Ways to Stay Current on Compliance Regulations

因應法規變更藥廠之策略與措施

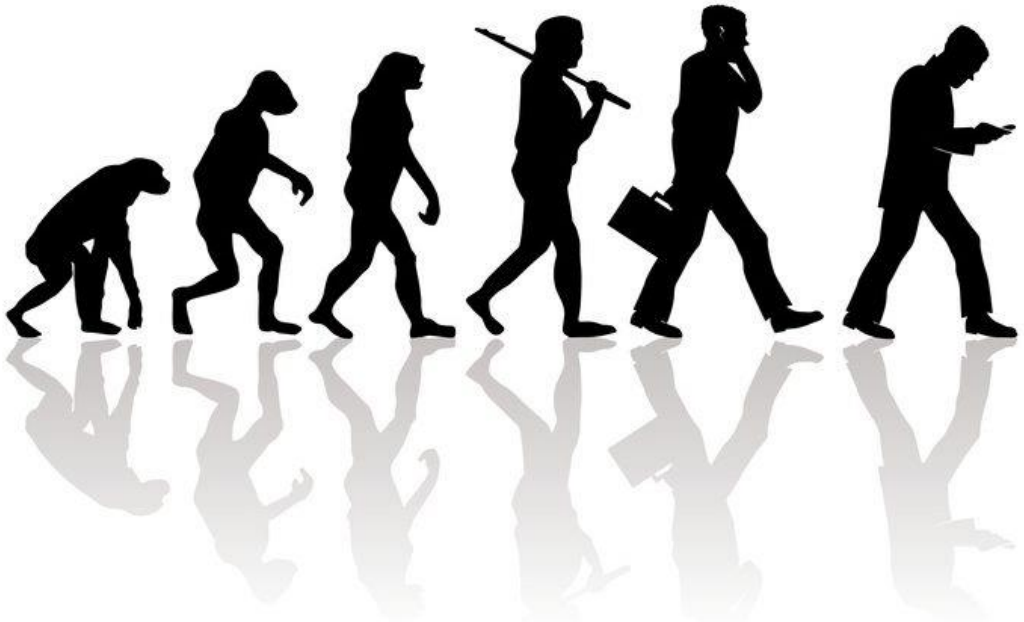
Date: Oct 2023

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

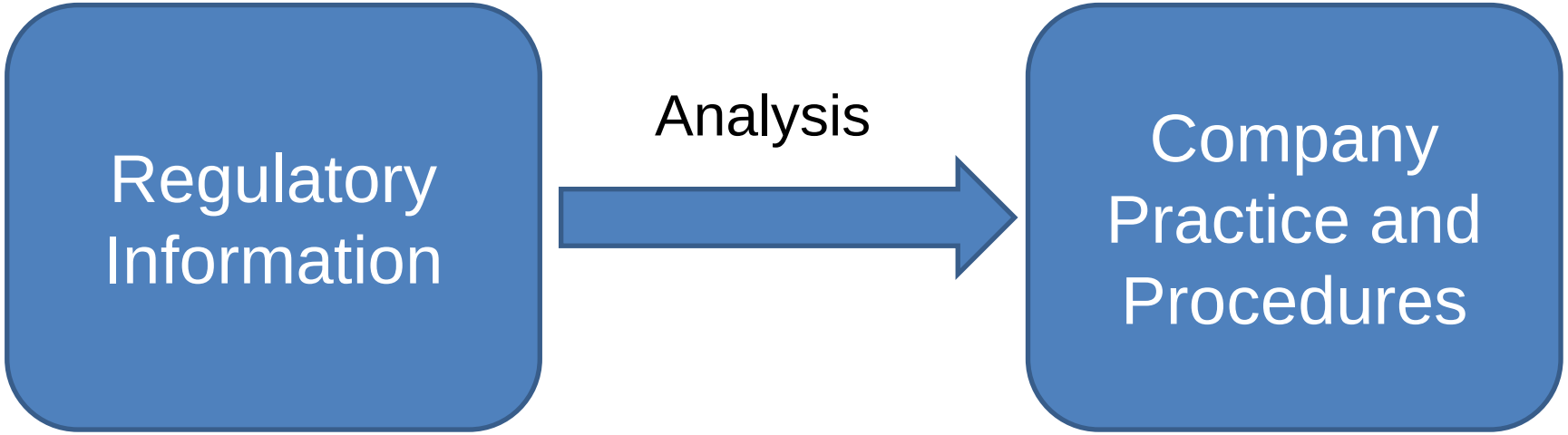
- Information is the raw data used to create intelligence
- Intelligence is active and related to analysis
- The data analysis and integration into company practice and procedures produces regulatory intelligence

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

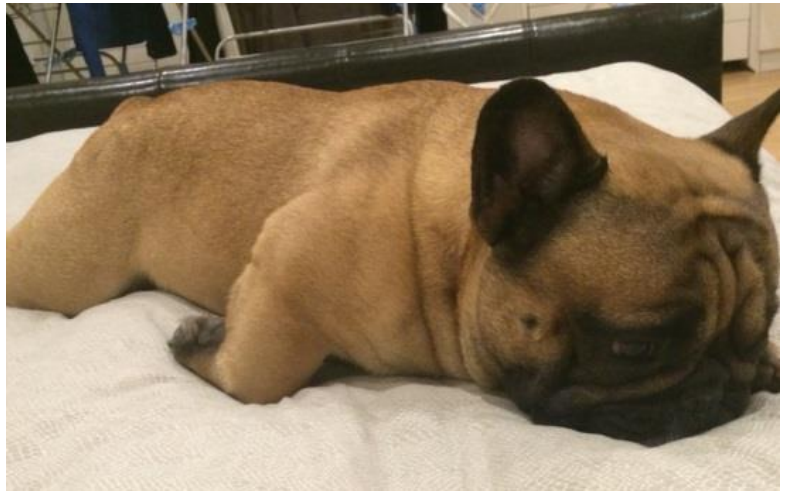
Benefits of Regulatory Intelligence

- 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:

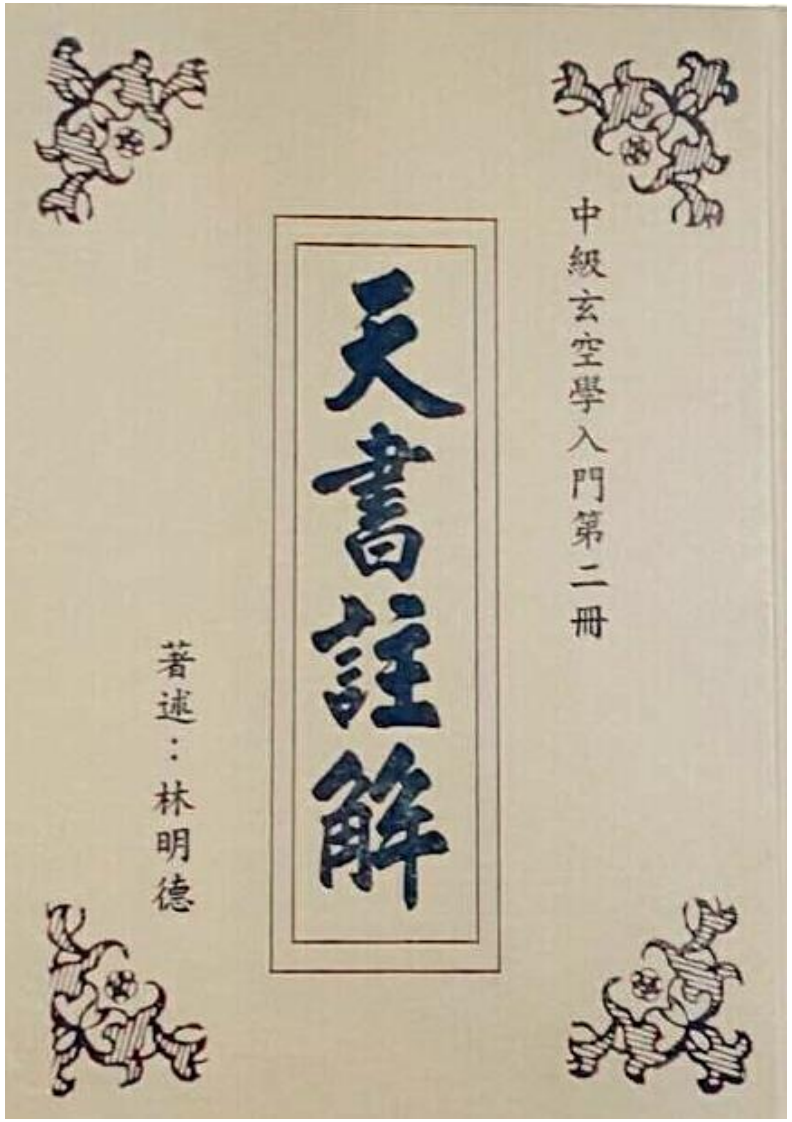
- regulatory research
- monitoring and surveillance of the regulatory landscape
- drug approval summaries
- news letters
- hot topics (analysis of regulatory trends)
- training
- knowledge management

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……..

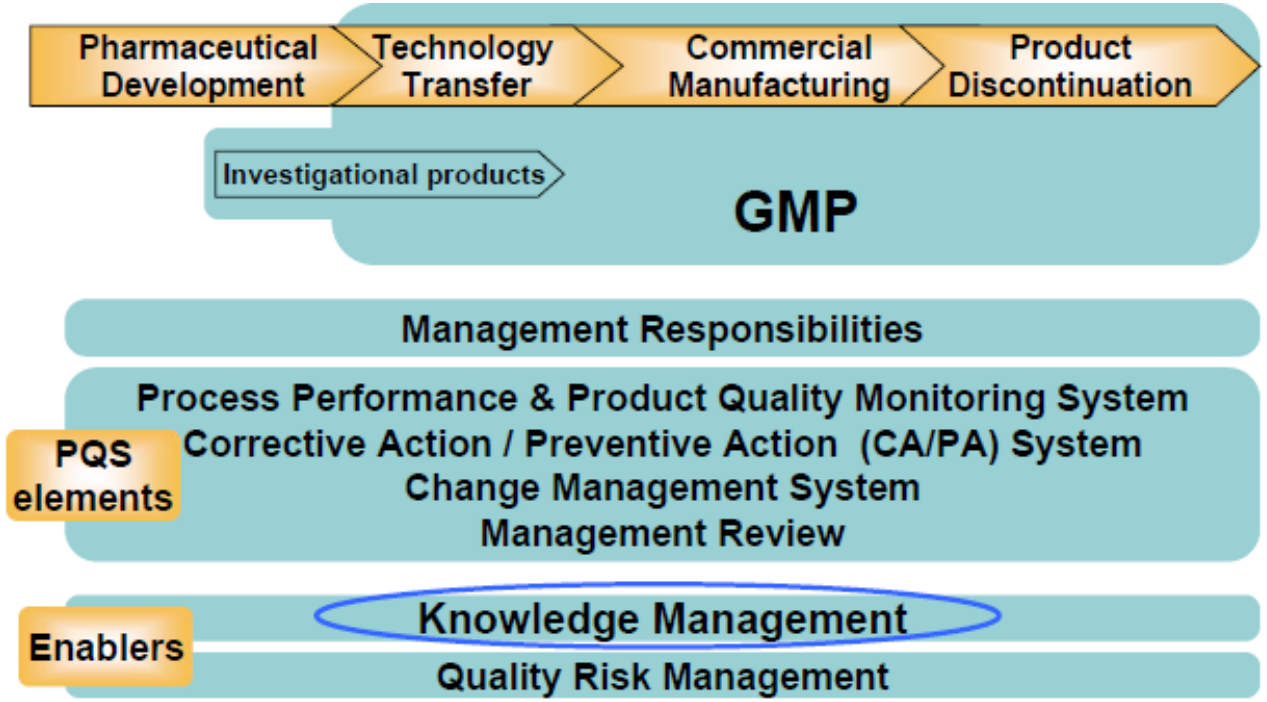
NETWORKING

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**.* 4

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?

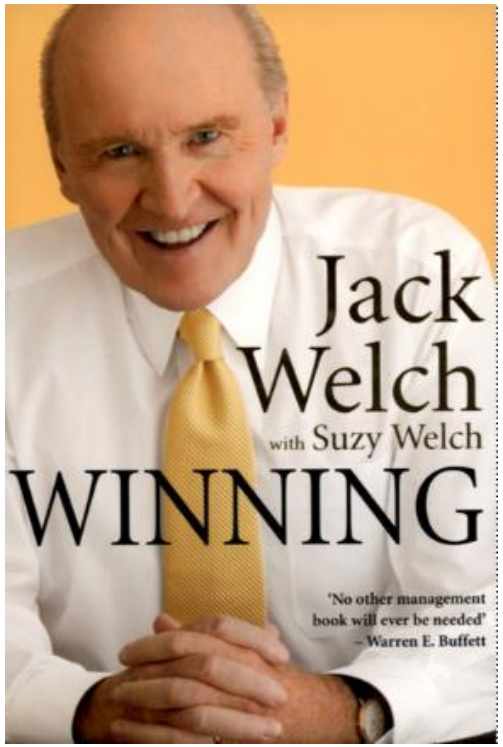
  - Keep it hard copy in the filing cabinet
  - Scan it and put it on an electronic shared drive
  - Scan it and include it in an RI database

- 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 andTechnological 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

CPMDA 中華民國製藥發展協會
Taiwan Pharmaceutical Manufacture and Development Association

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。

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CPMDA 中華民國製藥發展協會
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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

CPMDA 中華民國製藥發展協會
Taiwan Pharmaceutical Manufacture and Development Association

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（A21020000I108110660100-1.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

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

2023 年藥廠 GMP 主題論壇

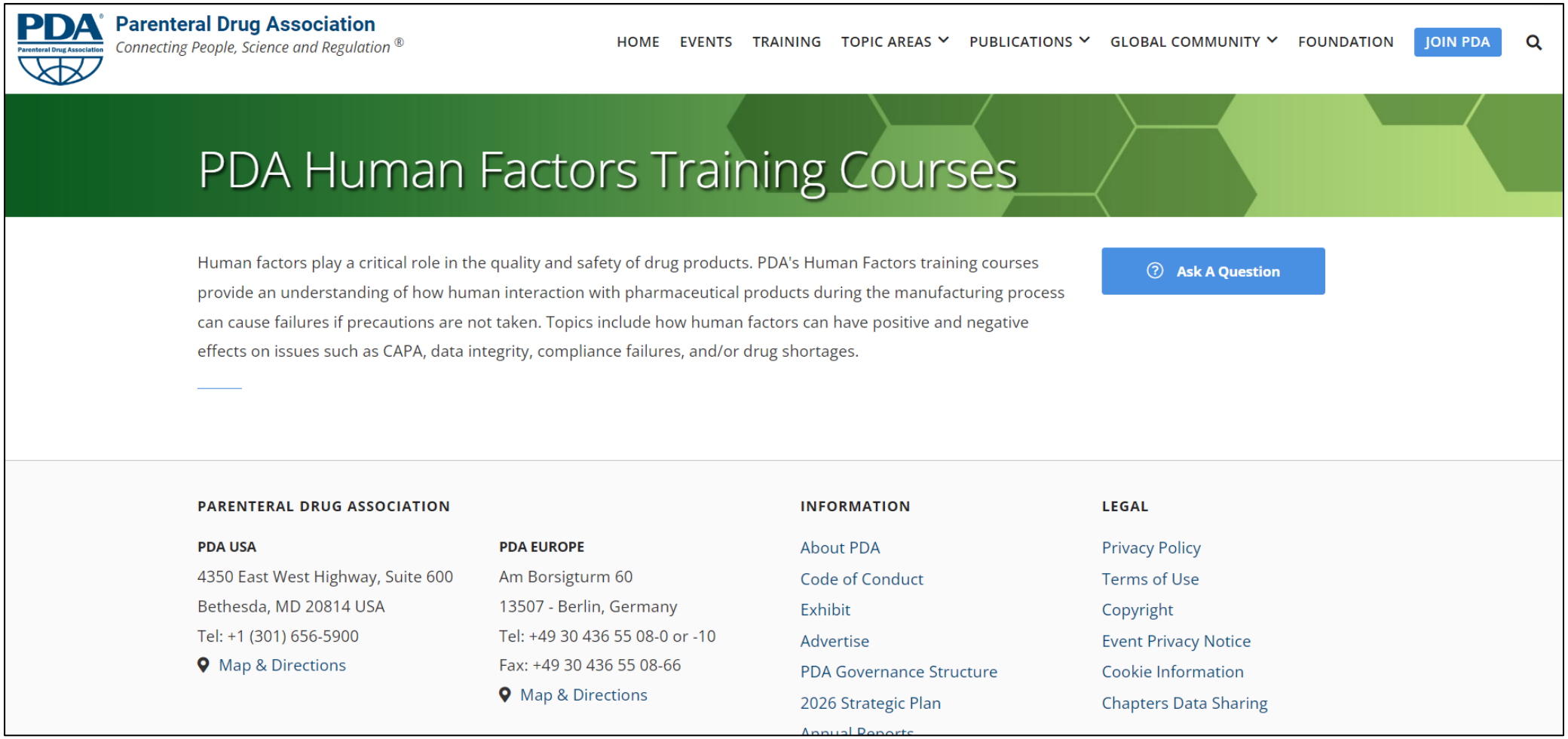
『品質被授權人專業論壇』課程簡章

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



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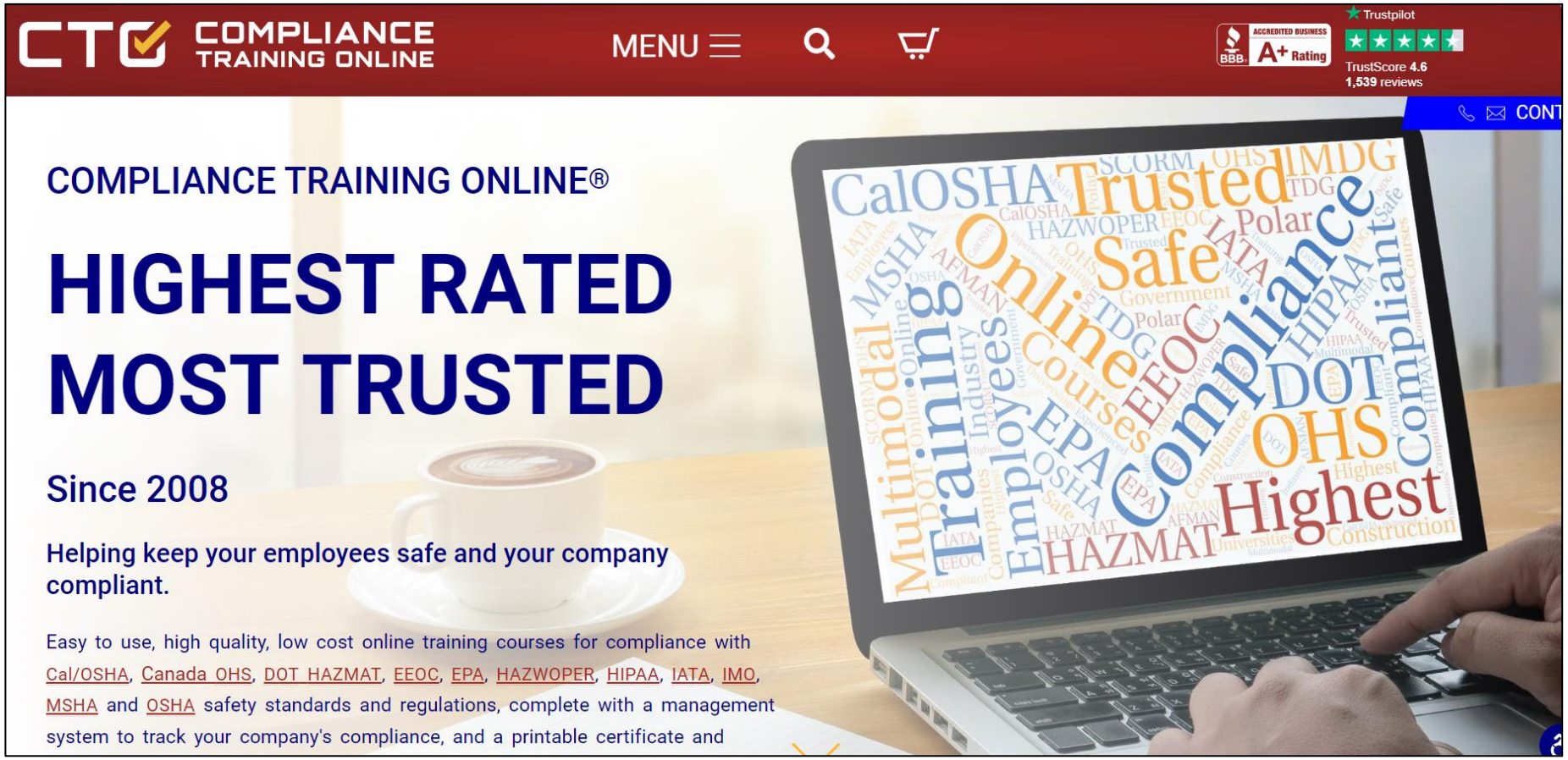


4. Subscribe to newsletters

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/

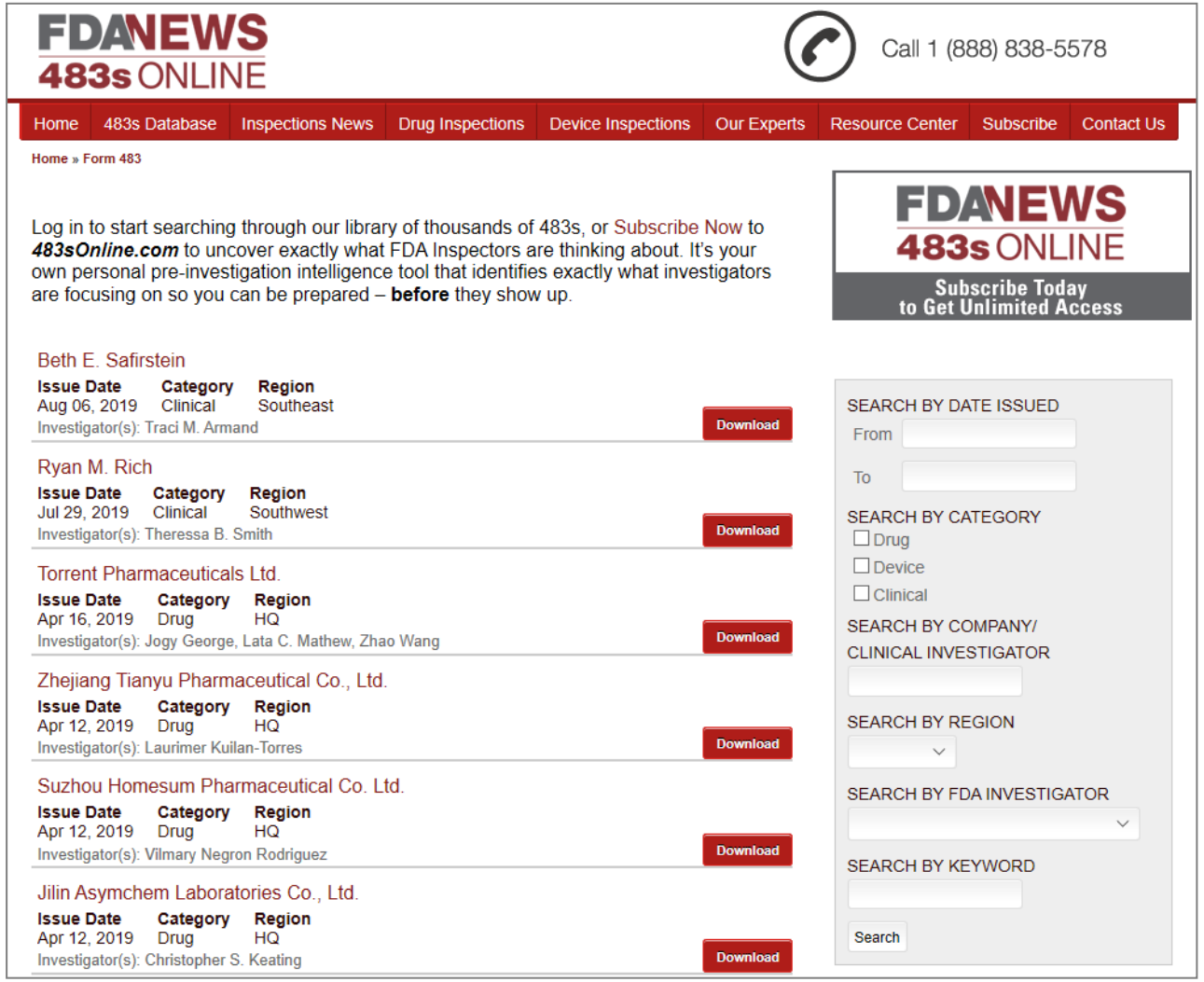
RI Newsletters – Recent 483

FDANEWS
483s ONLINE

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 **keyword**s.
- A weekly email update to alert you to any new 483s we've added, so you're sure never to miss a thing.

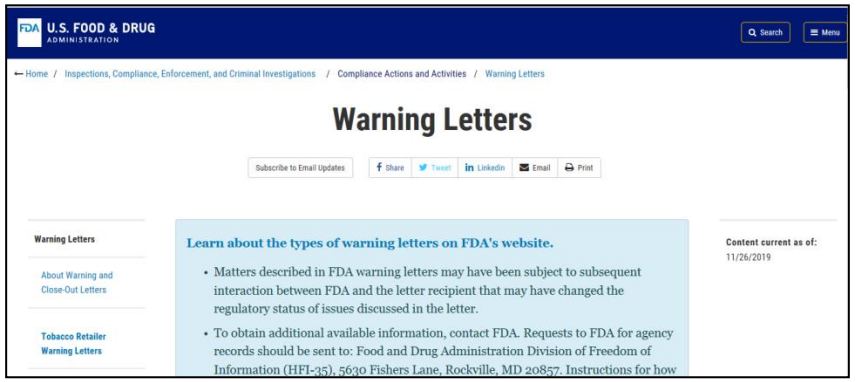
RI Newsletters – Recent 483

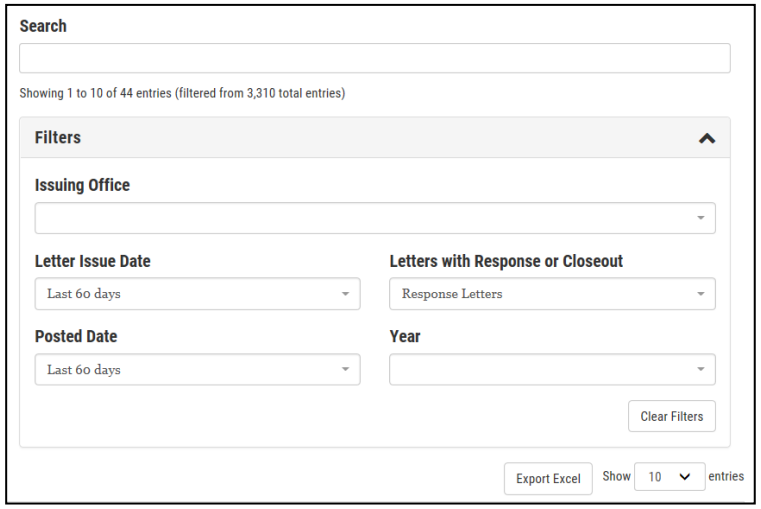


RI Newsletters - Warning letters

Google FDA

RI Newsletters - Warning letters





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		

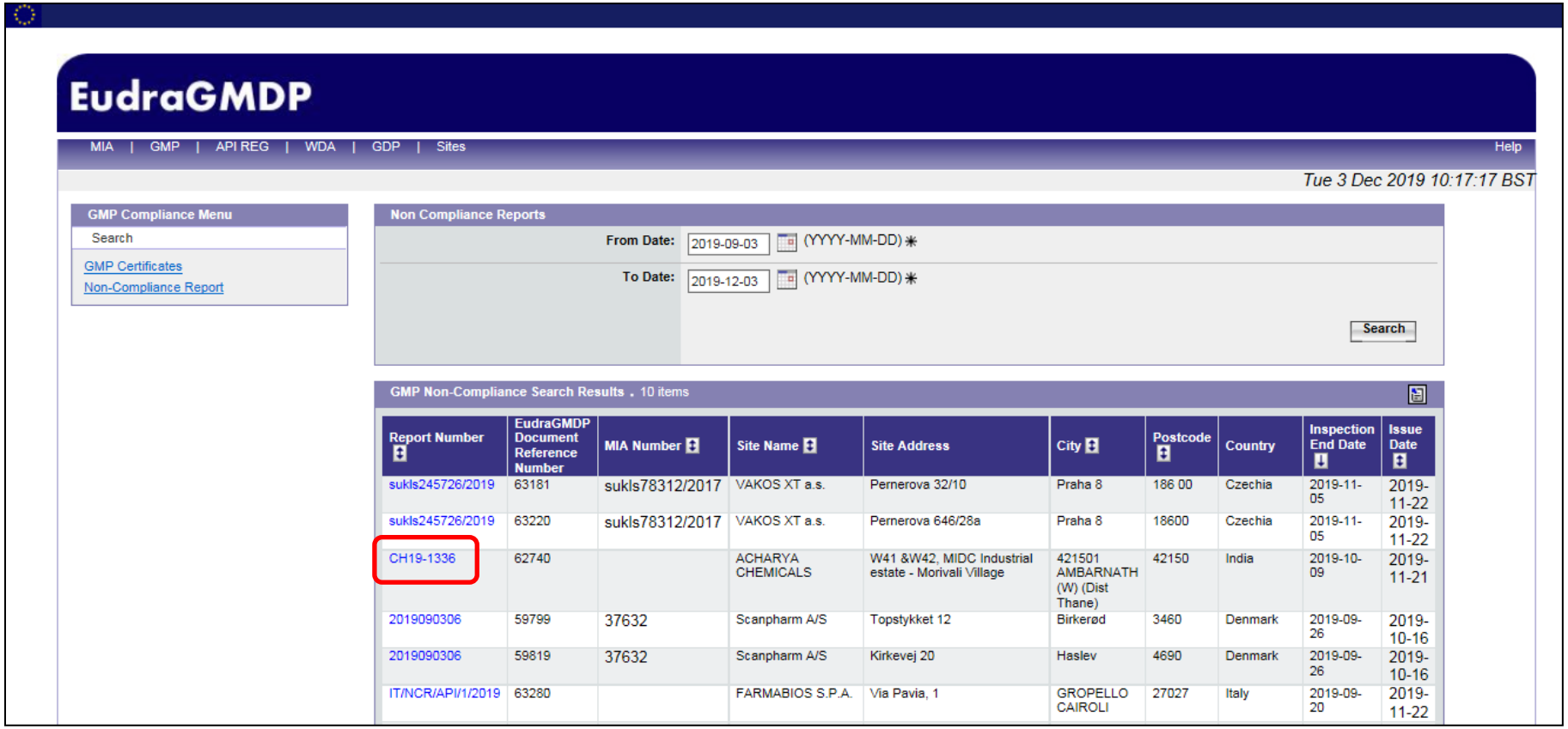
RI Newsletters - Warning letters

RI Newsletters - EU Non-compliance

Google Eudra GMDP website

RI Newsletters - EU Non-compliance

RI Newsletters - EU Non-compliance



EudraGMDP

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

Tue 3 Dec 2019 10:17:17 BST

GMP Compliance Menu

Search

GMP Certificates

Non-Compliance Report

Non Compliance Reports

From Date: 2019-09-03 (YYYY-MM-DD) *

To Date: 2019-12-03 (YYYY-MM-DD) *

Search

GMP Non-Compliance Search Results . 10 items

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	Topstykket 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

EudraGMDP

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

Tue 3 Dec 2019 10:19:20 BST

GMP Compliance Menu

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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***

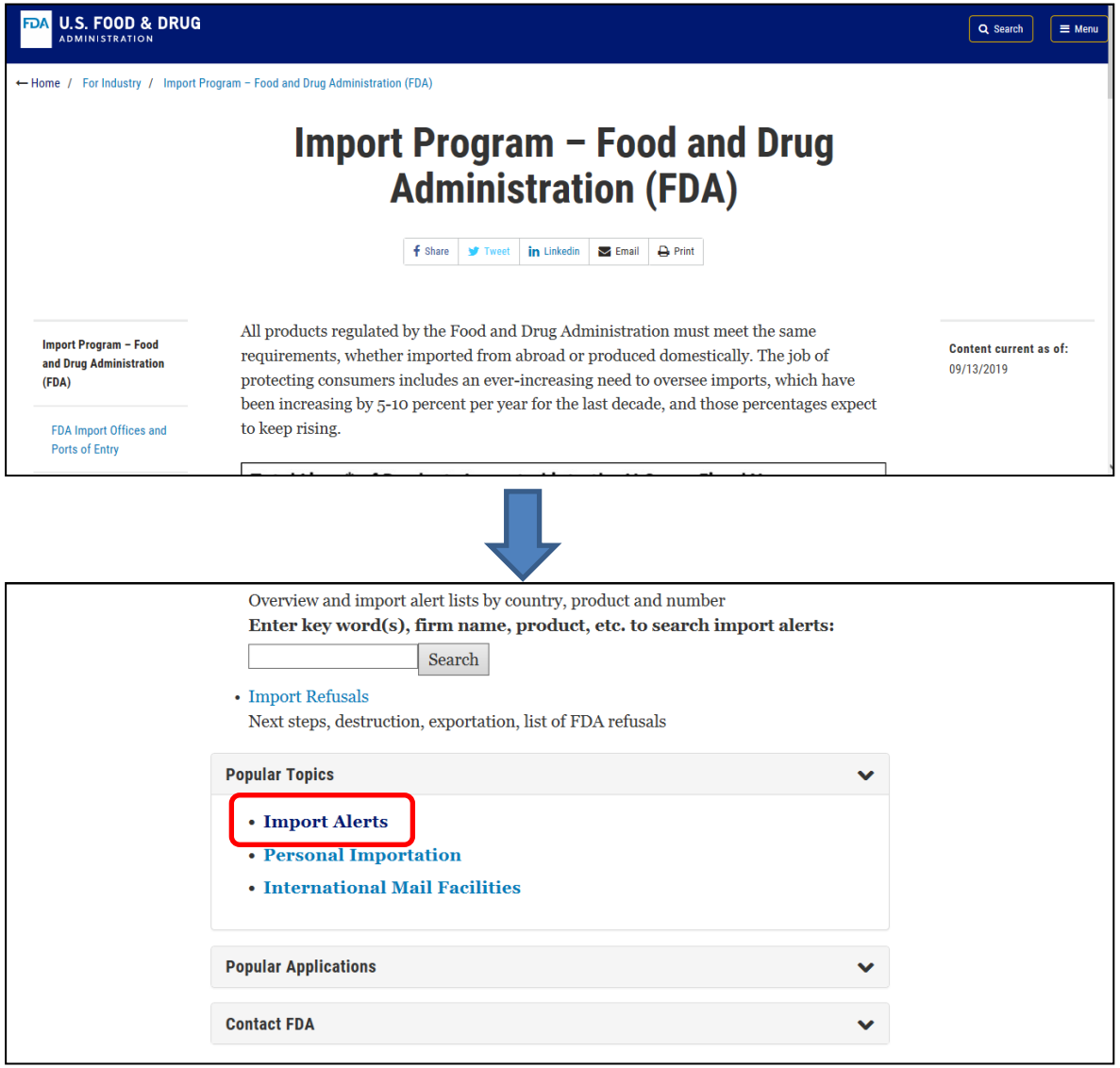
Site address : ***W41 &W42, MIDC Industrial estate - Morivali Village, 421501 AMBARNATH (W) (Dist Thane), 42150, India***

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

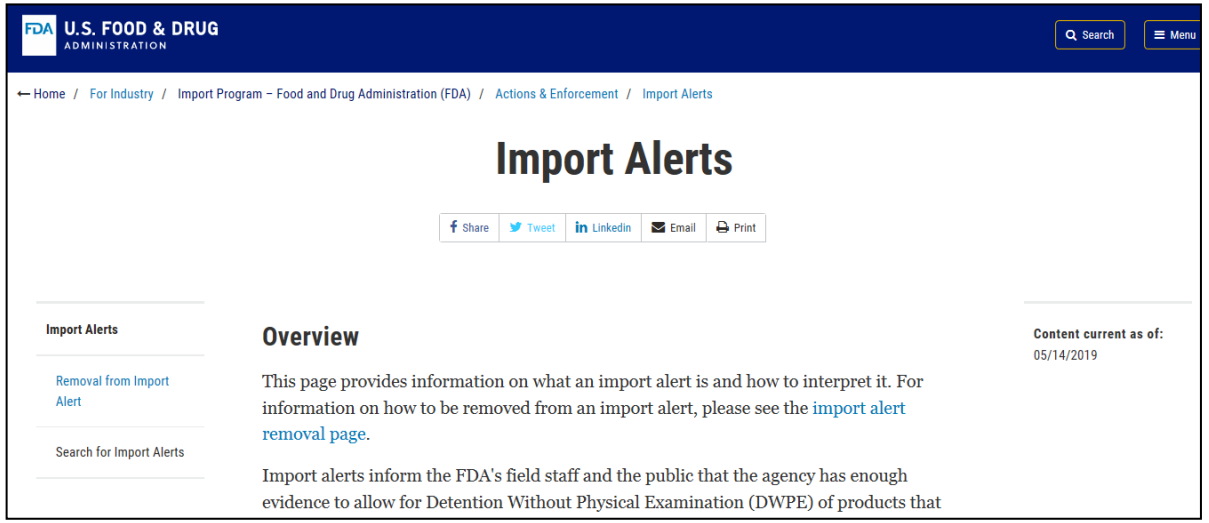
RI Newsletters – Import Alert

Google FDA

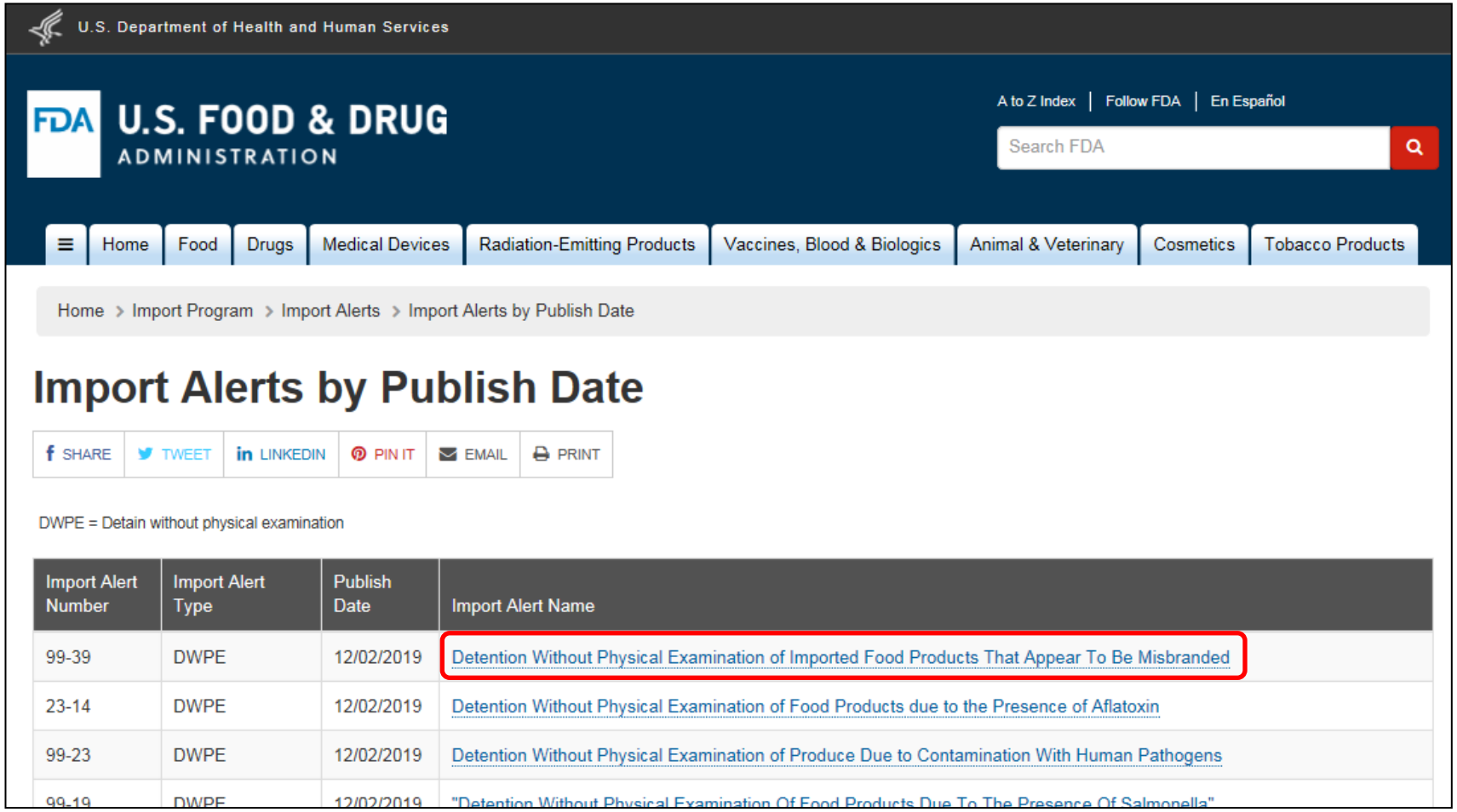
RI Newsletters – Import Alert



RI Newsletters – Import Alert



RI Newsletters – Import Alert



U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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

Import Alerts by Publish Date

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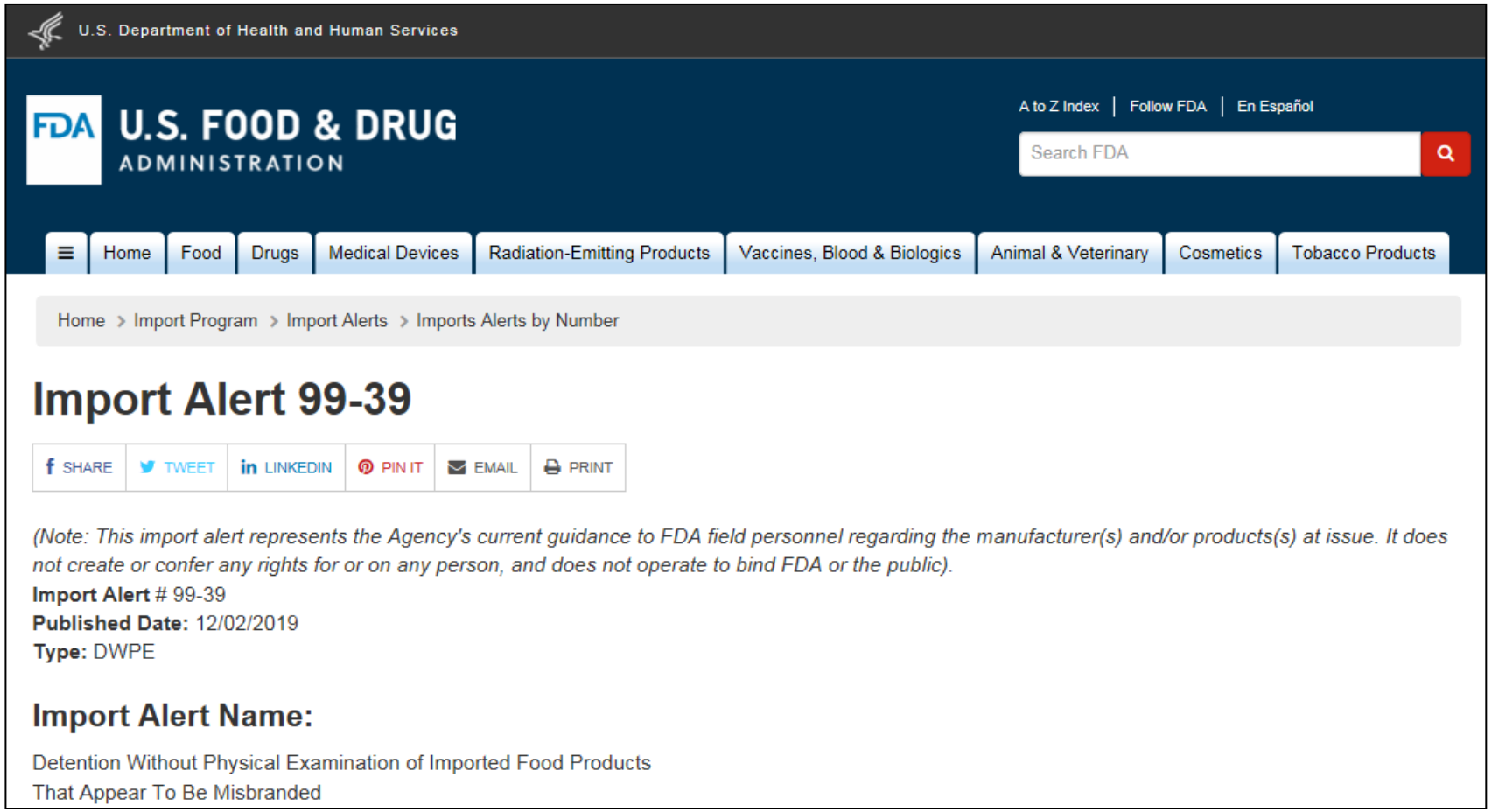
DWPE = Detain without physical examination

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

FDA U.S. FOOD & DRUG ADMINISTRATION

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

Import Alert 99-39

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(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

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

FDA U.S. FOOD & DRUG ADMINISTRATION

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← 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

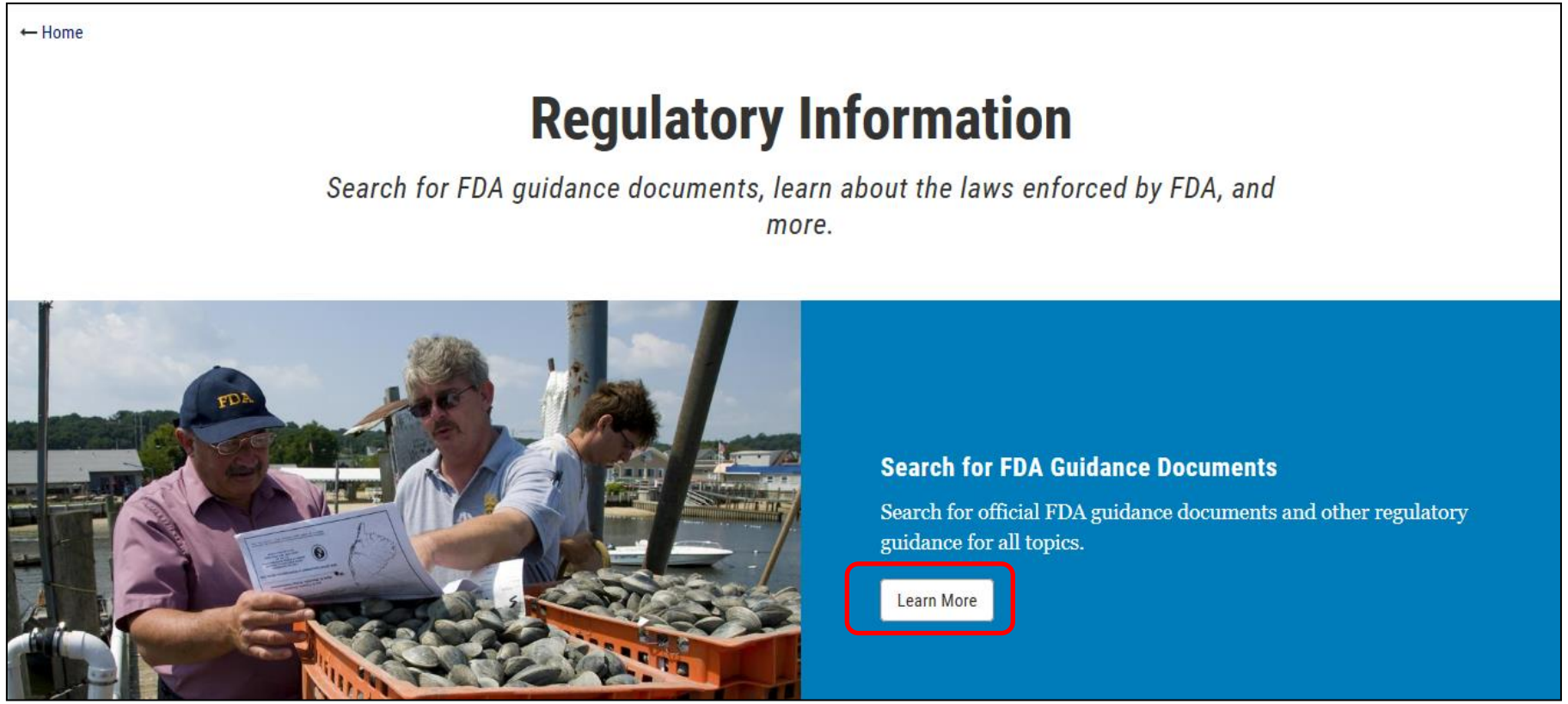
Amneal Pharmaceuticals, LLC. Issues Voluntary Nationwide Recall of Ranitidine Tablets, USP, 150mg and 300mg, and Ranitidine Syrup (Ranitidine Oral Solution, USP), 15 mg/mL, Due to Possible Presence of N-nitrosodimethylamine (NDMA)

RI Newsletters – Regulatory Information

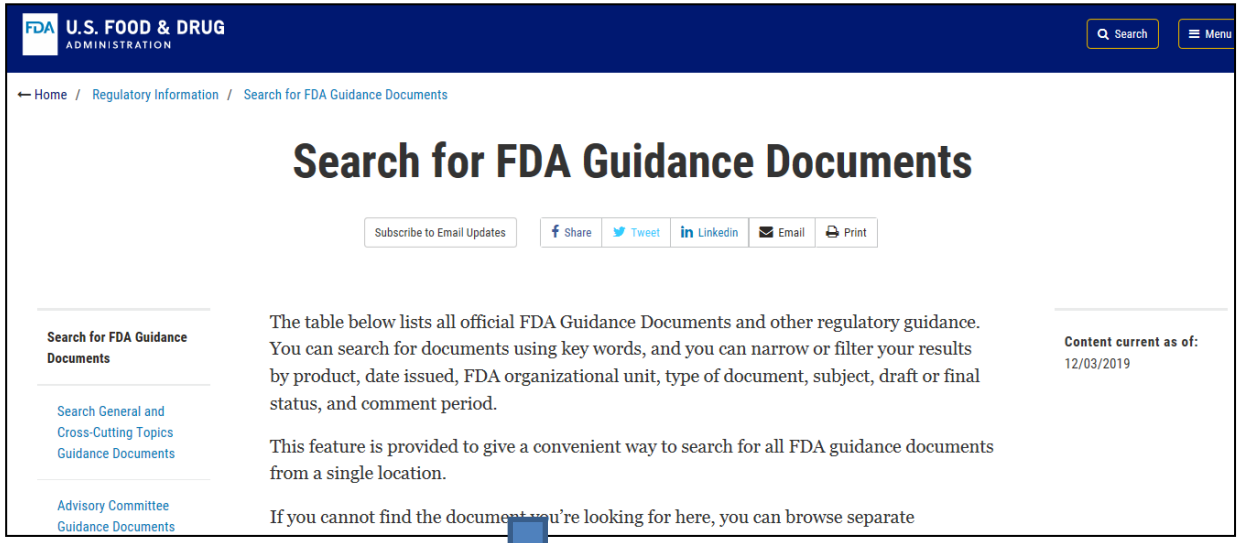
Google FDA

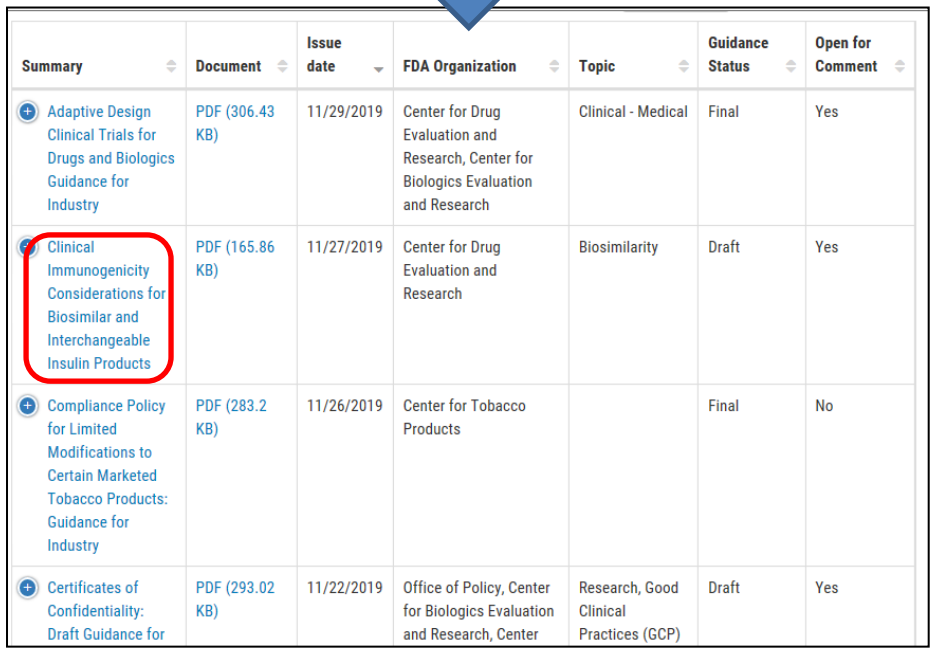
RI Newsletters – Regulatory Information

RI Newsletters – Regulatory Information



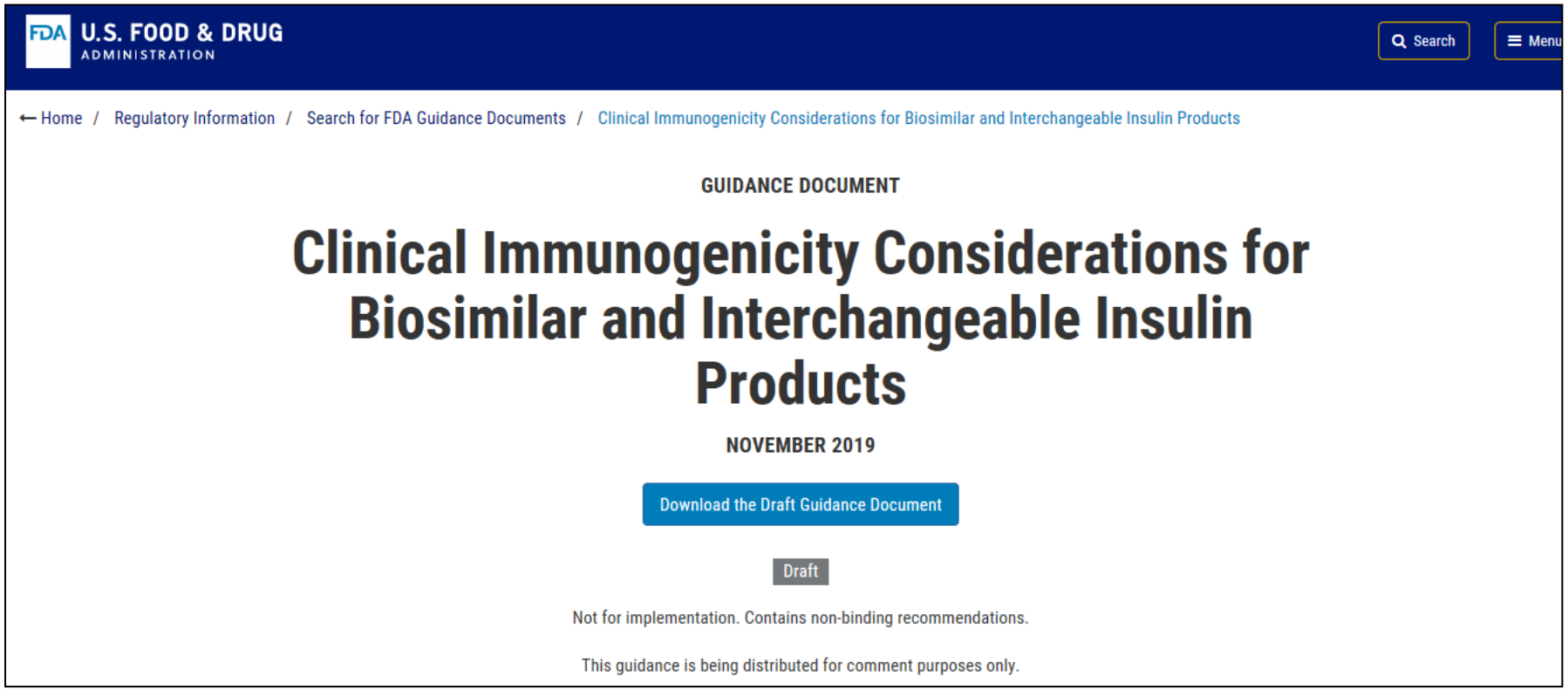
RI Newsletters – Regulatory Information





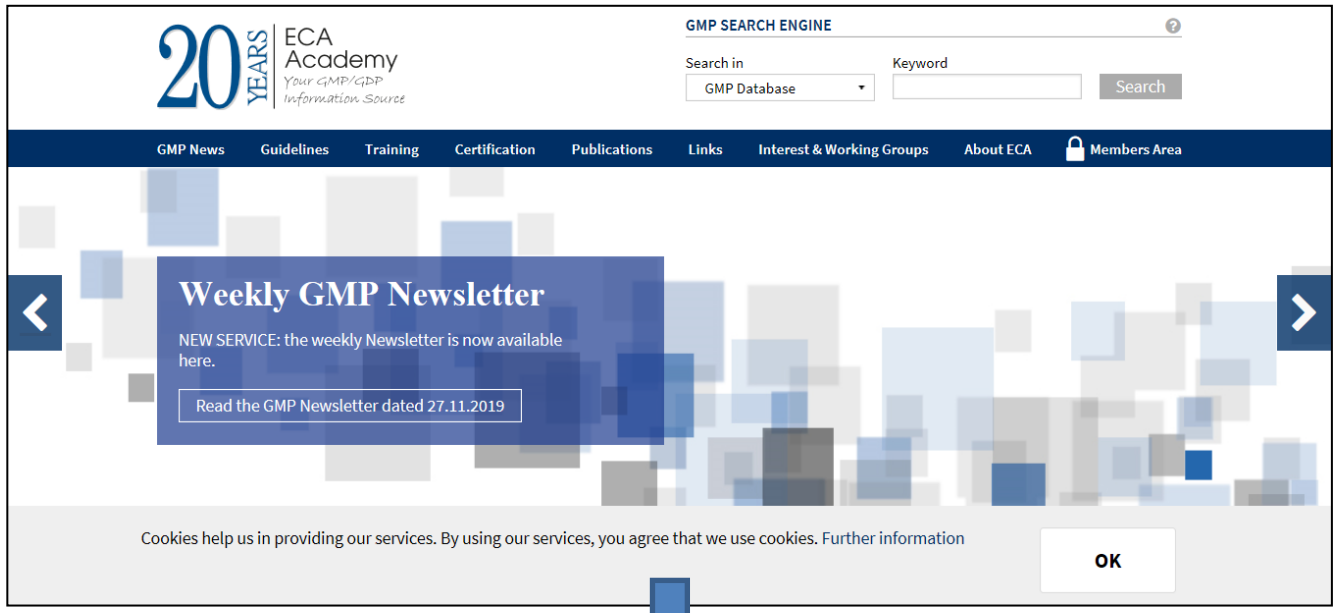
Summary	Document	Issue date	FDA Organization	Topic	Guidance Status	Open for Comment
Adaptive Design Clinical Trials for Drugs and Biologics Guidance for Industry	PDF (306.43 KB)	11/29/2019	Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research	Clinical - Medical	Final	Yes
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



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

20 YEARS ECA Academy
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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

Recommendation

21/22 April 2020
Heidelberg, Germany

Handling Changes and Variations

RI Sharing Meeting

Pic source: https://sloanreview.mit.edu/article/the-surprising-science-behind-successful-remote-meetings/

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

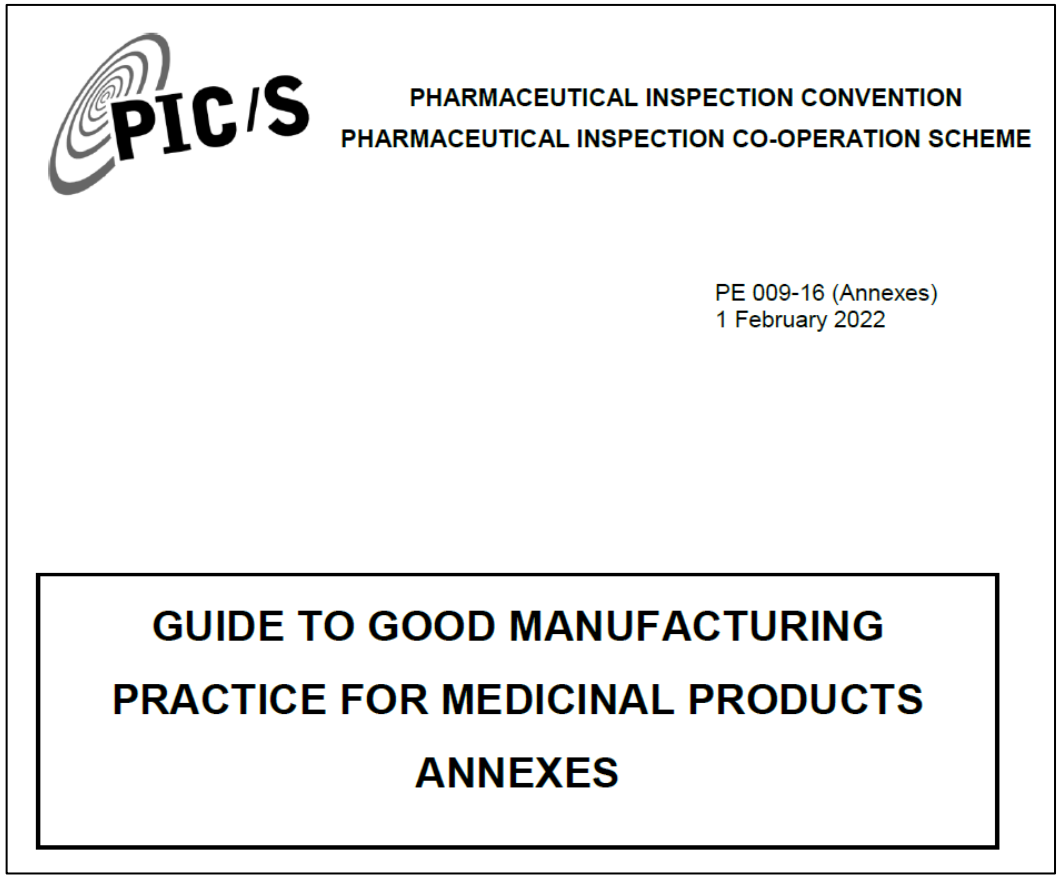
Observation review tips:

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


PIC/S

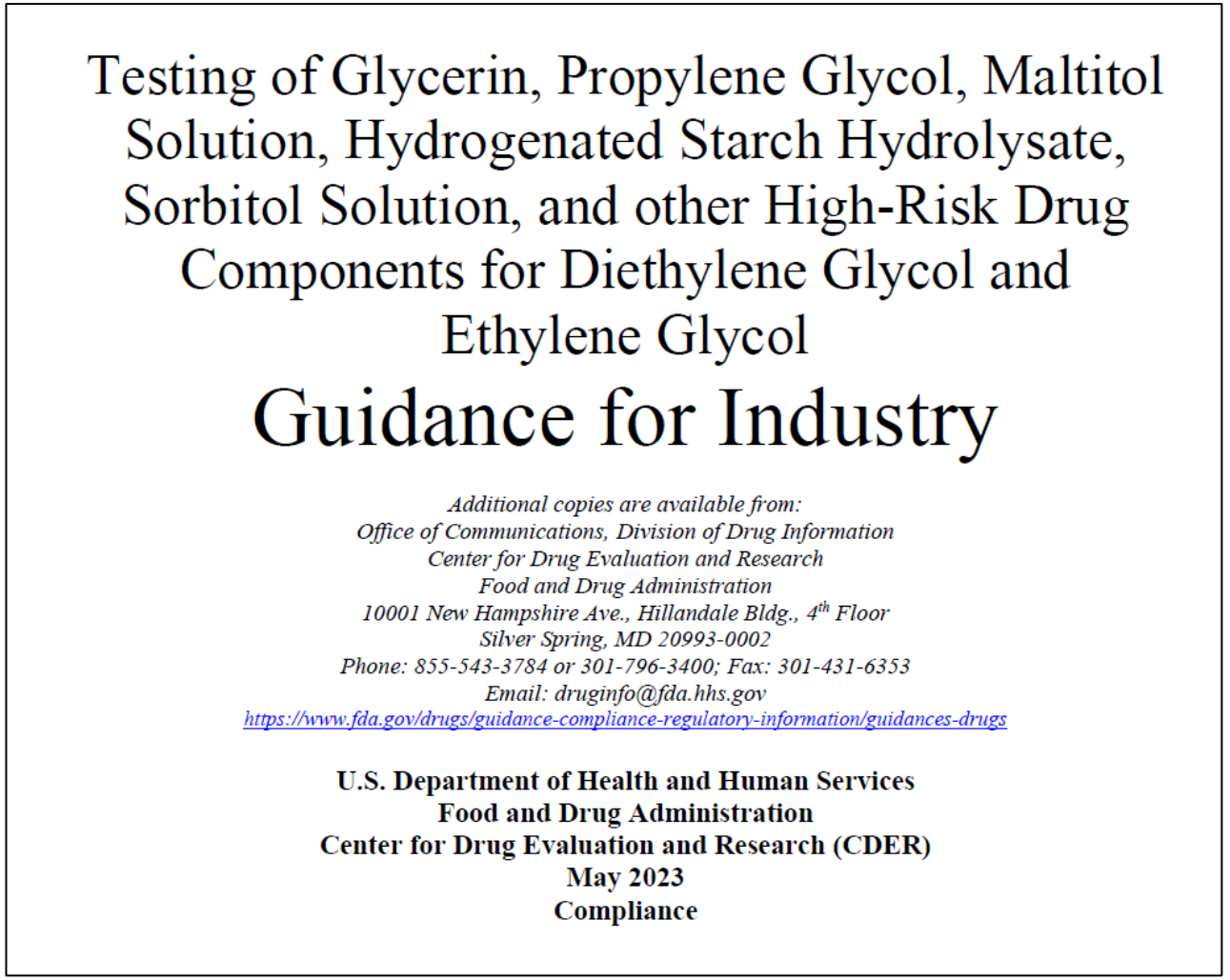
PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PE 009-16 (Annexes)
1 February 2022

GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS
ANNEXES

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 #:**_____ ☐ N/A

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

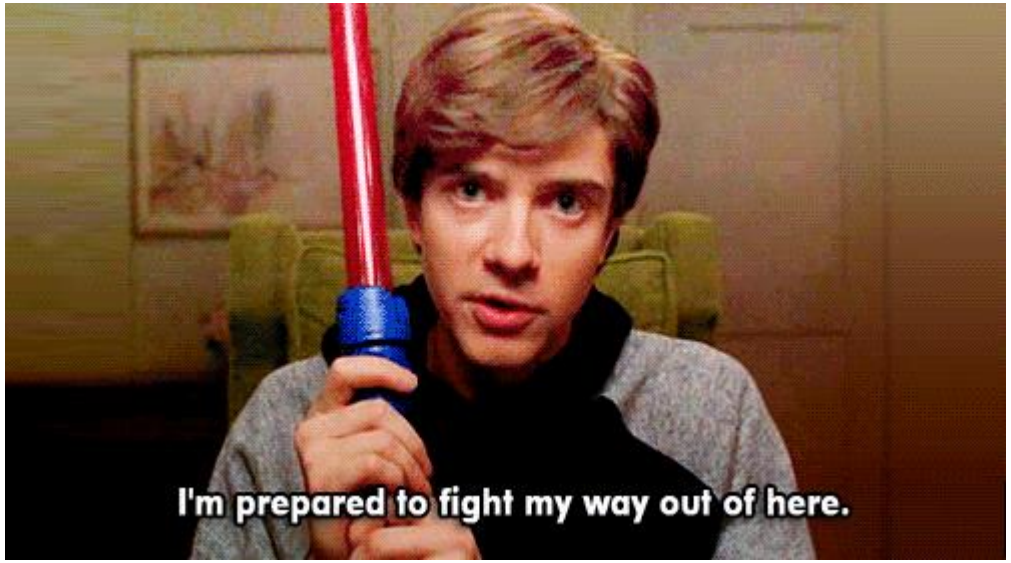
SOP revision required? Yes ___ No ___
Proposed revision date(s) _____

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?