USFDA 查廠經驗分享

楊正梅

2016/09

orient PHARMA CO.,Ltd.

Notice

FDA is coming

From: Condon, Cathy L. [mailto:Cathy.Condon@fda.hhs.gov]
Sent: Thursday, November 15, 2012 4:36 AM
To: Sally Chan 詹文寧
Cc: ORAHQDFFI IOB DRUG FIRM NOTIFICATION
Subject: U.S. FDA Notice of Inspection - Orient Pharma Co. (Taiwan) FEI 3009057557 (January)

U.S. Food and Drug Administration

Date: November 14, 2012	
Send to: Sally Chan FEI: 3009057557	From: FDA
Firm: Orient Pharma Co., Ltd. Location: 8, Kehu 1st Road Huwei Chen, Yunlin 63247, TWN	Office Location: 12420 Parklawn Dr. Element BLDG. Room 2044 Rockville, MD 20857
Fax Number: Tel Number: 886.5.631.1331 x8105	Fax Number: 301-827-9791 Tel Number: 301-796-5814
E-mail : sally.chan@oppharma.com	E-mail: cathy.condon@fda.hhs.gov and ORAHQDFFIIOBDRUGFIRMNOTIFICATION@fda.hhs.gov
If you fail to respond to this notice before November 19, 2012, your products may be refused entry into the United States.	

From: ORAHQDFFI IOB DRUG FIRM NOTIFICATION [mailto:ORAHQDFFIIOBDRUGFIRMNOTIFICATION@fda.hhs.gov]
Sent: Thursday, September 04, 2014 2:52 AM
To: Sally Chan 詹文寧; paulrong.chen@gmail.com
Cc: Condon, Cathy L.; ORAHQDFFI IOB DRUG FIRM NOTIFICATION
Subject: U.S. FDA Notice of Inspection- Orient Pharma Co (Taiwan)- 3009057557 (Nov-Jan)

U.S. Food and Drug Administration

Date: September 3, 2014	
Send to: Dr. Sally Chan & Mr. Paul Rong FEI: 3009057557	From: FDA
Firm: Orient Pharma Co., Ltd. Location: 8 Kehu 1st Road Huwei Chen, Yunlin county 63247 TWN	Office Location: 12420 Parklawn Dr. Element BLDG. Room 2044 Rockville, MD 20857
Tel Number: 886-5-631-1331, 858-793-2537	Fax Number: 301-827-9791 Tel Number: 301-796-5814
E-mail: sally.chan@oppharma.com; paulrong.chen@gmail.com	E-mail: cathy.condon@fda.hhs.gov and ORAHQDFFIIOBDRUGFIRMNOTIFICATION@fda.hhs.gov
If you fail to respond to this notice before September 10, 2014, your products may be refused entry into the United States.	

Preparation

查廠前

- 了解稽查人員背景
- 稽查經驗

查廠時

- 住宿飯店
- 接送人員

- 查廠簡報
- 稽查室
- 準備室
- 翻譯人員
- 記錄人員

Inspection Process

- Presentation
- Site tour
- Document review

FDA investigator attitude

- 從完全懷疑開始 建立信任
- 批次與ANDA送件資料是否完全相同

(ANDA 資料準備一份)

  - 批次管理與發放
  - 紙張新舊程度
  - 批次骯髒程度
  - 筆跡穿透程度
  - 人員字跡與填寫順序

Warehouse

- Materials receiving process
- Goods return process
- Suppliers assessment

Follow Ups

- To consider establishment of identified code for incoming materials.
- Meeting DSCSA requirements for commercial products to the US.

Production

- Batch processing record
- Process validation protocol
- Clean validation

Follow Ups

- Room Data list
- 人員的權限

QC

- API testing review by item
- Data integrity
- Method Validation
- Stability
- Microbial lab

Quality System

- QA system (Deviation, OOS, Change control)
- Reviewed all reports and completed PA.
- Annual report
- Quality Agreement of Complaint and Recall.
- ANDA batch finial review

Focus on FDA inspection

- ***21CFR <Part 11> CSV (Computer system validation)***

  - CSV is to provide a high degree of assurance that a specific process will consistently produce a product which meets quality attributes

- ***QbD (Quality by Design) concept***

  - Higher level of assurance of product quality
  - Cost saving and high efficiency for industry
  - More efficient regulatory oversight

- ***CAPA should be timely***

03.30.2015~04.03.2015 USFDA Inspection

OP opening presentation

Site inspection (warehouse, production area)

Go through testing reports on the analysis equipment (QC Lab)

Production Area/ Water system/ Microbiological Lab/ QA OOT, OOS, deviation system

Close meeting/ Form 483- Observations

Reply in 15 days

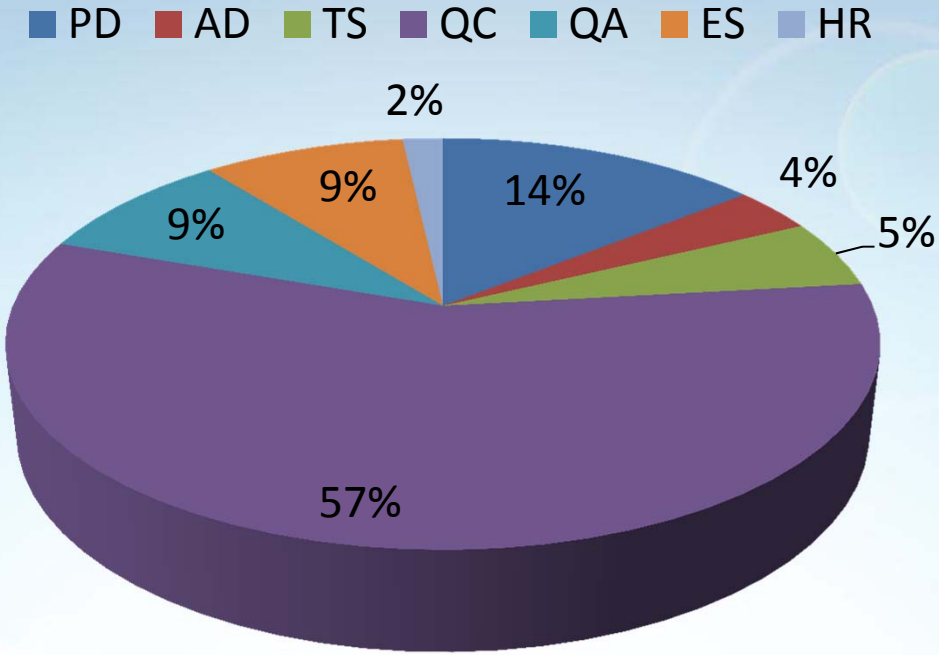
orient PHARMA CO.,Ltd.

OOT: out of trend

OOS: out of specification

03.30.2015~04.03.2015 USFDA Inspection

Time (hr)



Thank you