



Ways to Stay Current on Compliance Regulations

因應法規變更藥廠之策略與措施

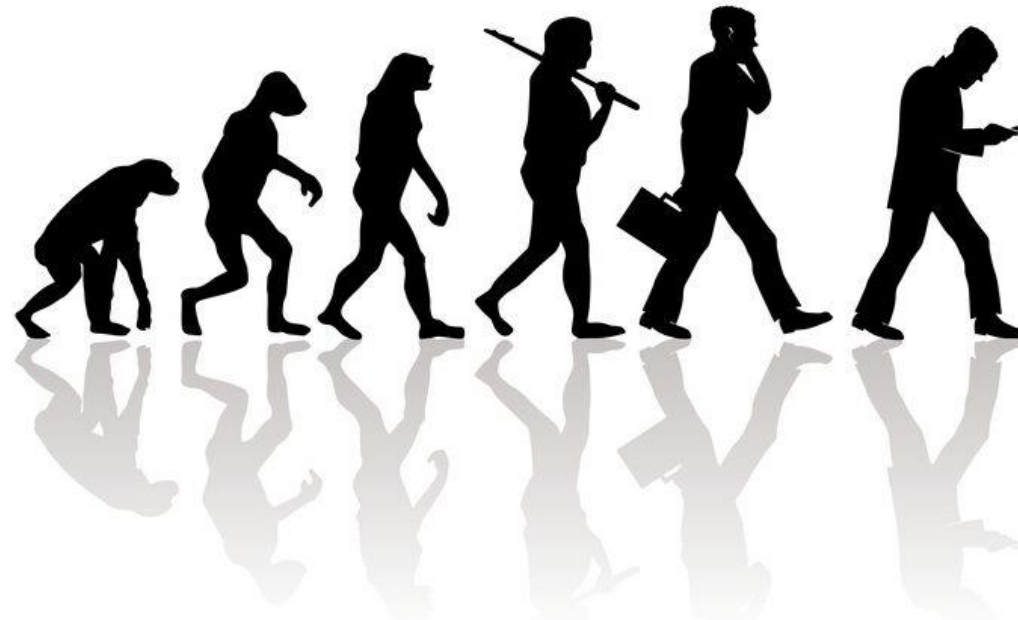
Date: Oct 2023

Speaker: Dr. Pichiang Hsu (許弼強)

Email: pichiang.hsu@gmail.com

“It is not the strongest or the most intelligent who will survive but those who can best manage change.”

— Charles Darwin



Source: <https://www.bluhmsysteme.com/blog/bompeln-fuer-smombies/>

Course Overview

- Provide an overview of regulatory intelligence (RI)
- Link RI to the existing quality systems
- Introduce the use of various ways to keep up-to-date on regulatory intelligence
- Application of RI newsletters and RI sharing meeting



References:

- <https://www.raps.org/news-and-articles/news-articles/2019/1/proactive-regulatory-intelligence-communication>
- <https://www.raps.org/news-and-articles/news-articles/2019/1/managing-regulatory-intelligence-for-medical-devic>
- <https://www.pda.org/docs/default-source/website-document-library/chapters/presentations/west-coast/regulatory-intelligence-101.pdf?sfvrsn=4>
- <https://beinetworks.com/7-ways-to-stay-current-on-compliance-regulations/>



Regulatory Intelligence (RI)

What is A.I.?



Source: <http://www.aiiottalk.com/artificial-intelligence/relation-between-data-science-and-ai/>

Information vs. Intelligence

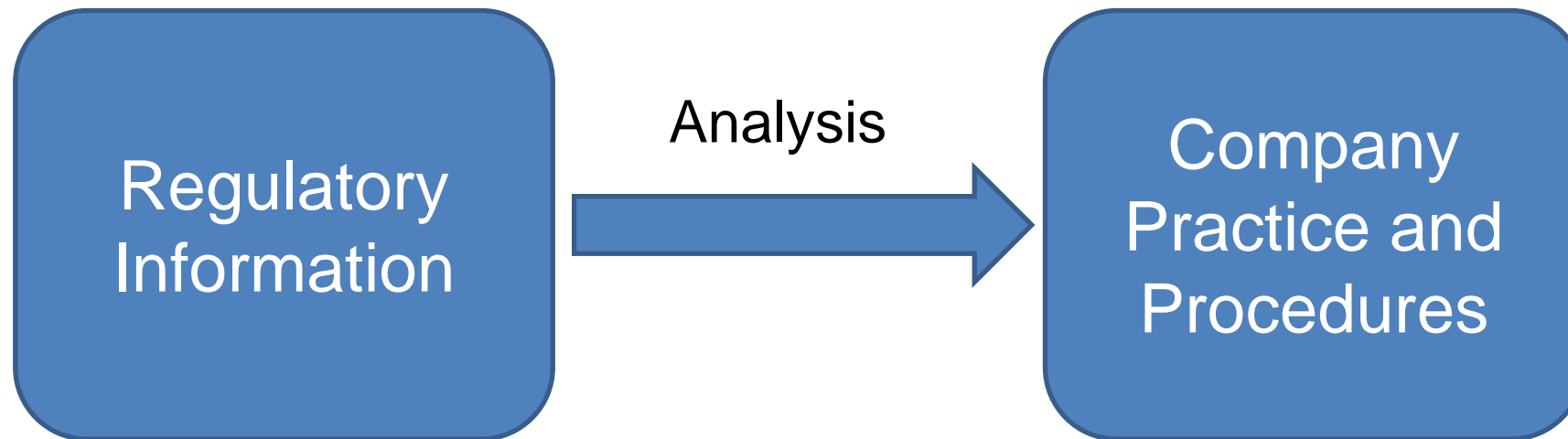
- **Information** is the raw data used to create intelligence
- **Intelligence** is active and related to analysis
- The **data analysis** and **integration into company practice and procedures** produces regulatory intelligence

Definition of RI

The RI professional's responsibilities are best summarized within the Drug Information Association Regulatory Intelligence Working Group definition of regulatory intelligence:

“The act of **gathering** and **analyzing** publicly available **information**. This includes communicating the implications of that information and monitoring the regulatory environment for opportunities to shape future **regulations, guidance, policy and legislation**.”

Regulatory Intelligence Process





Source: <https://screenrant.com/matrix-4-trinity-death-bad-fix/>

Why is Regulatory Intelligence Important?

- Identify **opportunities**
- Identify possible **pitfalls**
- Predict review times for product and/or change to product
- Answer specific development questions poised by team

Benefits of Regulatory Intelligence

- Increase **compliance**
- Increase likelihood of marketing **application approval**
- **Shorten time** from filing to approval
- Increased efficiency
- **Optimize study design** for regulatory endpoints
- Optimize messaging about product benefit
- **Maximize target market potential**

What are We Facing to?

Federal government agencies issue **thousands of rules every year**. Congress enacts hundreds of laws annually. New regulations sometimes replace existing ones and sometimes they add more layers of compliance complexity. If your business is **required to follow these regulations** it can seem overwhelming keeping up with all the requirements.

What should we do?



Give up and cry alone?

Regulatory Intelligence Operations

This function of RI typically conducts the following activities:

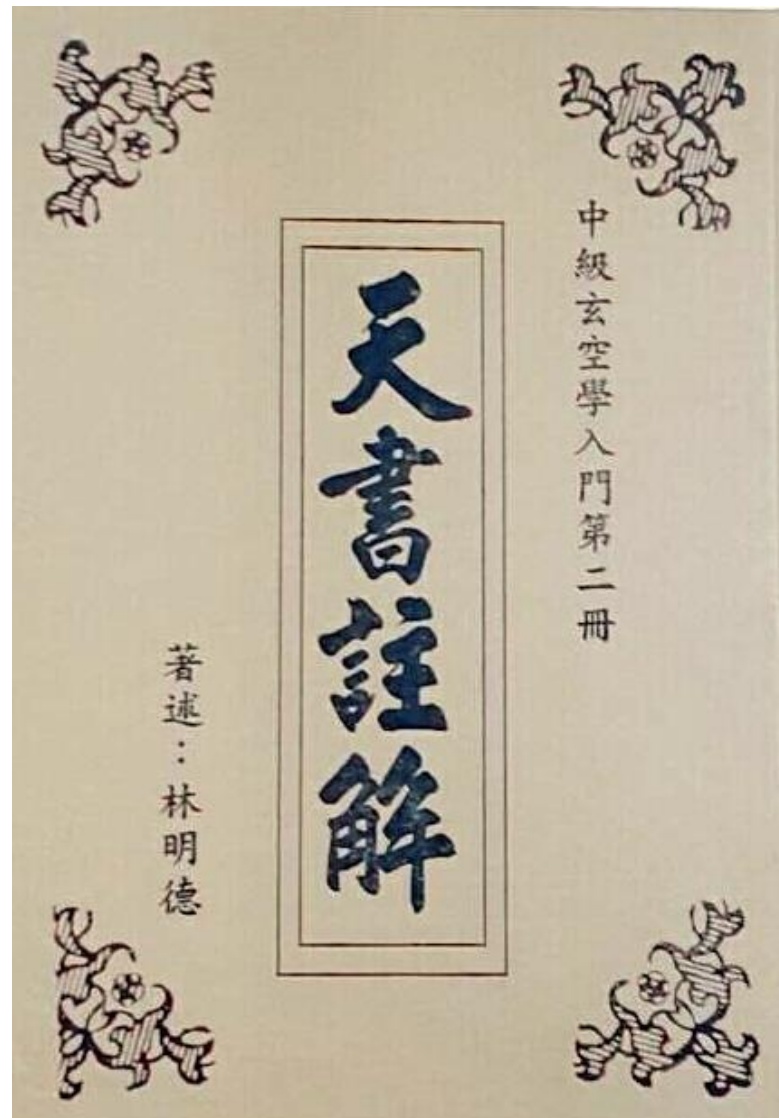
- regulatory **research**
- **monitoring** and **surveillance** of the regulatory landscape
- drug approval summaries
- **news letters**
- **hot topics** (analysis of regulatory trends)
- **training**
- **knowledge management**

Regulatory Information

- Regulatory information is **not usually found in one location**
- You need to have various **searching techniques** to be able to address the scope and breadth of questions posed to you
- For each question put forth, there are **numerous sources** to begin your search or project

More than Regulations and Guidance Documents

- Regulations and guidance documents tell **part of the story**
- **Gray area** in these sources are hard to follow
- Interpretation of guidance varies with **SMEs, company**, and sometimes even the **regulatory inspectors**



Source:
http://www.theregentstore.com/main.php?fid=04&page_name=product_detail&prod_id=14052

Regulatory Intelligence Tools

One of the most important RI skills you can develop is.....

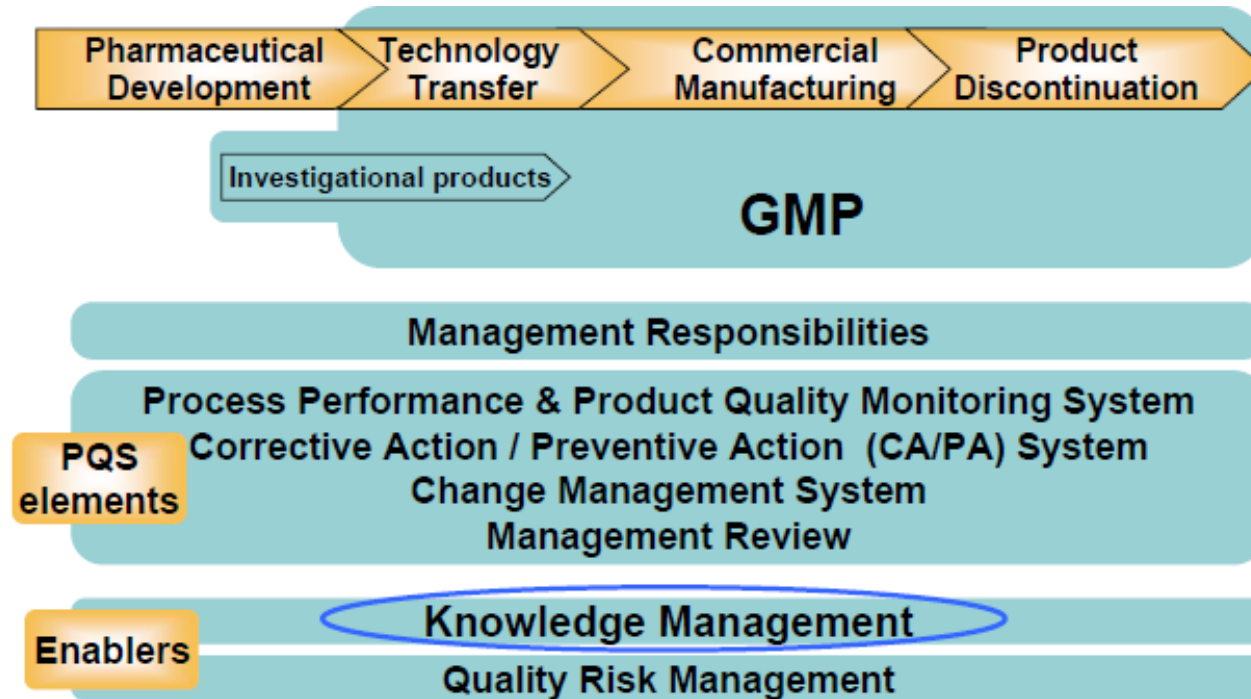
NETWORKING

Within your department, company, working groups and at industry/professional association **meetings**.

Why Document RI?

- Constructing or documenting a formal written analysis of the regulatory strategy for personal use or presentation to the team **allows future reference** to determine **why a decision was made** at a particular time in the development timeline.
- In addition, it can serve as the foundation document for any **future updates and analysis**, as needed for that topic.

Knowledge Management



*[KM is an enabler applicable throughout the lifecycle stages, and supports] the PQS goals of achieving **product realisation**, establishing and maintaining a **state of control**, and facilitating **continual improvement**.*

Knowledge Management

- Develop and maintain RI database
- Hot topics updates
- Internal regulatory workshops
- Conference participation
- Regulatory Library; Approvals, transcripts, videos, external course notes

RI Sharing

Sharing can take many forms, depending on the company and their culture

- E-mail
- Presentations
- Databases
- Newsletters
- Intranet
- Lunch meetings

Needs to be timely!

Regulatory Intelligence Communications

- Proactive communication
- Horizontal communication
- Vertical communication
- Companywide communication

Archiving and Filing

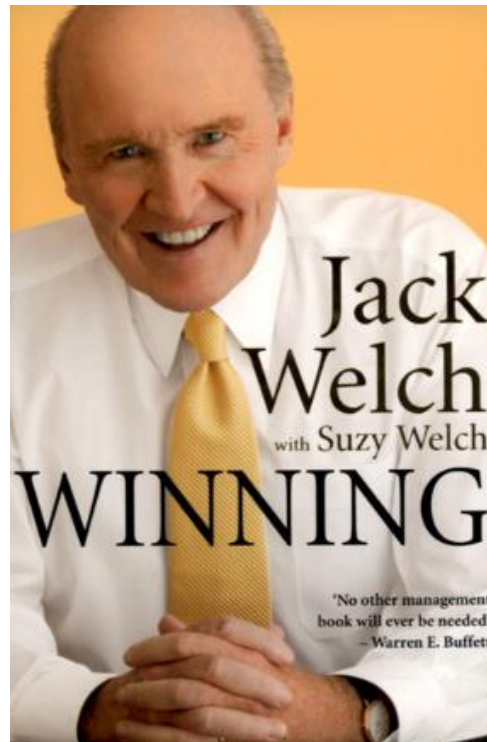
- Once you do the research, and distribute it, **what do you do with it next?**
 - Keep it hard copy in the filing cabinet
 - Scan it and put it on an electronic shared drive
 - Scan it and include it in an **RI database**
- How or where put it so that **everyone can access it**, if needed?



Keeping Up-to-Date on Regulatory Intelligence

“An organization's ability to learn, and translate that learning into action rapidly, is the ultimate competitive advantage.”

— Jack Welch



6 Ways to keep up-to-date on regulatory intelligence

1. Regularly check sites for updated standards

Make it a habit to **regularly visit websites** that post updated standards for your industry. **FDA** and **ECA** sites offer many resources and provide regularly updated information on compliance standards.

2. Join industry associations

Become a member of trade groups and associations connected with your industry. These organizations alert their membership to significant changes relevant to your business, and they usually can serve as a resource when you have compliance questions.

2. Join Industry Associations



From: 中華民國製藥發展協會 <cpmda@cpmda.org.tw>

Sent: Thursday, November 28, 2019 2:40 PM

To: 中華民國製藥發展協會 <cpmda@cpmda.org.tw>

Subject: <公函轉知>原料藥廠不符合 GMP 相關訊息

各會員/藥政委員會委員 您好:

食藥署 公函 (如附件)

主旨：有關中國/義大利/印度原料藥廠不符合GMP相關訊息乙案，請查照。

1. 中國「NCPC HEBEI HUAMIN PHARMACEUTICAL CO.,LTD.(廠址: No. 98 Hainan Road Economic and Technological Development Zone China-052 165 Shijiazhuang, Hebei Province, China)」
2. 義大利「FARMABIOS S.P.A. (廠址：Via Pavia, 1, GROPELLO CAIROLI, 27027, Italy)」
3. 印度「Mylan Laboratories Limited, Unit 8」(廠址：G. Chodavaram Village, Vizianagaram, Andhra Pradesh, India)」

2. Join Industry Associations



檔 號:
保存年限:

衛生福利部食品藥物管理署 函

地址：11561 臺北市南港區昆陽街161-2
號

聯絡人：賴蔚榕

聯絡電話：(02)2787-7025

傳真：(02)2787-7023

電子信箱：luvkumara@fda.gov.tw

受文者：中華民國製藥發展協會

發文日期：中華民國108年11月28日

發文字號：FDA品字第1081106611號

速別：普通件

密等及解密條件或保密期限：

附件：原料藥廠違反GMP警訊乙份

主旨：義大利原料藥廠「FARMABIOS S.P.A. (廠址：Via

Pavia, 1, GROPELLO CAIROLI, 27027, Italy)」經國外

官方判定違反GMP乙案，詳如說明段，請轉知所屬會員知

照。

2. Join Industry Associations



檔 號：
保存年限：

衛生福利部食品藥物管理署 函

地址：11561 臺北市南港區昆陽街161-2

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受文者：中華民國製藥發展協會

發文日期：中華民國108年11月28日

發文字號：FDA品字第1081106625號

速別：普通件

密等及解密條件或保密期限：

附件：原料藥廠違反GMP警訊乙份 (A21020000I108110662500-1.pdf)

主旨：美國FDA發布印度原料藥廠Warning Letter乙案，詳如說

明段，請轉知所屬會員知照。

說明：

2. Join Industry Associations



檔 號:
保存年限:

衛生福利部食品藥物管理署 函

地址：11561 臺北市南港區昆陽街161-2
號

聯絡人：黃瀚賜

聯絡電話：02-2787-7171

傳真：02-2787-7178

電子信箱：hantzehuang@fda.gov.tw

受文者：中華民國製藥發展協會

發文日期：中華民國108年11月27日

發文字號：FDA品字第1081106601號

速別：普通件

密等及解密條件或保密期限：

附件：原料藥廠違反GMP警訊乙份 (A210200001108110660100-1.pdf)

主旨：有關國際醫藥品稽查協約組織（PIC/S組織）會員發布中

國原料藥廠「NCPC HEBEI HUAMIN PHARMACEUTICAL CO.,

LTD.(廠址：No. 98 Hainan Road Economic and

Technological Development Zone China-052 165

Shijiazhuang, Hebei Province, China)」不符合GMP相

關訊息乙案，詳如說明段，請轉知所屬會員知照。

3. Attend trainings, conferences, and seminars

Whether **online** or **in person**, attend regulatory compliance **training sessions** and **seminars** as well as participate in **conferences**. You'll expand your knowledge, learn new standards, get best practices for implementing the standards, and connect with industry peers.

3. Attend trainings, conferences, and seminars



社團台灣藥物品質協會
法人 Taiwan Product Quality Research Institute

2023 年藥廠 GMP 主題論壇


『品質被授權人專業論壇』課程簡章

為使我國西藥藥品製造品質能持續提升，符合國際上GMP管理規範，以提升我國製藥工業在全球市場之競爭力，承辦衛生福利部食品藥物管理署112年度計畫辦理「藥廠GMP主題論壇」，提供業者GMP之相關課程，進而提升我國西藥廠從業人員GMP製造與品質管理。

品質被授權人(Authorised Person, AP)之職責係於產品放行前檢視藥品製造(含管制)之全部環節，以確保藥品皆依法規及產品上市許可要求予以製造與檢驗，可見AP職務之落實至關重要，因此，衛生福利部食品藥物管理署因應國際趨勢，已於112年2月24日公告增訂的附則16「由被授權人認可與批次放行」，提供了AP執行認可與批次放行之指引，食藥署並表示未來AP人員之管理與職務之落實將納入查核重點；因此，本協會特辦理此次主題論壇，以國內各西藥製造業者AP及監製藥師為開課對象，除邀請TFDA長官向業界說明增訂法規之重點外，另，特別邀請在業界具有豐富實務品保經驗的許弼強博士與蔡豈翰經理擔任此次會議之講師，跟大家分享「GMP藥廠之QA系統運作」及「GMP附則 16 由被授權人認可與批次放行」等議題之實務經驗，期許透過官方的法規解析及業界的實務經驗分享，讓現場與會的AP人員清楚相關法規要求之內涵並予以落實，進而達到確保廠內生產之藥品品質以維護國人用藥安全之終極目標。

本課程提供【藥事人員繼續教育學分 7 點】/品質授權人員持續教育 6 小時機會難得，敬請把握！

3. Attend trainings, conferences, and seminars

**PDA** Parenteral Drug Association
Connecting People, Science and Regulation®

HOMEEVENTSTRAININGTOPIC AREAS▼PUBLICATIONS▼GLOBAL COMMUNITY▼FOUNDATIONJOIN PDAQ

PDA Human Factors Training Courses

Human factors play a critical role in the quality and safety of drug products. PDA's Human Factors training courses provide an understanding of how human interaction with pharmaceutical products during the manufacturing process can cause failures if precautions are not taken. Topics include how human factors can have positive and negative effects on issues such as CAPA, data integrity, compliance failures, and/or drug shortages.

[? Ask A Question](#)

PARENTERAL DRUG ASSOCIATION
PDA USA
4350 East West Highway, Suite 600
Bethesda, MD 20814 USA
Tel: +1 (301) 656-5900
[Map & Directions](#)

PDA EUROPE
Am Borsigturm 60
13507 - Berlin, Germany
Tel: +49 30 436 55 08-0 or -10
Fax: +49 30 436 55 08-66
[Map & Directions](#)

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3. Attend trainings, conferences, and seminars

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4. Subscribe to newsletters

Sign up for **mailing lists** and **newsletters** issued by regulatory agencies and other industry-specific groups. Don't forget to **actually read** those newsletters so you get alerted to changes in compliance standards.

5. Designate a compliance officer

Consider appointing a **designated person** to handle your business' compliance matters. At the least, **designate a staff person tasked** with regularly checking for updates to relevant regulations.

6. Outsource with experts

Partner with a reputable vendor who can provide expertise and up-to-date knowledge in a specific area of compliance. Define the responsibility in your **quality agreement**.

How to do it in your company?

- Weekly RI News Letter
- Monthly RI Sharing meeting

Weekly RI News Letter



RI Newsletters

Non-Compliance News:

- Warning letters
- EU Non-compliance
- Recent 483s
- Import alert
- Recent recalls

New/Revised Guidance and Regulations:

Index of RI Newsletters

○ NON-COMPLIANCE

- **Warning Letter**
 - <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters>
- **EU Non-Compliance**
 - <http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPNonCompliance.do>
- **Recent 483s**
- **Import Alert**
 - https://www.accessdata.fda.gov/cms_ia/importalert_189.html (Import Alert 66-40)
 - https://www.accessdata.fda.gov/cms_ia/importalert_521.html (Import Alert 99-32)

○ Recent Recalls

- <https://www.accessdata.fda.gov/scripts/ires/index.cfm>

○ New/Revised Guidance and Regulations

- <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/>

RI Newsletters – Recent 483



<http://inspections.fdanews.com/>

- More than 4,700 Form 483s ... with round-the-clock, unlimited access. New 483s are added as soon as we receive them from the FDA.
- Searchable access to the 483s by the name of the company that received the Form 483, by the **date of the inspection**, by the **inspector's name**, by **region** and by **keywords**.
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RI Newsletters – Recent 483

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Beth E. Safirstein

Issue Date	Category	Region
Aug 06, 2019	Clinical	Southeast

Investigator(s): Traci M. Armand

Download

Ryan M. Rich

Issue Date	Category	Region
Jul 29, 2019	Clinical	Southwest

Investigator(s): Theresa B. Smith

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Torrent Pharmaceuticals Ltd.

Issue Date	Category	Region
Apr 16, 2019	Drug	HQ

Investigator(s): Jogy George, Lata C. Mathew, Zhao Wang

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Zhejiang Tianyu Pharmaceutical Co., Ltd.

Issue Date	Category	Region
Apr 12, 2019	Drug	HQ

Investigator(s): Laurimer Kuilan-Torres

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Suzhou Homesum Pharmaceutical Co. Ltd.

Issue Date	Category	Region
Apr 12, 2019	Drug	HQ

Investigator(s): Vilmary Negron Rodriguez

Download

Jilin Asymchem Laboratories Co., Ltd.

Issue Date	Category	Region
Apr 12, 2019	Drug	HQ

Investigator(s): Christopher S. Keating

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SEARCH BY DATE ISSUED

From

To

SEARCH BY CATEGORY

☐ Drug

☐ Device

☐ Clinical

SEARCH BY COMPANY/
CLINICAL INVESTIGATOR

SEARCH BY REGION

SEARCH BY FDA INVESTIGATOR

SEARCH BY KEYWORD

Search

47

RI Newsletters - Warning letters

Google FDA



RESOURCES AND PROGRAMS			
Jobs at FDA	Inspections and Compliance	MedWatch: Safety Alerts	Science & Research
FDA Organization	Import Program	Warning Letters	Combination Products
What does FDA regulate?	Criminal Investigations	Disposal of Unused Medicines	Emergency Preparedness

RI Newsletters - Warning letters

FDA U.S. FOOD & DRUG ADMINISTRATION

Home / Inspections, Compliance, Enforcement, and Criminal Investigations / Compliance Actions and Activities / Warning Letters

Warning Letters

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Warning Letters

About Warning and Close-Out Letters

Tobacco Retailer Warning Letters

Learn about the types of warning letters on FDA's website.

- Matters described in FDA warning letters may have been subject to subsequent interaction between FDA and the letter recipient that may have changed the regulatory status of issues discussed in the letter.
- To obtain additional available information, contact FDA. Requests to FDA for agency records should be sent to: Food and Drug Administration Division of Freedom of Information (HFI-35), 5630 Fishers Lane, Rockville, MD 20857. Instructions for how

Content current as of: 11/26/2019



Search

Showing 1 to 10 of 44 entries (filtered from 3,310 total entries)

Filters

Issuing Office

Letter Issue Date

Last 60 days

Letters with Response or Closeout

Response Letters

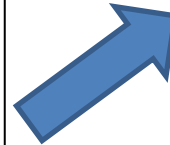
Posted Date

Last 60 days

Year


Clear Filters

Export Excel Show 10 entries



Posted Date	Letter Issue Date	Company Name	Issuing Office	Subject	Response Letter	Closeout Letter
11/26/2019	09/10/2019	Lohxa LLC	Division of Pharmaceutical Quality Operations I	CGMP/Finished Pharmaceuticals/Adulterated		
11/26/2019	11/18/2019	EPH Technologies, Inc.	Center for Drug Evaluation and Research CDER	Unapproved New Drugs/Misbranded		
11/26/2019	11/19/2019	California Cereal Products	Office of Human and Animal Foods - III East	CGMP/Food/Prepared, Packed or Held Under Insanitary Conditions/Adulterated		
11/25/2019	11/22/2019	KOI CBD LLC	Center for Drug Evaluation and Research CDER	Unapproved New Drugs/Misbranded/Cannabidiol (CBD) Products		
11/25/2019	11/22/2019	Mr. Pink Collections, LLC	Center for Drug Evaluation and Research CDER	Unapproved New Drugs/Misbranded/Cannabidiol (CBD) Products		

RI Newsletters - Warning letters

 **U.S. FOOD & DRUG**
ADMINISTRATION

SearchMenu

← Home / Inspections, Compliance, Enforcement, and Criminal Investigations / Compliance Actions and Activities / Warning Letters / EPH Technologies, Inc. - 590707 - 11/18/2019

WARNING LETTER

EPH Technologies, Inc.

MARCS-CMS 590707 – NOVEMBER 18, 2019

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More Warning Letters

Warning Letters

About Warning Letters

Delivery Method: Via Overnight Delivery

Product: Drugs

Content current as of:
11/26/2019

Regulated Product(s)
Drugs

RI Newsletters - EU Non-compliance

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EudraGMDP

MIA | **GMP** | API REG | WDA | GDP | Sites

Help English Go

Tue 3 Dec 2019 10:11:56 BST

Welcome to EudraGMDP

Directives 2004/27/EC on human medicinal products and 2004/28/EC on veterinary medicinal products introduce the legal framework for the Community database.

The concept of a European Inspections database is included in the above specified legislation to provide EEA National Competent Authorities and the European Medicines Agency (EMA) with an overview of the status of pharmaceutical manufacturers. The legislation provides for an electronic tool containing complete information on all pharmaceutical manufacturers. This includes information on Manufacturing and Importation Authorisations (MIA) and Good Manufacturing Practice (GMP) Certificates for authorised sites in the EEA and information on GMP certificates for manufacturers in third countries.



Compliance with Good Manufacturing Practice:

A certificate of Good Manufacturing Practice (GMP) is issued to a manufacturer by the national competent authority that carried out an inspection if the outcome of the inspection confirms that the manufacturer complies with the principles of Good Manufacturing Practice, as provided by European Union legislation. If the outcome of the inspection is that the manufacturer does not comply a statement of non-compliance may be entered into EudraGMDP. Certificates and statements of non-compliance may be issued to manufacturers of medicinal products and manufacturers of active substances located inside and outside of the European Union.


Manufacturing and Importation Authorisation:

Manufacture of medicinal products in the EU or importation from a third country is subject to the holding of a Manufacturing and Importation Authorisation. The National Competent Authority of the Member State in which the manufacturer or importer operates issues these authorisations.

Compliance with Good Distribution

Wholesale Distribution Authorisation:

RI Newsletters - EU Non-compliance



The screenshot displays the EudraGMDP website interface. At the top, there is a dark blue header with the 'EudraGMDP' logo. Below the header, a navigation bar contains links for MIA, GMP, API REG, WDA, GDP, and Sites. A 'Help' link and a language dropdown set to 'English' are also present. The date and time 'Tue 3 Dec 2019 10:14:42 BST' are shown in the top right corner. On the left side, a 'GMP Compliance Menu' is visible, featuring a search bar and two links: 'GMP Certificates' and 'Non-Compliance Report'. The 'Non-Compliance Report' link is highlighted with a red rectangular box. The main content area is titled 'Compliance with Good Manufacturing Practice:' and contains text explaining the GMP Certificate format and its publication in the Compilation of Community Procedures. A URL is provided for the compilation. To the right of the text, there is a small thumbnail image of the EudraGMDP interface. At the bottom of the page, a disclaimer states that the database is maintained by the EMA and that the EMA accepts no responsibility for any loss or damage. The footer also includes the text '(EMA © 2014, EudraGMDP 6.4.4.0 build 2019/09/23 08:29)'.

EudraGMDP

MIA | GMP | API REG | WDA | GDP | Sites

Help English Go

Tue 3 Dec 2019 10:14:42 BST

GMP Compliance Menu

Search

[GMP Certificates](#)

[Non-Compliance Report](#)

Compliance with Good Manufacturing Practice:

The Community format for the GMP Certificate was established in accordance with Art. 47 of Directive 2004/27/EC and Art. 51 of Directive 2004/28/EC, amending Directives 2001/83/EC and 2001/82/EC respectively.

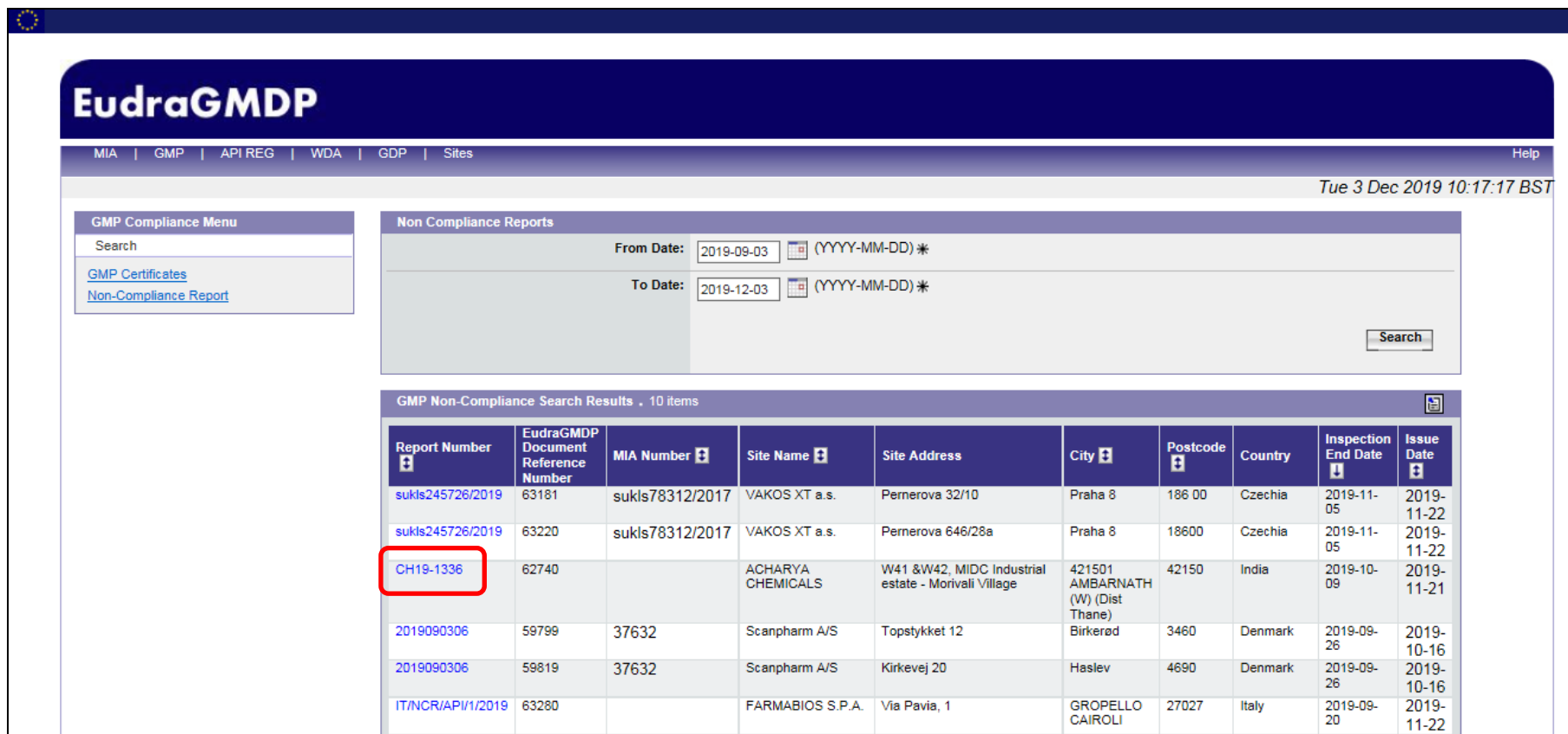
The Community format for the GMP Certificate is published in the Compilation of Community Procedures, which can be found at the following location:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000156.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800296cb&jsenabled=true

GMP Certificates are to be entered into EudraGMDP, as referred to in Art. 111(6) of Directive 2001/83/EC and Art. 80(6) of Directive 2001/82/EC.

The EudraGMDP database is maintained and operated by the EMA. Access to the general public is granted in order to enhance availability of information related to the EMA mandate. The content of the database is provided by the National Competent Authorities (NCA) of the EEA. For this reason, the EMA accepts no responsibility or liability whatsoever (including but not limited to any direct or consequential loss or damage it might occur to you and/or any other third party) arising out of or in connection with the information on this database. Any questions about the content should be addressed to the relevant NCA. Please [click here](#) to get list of NCA's.

(EMA © 2014, EudraGMDP 6.4.4.0 build 2019/09/23 08:29)

RI Newsletters - EU Non-compliance



The screenshot displays the EudraGMDP (European Drug Regulatory Gateway) interface. At the top, there is a navigation bar with links for MIA, GMP, API REG, WDA, GDP, and Sites, along with a Help link. The date and time 'Tue 3 Dec 2019 10:17:17 BST' are shown in the top right corner. On the left, a 'GMP Compliance Menu' includes a search bar and links to 'GMP Certificates' and 'Non-Compliance Report'. The main section is titled 'Non Compliance Reports' and features search filters for 'From Date' (2019-09-03) and 'To Date' (2019-12-03), both in YYYY-MM-DD format, with a 'Search' button. Below this, a table titled 'GMP Non-Compliance Search Results . 10 items' lists various reports. The table has columns for Report Number, EudraGMDP Document Reference Number, MIA Number, Site Name, Site Address, City, Postcode, Country, Inspection End Date, and Issue Date. The row with Report Number 'CH19-1336' is highlighted with a red box.

Report Number	EudraGMDP Document Reference Number	MIA Number	Site Name	Site Address	City	Postcode	Country	Inspection End Date	Issue Date
sukls245726/2019	63181	sukls78312/2017	VAKOS XT a.s.	Pernerova 32/10	Praha 8	186 00	Czechia	2019-11-05	2019-11-22
sukls245726/2019	63220	sukls78312/2017	VAKOS XT a.s.	Pernerova 646/28a	Praha 8	18600	Czechia	2019-11-05	2019-11-22
CH19-1336	62740		ACHARYA CHEMICALS	W41 & W42, MIDC Industrial estate - Morivali Village	421501 AMBARNATH (W) (Dist Thane)	42150	India	2019-10-09	2019-11-21
2019090306	59799	37632	Scanpharm A/S	Topstykke 12	Birkerød	3460	Denmark	2019-09-26	2019-10-16
2019090306	59819	37632	Scanpharm A/S	Kirkevej 20	Haslev	4690	Denmark	2019-09-26	2019-10-16
IT/NCR/API/1/2019	63280		FARMABIOS S.P.A.	Via Pavia, 1	GROPELLO CAIROLI	27027	Italy	2019-09-20	2019-11-22

RI Newsletters - EU Non-compliance

The screenshot displays the EudraGMDP (European Drug Regulatory Gateway) interface. At the top, there is a dark blue header with the EudraGMDP logo and a navigation bar containing links for MIA, GMP, API REG, WDA, GDP, Sites, and Help. The date and time 'Tue 3 Dec 2019 10:19:20 BST' are shown in the top right corner. On the left, a 'GMP Compliance Menu' includes a search bar and links to 'GMP Certificates' and 'Non-Compliance Report'. The main content area features a search results box with buttons for 'Print Preview', 'Print Preview (Short version)', and 'Back To Search', along with a checkbox for 'Exclude Teleconference info'. Below this, the title 'Swissmedic, Swiss Agency for Therapeutic Products' is centered. To the right, the 'Report No : CH19-1336' is displayed. The main heading is 'STATEMENT OF NON-COMPLIANCE WITH GMP', followed by a subtitle: 'Exchange of information between National Competent Authorities (NCAs) of the EEA following the discovery of serious GMP non-compliance at a manufacturer'. Below this, 'Part 1' is indicated. A large box contains the following text: 'Issued under the provisions of the Mutual Recognition Agreement between the European Union and Switzerland', 'The competent authority of Switzerland confirms the following:', 'The manufacturer : ACHARYA CHEMICALS', and 'Site address : W41 &W42, MIDC Industrial estate - Morivali Village, 421501 AMBARNATH (W) (Dist Thane), 42150, India'. At the bottom, a note states: 'From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2019-10-09, it is considered that it does not comply with the Good Manufacturing Practice requirements referred to in The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union'.

EudraGMDP

MIA | GMP | API REG | WDA | GDP | Sites | Help

Tue 3 Dec 2019 10:19:20 BST

GMP Compliance Menu

Search

[GMP Certificates](#)

[Non-Compliance Report](#)

Print Preview Print Preview (Short version) Back To Search

☐ Exclude Teleconference info

Swissmedic, Swiss Agency for Therapeutic Products

Report No : CH19-1336

STATEMENT OF NON-COMPLIANCE WITH GMP

Exchange of information between National Competent Authorities (NCAs) of the EEA following the discovery of serious GMP non-compliance at a manufacturer

Part 1

Issued under the provisions of the Mutual Recognition Agreement between the European Union and Switzerland

The competent authority of Switzerland confirms the following:

The manufacturer : ACHARYA CHEMICALS

Site address : W41 &W42, MIDC Industrial estate - Morivali Village, 421501 AMBARNATH (W) (Dist Thane), 42150, India

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2019-10-09, it is considered that it does not comply with the Good Manufacturing Practice requirements referred to in The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union

RI Newsletters – Import Alert

Google FDA

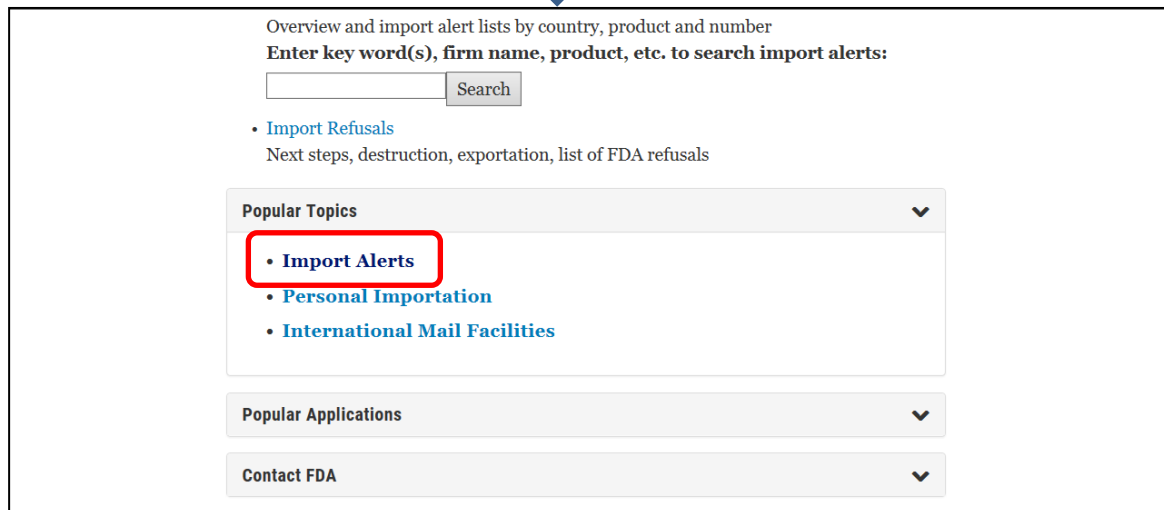


RESOURCES AND PROGRAMS			
Jobs at FDA	Inspections and Compliance	MedWatch: Safety Alerts	Science & Research
FDA Organization	Import Program	Warning Letters	Combination Products
What does FDA regulate?	Criminal Investigations	Disposal of Unused Medicines	Emergency Preparedness

RI Newsletters – Import Alert



The screenshot shows the top of the FDA website. The header includes the FDA logo and the text "U.S. FOOD & DRUG ADMINISTRATION". Below the header is a navigation bar with links: "Home", "For Industry", and "Import Program – Food and Drug Administration (FDA)". The main heading is "Import Program – Food and Drug Administration (FDA)". Below the heading are social media sharing buttons for Facebook, Twitter, LinkedIn, Email, and Print. The main content area has a sidebar on the left with the text "Import Program – Food and Drug Administration (FDA)" and a link to "FDA Import Offices and Ports of Entry". The main text area contains a paragraph: "All products regulated by the Food and Drug Administration must meet the same requirements, whether imported from abroad or produced domestically. The job of protecting consumers includes an ever-increasing need to oversee imports, which have been increasing by 5-10 percent per year for the last decade, and those percentages expect to keep rising." On the right, it says "Content current as of: 09/13/2019".



The screenshot shows the "Import Alerts" page. At the top, it says "Overview and import alert lists by country, product and number". Below this is a search bar with the text "Enter key word(s), firm name, product, etc. to search import alerts:" and a "Search" button. Below the search bar is a list of links: "• Import Refusals" and "Next steps, destruction, exportation, list of FDA refusals". Below this is a "Popular Topics" section with a dropdown arrow. The dropdown menu is open, showing a list of topics: "• Import Alerts" (highlighted with a red box), "• Personal Importation", and "• International Mail Facilities". Below the "Popular Topics" section is a "Popular Applications" section with a dropdown arrow. At the bottom is a "Contact FDA" section with a dropdown arrow.

RI Newsletters – Import Alert



The screenshot shows the FDA's 'Import Alerts' page. The header includes the FDA logo and navigation links. The main heading is 'Import Alerts'. Below it are social media sharing options. The page is divided into a left sidebar with links like 'Import Alerts', 'Removal from Import Alert', and 'Search for Import Alerts'. The main content area has an 'Overview' section with text explaining import alerts and a link to the 'import alert removal page'. A date stamp indicates the content is current as of 05/14/2019.



Where can I find a list of the FDA's import alerts?

- Enter key word(s), firm name, product, etc. to search import alerts:

- [Browse import alerts by country/ area](#)
- [Browse import alerts by industry](#)
- [Browse import alerts by number assigned to each alert](#)
- [Browse import alerts by last published date](#)

[Back to top](#)

RI Newsletters – Import Alert

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En Español

Search FDA

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

Home > Import Program > Import Alerts > Import Alerts by Publish Date


Import Alerts by Publish Date


f SHARE t TWEET in LINKEDIN p PIN IT e EMAIL p PRINT

DWPE = Detain without physical examination

Import Alert Number	Import Alert Type	Publish Date	Import Alert Name
99-39	DWPE	12/02/2019	Detention Without Physical Examination of Imported Food Products That Appear To Be Misbranded
23-14	DWPE	12/02/2019	Detention Without Physical Examination of Food Products due to the Presence of Aflatoxin
99-23	DWPE	12/02/2019	Detention Without Physical Examination of Produce Due to Contamination With Human Pathogens
99-19	DWPE	12/02/2019	"Detention Without Physical Examination Of Food Products Due To The Presence Of Salmonella"

RI Newsletters – Import Alert

 U.S. Department of Health and Human Services

 **U.S. FOOD & DRUG**
ADMINISTRATION

A to Z Index | Follow FDA | En Español

Search FDA

[Home](#) [Food](#) [Drugs](#) [Medical Devices](#) [Radiation-Emitting Products](#) [Vaccines, Blood & Biologics](#) [Animal & Veterinary](#) [Cosmetics](#) [Tobacco Products](#)

Home > Import Program > Import Alerts > Imports Alerts by Number

Import Alert 99-39

[f SHARE](#) [TWEET](#) [in LINKEDIN](#) [PIN IT](#) [EMAIL](#) [PRINT](#)

(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

Import Alert # 99-39
Published Date: 12/02/2019
Type: DWPE

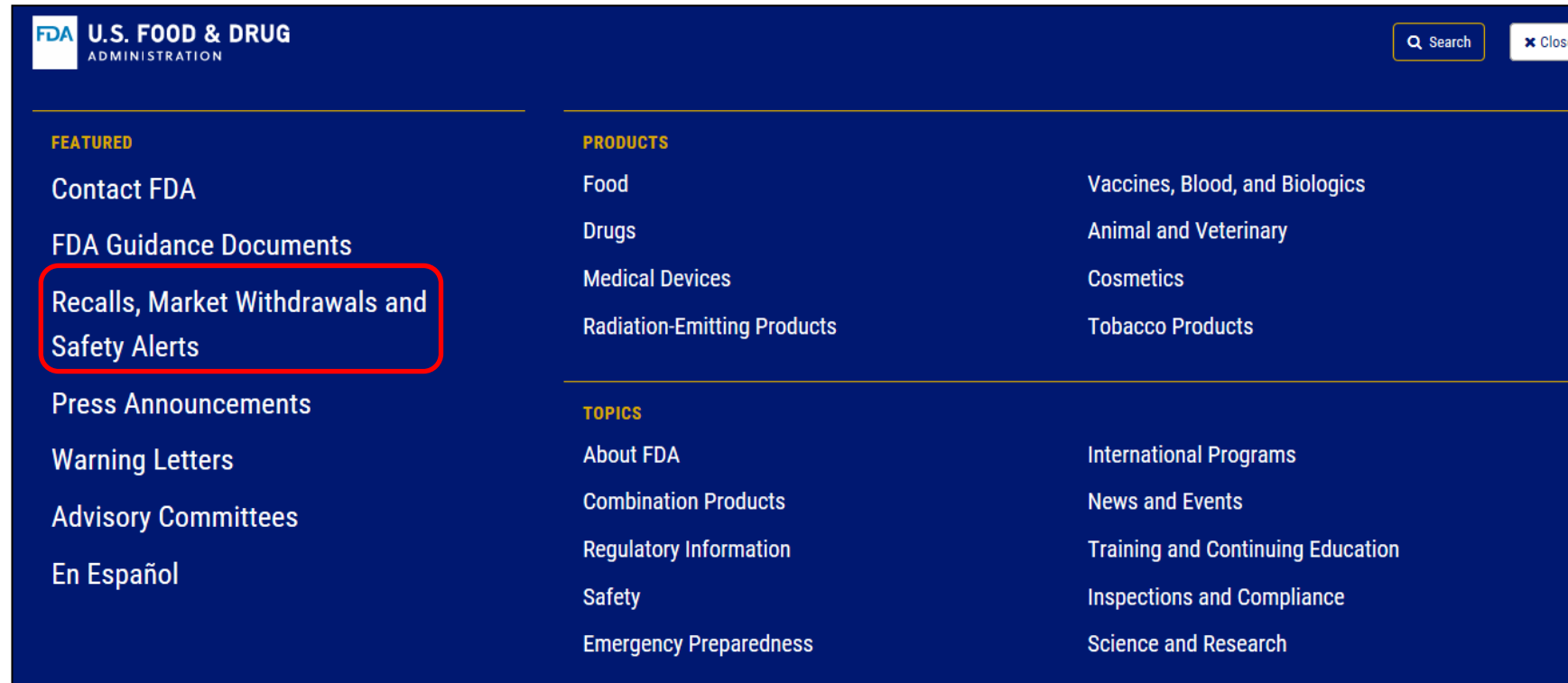
Import Alert Name:
Detention Without Physical Examination of Imported Food Products
That Appear To Be Misbranded

RI Newsletters – Recent Recalls

Google FDA



RI Newsletters – Recent Recalls



RI Newsletters – Recent Recalls

U.S. FOOD & DRUG ADMINISTRATION

Home / Safety / Recalls, Market Withdrawals, & Safety Alerts

Recalls, Market Withdrawals, & Safety Alerts

Share Tweet LinkedIn Email Print

The list below provides information gathered from press releases and other public notices about certain recalls of FDA-regulated products. Not all recalls have press releases or are posted on this page. See [Additional information about recalls](#) for a more complete listing.

Content current as of: 12/03/2019

Recalls, Market Withdrawals, & Safety Alerts

[Recall Resources](#)

The Recalls, Market Withdrawals & Safety Alerts are available on FDA's website for three years before being archived. To search archived content, visit [Search FDA Archive](#) and input the name of the product and/or company name in the Search terms box as well as the year to get the most inclusive search results. To scroll through archived Recalls, Market Withdrawals & Safety Alerts content by year, see the [Recalls and Safety Alerts Linking](#).

Date	Brand Name(s)	Product Description	Product Type	Recall Reason Description	Company Name
11/27/2019	Hodgson Mill	Unbleached Flour	Food & Beverages,	Potential E. Coli Contamination	Hodgson Mill, Inc.
11/27/2019	Wild Harvest	Organic All-Purpose Flour	Food & Beverages,	Potential E.coli Contamination	UNFI
11/27/2019	Okami & Trader Joes	Ready to eat sushi, salads and spring rolls	Food & Beverages,	Potential Listeria monocytogenes Contamination	Fuji Food Products, Inc.
11/26/2019	B. Braun	Blood Administration Kits	Medical Devices,	Potential leakage at joint between blood filter and tubing	B. Braun Medical, Inc.
11/25/2019	Tuna King	Yellowfin Tuna Medallions	Food & Beverages, Fish	Elevated Histamine Levels	Northern Fisheries LTD
11/22/2019	Amneal	Ranitidine Tablets, 150 mg and 300 mg, and Ranitidine Syrup (Ranitidine Oral Solution, USP), 15 mg/mL	Drugs,	Due to potential N-Nitrosodimethylamine (NDMA) amounts above levels established by the FDA	Amneal Pharmaceuticals, LLC
11/22/2019	Whole Foods Market	Raspberry Cheesecake Italian Gelato	Food & Beverages,	Undeclared egg	Whole Foods Market
11/21/2019	Tainy Vostoka	Dried Fruit Mix	Food &	Undeclared sulfites	Euroline Foods

RI Newsletters – Recent Recalls

 **U.S. FOOD & DRUG**
ADMINISTRATION

Q Search

Menu

[← Home](#) / [Safety](#) / [Recalls, Market Withdrawals, & Safety Alerts](#)
/ [Amneal Pharmaceuticals, LLC. Issues Voluntary Nationwide Recall of Ranitidine Tablets, USP, 150mg and 300mg, and Ranitidine Syrup \(Ranitidine Oral Solution, USP\), 15 mg/mL, Due to Possible Presence of N-nitrosodimethylamine \(NDMA\) Impurity](#)

COMPANY ANNOUNCEMENT

**Amneal Pharmaceuticals, LLC. Issues
Voluntary Nationwide Recall of Ranitidine
Tablets, USP, 150mg and 300mg, and
Ranitidine Syrup (Ranitidine Oral Solution,
USP), 15 mg/mL, Due to Possible Presence
of N-nitrosodimethylamine (NDMA)**

RI Newsletters – Regulatory Information

Google FDA



RI Newsletters – Regulatory Information



RI Newsletters – Regulatory Information

← Home

Regulatory Information

Search for FDA guidance documents, learn about the laws enforced by FDA, and more.

A photograph showing three men in a boat. The man on the left is wearing a blue cap with 'FDA' on it and a pink shirt, holding a clipboard. The man in the middle is wearing sunglasses and a light blue shirt, pointing at the clipboard. The man on the right is wearing a light blue shirt and is looking down at a large orange crate filled with oysters. The background shows a body of water and some buildings.

Search for FDA Guidance Documents

Search for official FDA guidance documents and other regulatory guidance for all topics.

[Learn More](#)

RI Newsletters – Regulatory Information

 **U.S. FOOD & DRUG**
ADMINISTRATION

Search

Menu

← Home / Regulatory Information / Search for FDA Guidance Documents

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Search for FDA Guidance Documents

Search General and Cross-Cutting Topics Guidance Documents


Advisory Committee Guidance Documents




The table below lists all official FDA Guidance Documents and other regulatory guidance. You can search for documents using key words, and you can narrow or filter your results by product, date issued, FDA organizational unit, type of document, subject, draft or final status, and comment period.

This feature is provided to give a convenient way to search for all FDA guidance documents from a single location.

If you cannot find the document you're looking for here, you can browse separate

Content current as of:
12/03/2019



Summary	Document	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment
 Adaptive Design Clinical Trials for Drugs and Biologics Guidance for Industry	PDF (306.43 KB)	11/29/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	Yes
 Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products	PDF (165.86 KB)	11/27/2019	Center for Drug Evaluation and Research	Biosimilarity	Draft	Yes
 Compliance Policy for Limited Modifications to Certain Marketed Tobacco Products: Guidance for Industry	PDF (283.2 KB)	11/26/2019	Center for Tobacco Products		Final	No
 Certificates of Confidentiality: Draft Guidance for	PDF (293.02 KB)	11/22/2019	Office of Policy, Center for Biologics Evaluation and Research, Center	Research, Good Clinical Practices (GCP)	Draft	Yes

RI Newsletters – Regulatory Information

The screenshot displays the FDA's website header with the logo and navigation links. Below the header, a breadcrumb trail leads to the specific guidance document page. The main heading is 'Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products', dated November 2019. A prominent blue button offers to download the draft guidance document, which is also labeled as a 'Draft' in a grey box. Disclaimers at the bottom state that the document is not for implementation and is for comment purposes only.

FDA U.S. FOOD & DRUG ADMINISTRATION

Search Menu

← Home / Regulatory Information / Search for FDA Guidance Documents / Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products

GUIDANCE DOCUMENT

Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products

NOVEMBER 2019

[Download the Draft Guidance Document](#)

Draft

Not for implementation. Contains non-binding recommendations.

This guidance is being distributed for comment purposes only.

RI Sharing - GMP Newsletter

Google ECA Academy



RI Sharing - GMP Newsletter

Latest GMP News

Dec
03

FDA continues to warn companies for illegally selling
CBD products ...

Dec
03

ICH Q12 adopted ...

Dec
03

FDA's Current Thinking on Process Validation ...

Dec
03

Final Guideline on GCP for ATMPs published ...

Nov
28

Clinical Trials Regulation Questions & Answers Version
2.2 ...

Nov
28

FDA Warning Letter for receiving potentially unsafe
drugs ...

Upcoming Conferences and Courses



Berlin, Germany
4/5 December 2019

**Continuous Manufacturing - Development,
Production and Quality**



Barcelona, Spain
4-5 December 2019


**Lab Data Integrity - Meeting FDA & EU
Concerns - Part 1**



Barcelona, Spain
4-6 December 2019

**Lab Data Integrity - Meeting FDA & EU
Concerns - Part 1 & 2**

RI Sharing - GMP Newsletter



GMP SEARCH ENGINE

Search in
News & Press

Keyword

Search

[GMP News](#)[Guidelines](#)[Training](#)[Certification](#)[Publications](#)[Links](#)[Interest & Working Groups](#)[About ECA](#)[Members Area](#)


ECA Academy > GMP News > News Details

03.12.2019

ICH Q12 adopted

The International Council for Harmonization (ICH) met in Singapore from 16 – 20 November 2019. The key milestone reached was the adoption of the new ICH Q12 Guideline (Step 4 of the ICH process) on the **Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management**. The new [ICH Q12 Guideline including two Annexes](#) is complementary to ICH Quality Guidelines Q8 to Q11. According to ICH, it aims to "promote innovation and continual improvement in the pharmaceutical sector, and strengthen quality assurance and reliable supply of product, including proactive planning of global supply chain adjustments".

In order to ensure a standardized approach, the guidance defines the categorization of Post-Approval CMC changes. Established Conditions



Recommendation

21/22 April 2020
Heidelberg, Germany

[Handling Changes and Variations](#)

71

RI Sharing Meeting



RI Sharing Meeting

- Monthly RI Newsletter overview and discussion
- Sharing of New/Revised Guidance and Regulations
- Gap assessment

RI Sharing Meeting

Non-compliance discussion:

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 466 Fernandez Juncos Avenue San Juan, PR 00901-3223 (787) 729-8500 Fax: (787) 729-6809 ORAPHARM2_RESPONSES@fda.hhs.gov	DATE(S) OF INSPECTION 2/7/2022-2/17/2022* FEI NUMBER 2623619
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Jose Campos, General Manager	
FIRM NAME Pfizer Pharmaceuticals LLC	STREET ADDRESS Road 689, Km 1.9
CITY, STATE, ZIP CODE, COUNTRY Vega Baja, PR 00693	TYPE ESTABLISHMENT INSPECTED Drug Manufacturer

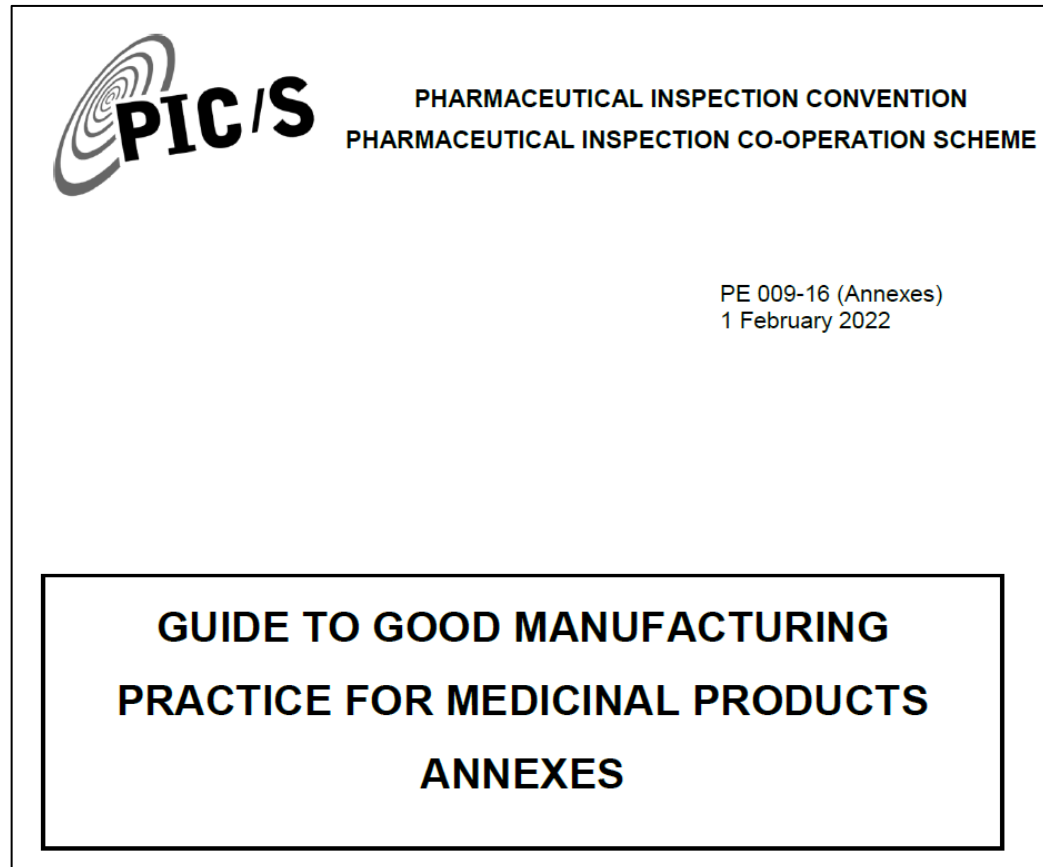
Observation review tips:

1. What is the rational of the citation?
2. What about our own practices?
3. What is trending now?

RI Sharing Meeting

Guidance Revision:

PIC/S Revised Annex 1 in Contamination Control Strategy (CCS),
Cleanroom, and Environmental Monitoring



RI Sharing Meeting

New guidance

Testing of Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution, and other High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol Guidance for Industry

Additional copies are available from:
Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
<https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
May 2023
Compliance

New Regulation Gap Analysis

Quality System:			RI Number: _____	
Title:			Regulatory Guideline #: _____ <input type="checkbox"/> N/A	

Regulation Section #	Regulation Requirement	Global or Site SOP # & Section #	Explanation for Gap/Justification for NO Gap	Performer Initial and Date

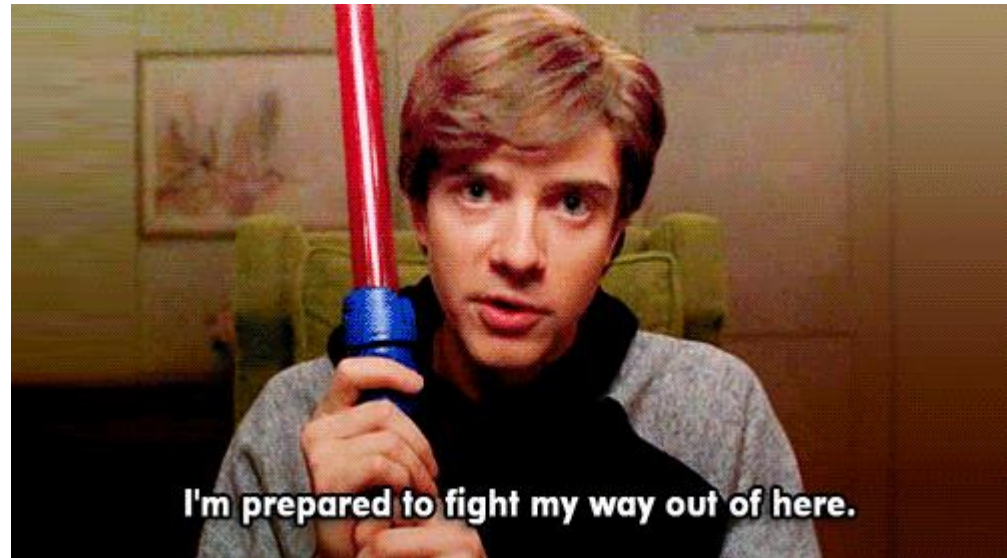
SOP revision required? Yes ___ No ___
Proposed revision date(s) _____

Performed By/Date: _____ Approved By/Date: _____ (Dpt. Management)
Verified By/Date: _____

When Gaps are Identified



VS



RI Gap Analysis

Linking the identified gaps in following quality systems:

- CAPA
- QIP
- Quality Council
- QRM

Good Luck!

Thank you for your attention

Questions?