



Be inspection-ready with Cortellis Regulatory Intelligence

Claudia Haas ~ Beth Wise | Customer Education Team | April 2025

Agenda

- What is Cortellis Regulatory Intelligence?
- Live demo: use cases
- Feedback, wrap up, Q&A

What is Cortellis Regulatory Intelligence?

Global regulatory information, across all functions and responsibilities:



300K+ official documents



8K+ Value-add regulatory reports, analyses and global comparisons



English translations for all native language documents



**81 countries and regions
Drugs & Biologic and
75 Medical Devices & IVDs**

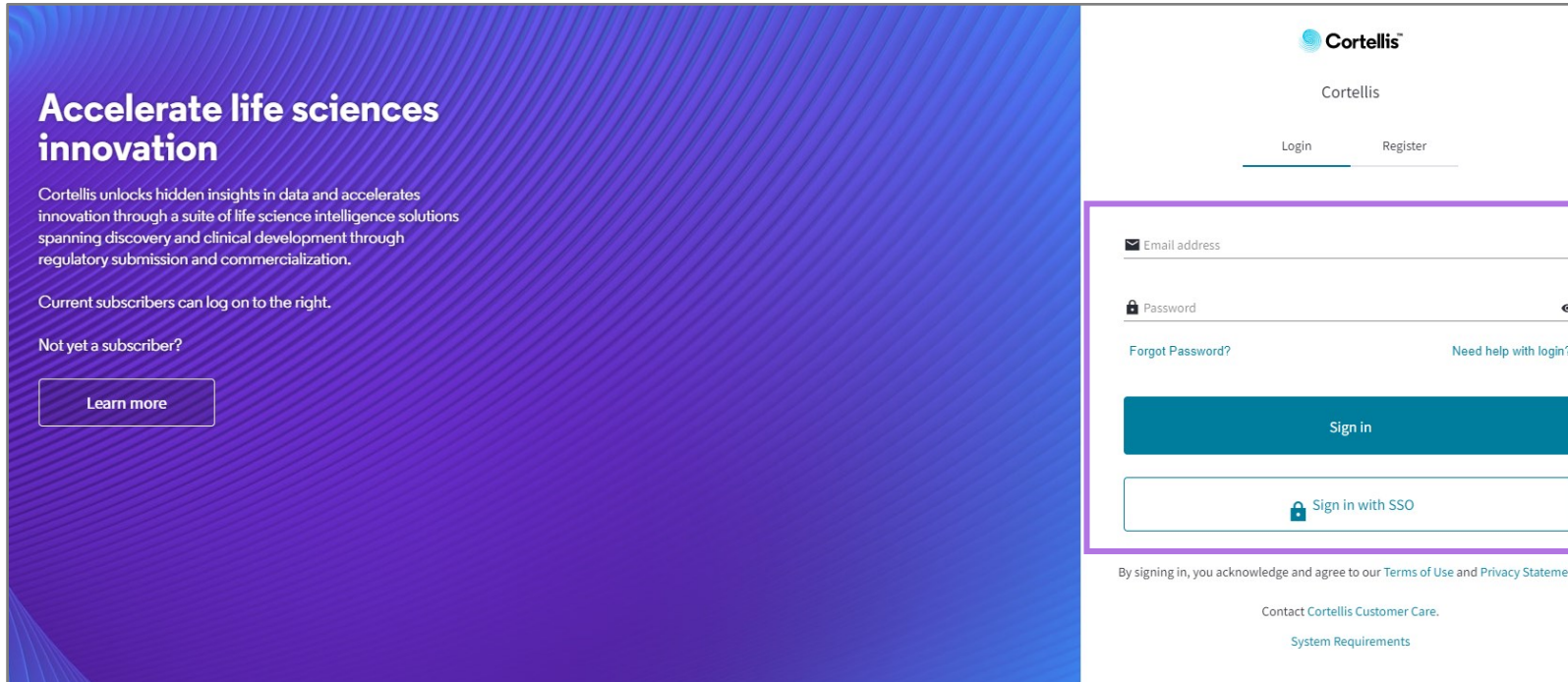


Updated daily



Regulatory experts & local consultants

How can I access Cortellis?



[Go to this URL](https://cortellis.com)

Cortellis.com

- Username/password access:
Enter your email address
- If you can't find the Clarivate email with your password, click Forgot Password to reset
- If you are a Single Sign On user, click the Sign in with SSO button, enter your company name and click Go.
- Contact Customer Care from this link if you need help

What will we cover today?

Use Case 1 (Slides 6-14):

Quickly locate recent or specific inspection reports and warning letters

Use Case 2 (Slides 15-17):

Better prepare for upcoming inspections and learn from precedence

Use Case 3 (Slides 20-28):

Easily analyze patterns and types of violations in FDA compliance letters and understand inspector behaviors

Use Case 1: Quickly locate recent or specific inspection reports

Use Quick Search and the Document Type and Country/Region filters

Quick Search

Quick search English keywords

Filter

Country/Region Topic **Document Type** Document Category Date Translation Status All other filters

Q

510(k) (39328) Guideline (37277) EPAR (29273) Supplemental Approval - NDA (14062) Meeting (13558) Federal Register Announcement (10000) Public Comment (8234) Press Release (8205) Regulation (7878) Product Miscellaneous (7642) **Inspection Report (7519)** War (10000) Information Note (5416) Curriculum Vitae (5355) Decree (4877) Order (4488) Questions & Answers (4060) Opinion (3898)

1. In Quick Search click Document Type
2. Select Inspection Report and click Apply
3. Click Country/Region
4. Select country of interest (e. g. Canada) and click Apply
5. Click the blue Search button
6. To change country/region selection: Deselect the chosen country, select another country and click Apply
7. Click the blue Search button to update your results

Quick Search

Quick search English keywords

Filter

Country/Region Topic **Document Type** Document Category Date Translation Status All other filters

Q

Country/Region

USA (6829) **Canada (314)** European Union (210) South Korea (166)

Quick Search

Quick search English keywords

Filter

Country/Region Topic **Document Type** Document Category Date Translation Status All other filters

Q

Country/Region

USA (6829) Canada (314) European Union (210) **South Korea (166)**

Use Case 1: Quickly locate recent or specific inspection reports

Sorting and viewing documents

The screenshot shows the 'Regulatory > All Results' page with 314 results. A search bar and filter buttons are at the top. The 'Sort by' dropdown menu is open, showing options: Relevance (selected), Title, Country/Region, Authority Acceptance Date, and IDRAC Number. The 'Authority Acceptance Date' option is highlighted, and its sub-menu is open, showing 'Most Recent' (selected) and 'Oldest'.

Regulatory > All Results
314 results
[Switch to Comparison Tables](#)

Quick search English keywords [Search](#)

Filter: Country/Region Topic Document Type Document Category Date Translation Status All other filters

Side by Side Viewer Showing 1-10

Customize Columns Sorted by Relevance

- Summary
- Relevance (selected) Lowest to Highest
- Title A to Z
- Country/Region A to Z
- Authority Acceptance Date Most Recent (selected) Oldest
- IDRAC Number
- Abstract

19-Sep-2024 Title c, 19-Sep-2014 Inspection of: Celgene Inc. Country: Canada Type of Sponsor Reference/Cont...

08-Aug-2023 GVP) Inspections: Aug-2023 Inspection of: HUMN Phar Province: Manitoba Coun Establishment: Not appli

05-Nov-2024 Good Pharmacovigilance Practices (GVP) Inspections: Mission Pharmacal Company, 04-05-Nov-2024 Inspection of: Mission Pha Province: Not applicabl

8. Click Sorted by – Authority Acceptance Date – Most Recent to see latest inspection reports at the top

9. Click the blue hyperlinked title to open a report of interest

The screenshot shows the search results table sorted by Authority Acceptance Date. The table has columns for Summary, Title, and Abstract. The first row is highlighted with a blue arrow pointing to the title 'Good Pharmacovigilance Practices (GVP) Inspections: Laboratoire Lalco Inc., 20-22-Nov-2024'.

Summary	Title	Abstract
10-Feb-2025 V CA EN RD	Medical Device Inspections: 6112919 Canada Lté. DBA Oxygène Médical Plus, 23-Jan-10-Feb-2025	Inspection of: 6112919 Canada Lté. DBA Oxygène Médical Plus Province: Quebec Country: Canada Type of Establishment: ...
21-Jan-2025 V CA EN RD	Drug & Health Product Inspections: TJP Labs Inc., 13-21-Jan-2025	Inspection of: TJP Labs Inc. Province: Ontario Country: Canada Type of Establishment: Distribute (Pharmaceutical) ...
02-Dec-2024 V CA EN RD	Medical Device Inspections: 2864024 Ontario Inc. (Dba Rapid Test Canada), 25-Nov-02-Dec-2024	Inspection of: 2864024 Ontario Inc. (Dba Rapid Test Canada) Province: Ontario Country: Canada Type of Establishment: ...
22-Nov-2024 V CA EN RD	Good Pharmacovigilance Practices (GVP) Inspections: Laboratoire Lalco Inc., 20-22-Nov-2024	Inspection of: Laboratoire Lalco Inc. Province: Quebec Country: Canada Type of Establishment: Not applicable

New: Expanded Content Coverage in Inspection Reports

Enhanced Insights with Korean GMP Inspection Reports and Canadian Inspection Reports

- **Canadian Inspection Reports**

- **Source:** Health Canada
- **Scope:** Covers various inspections (drug, clinical trial, medical device, GVP, blood, cells, tissues, and organ inspections) dating from 2012.
- **Volume:** around >310 documents as of mid April 2025
- **Cortellis abstract:** provides details about the organization being inspected and lists the observations
- **Cortellis pdf:** includes inspection report card summary, summary of observation(s), inspection outcome, measures taken by Health Canada

- **Korean GMP Inspection Reports**

- **Source:** Ministry of Food and Drug Safety
- **Scope:** Inspections conducted at pharmaceutical manufacturing facilities since 2024. South Korea inspections can be on-site or document-based and are aimed at verifying the quality, safety, and efficacy of pharmaceutical products.
- **Volume:** around >160 documents as of mid April 2025
- **Cortellis abstract:** provides details about the organization being inspected and lists the observations
- **Cortellis pdf:** in local language and English Machine translation

New: Expanded Content Coverage in Inspection Reports

Enhanced Insights with Korean GMP Inspection Reports and Canadian Inspection Reports

- [Click HERE](#) to open a sample document for Canada

▼ Medical device inspections report card summary

Measures taken by Health Canada

Enforcement Actions

Summary of observations

Government of Canada / Gouvernement du Canada

Home > Health > Drug and health products

> Inspecting and monitoring drug and health products

> Drug and health product inspections

Medical device inspections report card summary

Some fields may be left blank (e.g., previous licence(s), MDEL status, risk classification, enforcement actions, etc.) as historical information has yet to be entered into the database or the action(s) have not transpired.

Inspection report card summary

[Initial inspection deficiencies report](#)

Establishment name	Reference number	Inspection start date	Type of inspection	Inspection rating
2864024 Ontario Inc. Dba Rapid Test Canada	0967113F	2024-11-25	Domestic - New - Onsite	Non-compliant

Inspection outcome

The inspection resulted in a 'non-compliant' rating. A non-compliant inspection rating means that at the time of the inspection the company's licensable activities did not comply with the Food and Drugs Act and its Medical Devices Regulations. If a company receives a non-compliant inspection rating the company's licence may be suspended. The inspection rating considers the risk classification of all

<https://www.drug-inspections.canada.ca/mdr/fullReportCard-en.html?lang=en&insNumber=18834>

- [Click HERE](#) to open a sample document for South Korea

Machine Translated Document

Preview (English) Download (English) View on Side by side

Disclaimer: AUTOMATED TRANSLATIONS POWERED BY GOOGLE are not modified or altered by Clarivate and are provided "as is" without warranty. Any discrepancies or differences created in the translation are not binding and have no legal effect for compliance or enforcement purposes. If any questions arise related to the accuracy of the translated information, please refer to the official source language version.

의약품 해외 제조소 현지실사 결과

1 제조소 현황

- 제조소명 : Mundipharma Pharmaceuticals Ltd
- 소재지 : Dhali Industrial Area, Othellou 13-15, Nicosia 2540, Cyprus

2 실태조사 개요

- 실사 목적 : 「약사법」 제69조의5 및 「의약품 등의 안전에 관한 규칙」 제87조의3에 따라 수입의약품 해외제조소의 GMP 준수 여부 등을 확인하기 위하여 의약품 해외제조소 실태조사를 실시
- 실사 방식 : 현지실사
- 실사 기간 : 2024.11.26. ~ 2024.11.28. (3일)
- 실사자

Inspection Reports for the USA and the European Union (EU)

Get inspection-ready with FDA and Eudra GMP & GDP Inspection Reports in Cortellis

- **FDA Inspection Reports**

- **Source:** U.S. Food and Drug Administration (FDA)
- **Scope:** FDA forms 483, EIRs (Establishment Inspections Reports) and correspondence requested by Clarivate from the FDA via the FOIA act. Coverage depends on what we receive by the FDA: in average 400 requests per year/300 reports received). Priority given to inspections with issued warning letters & those with voluntary (VAI) or official actions (OAI) indicated.
- **Volume:** around >6800 documents as of mid-April 2025
- **Cortellis abstract:** provides overview of company inspected, type of inspection, inspector name and observations
- **Cortellis pdf:** reports include FDA form 483s and/or EIRs and/or correspondence

- **EU GMP & GDP Inspection Reports**

- **Source:** Eudra GMDP website (maintained by EMA)
- **Scope:** Covers non-compliant GMP inspections both within EU member states and internationally from 2009, as well as GDP inspections within EU member states from 2014
- **Volume:** around >200 documents as of mid-April 2025
- **Cortellis abstract:** actions to be taken are listed as confirmed by the national authority
- **Cortellis pdf:** reference documents include links to the full text on the Eudra GMDP website

Inspection Reports for the USA and the European Union (EU)

Get inspection-ready with FDA and Eudra GMP & GDP Inspection Reports in Cortellis

• [Click HERE](#) to open a sample document for the USA

• [Click HERE](#) to open a sample document for the EU

Summary

Abstract

Inspection of: Celltrion, Inc (Incheon, Republic of Korea)

Region: Foreign Inspection

Type of Establishment: Drug Manufacturer

Inspector: Justin A. Boyd

District Decision: OAI

Observations: Deviations observed in: Unexplained discrepancy; procedures designed to prevent microbiological contamination of drug products; environmental conditions, cleaning and disinfecting the equipment; manufacturing process; laboratory records; appropriate controls over computerized systems

Food and Drug Administration Establishment Inspection Report

Date Assigned: 05/16/2017

Inspection Start Date: 05/22/2017

Inspection End Date: 06/02/2017

Firm Name & Address: Celltrion Inc. , Yeonsu-gu , Plant 1: 23 Academy-Ro Incheon City

Firm Mailing Address: Yeonsu-Gu, Plant 1: 23 Academy-Ro, Incheon City ,406-840, Korea (the Republic of)

FEI: 3005241015

JD/TA:

County:

Est Size: Unknown

Phone:

District: IOG

Profiled: Yes

Conveyance Type:

% Interstate:

Inspectional Responsibility:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

Food and Drug Administration, CDER Inspection Assessment Branch

10903 New Hampshire Avenue Bldg. 51, Room 4316

Silver Spring, MD 20993 Phone: 1-301-796-3254

DATE(S) OF INSPECTION

May 22-26 and May 29-June 2, 2017

FEI NUMBER

3005241015

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Myung Keun Oh, Senior Vice President of Global Quality, Operation Division

FIRM NAME

Celltrion Inc.

STREET ADDRESS

23 Academy-ro, Yeonsu-gu

CITY, STATE AND ZIP CODE

Incheon, 22014, Republic of Korea

TYPE OF ESTABLISHMENT INSPECTED

Sterile Injectable Drug Product and Drug Substance Manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL

► EIR

FDA 483

► EIR

FDA 483



Summary

Abstract

This document provides the GMP non-compliance report concerning the Maithili Life Sciences Private Limited.

The National Competent Authority of Belgium confirms the following action to be taken:

- Requested Variation of the marketing authorisation(s)
- Recall of batches already released
- Prohibition of supply
- Suspension or voiding of CEP (action to be taken by

Reference Document

Insights from authorities and organizations

GMP Non Compliance Report: Maithili Life Sciences Private Limited, 13-Jan-2025 (European Union)

Reason for update	Date	Reason for update description
New	2025-02-10	

1. Content

- Non-Compliant Manufacturing Operations
- Non-Compliant Manufacturing Operations - Active Substances

2. Link to Full Text

<https://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPNonCompliance.do?ctrl=searchGMPNCRResultControlList&action=Drilldown¶m=175388>

Use Case 1: Quickly locate recent or specific inspection reports

Adding English keyword(s) to Quick Search finds specific inspections (e.g. company/inspector name)

Quick Search

Justin A. Boyd Search

Filter

Country/Region Topic Document Type Document Category Date Translation Status All other filters

Country/Region

USA (49)

10. Enter inspector name (Example: **Justin A. Boyd**) to retrieve FDA inspections conducted by this inspector (family name might be sufficient)

11. Click the blue Search button to view your results

12. Optional: Add a company name to find out if the inspector inspected a particular company – Enter:

Justin A. Boyd **and Celltrion**

13. Click the blue Search button to update your results

Refine Search

Justin A. Boyd and Celltrion Search

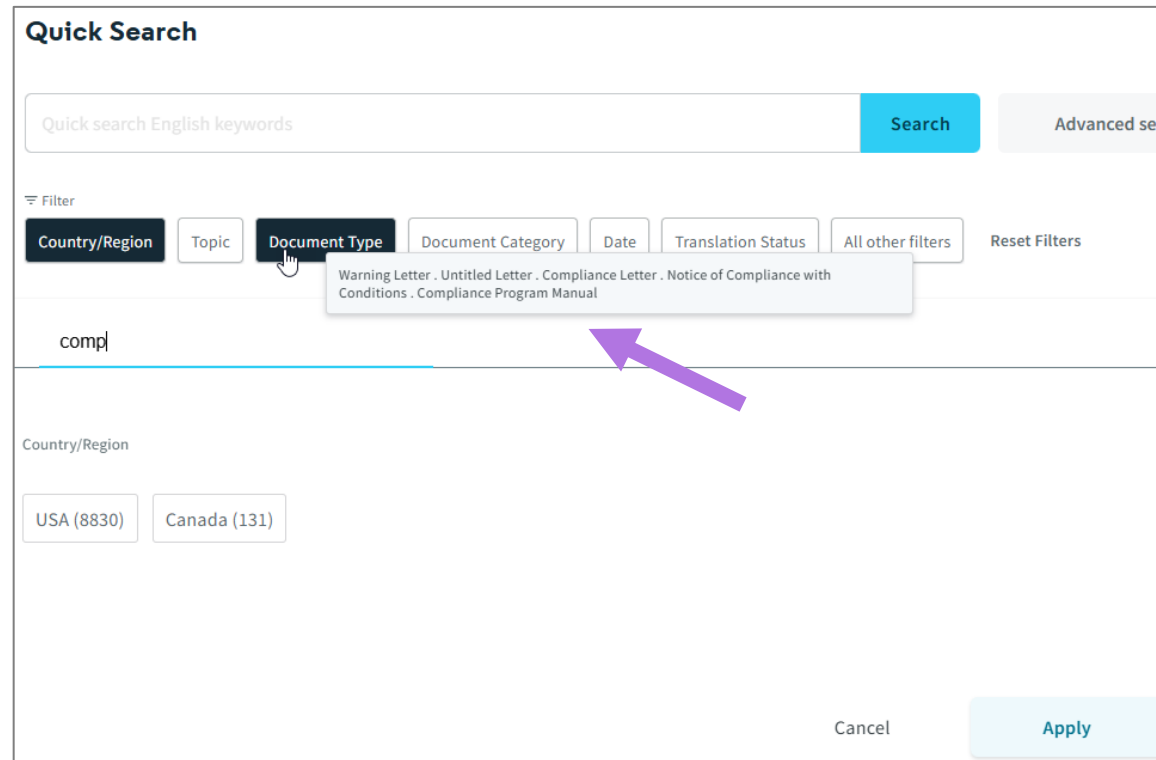
Filter

Country/Region Topic Document Type Document Category Date Translation Status All other filters

Side by Side Viewer			Showing 1-1 of 1 results
Customize Columns			Sorted by Authority Acceptance Date
<input checked="" type="checkbox"/>	Summary	Title	Abstract
<input checked="" type="checkbox"/>	02-Jun-2017 V US	Celltrion, Inc, 22-May-02-Jun-2017: EIR, FDA 483	Inspection of: Celltrion, Inc (Incheon, Republic of Korea) Region: Foreign Inspection Type of Establishment: Drug
EN	RD		Inspection of: Celltrion, Inc (Incheon, Republic of Korea) Region: Foreign Inspection Type of Establishment: Drug Manufacturer Inspector: Justin A. Boyd District Decision: OAI Observations: Deviations observed in: Unexplained discrepancy; procedures designed to prevent microbiological contamination of drug products; aseptic processing areas regarding the system for monitoring

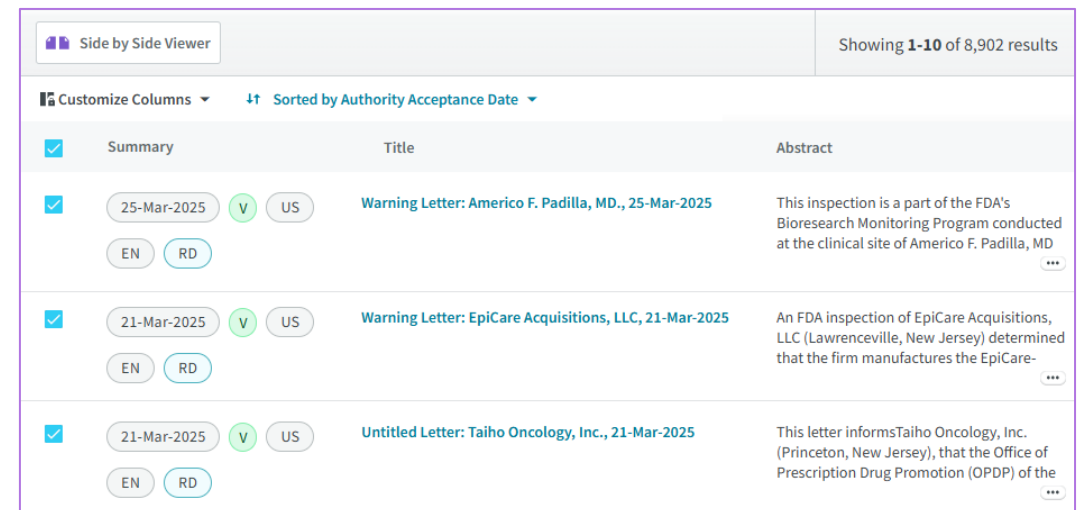
Use Case 1: Quickly locate warning letters and other compliance letters

Use Quick Search and the Document Type and Country/Region filters



The screenshot shows the 'Quick Search' interface. At the top is a search bar with the placeholder text 'Quick search English keywords' and a blue 'Search' button. Below the search bar is a 'Filter' section with several tabs: 'Country/Region', 'Topic', 'Document Type', 'Document Category', 'Date', 'Translation Status', and 'All other filters'. The 'Document Type' tab is selected, and a dropdown menu is open showing options: 'Warning Letter', 'Untitled Letter', 'Compliance Letter', and 'Notice of Compliance with Conditions'. A purple arrow points to the 'Compliance Letter' option. Below the filters, the 'Country/Region' section shows 'USA (8830)' and 'Canada (131)' buttons. At the bottom are 'Cancel' and 'Apply' buttons.

1. Click Document Type
2. Select appropriate type(s): warning letter, untitled letter, compliance letter etc.
3. Click Country/Region
4. Select country of interest (USA , Canada or both) and click Apply
5. Optional: add English keyword(s)
6. Click the blue Search button

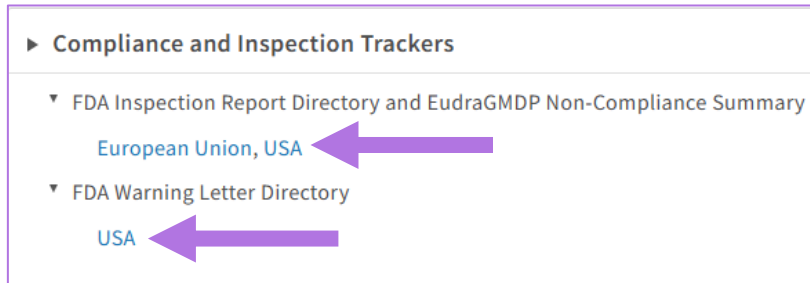


The screenshot shows the search results table. At the top, it says 'Side by Side Viewer' and 'Showing 1-10 of 8,902 results'. Below this is a 'Customize Columns' dropdown and a 'Sorted by Authority Acceptance Date' dropdown. The table has three columns: 'Summary', 'Title', and 'Abstract'. The first three rows are highlighted with a blue checkmark in the 'Summary' column. Each row shows a date, a status (V), a country (US), and a title. The first row is 'Warning Letter: Americo F. Padilla, MD., 25-Mar-2025'. The second row is 'Warning Letter: EpiCare Acquisitions, LLC, 21-Mar-2025'. The third row is 'Untitled Letter: Taiho Oncology, Inc., 21-Mar-2025'. Each row also has 'EN' and 'RD' buttons.

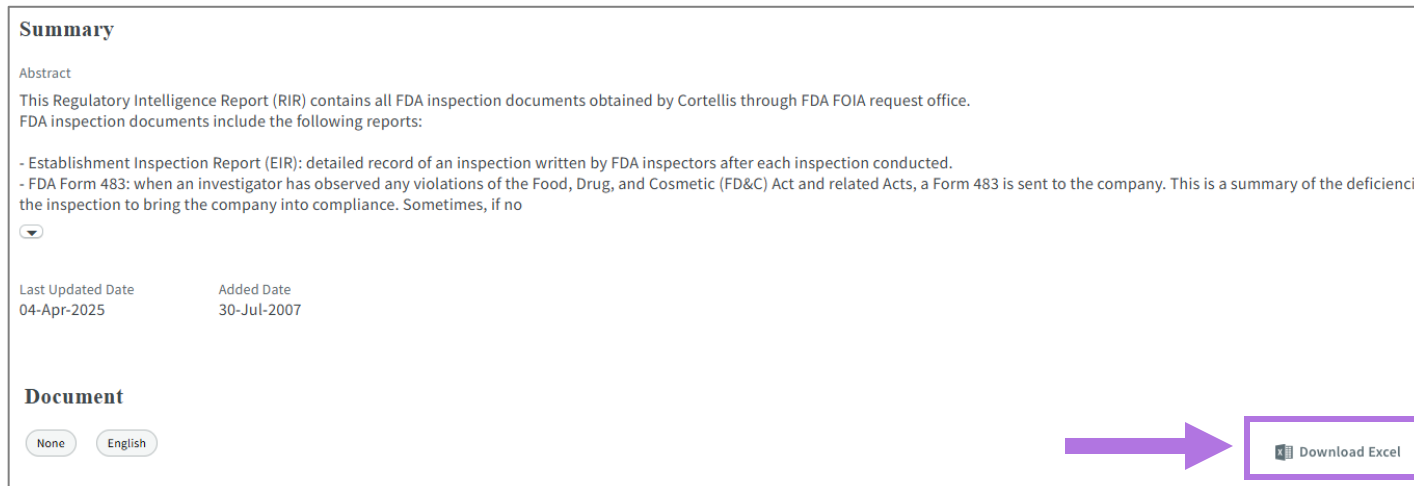
Summary	Title	Abstract
<input checked="" type="checkbox"/> 25-Mar-2025 V US EN RD	Warning Letter: Americo F. Padilla, MD., 25-Mar-2025	This inspection is a part of the FDA's Bioresearch Monitoring Program conducted at the clinical site of Americo F. Padilla, MD
<input checked="" type="checkbox"/> 21-Mar-2025 V US EN RD	Warning Letter: EpiCare Acquisitions, LLC, 21-Mar-2025	An FDA inspection of EpiCare Acquisitions, LLC (Lawrenceville, New Jersey) determined that the firm manufactures the EpiCare-
<input checked="" type="checkbox"/> 21-Mar-2025 V US EN RD	Untitled Letter: Taiho Oncology, Inc., 21-Mar-2025	This letter informs Taiho Oncology, Inc. (Princeton, New Jersey), that the Office of Prescription Drug Promotion (OPDP) of the

Use Case 2: Better prepare for upcoming inspections and learn from precedence

Consulting the Cortellis Compliance & Inspection Excel Trackers



1. Go to Intelligence Reports
2. Scroll down to Compliance and Inspections Trackers listed on the left (drugs & biologics) and right (devices: USA only)
3. Select the desired tracker (inspections or warning letters)
4. Click European Union or USA
5. On the document page scroll down and click Download Excel to open the tracker in Excel



Use Case 2: Better prepare for upcoming inspections and learn from precedence

EU Excel Tracker: EudraGMDP Non-Compliance Summary

1	Link to Inspection Report	Issuance Date	GMP/GDP Compliant	Inspection Ending Date	Inspecting National Competent Authority	Inspected Company	Inspected Individual	Inspected Territory
	389020	16-Aug-2024	GMP	29-May-2024	Netherlands	Anhui Bayi Chemical Industry Co. Ltd.		
12	381723	06-Mar-2024	GMP	10-Nov-2023	Finland	Liaoyuan City Baikang Pharmaceutical Co. Ltd.		
22	381722	12-Feb-2024	GMP	25-Aug-2023	France	Haimen Pharma Inc.		
25	321154	07-Nov-2019	GMP	06-Sep-2019	Croatia	NCPC Hebei Huamin Pharmaceutical Co. Ltd.		
60	321005	17-Oct-2019	GMP	27-Jun-2019	France	Jiangxi Dongfeng		

6. Sort and/or apply filters as desired (e.g. date, territory, activity type etc.)

7. Link out to associated inspections reports from column A

H	I	J	K
Inspected Territory	Type of Inspected Activity	Nature of Non-compliance	NCA Proposal/Action to Take
China	General firm Manufacture synthesis ;	During the inspection 1 critical and 7 major deficiencies were found: Critical: 1 The inspection revealed a substantial number of severe GMP violations in various areas. This indicated not only a substantial lack of GMP knowledge by the firm,	Suspension/voiding of CEP ; Other
China	General firm Manufacture synthesis ;	The inspection team identified 25 deficiencies against EU GMP. Of these, one was classified as critical and found in the area of data integrity controls in the QC laboratory. In addition, five deficiencies were classified as major and related	Prohibition of supply ; Suspension/voiding of CEP
China	Non sterile testing	Four critical deficiencies were raised : 1) poor handling of deviations (3 recorded in 2022, 0 in 2023). However, inspectors noticed 7 incidents which should lead to deviations, such as rust on clean Posaconazole punches, inner of coating pan	Other
China	General firm Manufacture synthesis ; ; Quality control	This inspection was carried out in the framework of the EDQM inspection programme on 2 – 6 September 2019. Scope of the inspection was Cefotaxime sodium, sterile (CEP 2014-197). The inspection revealed 31 deficiencies in total. Out of	Prohibition of supply ; Requested variation of marketing authorization ; Suspension/voiding of CEP ; Other
China	Manufacture	Overall, 28 deficiencies were observed during the	Prohibition of supply ; Recall of

Use Case 2: Better prepare for upcoming inspections and learn from precedence

USA Excel Tracker: FDA Inspection Report Directory

1	Link to Inspection Report	Inspection Starting Date	Inspection Ending Date	FDA Inspector	FDA District Office	Center	Company or Individual Inspected
44	391733	17-Sep-2024	27-Sep-2024	Sort A to Z	Foreign Inspection	CDER	Biocon Sdn Bhd
96	389555	29-Jul-2024	02-Aug-2024	Sort Z to A	Foreign Inspection	CDER	Global Calcium Pvt Limited
107	390138	15-Jul-2024	26-Jul-2024	Sort by Color	Foreign Inspection	CDER	Biocon Biologics Ltd.
173	383774	25-Apr-2024	03-May-2024	Sheet View	Foreign Inspection	CDER	Eugia Pharma Specialities Ltd.
184	383132	15-Apr-2024	23-Apr-2024	Clear Filter From "FDA Inspector"	Foreign Inspection	CDER	Zydus Lifesciences Ltd.
291	378888	22-Jan-2024	02-Feb-2024	Filter by Color	Foreign Inspection	CDER	Eugia Pharma Specialities Ltd.
303	387796	15-Jan-2024	19-Jan-2024	Text Filters	Foreign Inspection	CDER	Brassica Pharma Pvt. Ltd.
382	375295	12-Oct-2023	20-Oct-2023	boyd	Foreign Inspection	CDER	Kilitch Healthcare India Ltd
391	373169	03-Oct-2023	12-Oct-2023	(Select All Search Results)	Foreign Inspection	CDER	Panacea Biotech Pharma Ltd.
394	395689	03-Oct-2023	10-Oct-2023	Add current selection to filter	Foreign Inspection	CDER	Fresenius Kabi Oncology Limited
464	402531	07-Aug-2023	15-Aug-2023	Boyd, Justin A.	Foreign Inspection	CDER	Amman Pharmaceutical Industries
533	367441	01-May-2023	12-May-2023	Boyd, Sandra A.	Foreign Inspection	CDER	Intas Pharamaceuticals Ltd.
606	394819	06-Mar-2023	14-Mar-2023	Boyd-Seale, Debra	Foreign Inspection	CDER	Regeneron Ireland DAC
673	378079	19-Jan-2023	27-Jan-2023		Foreign Inspection	CDER	Baxter Pharmaceuticals India Pvt Ltd
720	358687	22-Nov-2022	02-Dec-2022		Foreign Inspection	CDER	Intas Pharamaceuticals Ltd.
907	354149	16-Aug-2022	26-Aug-2022		Foreign Inspection	CDER	Cipla Ltd.
942	354159	03-Aug-2022	12-Aug-2022				
1116	357614	12-May-2022	20-May-2022				
1140	354193	02-May-2022	10-May-2022				

6. Sort and/or apply filters as desired (e.g. date, inspector, company, country/region, inspection, available records etc.)

Optional: remove Blanks from Related letters to find inspections with a warning letter issued

- 7. Link out to associated inspections reports from column A
- 8. Link out to issued warning letters from column O

Country/Region	Type of Establishment Inspected	Project Area	District Decision	Inspection Ty	Available Records	Related Letters
India	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	483	Sort A to Z
India	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	483	Sort Z to A
India	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	483	Sort by Color
India	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	483	Sheet View
India	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	483	Clear Filter From "Related Letters"
India	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	483	Filter by Color
India	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	483	Text Filters
India	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	483	Search
South Korea	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	EIR ; 483	356493 (Warning letter)
Germany	API manufacturer	Drug quality assurance	Official action indicated	Not available	483	368910 (Warning letter)
Japan	API manufacturer	Drug quality assurance	Official action indicated	Not available	483	368911 (Warning letter)
Japan	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	483	379831 (Warning letter)
Hungary	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	483	382124 (Warning letter)
Italy	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	483	387630 (Warning letter)
Italy	API manufacturer	Drug quality assurance	Official action indicated	Not available	483	389161 (Warning letter)
United Kingdom	API manufacturer	Drug quality assurance	Official action indicated	Not available	483	390314 (Warning letter)
Italy	API manufacturer	Compliance: devices	Official action indicated	Not available	483	(Blanks)
India	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	483	
India	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	483	
India	Drug manufacturer	Postmarket surveillance	Voluntary action indicated	Not available	483	
Italy	Drug manufacturer	Drug quality assurance	Not available	Not available	483	

Learning Check

1. Cortellis includes inspection reports for:

- USA and EU
- Canada and South Korea
- All of the above

2. Cortellis Compliance & Inspection trackers are filterable?

- Yes
- No

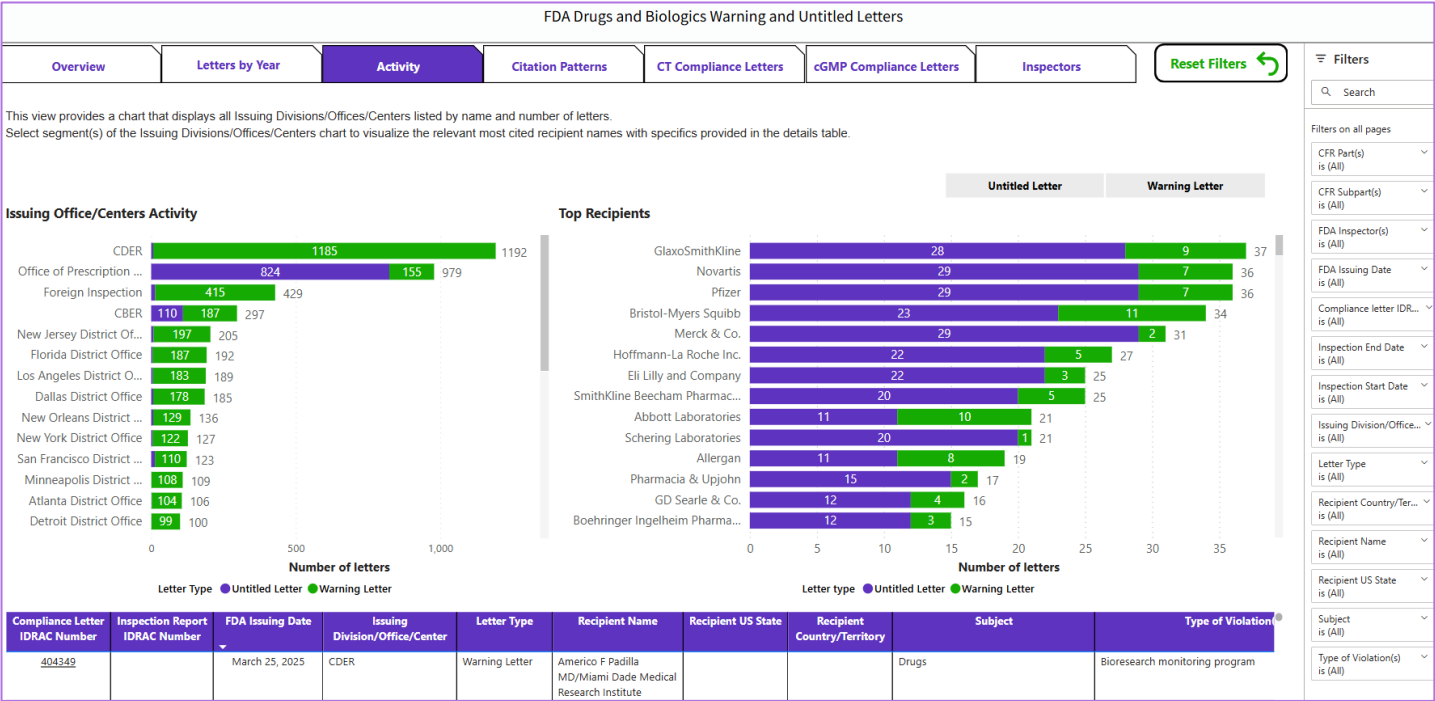
3. To quickly find recent or specific FDA inspections or warning letters you

- Use Quick Search
- Consult the trackers
- Both options will work

Use Case 3: Cortellis FDA Warning & Untitled letters Analytics (Drugs & Biologics)*

Gain deeper insights, make informed decisions

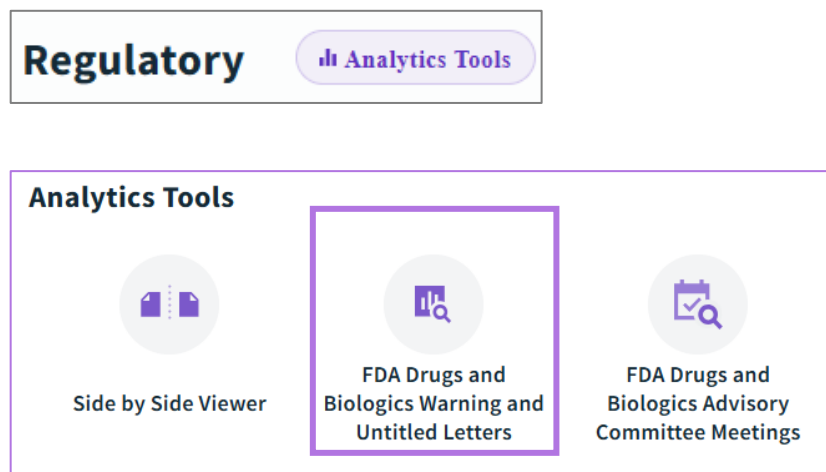
- Quickly draw conclusions from the data with easy-to-use analytics and save time preparing for FDA inspections
- Easily pinpoint Warning and Untitled Letters by inspector, citation, date, recipient, type, location, and more.
- Hyperlinks to original compliance letters and inspection reports
- Understand trends in citations from 1996 through today
- Based on Power BI



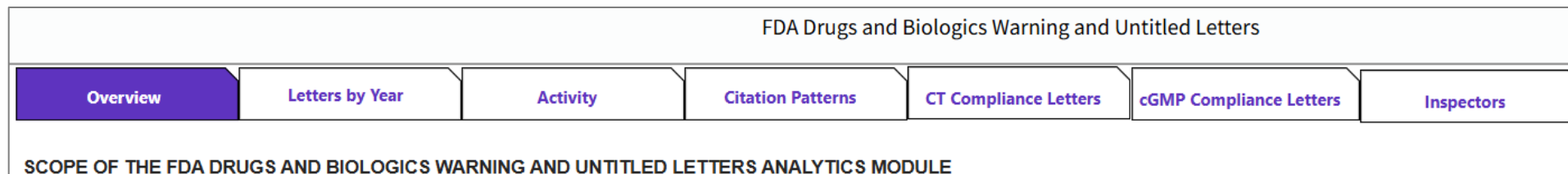
* Please note: Cortellis FDA Analytics are add-on modules, Access depends on your subscription.

Use Case 3: Cortellis FDA Warning & Untitled letters Analytics (Drugs & Biologics)*

Easily analyze patterns and types of violations in FDA compliance letters



1. Go to the Cortellis Regulatory Intelligence homepage
2. Click the Analytics Tools button at the top or scroll down to the Analytics Tools section at the bottom
3. Click on FDA Drugs and Biologics Warning and Untitled Letters to launch the analytics*
4. The analytics open in a new tab displaying the overview section that provides information about the analytics' scope, terminologies and rules
5. Next, select one of the top tabs



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Use Case 3: Cortellis FDA Warning & Untitled letters Analytics (Drugs & Biologics)*

Example: Did the number of compliance letters increase or decrease over the last 10 years?

FDA Drugs and Biologics Warning and Untitled Letters						
Overview	Letters by Year	Activity	Citation Patterns	CT Compliance Letters	cGMP Compliance Letters	Inspectors

1. Select the Letters by Year tab.
2. Use FDA Issuing Date filter on the right to narrow down:
3. Select Advanced filtering – show items when the value: is on or after – enter date (example: 4/1/2015).
4. Click Apply

FDA Issuing Date
is (All)

Filter type
Advanced filtering

Show items when the value
is on or after

4/1/2015

12 00 AM

☒ And ☐ Or

Apply filter

Filters

Search

Filters on all pages

CFR Part(s)
is (All)

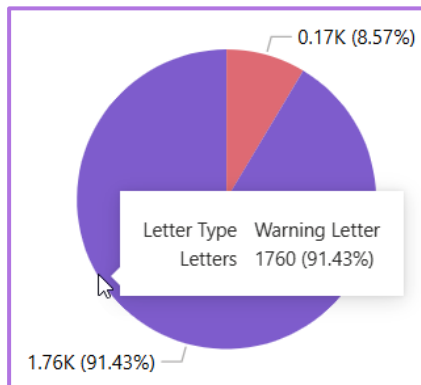
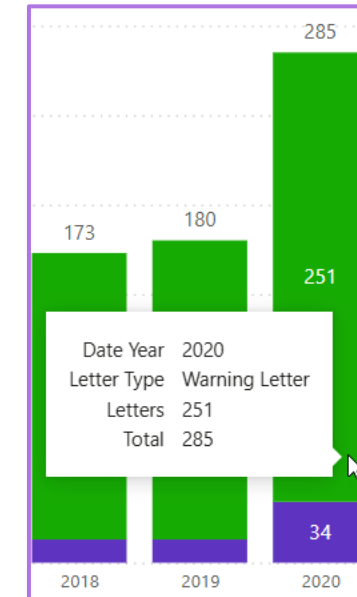
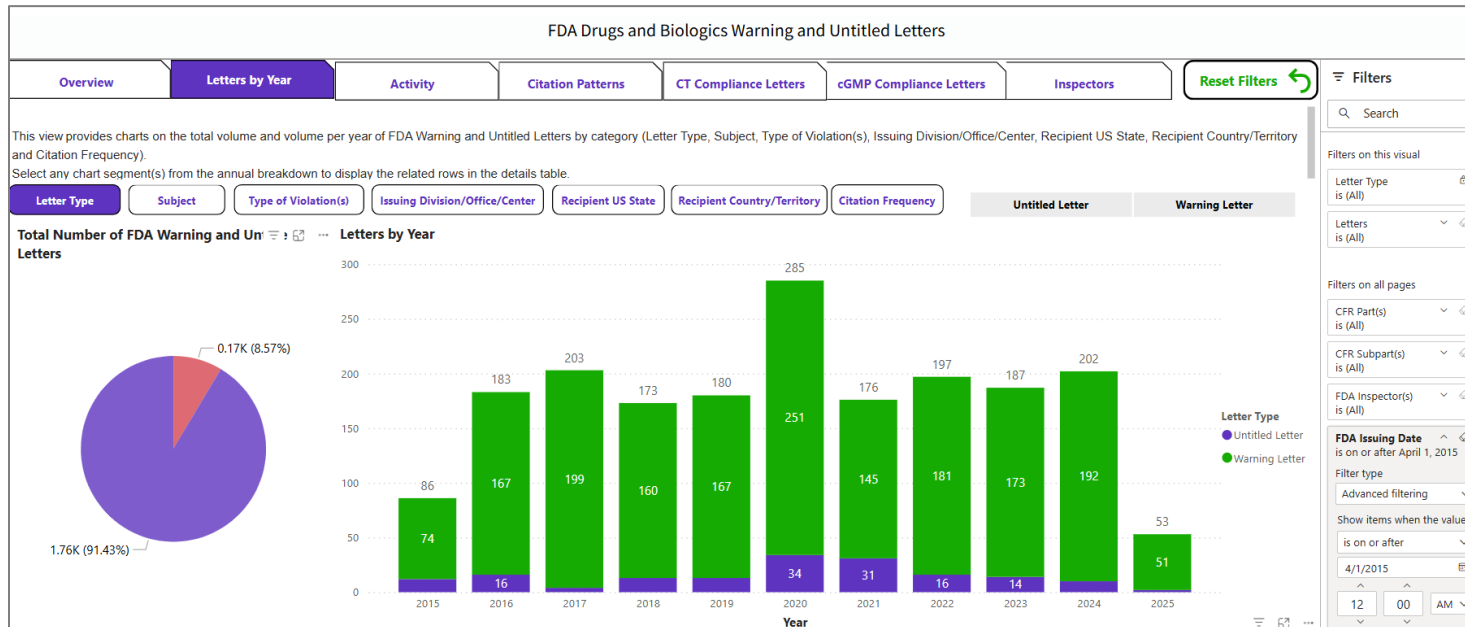
CFR Subpart(s)
is (All)

FDA Inspector(s)
is (All)

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Use Case 3: Cortellis FDA Warning & Untitled letters Analytics (Drugs & Biologics)*

Example: Did the number of compliance letters increase or decrease over the last 10 years?

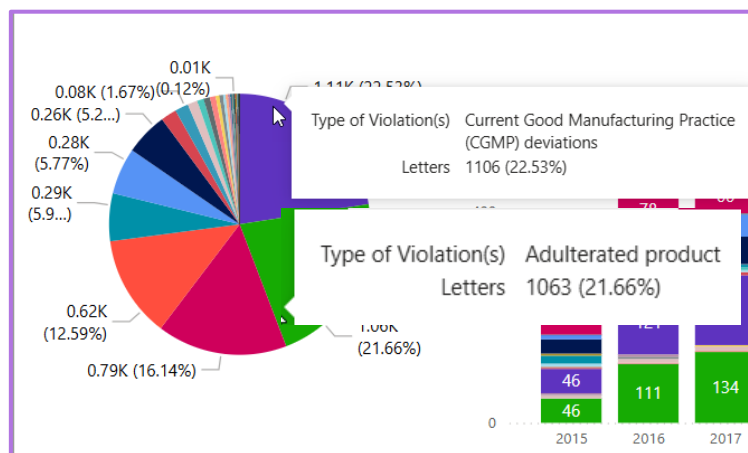
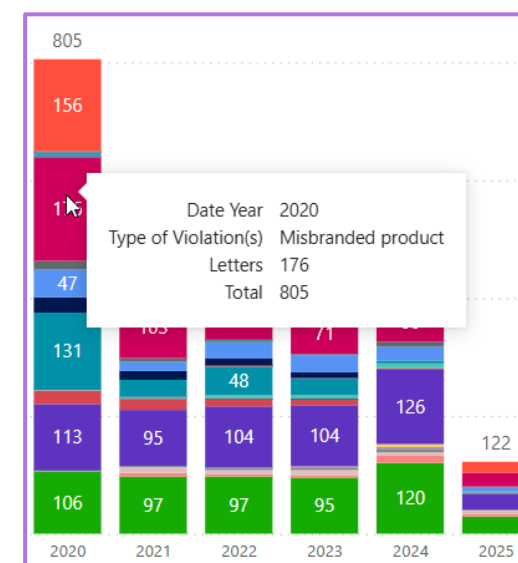
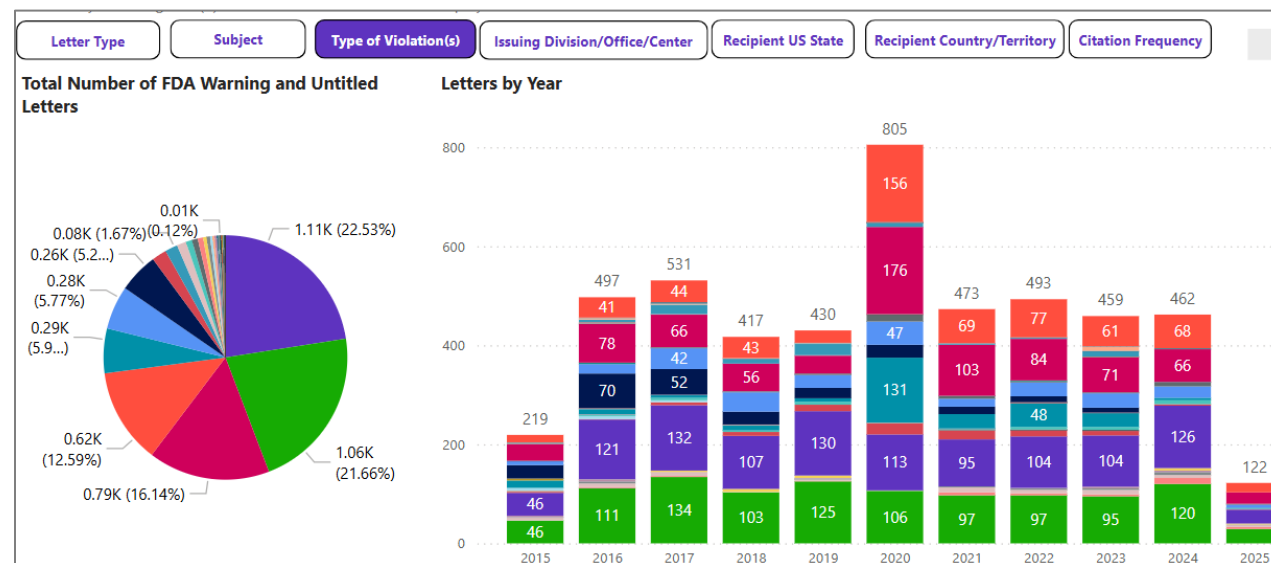


1. The pie chart shows total numbers of letters. Hover over to see more details
 2. The bar chart shows how the letters spread over time (example: last 10 years)
- Most letters were issued in 2020 (probably due to Covid-19), afterwards numbers decreased again, and levels seemed to have been stabilized now.

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Use Case 3: Cortellis FDA Warning & Untitled letters Analytics (Drugs & Biologics)*

Example: What violations are most prevalent in the compliance letters? What were the main concerns of the FDA?



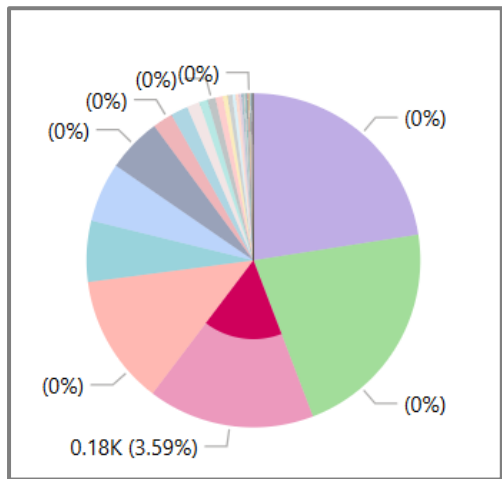
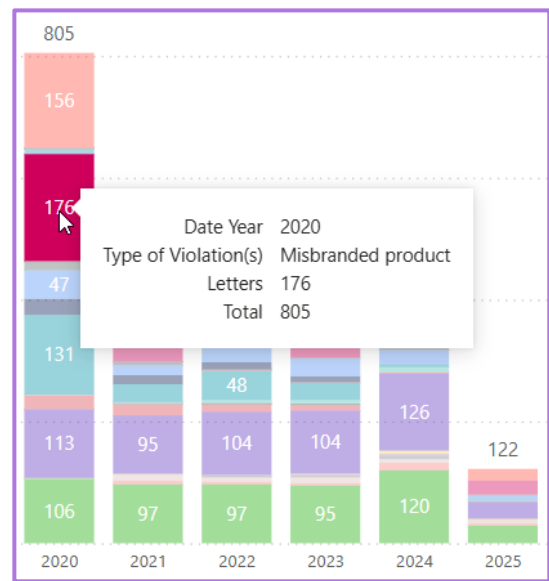
1. Select Type of Violation(s).

- Over the last 10 years cGMP and Adulterated products have been the most frequent violations
- In 2020 misbranded products were the FDA's primary concern

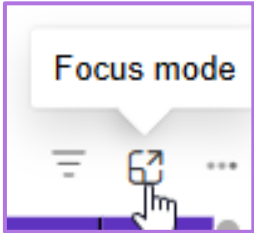
* Please note: Cortellis FDA Analytics are add-on modules, Access depends on your subscription.

Use Case 3: Cortellis FDA Warning & Untitled letters Analytics (Drugs & Biologics)*

Example: What violations are most prevalent in the compliance letters? What were the main concerns of the FDA?



- 2. Optional: Click within a chart (example: misbranded products, 2020) to drill down to a specific violation type
- 3. For deeper analysis access the individual compliance and inspection letters from the details table underneath. Click Focus mode to see it full screen



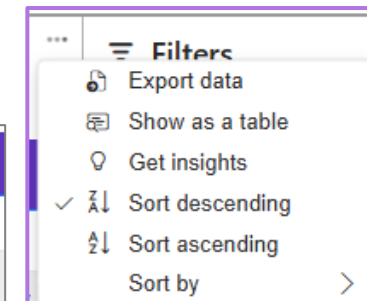
Year									
Compliance Letter IDRAC Number	Inspection Report IDRAC Number	FDA Issuing Date	Issuing Division/Office/Center	Letter Type	Recipient Name	Recipient US State	Recipient Country/Territory	Subject	Type d
323029		December 22, 2020	CDER	Warning Letter	New Leaf Pharmaceuticals LLC			Finished pharmaceuticals	Misbra
323029		December 22, 2020	CDER	Warning Letter	New Leaf Pharmaceuticals LLC			Finished pharmaceuticals	Misbra
323029		December 22, 2020	CDER	Warning Letter	New Leaf Pharmaceuticals LLC			New drugs	Misbra

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Use Case 3: Cortellis FDA Warning & Untitled letters Analytics (Drugs & Biologics)*

Example: What violations are most prevalent in the compliance letters? What were the main concern of the FDA?

Compliance Letter IDRAC Number	Inspection Report IDRAC Number	FDA Issuing Date	Issuing Division/Office/Center	Letter Type	Recipient Name	Recipient US State	Recipient Country/Territory	Subject	Type of Violation(s)
380632	309478	August 21, 2020	Dallas District Office	Untitled Letter	Claremore Compounding Center	Oklahoma	USA	Pharmacy compounding	Misbranded product
380632	309478	August 21, 2020	Dallas District Office	Untitled Letter	Claremore Compounding Center	Oklahoma	USA	Pharmacy compounding	Misbranded product
380632	309478	August 21, 2020	Dallas District Office	Untitled Letter	Claremore Compounding Center	Oklahoma	USA	Pharmacy compounding	Misbranded product
380632	309478	August 21, 2020	Dallas District Office	Untitled Letter	Claremore Compounding Center	Oklahoma	USA	Pharmacy compounding	Misbranded product
380956	309457	August 21, 2020	Dallas District Office	Untitled Letter	Mcalister Drug Corporation	Oklahoma	USA	Pharmacy compounding	Misbranded product
380956	309457	August 21, 2020	Dallas District Office	Untitled Letter	Mcalister Drug Corporation	Oklahoma	USA	Pharmacy compounding	Misbranded product
380956	309457	August 21, 2020	Dallas District Office	Untitled Letter	Mcalister Drug Corporation	Oklahoma	USA	Pharmacy compounding	Misbranded product
380956	309457	August 21, 2020	Dallas District Office	Untitled Letter	Mcalister Drug Corporation	Oklahoma	USA	Pharmacy compounding	Misbranded product



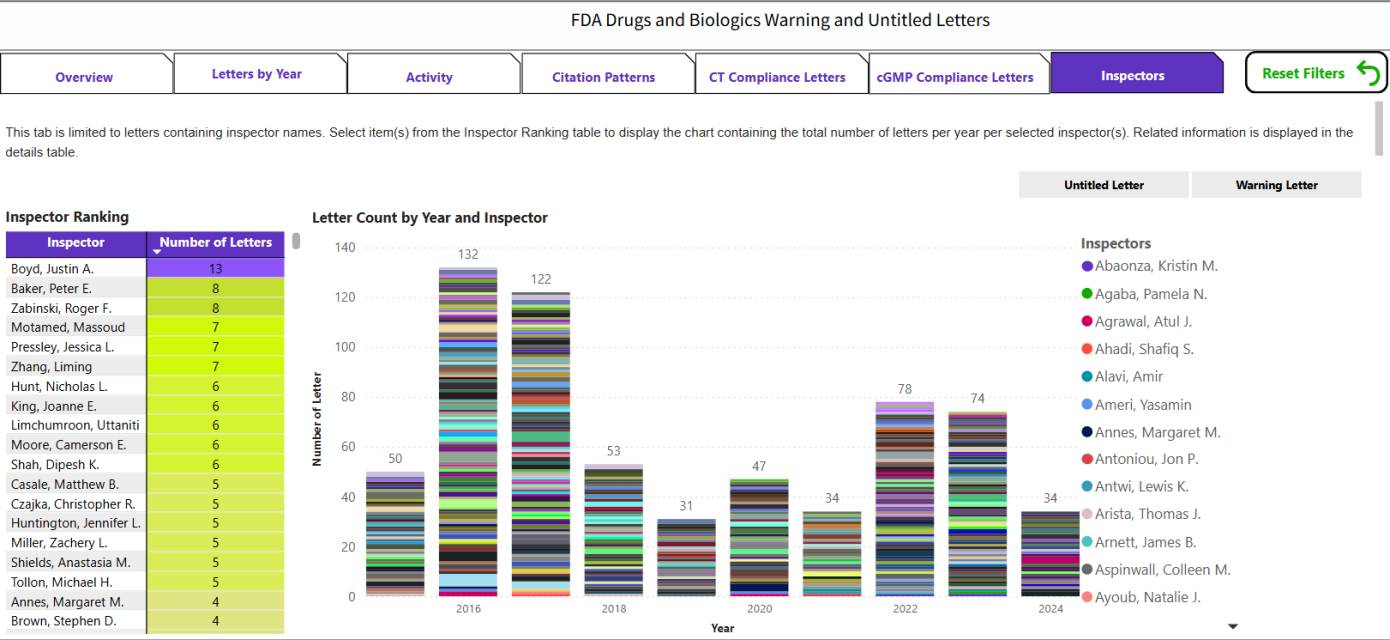
4. Click Compliance letter and/or related Inspection Report IDRAC numbers to open the associated documents in Cortellis

5. Optional: Click the 3 dots at the top right of the table to export the details to Excel

** Please note: Cortellis FDA Analytics are add-on modules, Access depends on your subscription.*

Use Case 3: Cortellis FDA Warning & Untitled letters Analytics (Drugs & Biologics)*

Example: What are inspectors citing in their compliance letters?

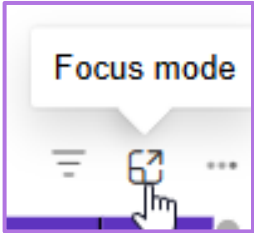


Inspector Ranking

Inspector	Number of Letters
Boyd, Justin A.	13
Baker, Peter E.	8
Zabinski, Roger F.	8
Motamed, Massoud	7
Pressley, Jessica L.	7
Zhang, Liming	7
Hunt, Nicholas L.	6

1. Click the Inspectors top tab
2. There's an inspector ranking on the left. Click an inspector name (example: Boyd, Justin) or click the number of letters (example: 13) to drill down to that inspector's inspections
3. Click Focus mode next to the details table underneath to see them full screen

Subject	Type of Violation(s)
Finished pharmaceuticals	Adulterated product
Finished pharmaceuticals	Adulterated product
Finished pharmaceuticals	Adulterated product
Finished pharmaceuticals	Adulterated product
Finished pharmaceuticals	Adulterated product
Finished pharmaceuticals	Adulterated product



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Use Case 3: Cortellis FDA Warning & Untitled letters Analytics (Drugs & Biologics)*

Example: What are inspectors citing in their compliance letters?

Type of Violation(s)	CFR Part(s)	CFR Subpart(s)	Inspection Start Date	Inspection End Date	FDA Inspector(s)
Adulterated product	21 CFR Part 210 - cGMP in manufacturing, processing, packing, or holding of drugs		January 15, 2024	January 19, 2024	Boyd, Justin A.
Adulterated product	21 CFR Part 211 - cGMP for finished pharmaceuticals	21 CFR Part 211 Subpart B - Organization and personnel	January 15, 2024	January 19, 2024	Boyd, Justin A.
Adulterated product	21 CFR Part 211 - cGMP for finished pharmaceuticals	21 CFR Part 211 Subpart C - Buildings and facilities	January 15, 2024	January 19, 2024	Boyd, Justin A.
Adulterated product	21 CFR Part 211 - cGMP for finished pharmaceuticals	21 CFR Part 211 Subpart D - Equipment	January 15, 2024	January 19, 2024	Boyd, Justin A.
Adulterated product	21 CFR Part 211 - cGMP for finished pharmaceuticals	21 CFR Part 211 Subpart F - Production and process controls	January 15, 2024	January 19, 2024	Boyd, Justin A.
Adulterated product	21 CFR Part 211 - cGMP for finished pharmaceuticals	21 CFR Part 211 Subpart J - Records and reports	January 15, 2024	January 19, 2024	Boyd, Justin A.
Current Good Manufacturing Practice (CGMP) deviations	21 CFR Part 210 - cGMP in manufacturing, processing, packing, or holding of drugs		January 15, 2024	January 19, 2024	Boyd, Justin A.
Current Good Manufacturing Practice (CGMP) deviations	21 CFR Part 211 - cGMP for finished pharmaceuticals	21 CFR Part 211 Subpart B - Organization and personnel	January 15, 2024	January 19, 2024	Boyd, Justin A.
Current Good Manufacturing Practice (CGMP) deviations	21 CFR Part 211 - cGMP for finished pharmaceuticals	21 CFR Part 211 Subpart C - Buildings and facilities	January 15, 2024	January 19, 2024	Boyd, Justin A.
Current Good Manufacturing Practice (CGMP) deviations	21 CFR Part 211 - cGMP for finished pharmaceuticals	21 CFR Part 211 Subpart D - Equipment	January 15, 2024	January 19, 2024	Boyd, Justin A.
Current Good Manufacturing Practice (CGMP) deviations	21 CFR Part 211 - cGMP for finished pharmaceuticals	21 CFR Part 211 Subpart F - Production and process controls	January 15, 2024	January 19, 2024	Boyd, Justin A.
Current Good Manufacturing Practice (CGMP) deviations	21 CFR Part 211 - cGMP for finished pharmaceuticals	21 CFR Part 211 Subpart J - Records and reports	January 15, 2024	January 19, 2024	Boyd, Justin A.
Adulterated product	21 CFR Part 210 - cGMP in manufacturing, processing, packing, or holding of drugs		October 12, 2023	October 20, 2023	Boyd, Justin A.
Adulterated product	21 CFR Part 211 - cGMP for finished pharmaceuticals	21 CFR Part 211 Subpart B - Organization and personnel	October 12, 2023	October 20, 2023	Boyd, Justin A.
Adulterated product	21 CFR Part 211 - cGMP for finished pharmaceuticals	21 CFR Part 211 Subpart C - Buildings and facilities	October 12, 2023	October 20, 2023	Boyd, Justin A.

4. In the details tables scroll to the right to investigate the citations in the CFR Part(s) and CFR Subpart(s) columns

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Access depends on your subscription.

Wrap up and feedback

What did you find most useful that we discovered today?

- A. Using **Quick Search** to identify recent and specific **Inspection reports and Compliance letters**.
- B. Consulting the Cortellis **Compliance & Inspection Excel Trackers** to prepare for inspections and learn from precedence.
- C. Using the Power BI **Cortellis FDA Analytics** to get even more insights into inspector behavior as well as patterns and types of violations in **FDA compliance letters**.

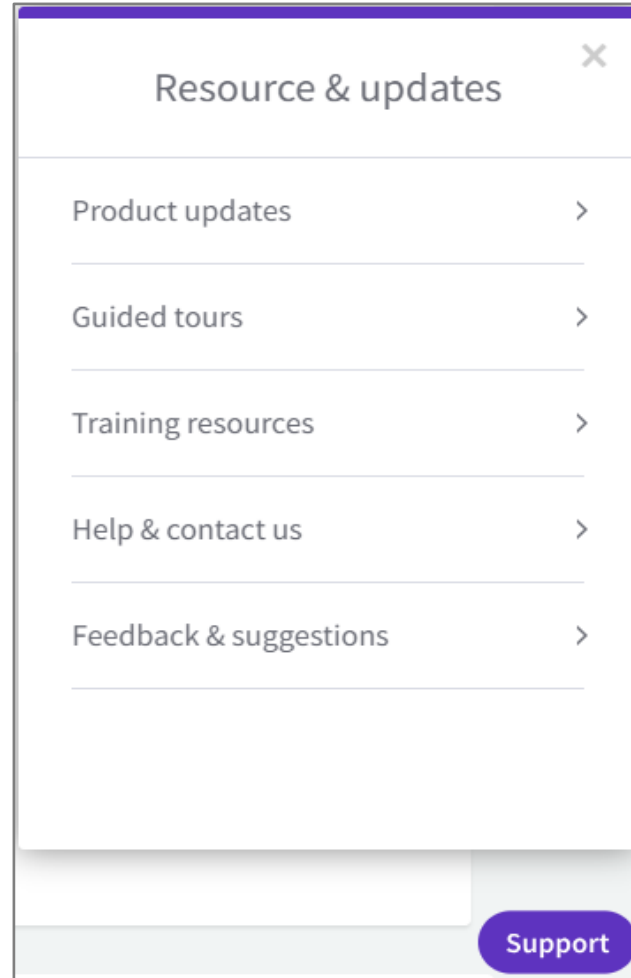
Get assistance with Cortellis

In-product guidance to assist you with your questions

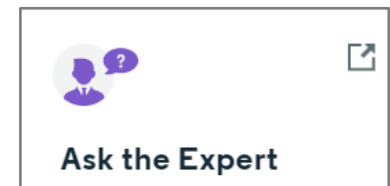
- Click the Support button in the bottom right corner

If not visible, please enable functional cookies under “Manage cookies preferences” at the bottom of the screen.

Manage cookies preferences



- Help & contact us – contact Customer Care
- Guided tours – walk through the Cortellis platform
- Training resources – recorded trainings, Quick guides and short videos
- Ask the Expert (on Regulatory homepage)



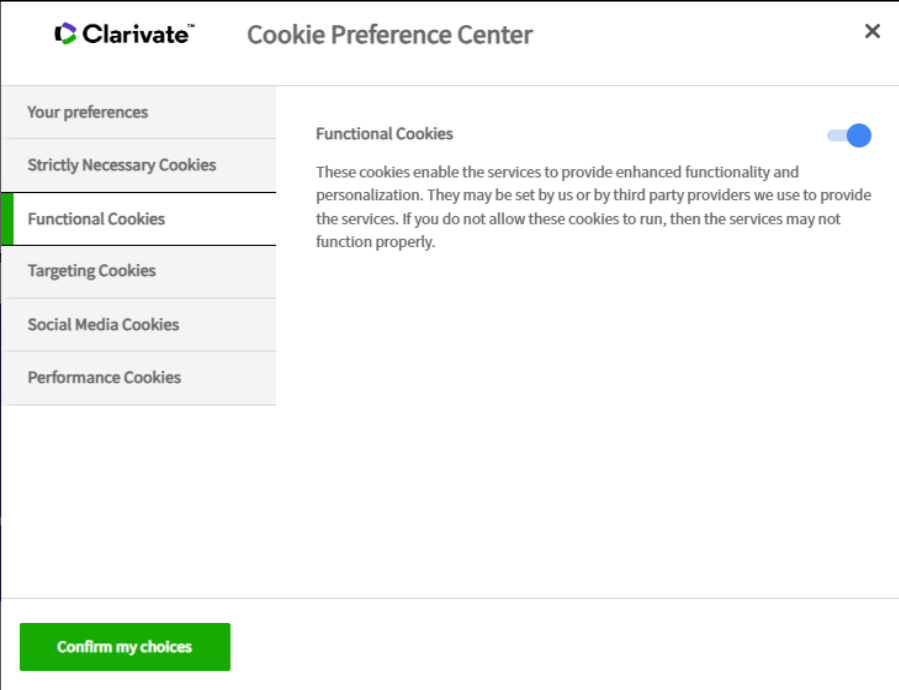
Manage Cookie preferences

Accept cookies to access the Support Center and get more insights

- Functional cookies need to be enabled to view the Support Center and other useful icons in Cortellis.
- We recommend accepting all cookies when you login for the first time or when you login again after clearing cache or cookies.
- Alternatively, scroll down to the bottom of the page in Cortellis and click on '**Manage cookie preferences**'.

Manage cookie preferences

- Once the pop-up Cookies preferences window appears, please click **Functional Cookies** and **activate** them. Then click **Confirm my choices**. You may need to refresh the browser page to make the Support button and additional icons visible.



The screenshot shows the 'Clarivate Cookie Preference Center' window. It has a sidebar on the left with five options: 'Your preferences', 'Strictly Necessary Cookies', 'Functional Cookies' (which is highlighted with a green bar), 'Targeting Cookies', and 'Social Media Cookies'. The main area on the right is titled 'Functional Cookies' and contains a blue toggle switch that is turned on. Below the toggle, there is a paragraph of text explaining that these cookies enable enhanced functionality and personalization, and that they may be set by the user or third-party providers. At the bottom of the window, there is a green button labeled 'Confirm my choices'.

“Research shows that an average learner forgets 70% of what they learned within 24 hours...”



Thank you! Questions?

LSH.support@Clarivate.com

About Clarivate

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