



Your Global Contract Service

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Welcome to Shandong Xinhua

保护健康 造福社会
For good health and better life



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Company Basic Information

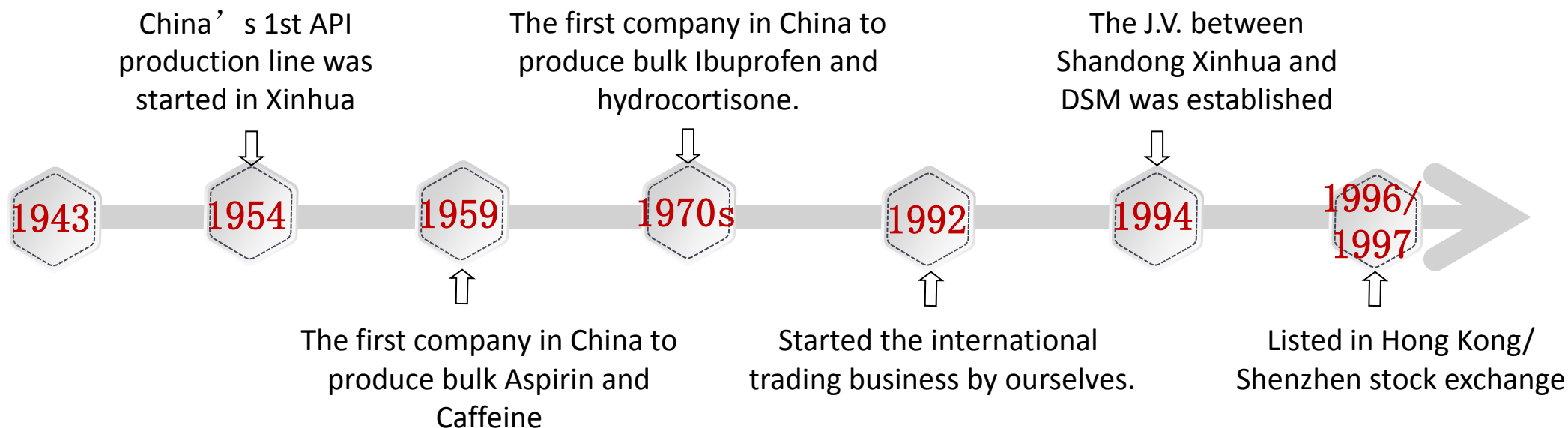


Established in 1943 during the 2nd world war from a medical group of army.



Leading Supplier for the manufacturing of antipyretics and analgesics, also a key manufacturer for anti-infective, cardio-vascular, central nervous system, steroids and anti-parasites drugs.





Company History and Milestones

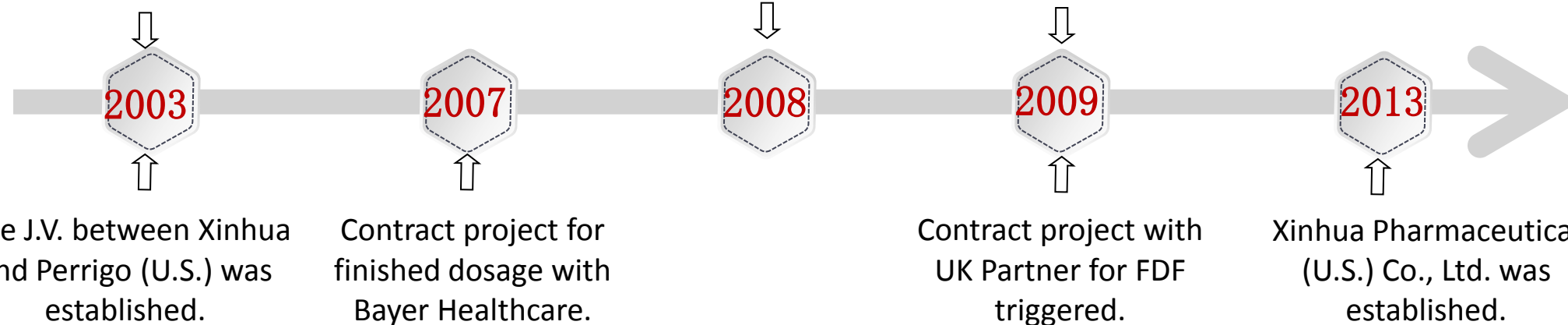




Xinhua Pharmaceutical (European) GmbH was established in Hamburg, in 2010 moved to the Netherlands

Shouguang Site was established (for Pharma intermediate).

Hutian Site was established (for innovative APIs).



Company History and Milestones





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1998

ISO 10012 was certified in 1998



1999

ISO 9001 was certified in 1999



2000

ISO 14001 was certified in 2000

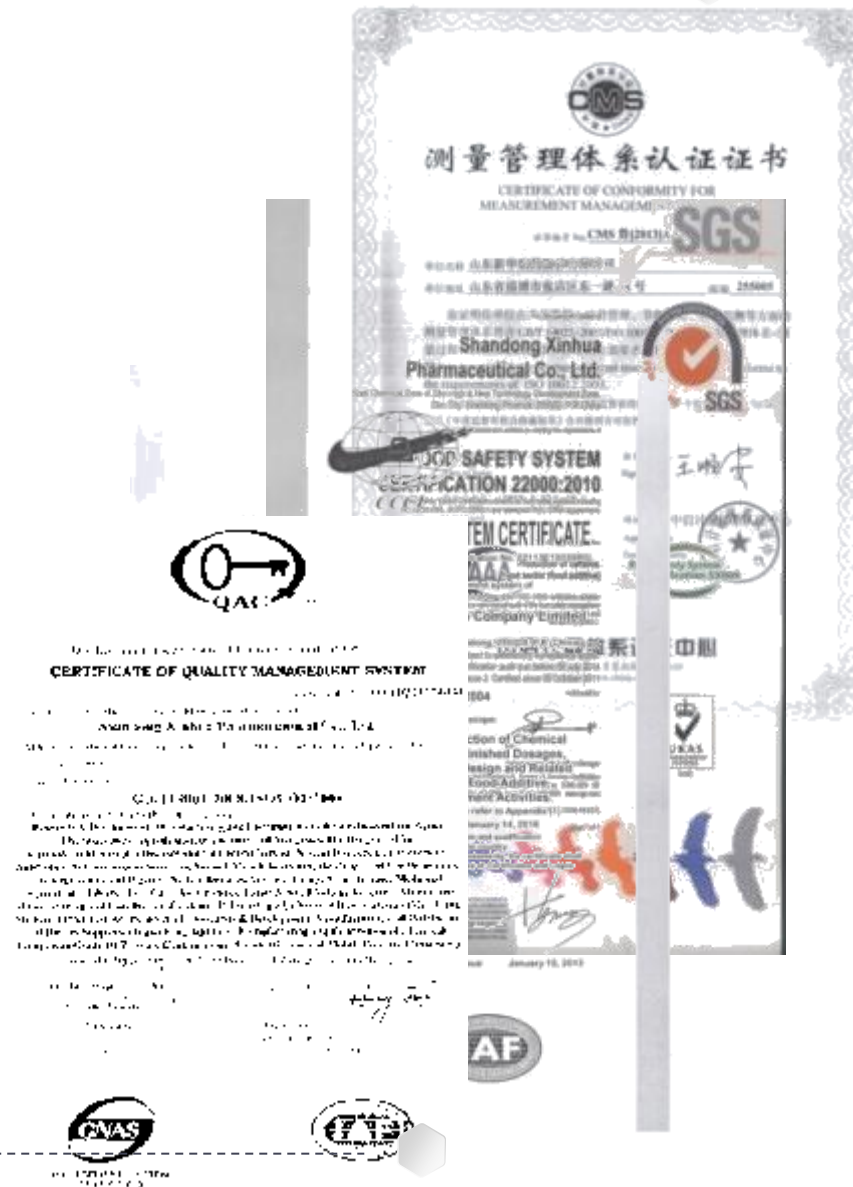


2009

ISO 22000 was certified in 2009



ISO management system





Dongyi Road: 490,000m²
API and Solid dosage
products

10km



Headquarters:
Administration and R&D
Center: 490,000m²
Finished Dosages: 280,000m²

10km



East site: 360,000m²,
APIs: Ibuprofen, Caffeine,
Levodopa, etc.



Nanding site: 20,000m²
Solid dosage products
(Cephalosporins and Hormone)

16km

18km



Hutian site: 270,000m²,
APIs: Aspirin, Analgin, etc.



Manufacturing Sites



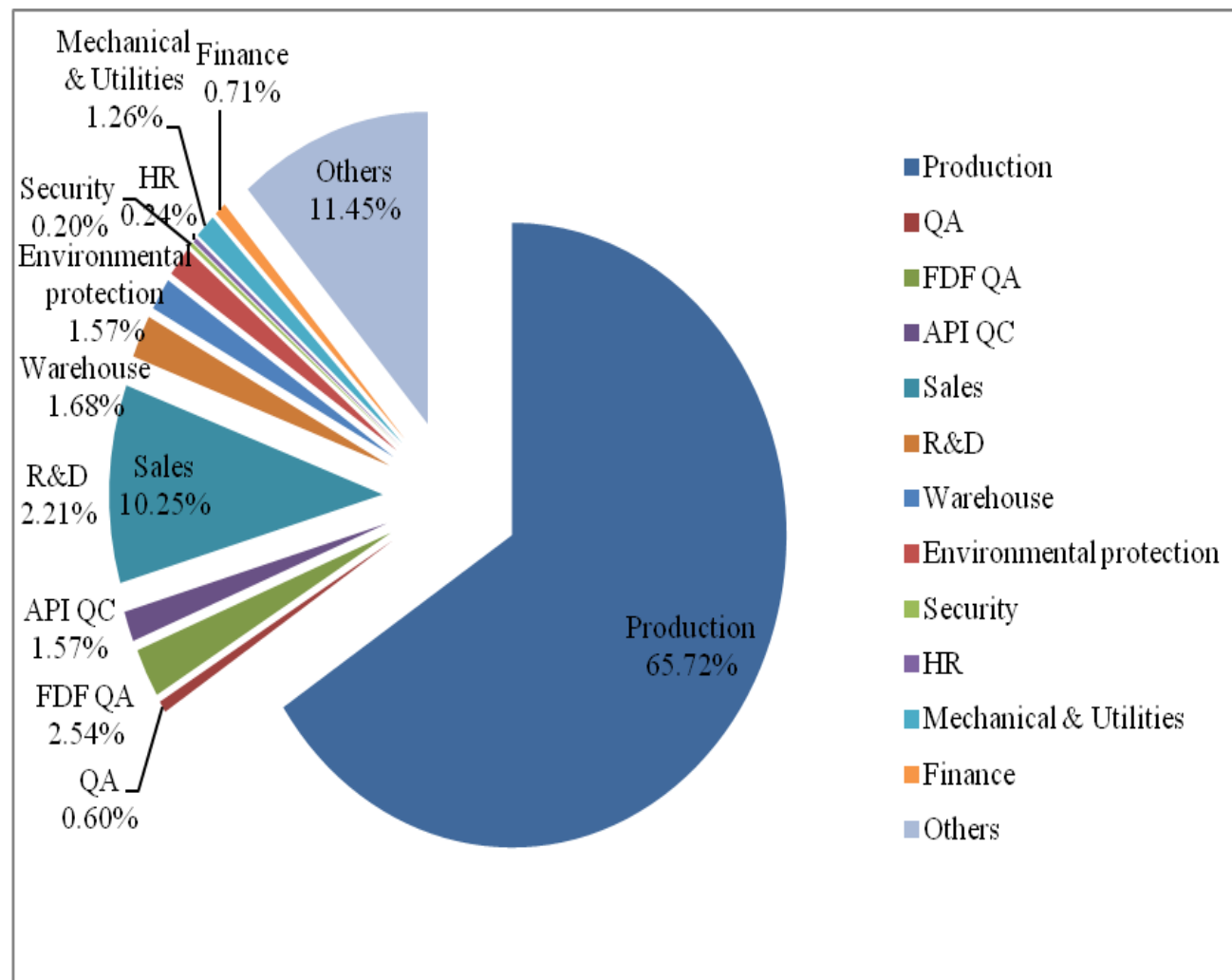


There are 4525 employees by the end of 2017.

- 2974 for production
- 27 for QA;
- 115 for FDF QA
- 71 for API QC
- 464 for Sales
- 100 for R&D;
- 76 for Warehouse
- 71 for Environmental protection
- 9 for Security
- 11 for HR
- 57 for Mechanical & Utilities

Among them:

- 902 obtained the B.S degree
- 220 obtained the M.S degree
- 11 obtained the Dr degree
- 95 for licensed pharmacist



Personal Distribution



2

Quality management



Company Mission

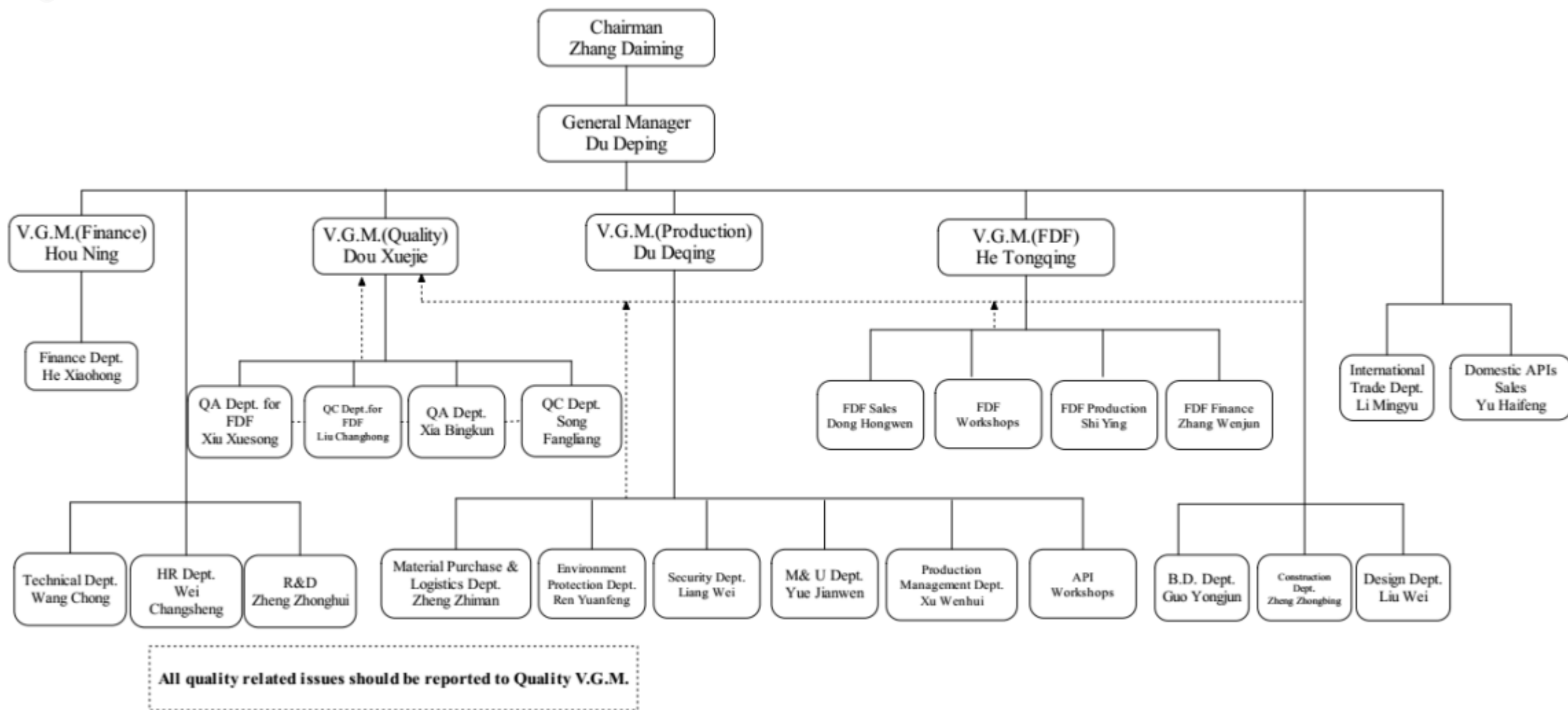
“For Good Health and Better Life ”

Company Quality Value

“the product quality effects the company’s development, and the drug quality effects the people’s life”

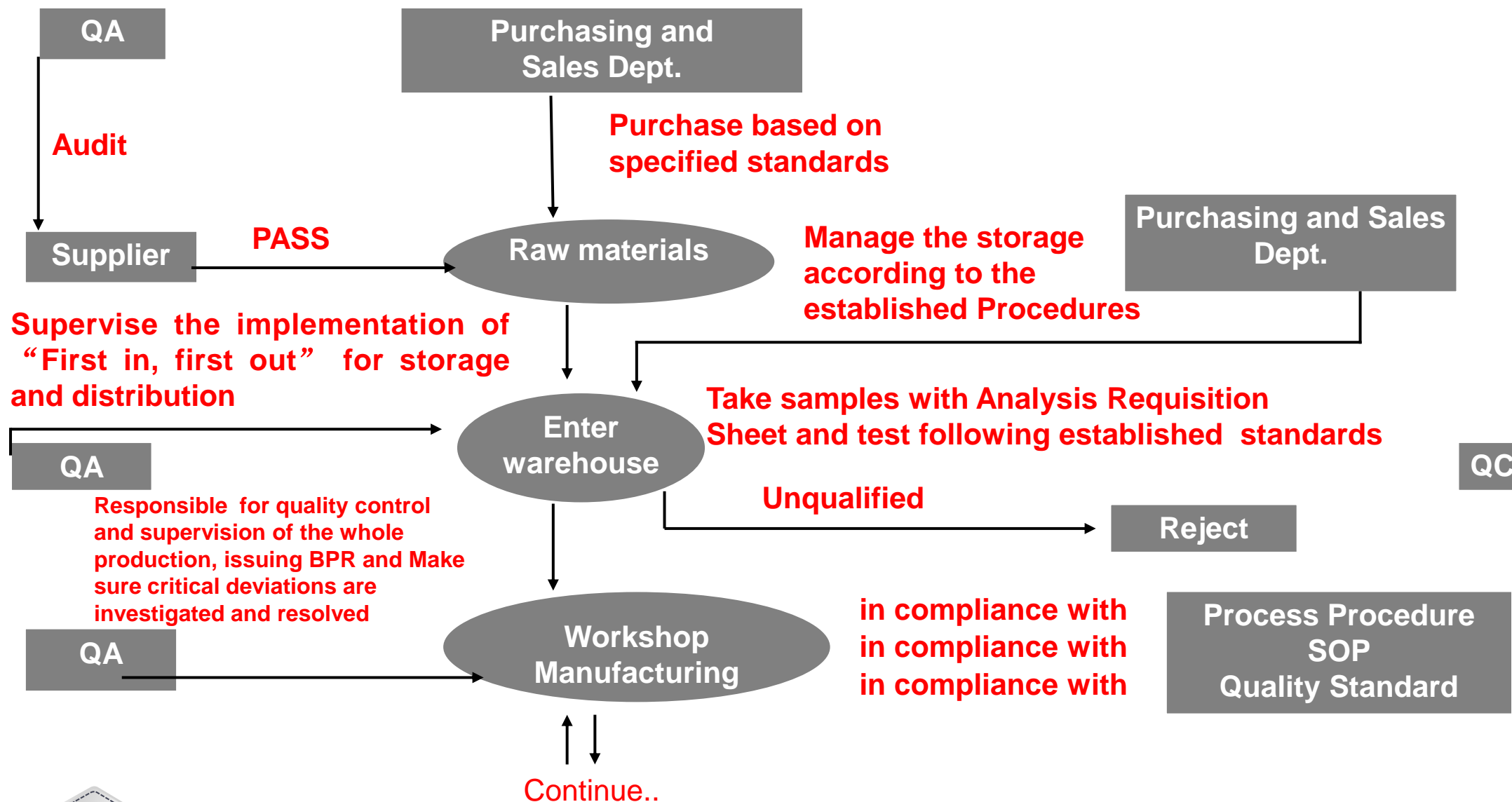
Continuing the dedication to improve the quality system and to meet the demands of the clients.

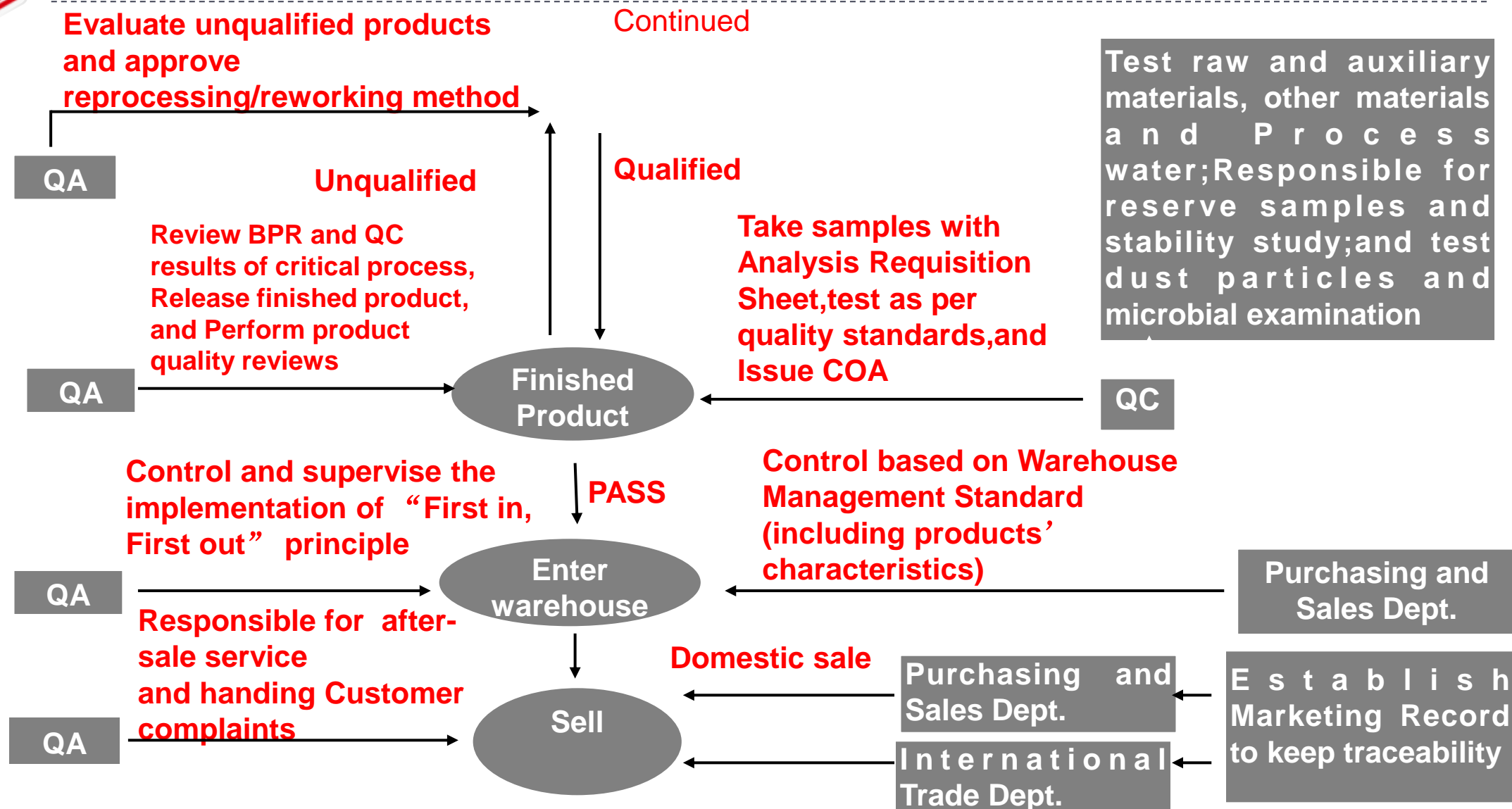




Organization Chart of Shandong Xinhua Pharma. Co., LTD









No.	DMF No.	Submitted Date	Product
1	4633	28-Jul-1982	THEOPHYLLINE
2	10730	20-Jan-1994	ASPIRIN
3	11606	27-Jul-1995	HYDROCORTISONE BASE
4	13092	10-Jul-1998	CAFFEINE ANHYDROUS
5	13144	18-Aug-1998	TRIMETHOPRIM
6	15511	3-Jul-2001	IBUPROFEN
7	17263	15-Mar-2004	HYDROCORTISONE ACETATE
8	22598	5-Mar-2009	LEVODOPA
9	24476	8-Dec-2010	MELOXICAM
10	26132	25-May-2012	AMLODIPINE BESYLATE
11	26844	18-Jan-2013	ASPIRIN REFINED
12	27430	23-Jul-2013	CARBIDOPA
13	27827	1-Dec-2013	PHENOBARBITAL
14	28403	10-Jun-2014	IBUPROFEN SODIUM
15	29184	2-Feb-2015	OMEGA-3-ACID-ETHYL ESTERS
16	29793	12-Oct-2015	Aspirin DC-90
17	31035	19-Oct-2016	DIPYRONE (Metamizole Sodium Monohydrate)



No.	Product	CEP No.	Certified Date
1	Metamizole Sodium	CEP 2001-356	2004-04
2	Phenazone	CEP 2002-093	2003-11
3	Caffeine Anhydrous	CEP 2003-027	2003-09
4	Acetylsalicylic Acid	CEP 2001-210	2002-04
5	Ibuprofen	CEP 2004-023	2005-12
6	Trimethoprim	CEP 2003-195	2004-19
7	Theophylline Anhydrous	CEP 1998-004	1999-07
8	Propyphenazone	CEP 2003-059	2004-05
9	Levodopa	CEP 2009-174	2011-04
10	Carbidopa	CEP 2016-052	2017-04



10 Products COS certified





Date	Investigator	Products	Result	Manufacturing Site
May 2002	Mr. Regina T. Brown, Mr. S Nasir Ali	Hydrocortisone	483:9 Pass	Dongyi Road site
Apr. 2007	Mr. Michael Taylor Mr. George Pyramides	Ibuprofen Hydrocortisone Trimtheoprim	483:4 Pass	East site Dongyi Road site
July 2010	Ms. Charisse Green	Levodopa/Ibuprofen Trimtheoprim	483:0 Pass	East site Dongyi Road site
March 24- April 4, 2014	Mr. Joel Hustedt	Acetylsalicylic Acid; Phenazone;	483:6	Hutian site
		Ibuprofen; Levodopa; Trimtheoprim; Caffeine; Theophylline; CPC;	483:6	East site
		Hydrocortisone; Hydrocortisone acetate;		Dongyi Road site
March 21- April 1, 2016	Mr. DiOrio	Acetylsalicylic Acid; Phenazone;ASA, Refined Aspirin	483:0	Hutian site
		Ibuprofen; Levodopa; Trimtheoprim; Caffeine; Theophylline; CPC;	483:0	East site
		Hydrocortisone; Hydrocortisone acetate;		Dongyi Road site

Inspection History of US-FDA



No.	Date	Authority	Products	Result	Manufacturing Site
1	Jan. 2013	K-FDA	Meloxicam	Pass	Ease site
2	Mar. 2013	EDQM	Levodopa Trimethoprim Ibuprofen	Pass	Ease site
3	May 2014	Germany -BGV	Propyphenazone Aspirin	Pass	Hutian site
4	April 2015	TGA	Aspirin	Pass	Hutian site
5	May 2015	KFDA	Hydrocortisone	Pass	Dongyi Road site
6	Nov 2015	PMDA	Caffeine	Pass	Ease site
7	Dec 2016	ANSM	Levodopa Theophylline	Pass	Ease site

Inspection History of Other Abroad Authorities



June, 2014	Local FDA	Ibuprofen, Meloxicam etc.	Plants 103 and 102	East Chemical Zone	Pass
		Etofesalamide, Glimepiride etc.	Multifunctional plant	Hutian Chemical Industrial Zone	Pass
November, 2014	Local FDA	Phenobarbital, Calcium Polycarbophil etc.	Plants 102 and 104	East Chemical Zone	Pass
September, 2015	Local FDA	Pipemidic acid, Theophylline and Aminophylline	Plants 102 and 105	East Chemical Zone	Pass
May 2016	Local FDA	Levodopa	Plant 104	East Chemical Zone	Pass
March 2017	Local FDA	Metamizole Magnesium	Plant 205	Hutian Chemical Industrial Zone	Pass
May 2017	Local FDA	Levodopa, Trimethoprim, Barbita, and Amobarbital	Plant 104 and 102	East Chemical Zone	Pass
August 2017	Local FDA	Aspirin, Salicylic Acid, and Nimodipine	Plant 204 and 207	Hutian Chemical Industrial Zone	Pass
December 2017	Local FDA	Tribendimidine	Plant 204	Hutian Chemical Industrial Zone	Pass

Inspection History by National Authorities



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EU-GMP



Certificate Granted



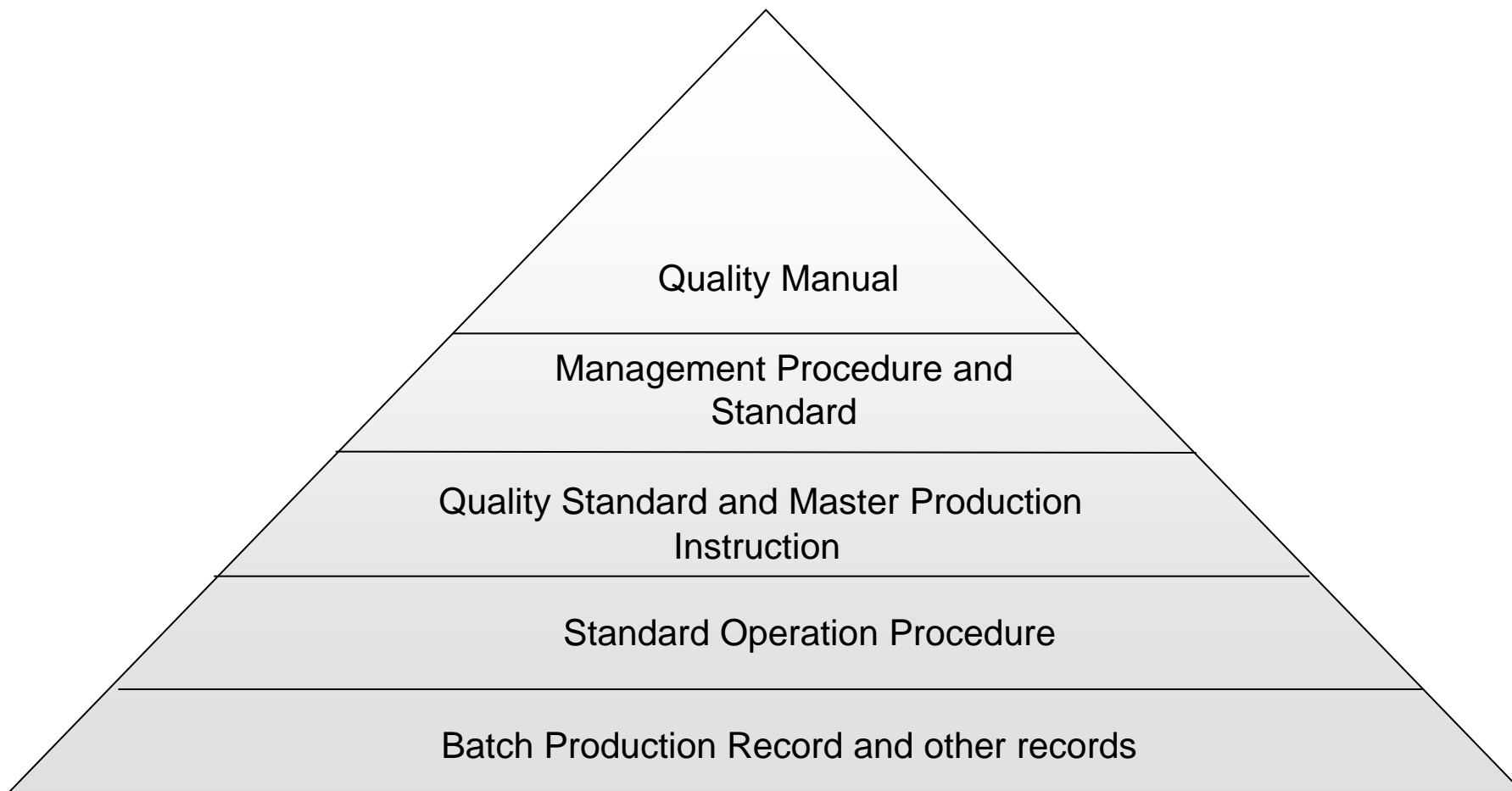


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Marketing Network

Xinhua has established a major worldwide marketing network, reaching over 60 countries. We are the regular supplies for the following multinational corporations, i.e.



Quality Documentation & Records System





3

Manufacturing Sites



Located in East Chemical Zone of Zibo High & New Technology Development Zone, Zibo, Shandong, P.R.China

Employees: 1300

1100 for production

18 for QA

40 for QC;

41 for Warehouse.

Area occupied: 36,000m²

Leading Products: Caffeine

Ibuprofen

Levodopa

Trimethoprim



East Site







Workshop No.	Leading Products	Remark
Workshop No.101	Power Supply	
Workshop No.102	Phenobarbital Pipemidic Acid	
	Meloxicam	Approved by KFDA
Workshop No.103	Ibuprofen	Approved by FDA and EDQM
Workshop No.104	Levodopa Trimethoprim	Approved by FDA and EDQM
Workshop No.105	Caffeine Theophylline	Approved by FDA and EDQM



Workshop & Leading Products





Working days: 5 days/week

Working shifts: 3 shifts/day and 8 hours/shift

Regular working hours:

a.m.: 8:00-12:00

p.m.: 13:00-17:00

Lunch time:

a.m.: 11:30-12:00





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Located in Hutian Chemical Industrial Zone, Zibo, Shandong, P.R.China

Employees: 1153

889 for production

8 for QA

26 for QC;

34 for Warehouse

Area occupied: 28,700m²

Leading Products: Aspirin

Metamizole

Phenazone

Propyphenazone

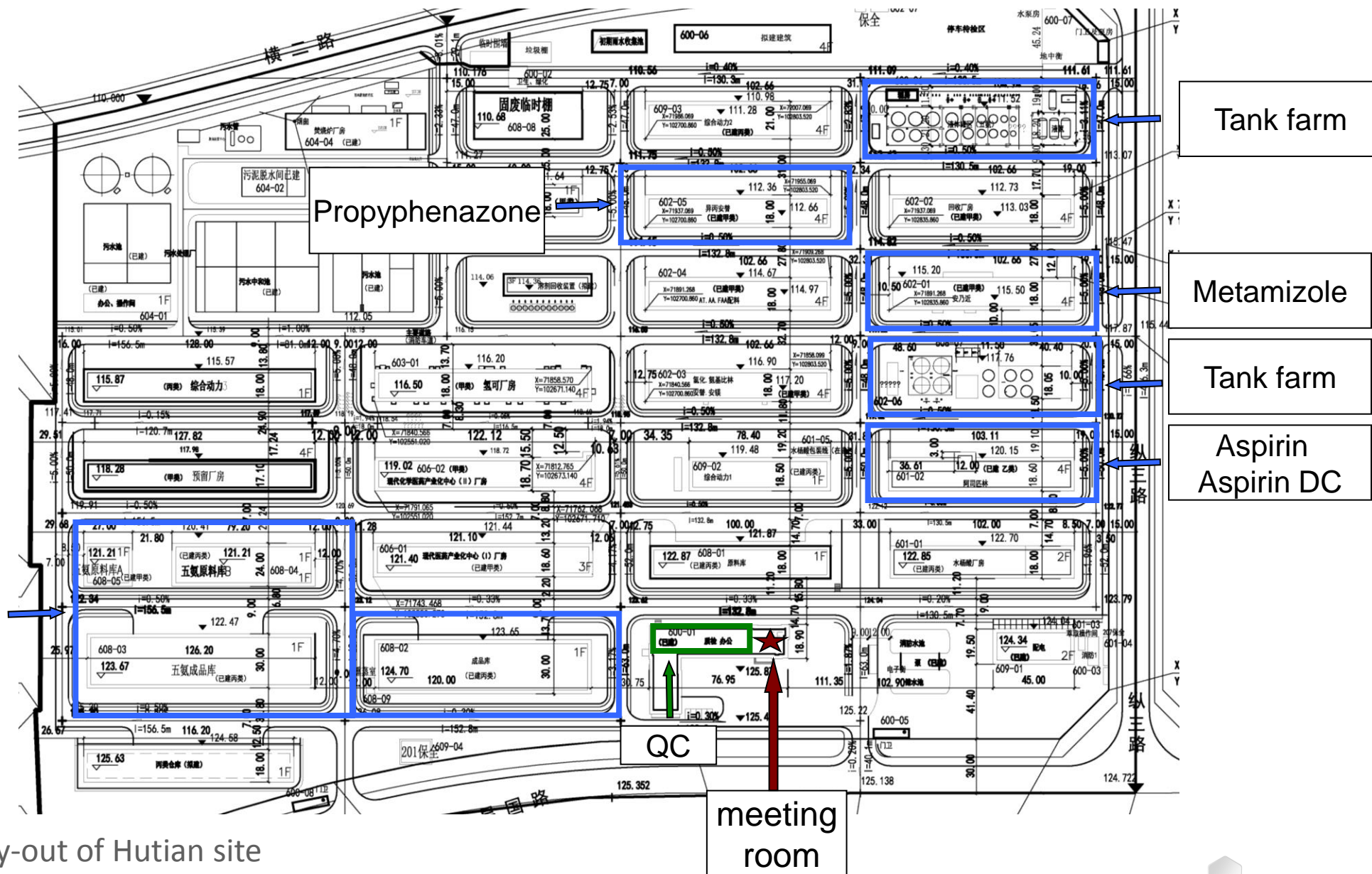


Hutian Site





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Lay-out of Hutian site



Workshop No.	Leading Products	Remark
Workshop No.201	Power Supply	
Workshop No.203	Hydrocortisone	Under construction
Workshop No.204	Propyphenazone	
Workshop No.205	Metamizole	
	Phenazone	
Workshop No.207	Aspirin	Approved by FDA and TGA
	Aspirin Refined DC Aspirin	Approved by FDA



Workshop & Leading Products





Working days: 5 days/week

Working shifts: 2 shifts/day and 12 hours/shift

Regular working hours:

a.m.: 8:00-12:00

p.m.: 13:00-17:00

Lunch time:

a.m.: 11:30-12:00





4

Safety Precaution



As a chemical pharmaceutical company, various species of chemical raw materials are used in the production process, most processes are completed under the conditions of high or low temperature, high or negative pressure, so accidents are easily caused.

In order to guarantee your safety and health, please abide by the following safety requirements when entering the production area:

- Please visit accompanied by Xinhua staff, don't be left behind
- Don't touch any equipment valve or switch;
- Don't smoke, take pictures and videos in the production area;
- Don't use cell phones in special areas
- In special and emergency circumstances, please obey the guidance of your companion, and gather in the safety zone.





We welcome your kind suggestions
during inspection
to Shandong Xinhua
so as to keep the continuous improvement
for our Quality System!



THANK YOU FOR YOUR GUIDANCE