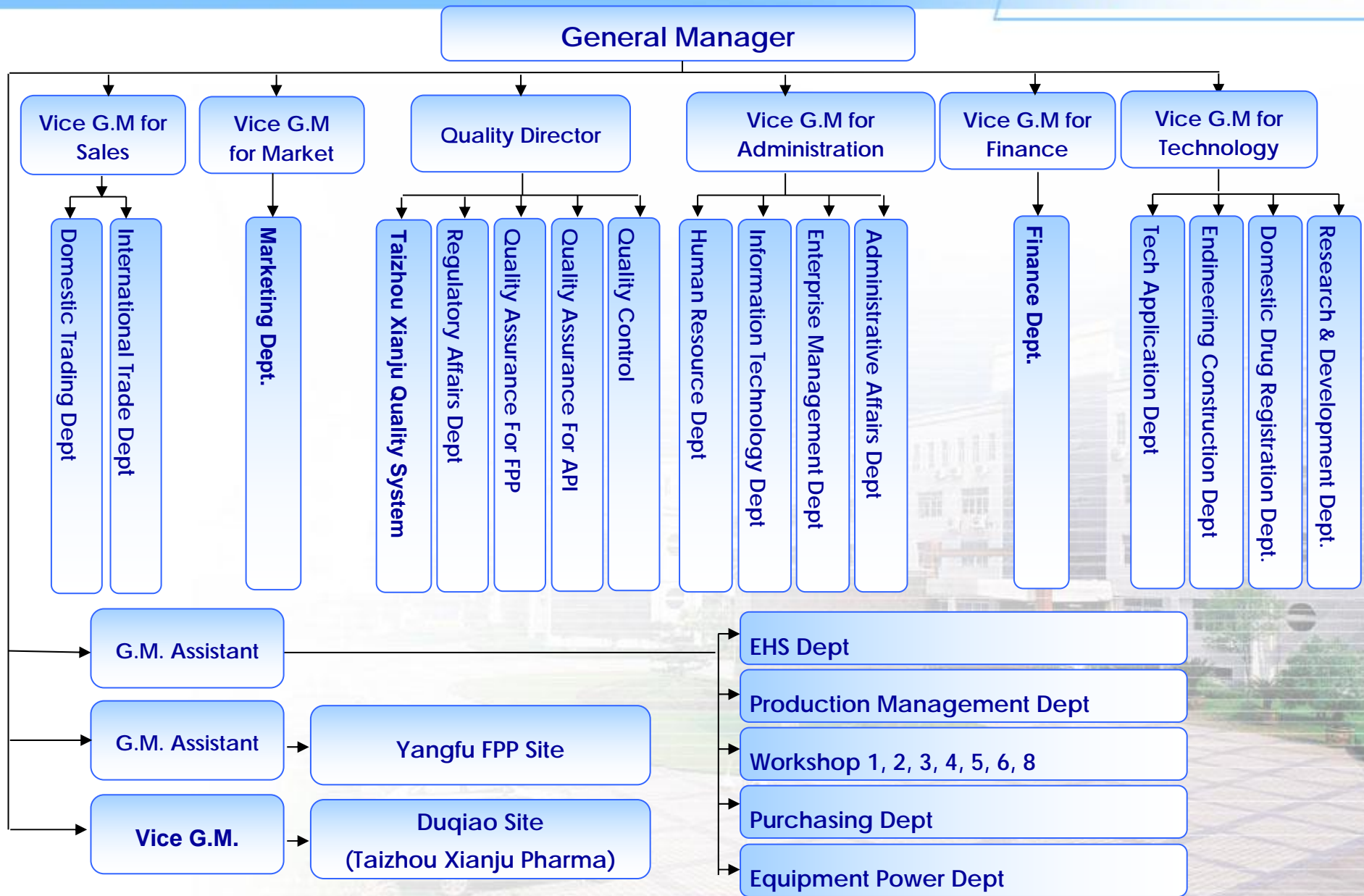
Headquarter
Located in Xianju, Taizhou City

Yangfu Site (FPPs)
Located in Yangfu, Xianju, Taizhou City 6.8km from headquarter

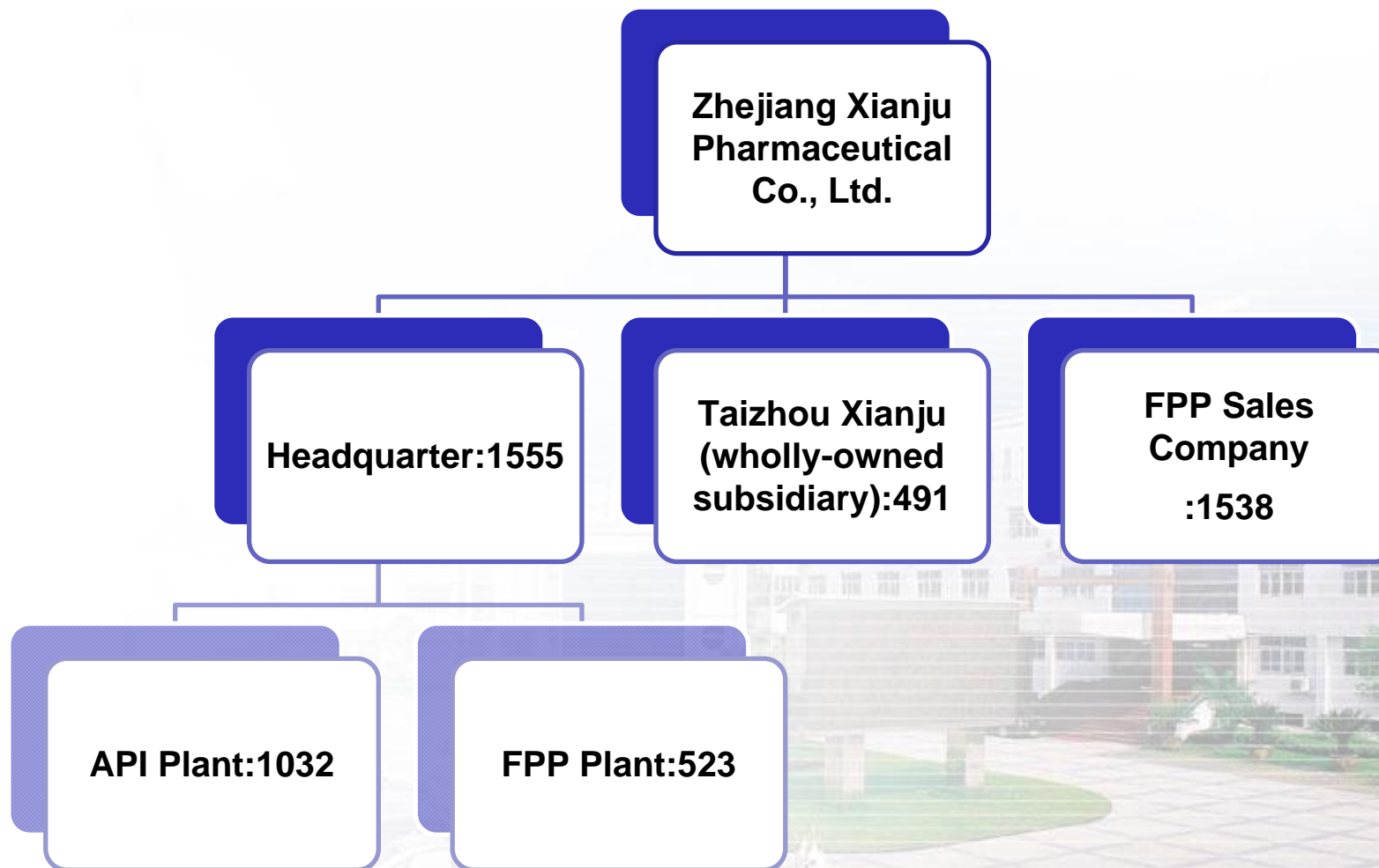
Duqiao Site (APIs)
Located in LinHai, TaiZhou City, 82.9km from headquarter

Yangfu Site (APIs)
Under construction, finish at 2017

Company Organization



Organization Chart

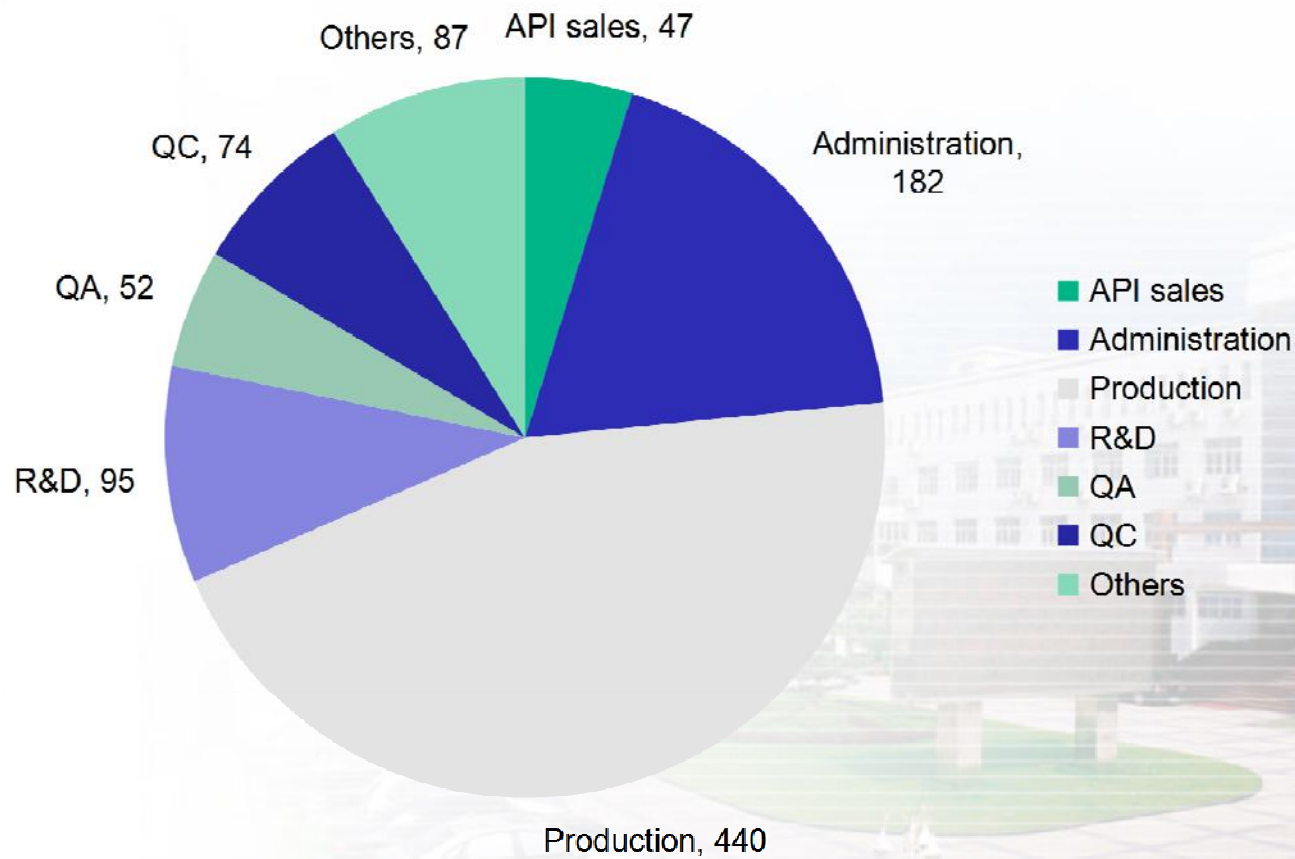


Date: 2016-04-20

Staff Structure (headquarter)



The total number of headquarter (API plant) is about 1000.



Date:2016-04-20

Main APIs



<p>☆ Cortical hormones</p>	<p>Prednisolone and its derivatives Dexamethasone and its derivatives Methylprednisolone and its derivatives Triamcinolone acetonide and its derivatives Betamethasone and its derivatives Hydrocortisone and its derivatives Mometasone furoate</p>	
<p>☆ Muscle relaxants</p>	<p>Vecuronium Bromide Rocuronium Bromide</p>	
<p>☆ Sex hormones</p>	<p>Androgen</p>	<p>Testosterone and its derivatives</p>
	<p>Estrogen</p>	<p>Estrone Estradiol and its derivatives</p>
	<p>Progestogen</p>	<p>Progesterone Cyproterone acetate Mifepristone Medroxyprogesterone acetate Megestrol acetate Norethisterone and its derivatives</p>

Main Dosage Forms:

- **Tablets**
- **Small Volume Injection**
- **Lyophilized Powder Injection**
- **Capsules**
- **Soft capsules**
- **Cream**
- **Gel**

- **Reproductive health products:**

Mifepristone Tablets & Soft Capsules, Misoprostol Tablets, Progesterone Capsules & Injection, Clindamycin Phosphate Vaginal Gel, Ethinylestradiol and Cyproterone Acetate Tablets, Compound Norethisterone Enanthate Injection, Compound Norethisterone Tablets and Testosterone Undecanoate Injection, etc.

- **Narcotic products:**

Vecuronium Bromide for Injection, Rocuronium Bromide Injection, Cisatracurium Besilate for Injection, Ropivacaine Mesylate Injection and Flumazenil Injection, etc.

- **Dermatologic products:**

Mometasone Furoate Cream, Beclometasone Dipropionate Cream, Hydrocortisone Butyrate Cream and Clotrimazole Betamethasone Cream, etc.

- **Anti-Asthmatic products:**

Tiotropium Bromide Powder for Inhalation.

- **Cortical hormone products:**

Prednisolone Acetate Injection ,Triamcinolone Acetonide Acetate Injection, Dexamethasone Sodium Phosphate Injection, Prednisone Acetate Tables, Dexamethasone Acetate Tablets, etc.

- **Other products:**

Pidotimod Granules, Meloxicam Tablets , Aciclovir Tablets.

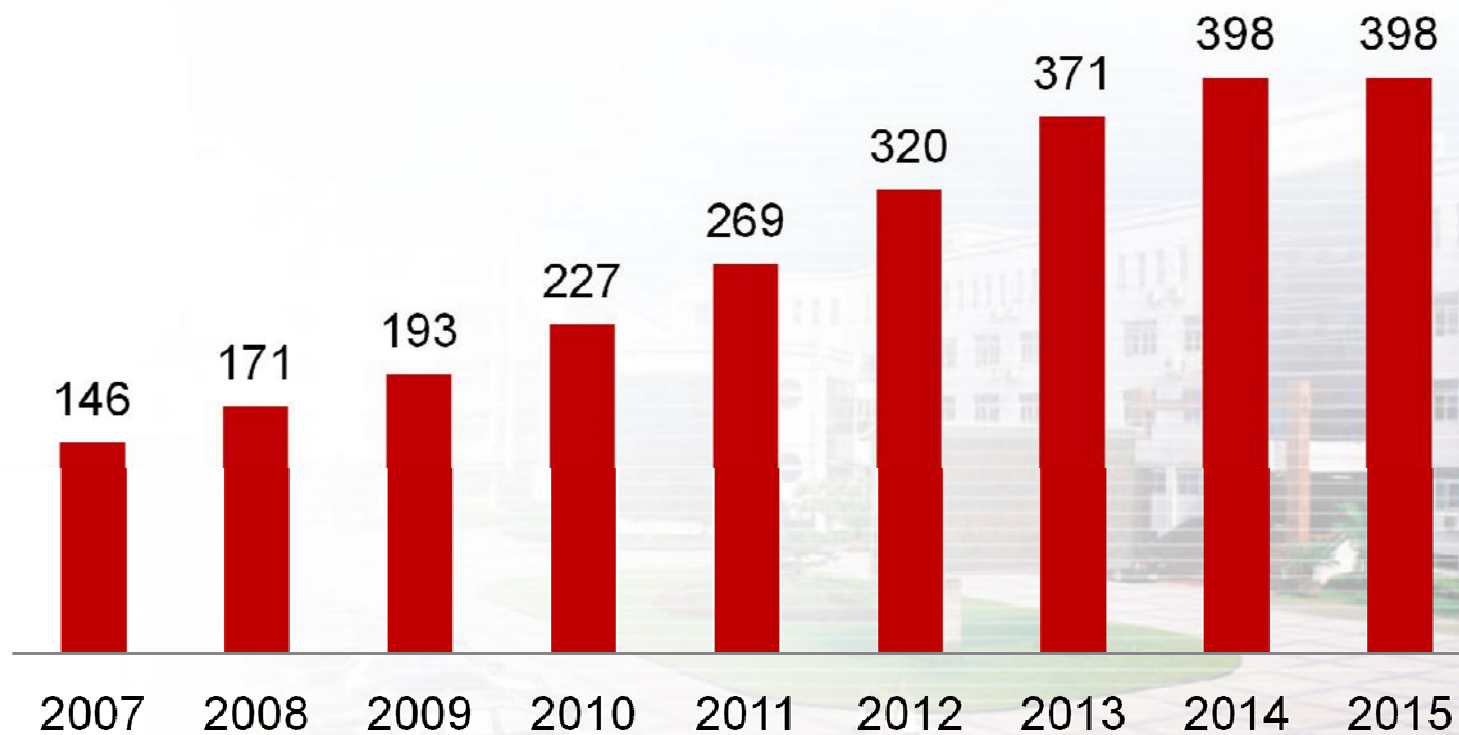


Sales revenue (by end-2015)



Sales revenue in the past 9 years

■ Sales revenue/USD (Million)

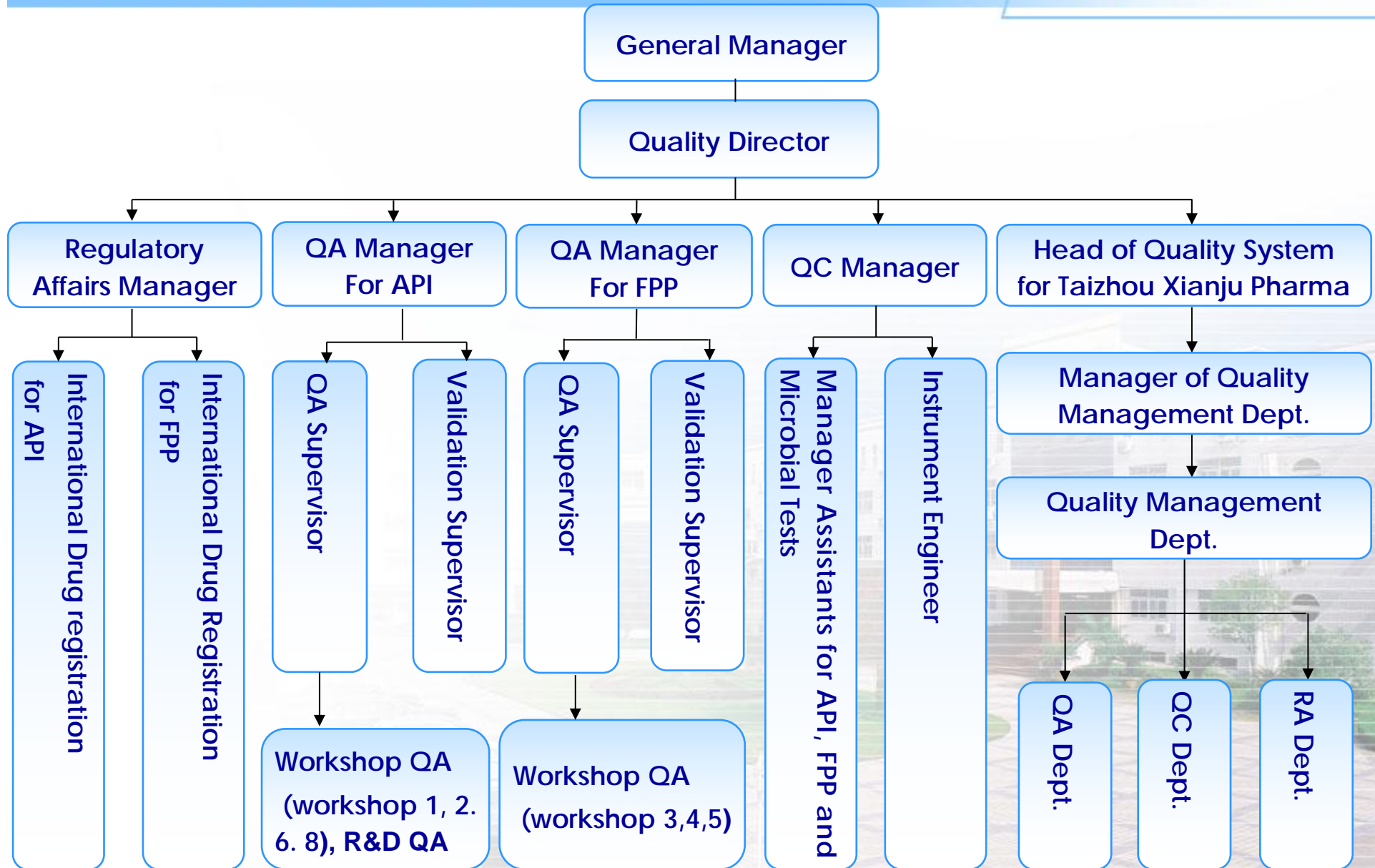




II. Quality Unit

Xianju Pharma adheres to the tenet of “producing first-class products, dedicated to the health of human beings”, advocating the concept of Quality-oriented, Safety and Effectiveness.

Quality Unit Organization



Quality Management Tree



APIs Registered in US FDA

No.	Product Name	U.S DMF Number	Status
1	Vecuronium Bromide	12050	Available for reference
2	Prednisolone	18063	
3	Medroxyprogesterone Acetate	19433	
4	Testosterone Undecanoate	23934	
5	Estradiol Hemihydrate	23942	Active
6	Megestrol Acetate	24592	
7	Methyl Prednisolone	25067	
8	Testosterone Propionate	25606	
9	Rocuronium Bromide	26765	
10	Testosterone Enanthate	27431	
11	Prednisone	30194	
12	Hydrocortisone	30230	

APIs Registered in EDQM

No.	Certificate Number	Product Name	Status
1	R1-CEP 2003-109	Cyproterone Acetate	Valid
2	R1-CEP 2004-062	Prednisolone	
3	R0-CEP 2010-369	Norethisterone	
4	R0-CEP 2011-027	6-Methylprednisolone	
5	R0-CEP 2012-010	Megestrol Acetate	
6	R0-CEP 2012-112	Ethinylestradiol	
7	R0-CEP 2013-065	Rocuronium Bromide	
8	CEP 2015-280	Progesterone	
9	CEP 2015-328	Eplerenone	Under Assessment

APIs Registered in Other Countries

No.	Countries	Product Name	Status
1	Japan	Prednisolone	Valid
2	Australia	Vecuronium Bromide	Valid
3	Korea	Prednisolone, Betamethasone Valerate, Betamethasone Dipropionate, Rocuronium Bromide, Mometasone Furoate, Methylprednisolone	Valid
4	India	Prednisolone, Medroxyprogesterone acetate, Mifepristone, Dexamethasone, Dexamethasone sodium phosphate, Norethisterone, Prednisolone, Progesterone	Valid

FPPs Registered in South America

No.	Countries	Product Name	Status
1	Colombia	Norethisterone Enanthate 50mg & Estradiol Valerate 5mg Injection; Cyproterone Acetate 50mg Tablets; Cyproterone Acetate 2mg & Ethinylestradiol 0.035mg Tablets	Valid
2	Chile	Norethisterone Enanthate 50mg & Estradiol Valerate 5mg Injection; Cyproterone Acetate 2mg & Ethinylestradiol 0.035mg Tablets.	Valid
3	Mexico	Norethisterone Enanthate 50mg & Estradiol Valerate 5mg Injection; Mifepristone 200mg Tablets.	Valid
4	Venezuela	Cyproterone Acetate 50mg Tablets;	Valid

GMP Compliance



Authority	Year	Result	Remark
CFDA	Routine Supervision	Pass	For All Products
US-FDA	1999, 2008, 2011 and 2014	Pass	For APIs
EDQM	2006 and 2009	Pass	For APIs
Korea FDA	2011	Pass	For APIs
DCGI (India)	2011	Pass	For APIs
Colombia INVIMA	2006, 2011 and 2014	Pass	For FPPs

FDA Inspection



DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Office of Manufacturing and Product Quality
Division International Drug Quality
International Compliance Branch
10503 New Hampshire Avenue
Building #51, Room 4234
Silver Spring, MD 20993

TELEPHONE: (301) 796-3200
FAX: (301) 647-8742

October 2, 2014

Mr. Yusong Zhang
General Manager
Zhejiang Xianju Pharmaceutical Co., Ltd.
No. 1 Xianyao Road,
Xianju, Zhejiang Province
China 317300

Reference: FEI 3003663256

Dear Mr. Zhang:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your non-sterile active pharmaceutical ingredient manufacturing facility in Xianju, China, by Investigator James MacLaughlin during the period of July 28, 2014 to August 1, 2014.

Based on the profile class covered during the inspection, we are classifying your facility as acceptable. This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to assure continued compliance with current good manufacturing practices (CGMPs).

Please be advised that all manufacturers must register annually as required by 21 C.F.R. § 207.46. Information on how to register is available at http://www.fda.gov/cder/ords/registration_listing.htm.

Additionally, we enclose a copy of the establishment inspection report (EIR). Releasing this EIR to you is part of FDA's effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the Freedom of Information Act and 21 C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions regarding this letter, you may contact me at the above address or number.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alicia Mozzachio'.

Alicia Mozzachio
Branch Chief
Division of International Drug Quality

Enclosure: EIR

FDA inspected XianJu in July 2014, and no 483 letter was issued. EIR was received in October 2014, providing Xianju's quality system is acceptable to FDA.





III. Production System

Production Sites Introduction



Site	Production Type	Area (m ²)	Remark
Xianju Site (Headquarter)	APIs and FPPs	83,488	Founded in 1972
Duqiao Site (Taizhou Xianju Pharmaceutical Co., Ltd)	APIs and Intermediates	141,796	Start production in 2010 and pass first Chinese GMP inspection in 2013
Yangfu FPP Site	FPPs	48,177	Start production in 2012 and pass first Chinese GMP inspection in 2012
Yangfu API Site	APIs	130,000	Under construction and will be completed in 2017

Aerial Views (Headquarter)



Aerial Views (Duqiao API Site)




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鸟瞰图

Aerial Views (Yangfu FPP Site)



 浙江仙琚制药有限公司



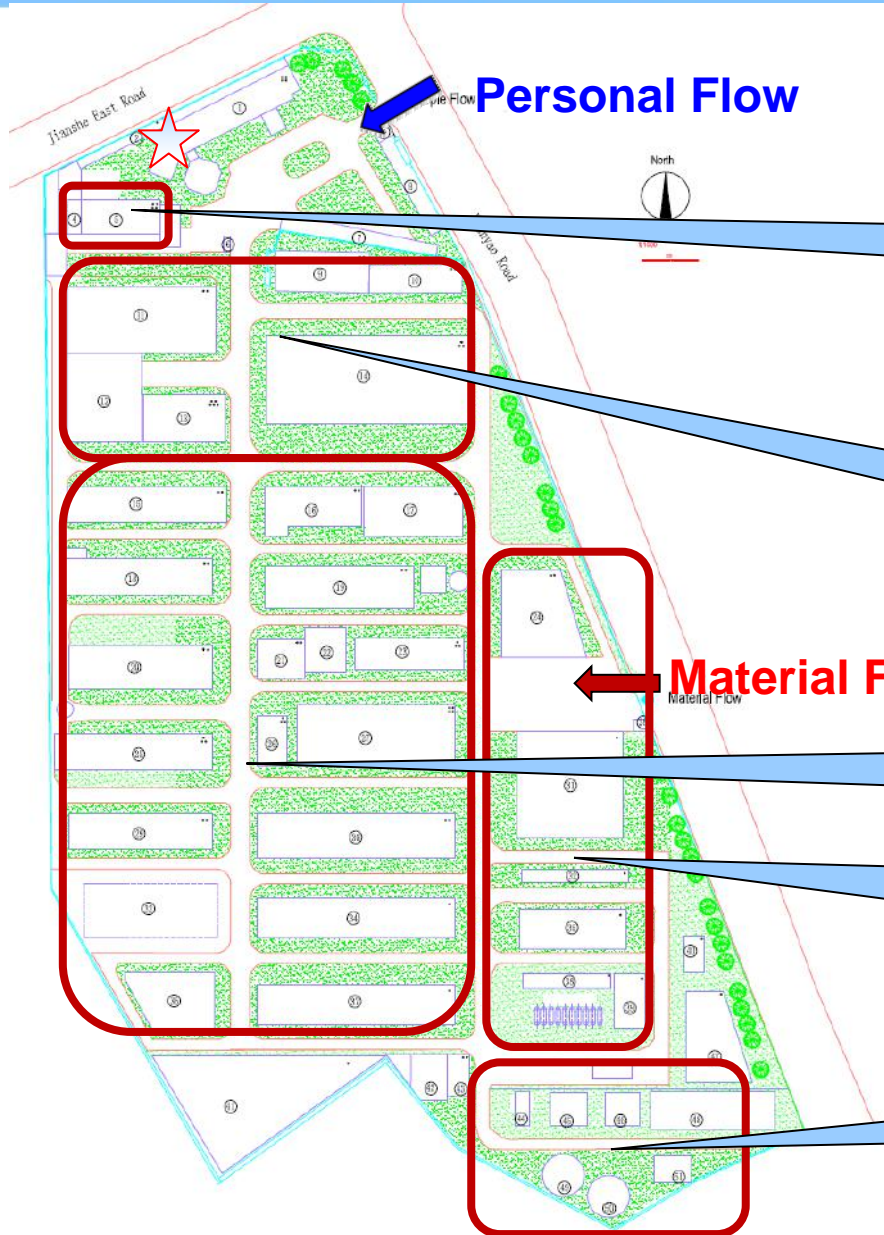
Aerial Views (Yangfu API Site)



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Layout of Headquarter



Personal Flow

Total Area: 83488 m²
Production Area: 74980 m²

QC Building

Production Area (FPP)

Material Flow

Production Area (API)

Warehouse for Raw Materials, Solvents, APIs and Formulation

Waste Water Treatment Station

API Plant (Headquarter)



Clean Area for APIs (Headquarter)



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Total construction area: 4,018m²



Warehouse (Headquarter)



Total area: 12,000 m²

- **API warehouse**
- **Chemical solid warehouse**
- **Chemical liquid warehouse**
- **Packaging Materials warehouse**
- **FPP warehouse**

QC laboratory (Headquarter)



Total construction area: 1,983 m², consisting of one laboratory for product release and one in-process control laboratory.

HPLC HP1100



GC HP 6890



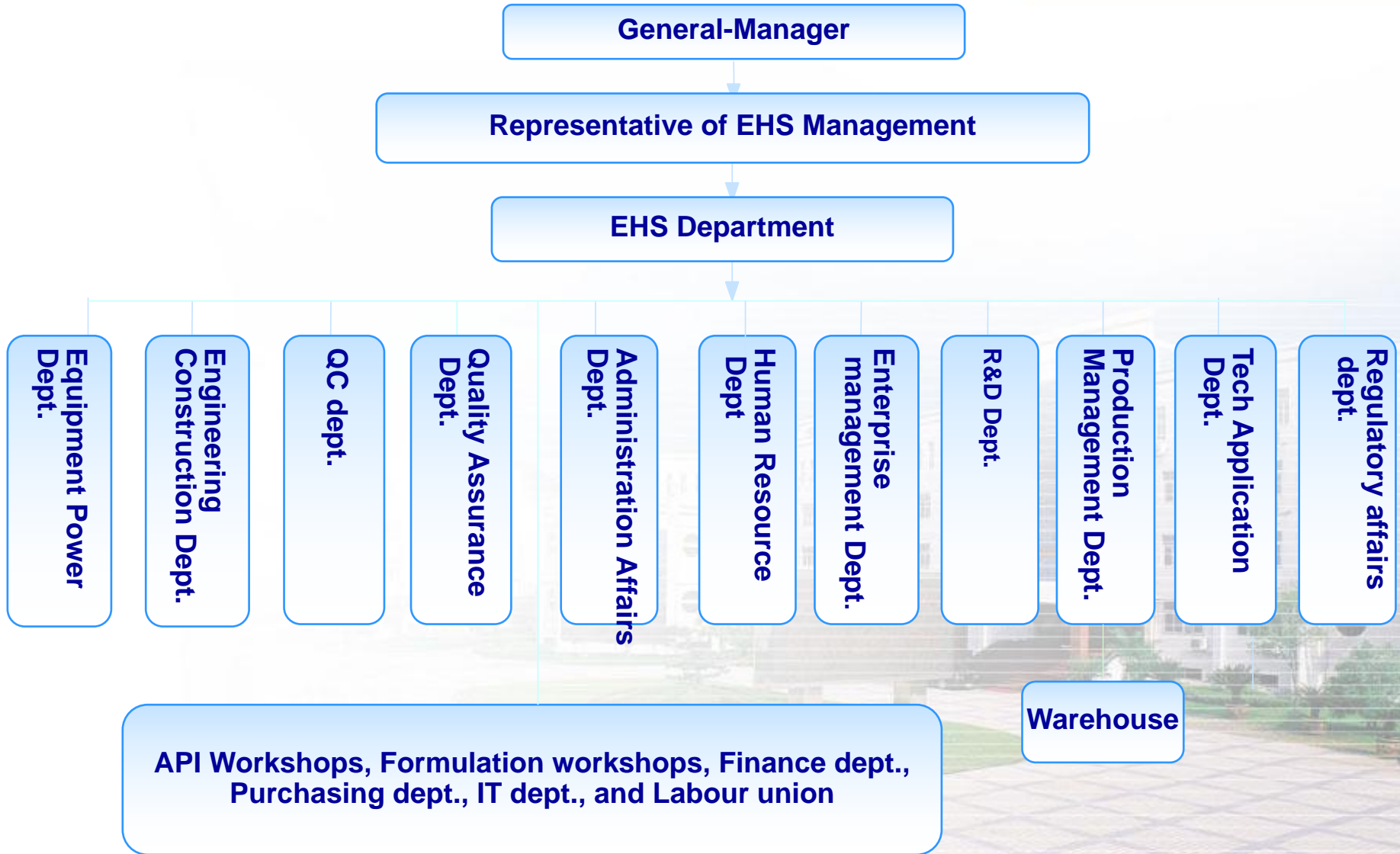


IV. EHS System

Xianju Pharma adheres to the tenet of “producing first-class products, dedicated to the health of human beings”, advocates the concept of green & environment-friendly, safety and health, pursues sustainable development. We are committed to the following:

- **Comply with the laws and regulations to ensure safe production and the proper discharge of pollutants.**
- **Promote and implement the policy of clean production, energy conservation and pollution reduction.**
- **Strive for the implementation of EHS management system and constant self improvement.**
- **Organize effective training to enhance the awareness and improve the capability of environmental protection and safety.**

EHS Organization Chart



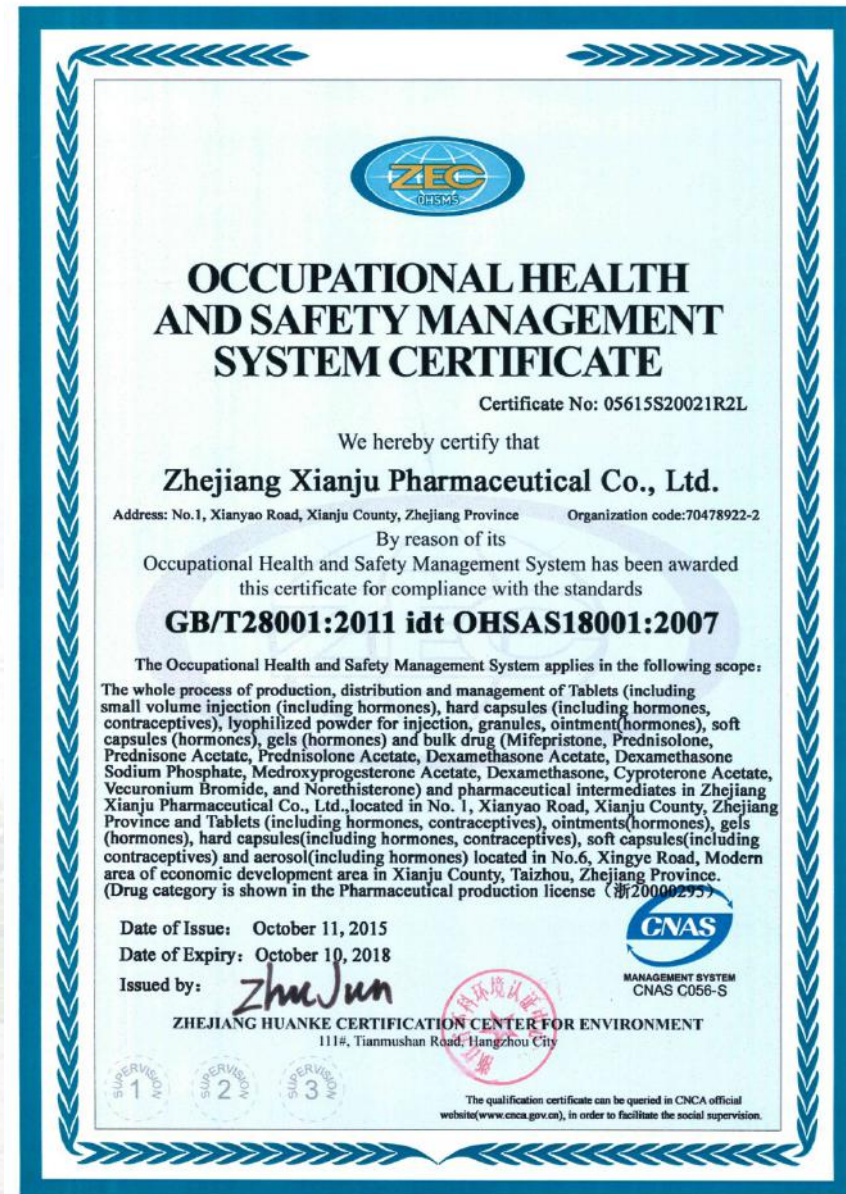
Environment Management



- **First ISO 14001 environment management system certificated in August 2004;**
- **Passed latest inspection in October 2015.**



- **First OHSAS18001 management system certificated in December 2005.**
- **Passed latest inspection in October 2015.**



Waste Treatment Station



Landscape of Xianju



Landscape of Xianju



Thanks