



# Welcome to Shandong Xinhua Pharmaceutical Co. Ltd



# Company Basic Information



- ◆ 1943 Founded in 1943
- ◆ 1950 Succeeded in developing sodium stibogluconate for stamping the Kala-Azar which was the epidemic last several decades in China.
- ◆ 1953 Developed the first glass-lined reactor in China
- ◆ 1954 China's the first API production line was started in Xinhua
- ◆ 1959 The first company in China to produce bulk Aspirin and Caffeine
- ◆ 1970s The first company in China to produce bulk Ibuprofen
- ◆ 1996 Listed in Hong Kong stock exchange.
- ◆ 1997 Listed in Shenzhen stock exchange.
- ◆ 2003 The J.V. between Xinhua and Perrigo (USA) was established.

# Company Basic Information



- ◆ 2007 Contract project for finished dosage with Bayer Healthcare
- ◆ 2010 Hutian Chemical Industrial Zone began to be built
- ◆ 2011 Contract project for finished dosage form with Perrigo (UK)
- ◆ 2012 Hutian Chemical Industrial Zone was put into use.
- ◆ 2013 Shandong Xinhua Pharmaceutical Co., Ltd. (USA) was founded

# Company Basic Information



- China's largest pharmaceutical manufacturer of bulk antipyretics and analgesics. The annual output for APIs is around 25,000 Mt. The major APIs include Levodopa, Trimethoprim, Ibuprofen, Caffeine, Theophylline, Hydrocortisone, Aspirin, metamizole sodium, propyphenazone etc.
- The total area is 0.85 million square meters. Among them the standard warehouse occupies about 25,000 square meters.
- By the end of 2013, there are 4,690 employees in Shandong Xinhua



# Overview of Headquarter office



**Our headquarter office is located in No.1, Lutai Road, High-tech District, Zibo, Shandong, P.R.China**  
**The finance dept., sales dept., R&D and other administrative dept. are in the headquarter.**



# Number of Employees



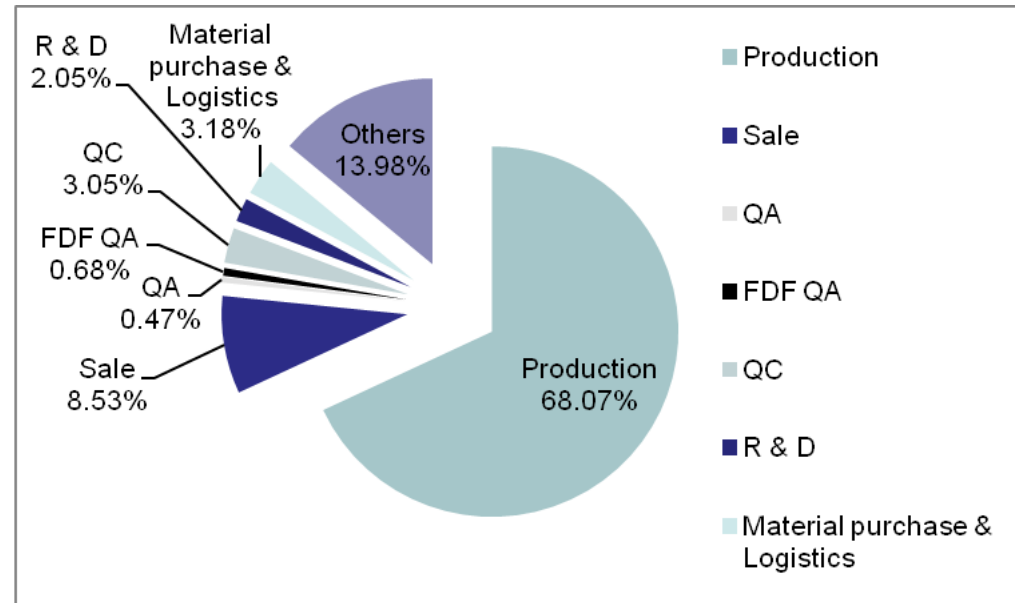
There are 4690 employees at the end of 2013

Among them:

- 3193 for production
- 400 for sales;
- 23 for QA;
- 36 for FDF QA
- 140 for QC;
- 96 for R&D.

Among them:

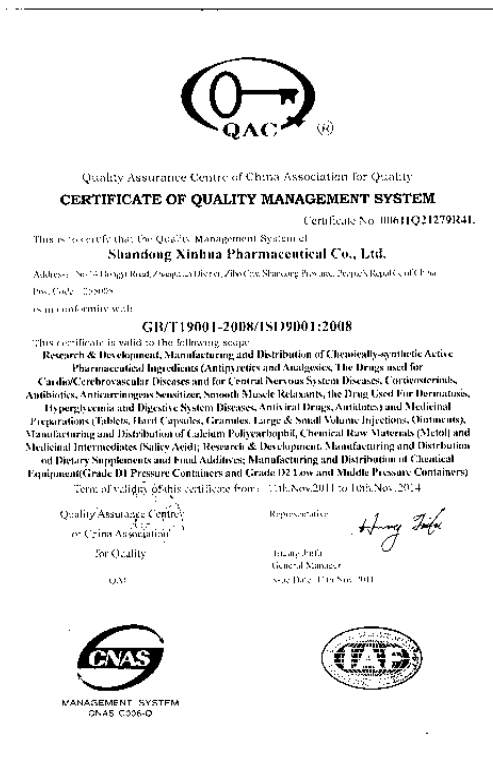
- 500 obtained the B.S degree
- 100 obtained the M.S degree
- 8 obtained the Dr degree
- 57 for licensed pharmacist



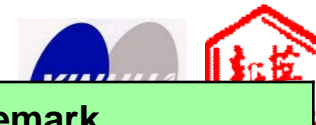
# Certificate Granted



**ISO 9001 was certified in 1999, and renewed in 2011 ;**  
**ISO 14001 was certified in 2000, and renewed in 2013;**  
**ISO 10012 was certified in 1998, and renewed in 2013;**  
**ISO 22000 was certified in 2009, and renewed in 2012**



# Inspection history by US FDA



Date	Investigator	Products	Result	Remark
Oct. 1999	Mr. Rebert L. Horon	Theophylline	483:18 Pass	Dongyi Road site
May 2000	Mr. Larry K. Austin	L-350 (intermediate)	483:3 Pass	East 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	483:4 Pass	East site
		Hydrocortisone Trimtheoprim		Dongyi Road site
July 2010	Ms. Charisse Green	Levodopa/Ibuprofen	483:0 Pass	East site
		Trimtheoprim		Dongyi Road site
March 24- April 4, 2014	Mr. Joel Hustedt	Acetylsalicylic acid; Phenazone; etc.	483:6	Hutian site
		Ibuprofen; Levodopa; Trimtheoprim; Caffeine; Theophylline; CPC; etc.	483:6	East site
		Hydrocortisone; Hydrocortisone acetate; etc.		Dongyi Road site



# Inspection by other oversea authorities in the past 3 years



No.	Date	Authority	Products	Result	Remark
1	May 2011	Germany --BGV	API - Propyphenazone	Pass	Dongyi Road site
2	May 2011	UK- MHRA	Oral solid dosage	Pass	Dongyi Road site
3	Aug.2012	UK- MHRA	Oral solid dosage	Pass	Dongyi Road site
4	Jan. 2013	K-FDA	Meloxicam	Pass	Ease site
5	Mar. 2013	EDQM	APIs -Levodopa -Trimethoprim -Ibuprofen	Pass	Ease site
6	May 2014	Germany --BGV	Propyphenazone Aspirin		Hutian site

# Inspection history by China FDA in the past 3 years



No.	Date	Products	Result	Remark
1	Sep. 2012	Trimethoprim	Pass	East site
		Aspirin, etc	Pass	Hutian site
2	Dec. 2012	Hydrocortisone Metamizole sodium, etc.	Pass	Dongyi Road site
3	Jan. 2013	Injections	Pass	West site
4	Apr. 2013	Oral solid dosage	Pass	Dongyi Road site
5	Jan. 2014	Metamizole sodium, Propyphenazone, etc.	Pass	Hutian site
		Caffeine	Pass	East site



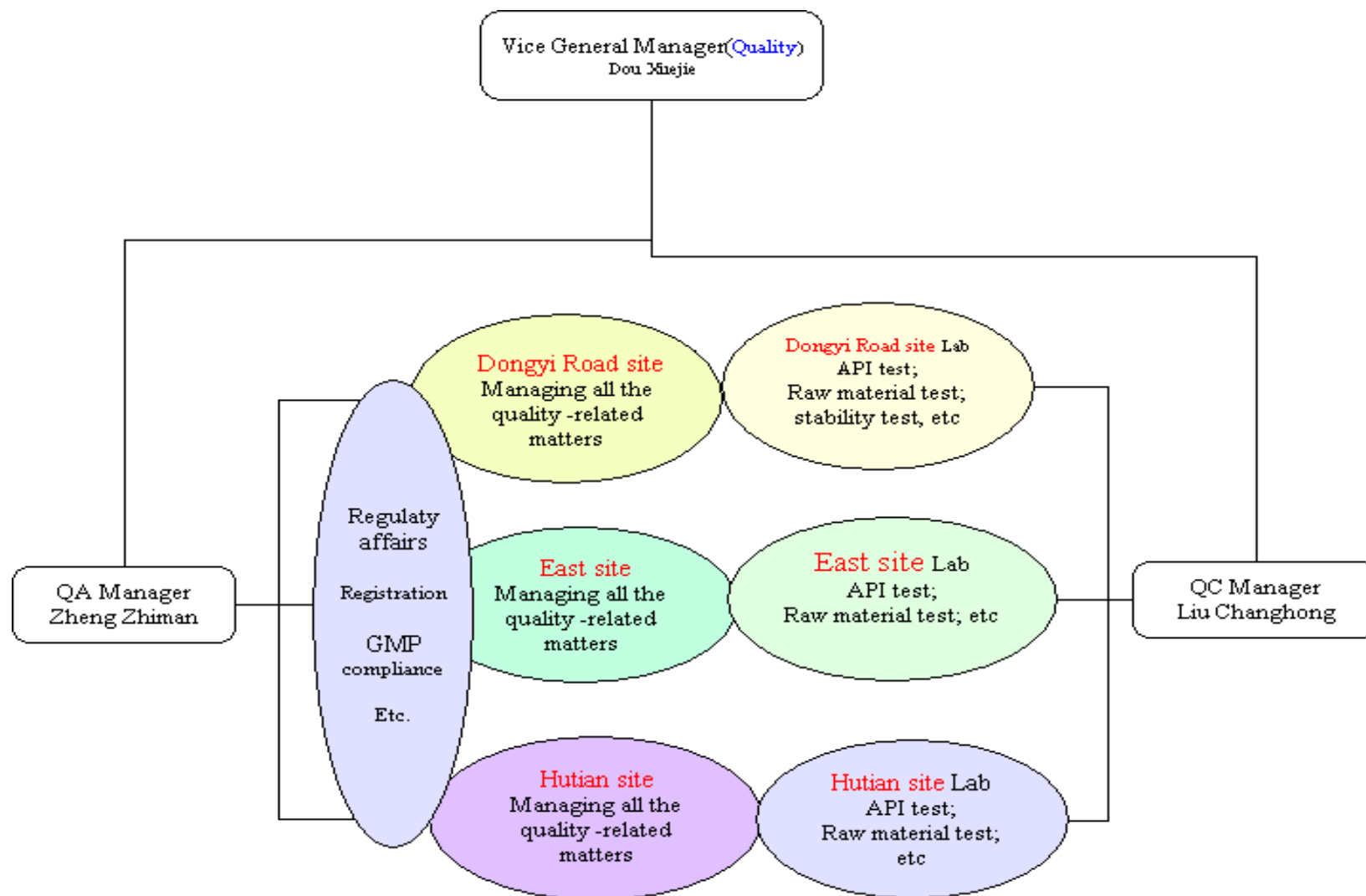
## Quality Policy

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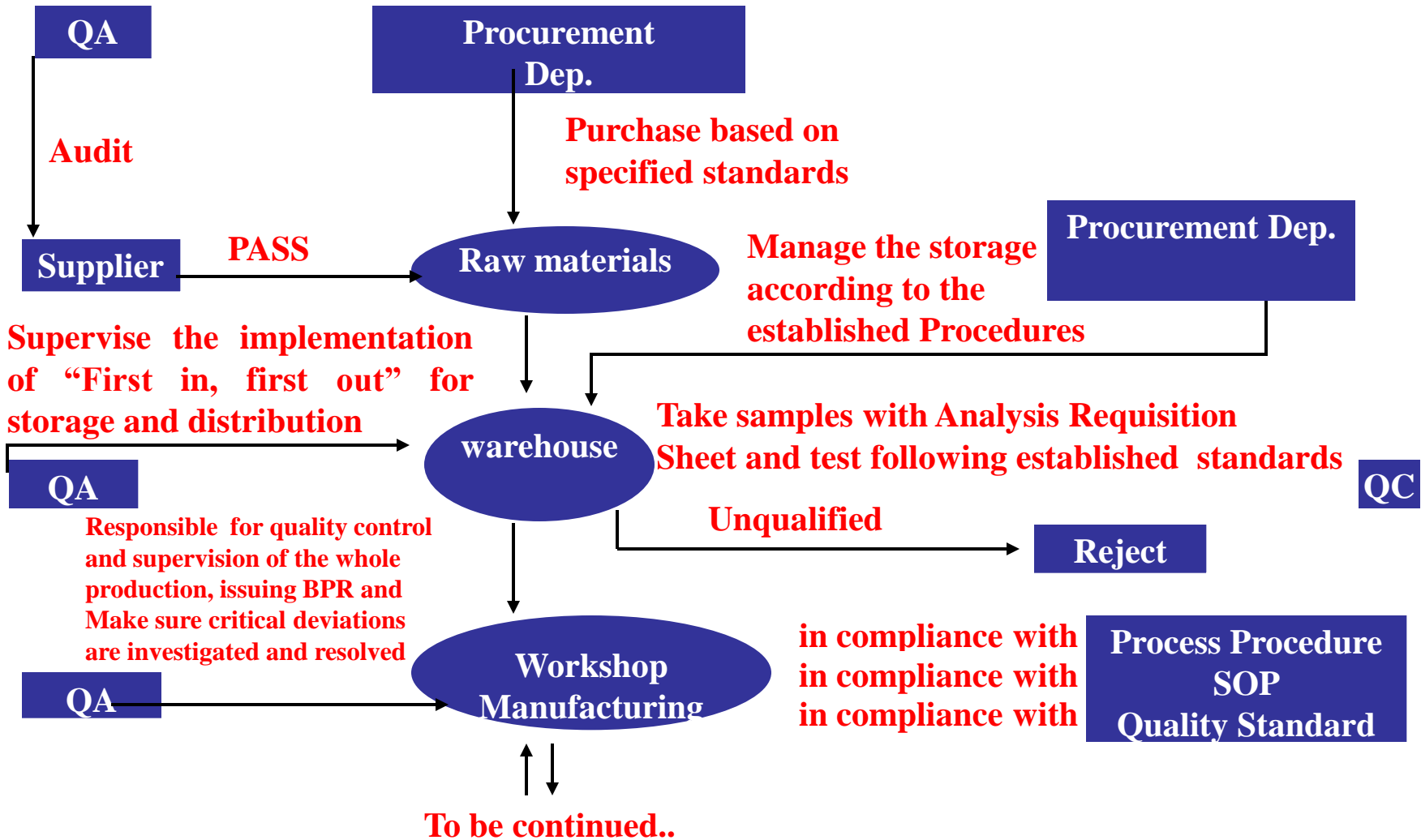
By taking the company mission of “*For Good Health and Better Life*”, and following the company quality value of “*the product quality effects the company’s development, and the drug quality effects the people’s life*”, meanwhile, strictly following the national laws and regulations, the company is **continuing the dedication to improve the quality system and to meet the demands of the clients.** With constant efforts to consolidate the advantage position of the API sector, more efforts is continuing to be paid in the finished dosages’ development and the new products research, so as to supply the superior products for the health of the human being with constantly improving the quality for the products and the service.

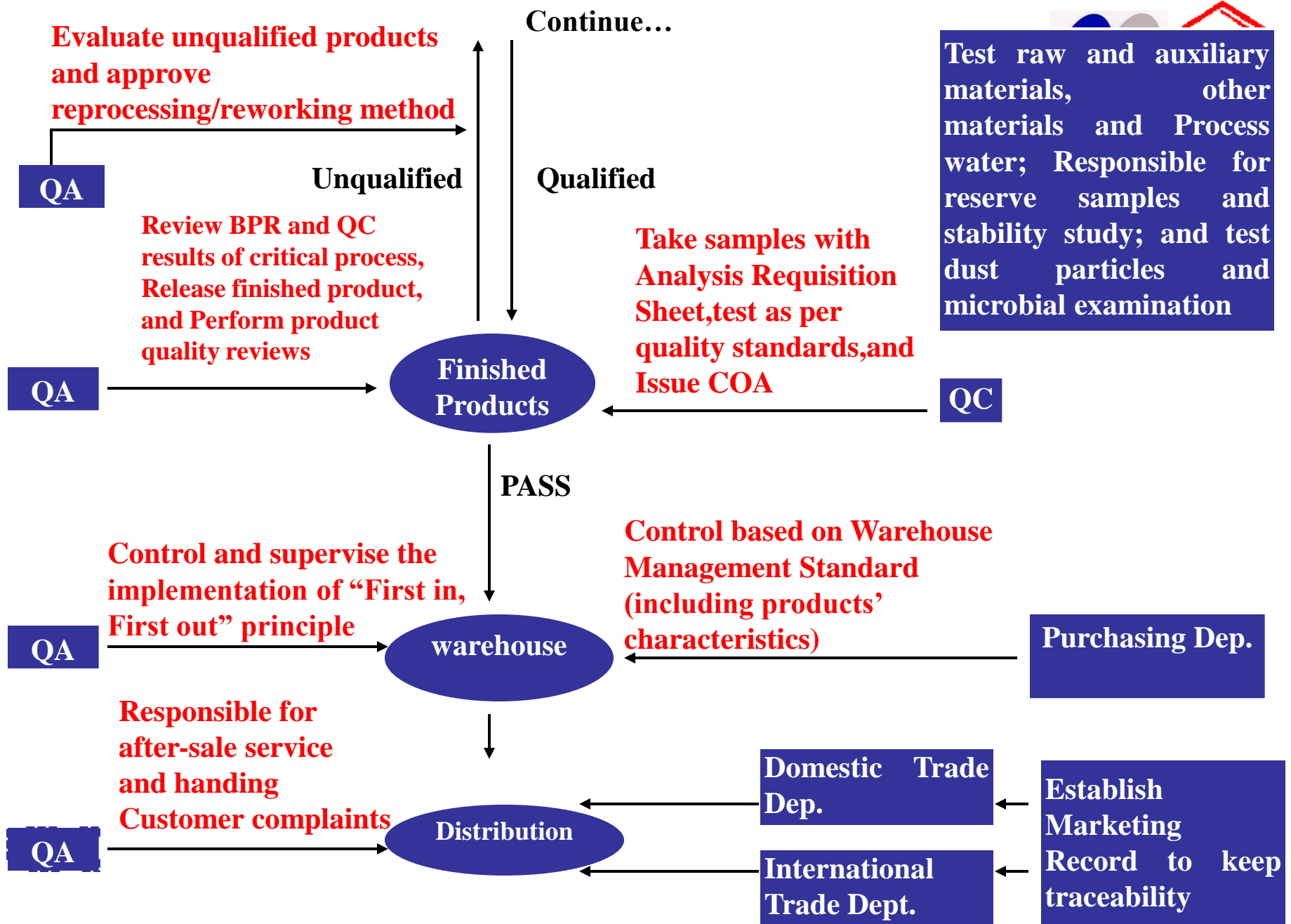


# QA and QC system



# Quality Assurance Procedure





# Introduction of QC



## Overview for the QC building



Labs in Ease site



API test for Caffeine, Theophylline etc.  
Raw material test for East site

API test for Levodopa, Trimethoprim,  
Ibuprofen etc.



Lab in Dongyi Road site



Lab in Hutian site



API test for Hydrocortisone, metamizole sodium etc.  
Raw material test for Dongyi Road site  
Stability study test for all APIs

API test for Aspirin, metamizole sodium etc.  
Raw material test for Hutian site

# Introduction of QC



## Particle size Test



## Chemical Analysis



## HPLC Test



## GC Test





# 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.



百时美施贵宝公司  
Bristol-Myers Squibb Company



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***Thanks for Your Attention!***

