
Clarivate™
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

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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

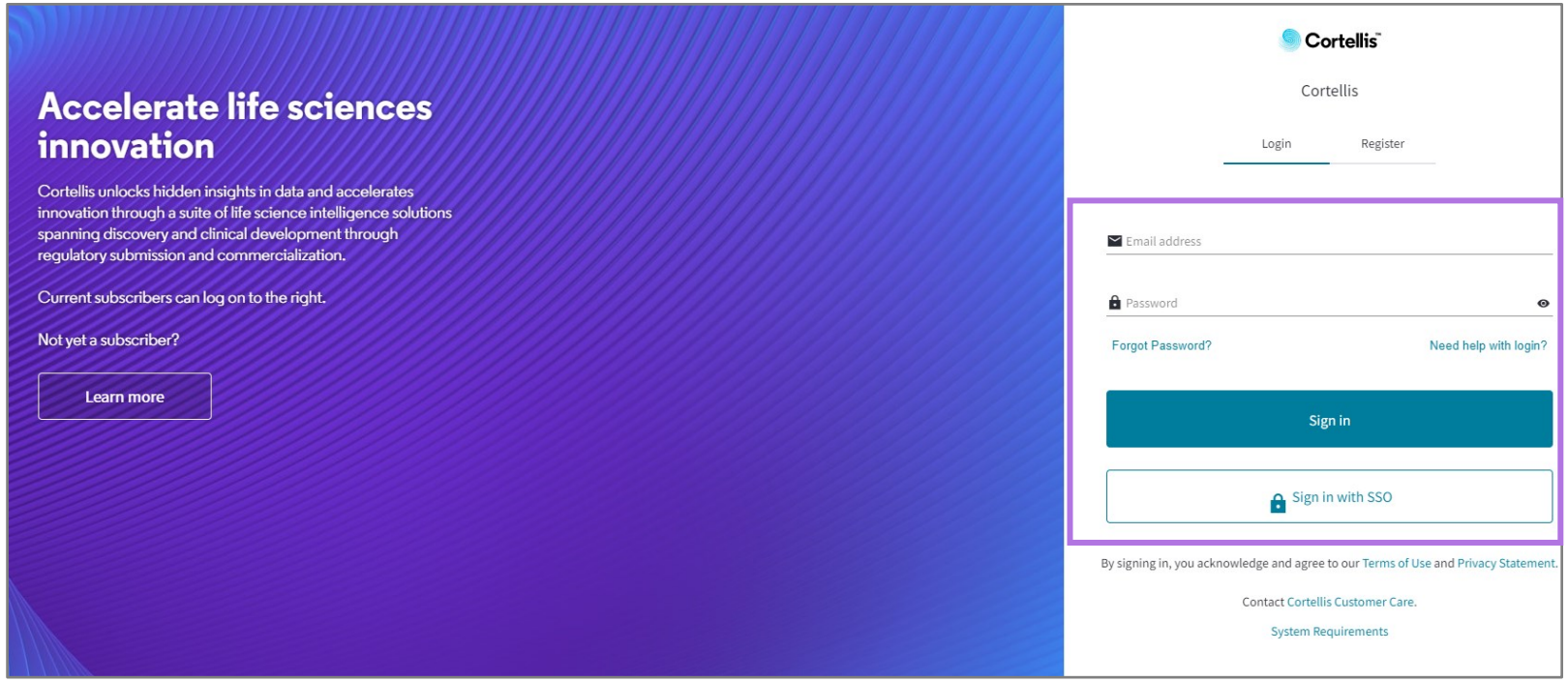
English translations for all native language documents

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

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

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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

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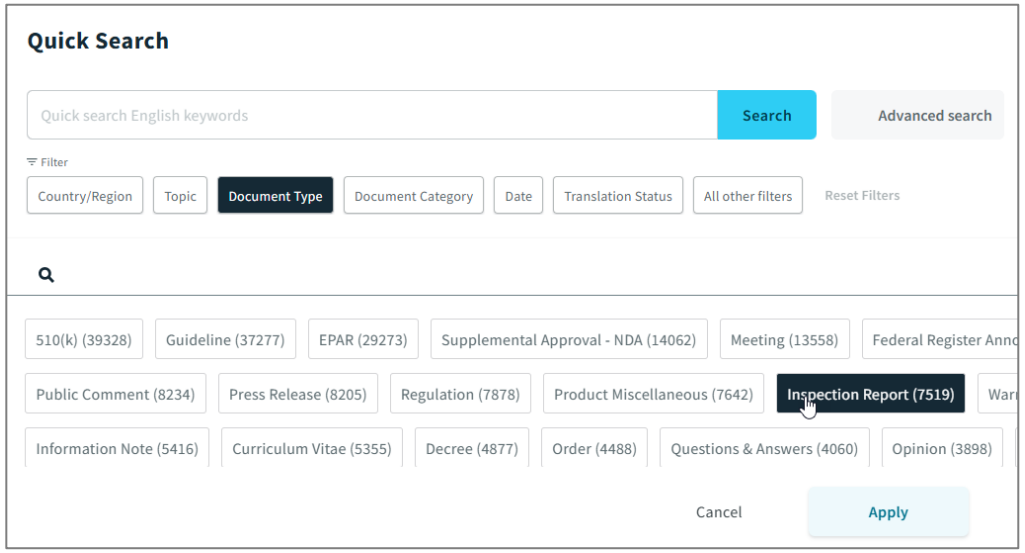
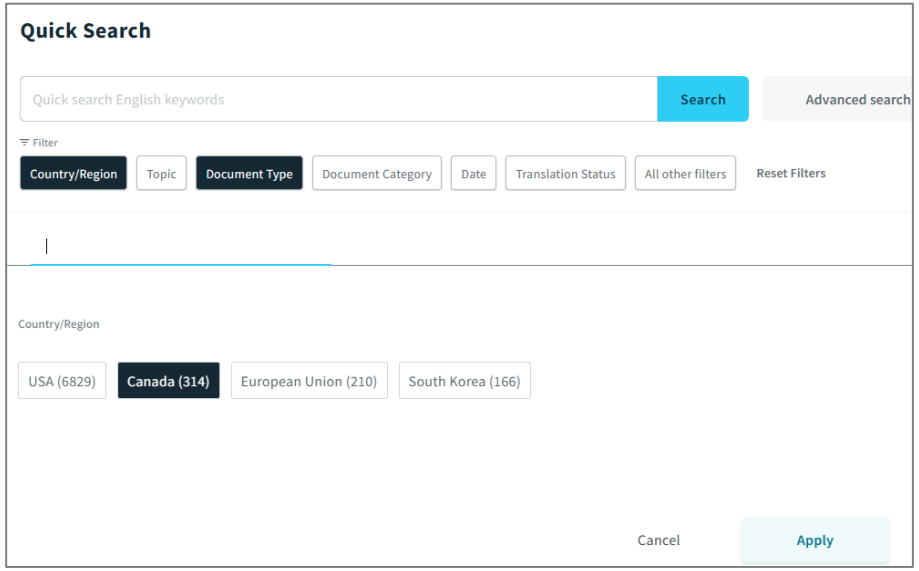
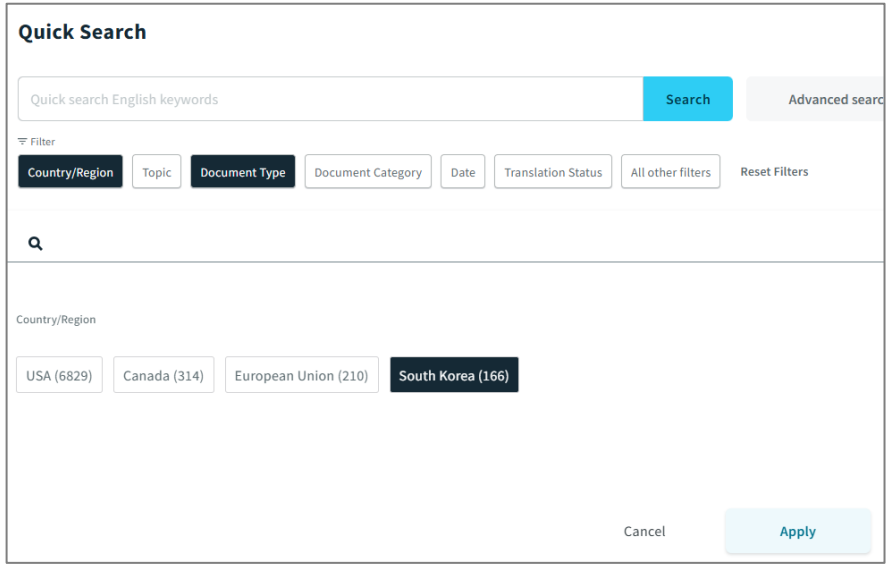
Use Case 1: Quickly locate recent or specific inspection reports

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



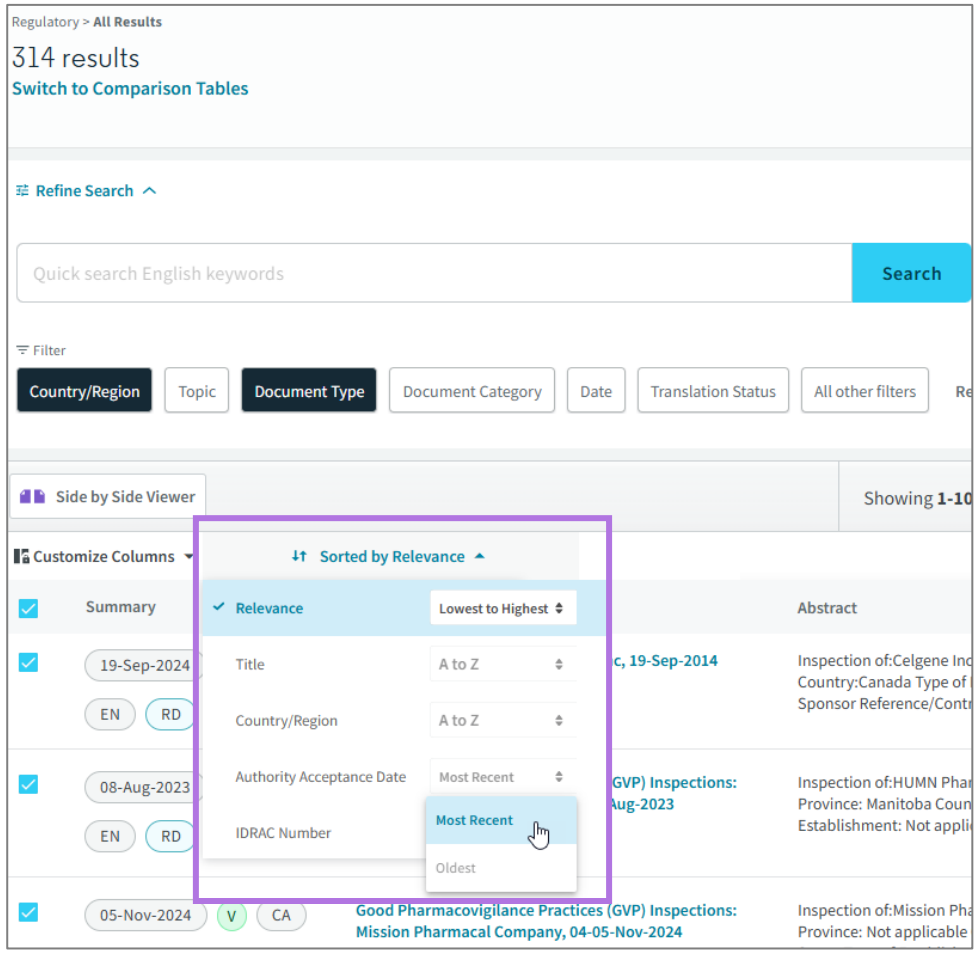
1. In Quick Search click Document Type
2. Select Inspection Report and click Apply
3. Click Country/Region
4. Select country of interest (e. g. Canada) and click Apply
5. Click the blue Search button
6. To change country/region selection: Deselect the chosen country, select another country and click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





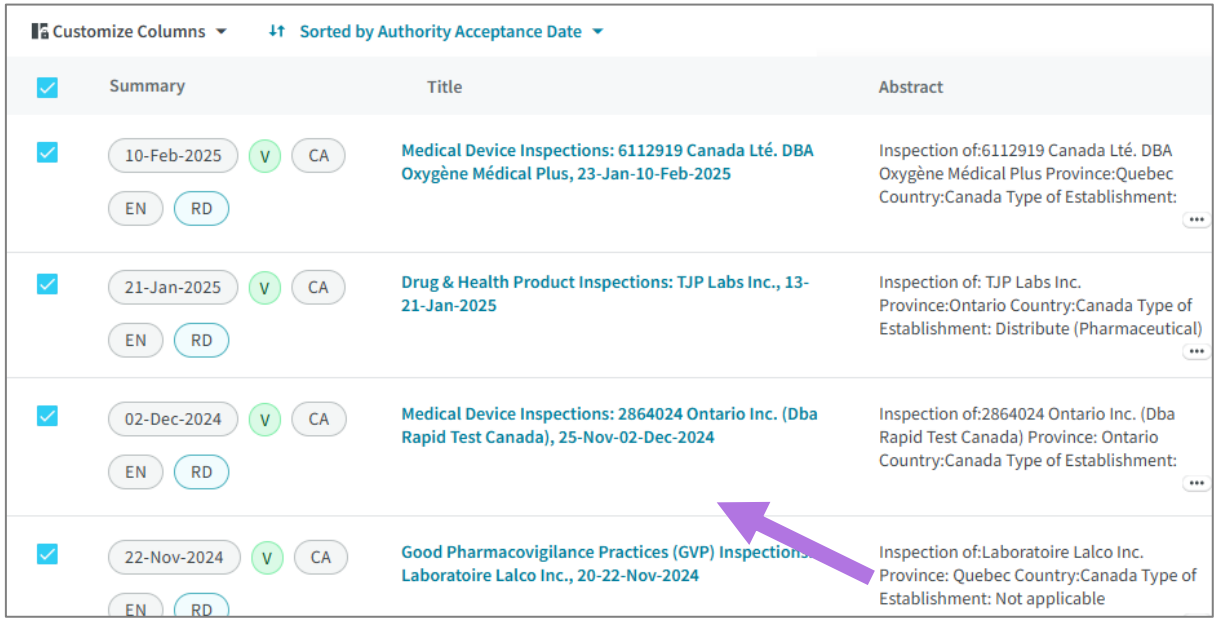
Use Case 1: Quickly locate recent or specific inspection reports

Sorting and viewing documents



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



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**

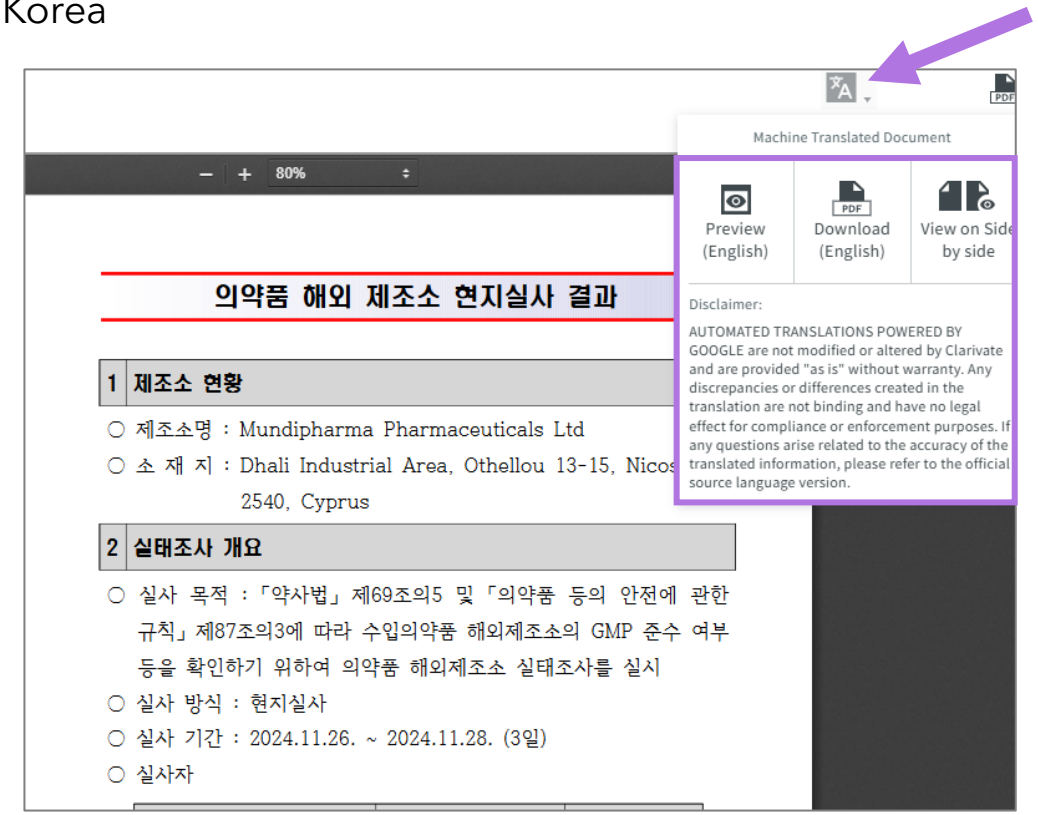
- **Source**: Ministry of Food and Drug Safety
- **Scope**: Inspections conducted at pharmaceutical manufacturing facilities since 2024. South Korea inspections can be on-site or document-based and are aimed at verifying the quality, safety, and efficacy of pharmaceutical products.
- **Volume**: around >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

- **Click HERE** to open a sample document for South Korea



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

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

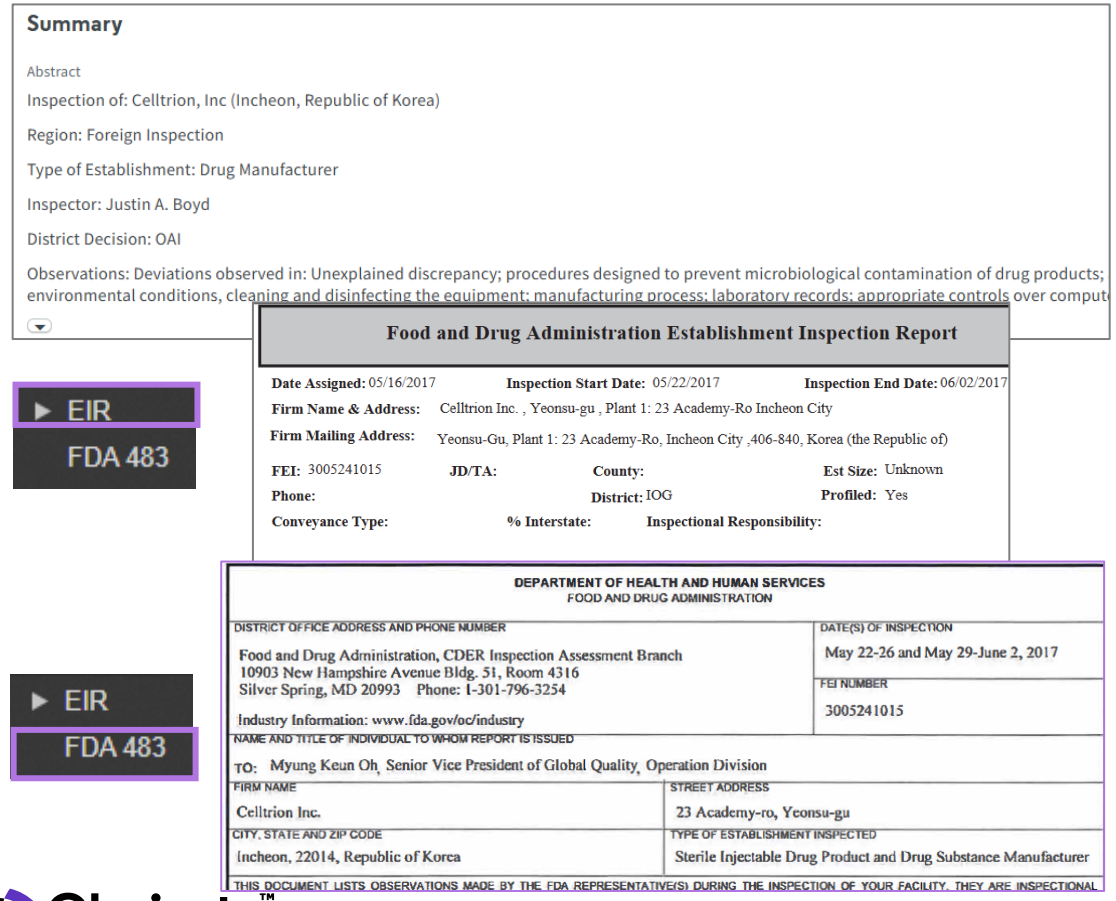
- **FDA Inspection Reports**
- **Source**: U.S. Food ad Drug Administration (FDA)
- **Scope**: FDA forms 483, EIRs (Establishment Inspections Reports) and correspondence requested by Clarivate from the FDA via the FOIA act. Coverage depends on what we receive by the FDA: in average 400 requests per year/300 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



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 comput

EIR

FDA 483

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:**

EIR

FDA 483

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

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

DATE(S) OF INSPECTION: May 22-26 and May 29-June 2, 2017

FEI NUMBER: 3005241015

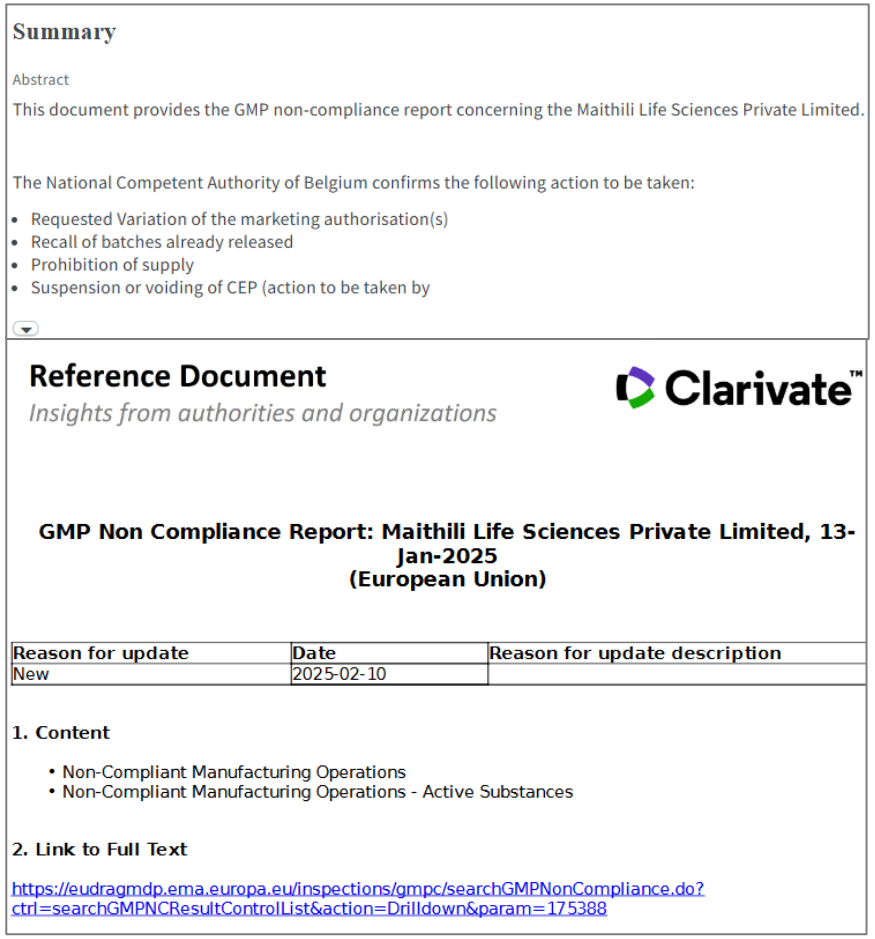
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

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

FIRM NAME	STREET ADDRESS
Celltrion Inc.	23 Academy-ro, Yeonsu-gu
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Incheon, 22014, Republic of Korea	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

- **Click HERE** to open a sample document for the EU



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

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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

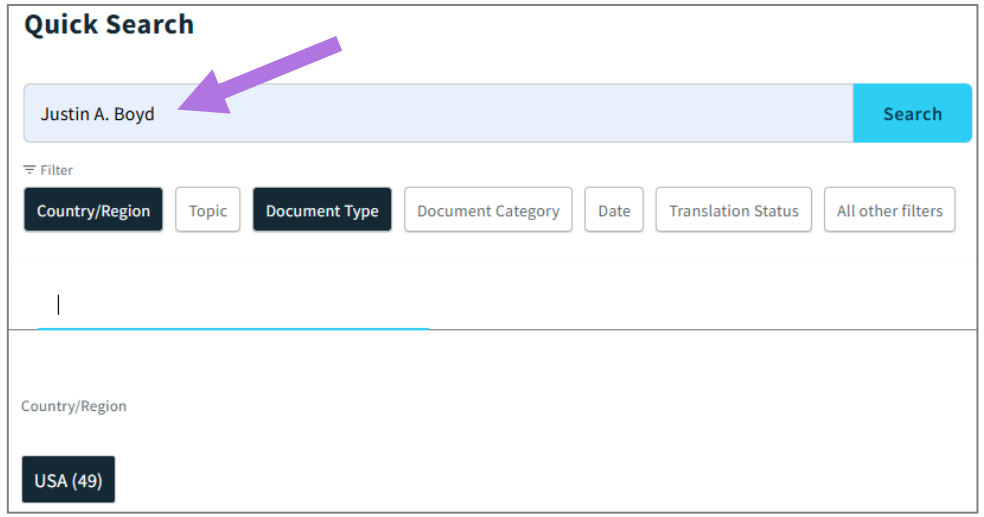
- Non-Compliant Manufacturing Operations
- Non-Compliant Manufacturing Operations - Active Substances

2. Link to Full Text

https://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPNonCompliance.do?ctrl=searchGMPNCResultControlList&action=Drilldown&param=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)



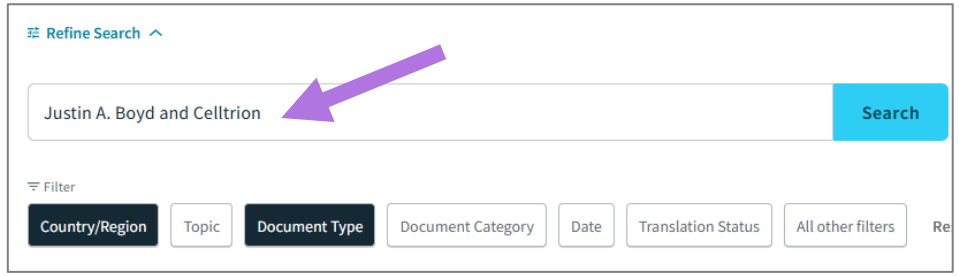
10. Enter inspector name (Example: **Justin A. Boyd**) to retrieve FDA inspections conducted by this inspector (family name might be sufficient)

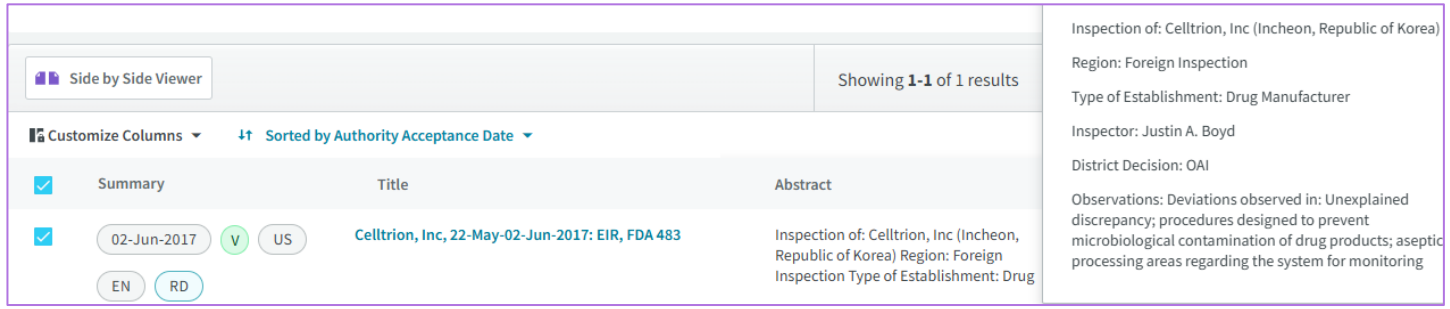
11. Click the blue Search button to view your results

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

Justin A. Boyd **and Celltrion**

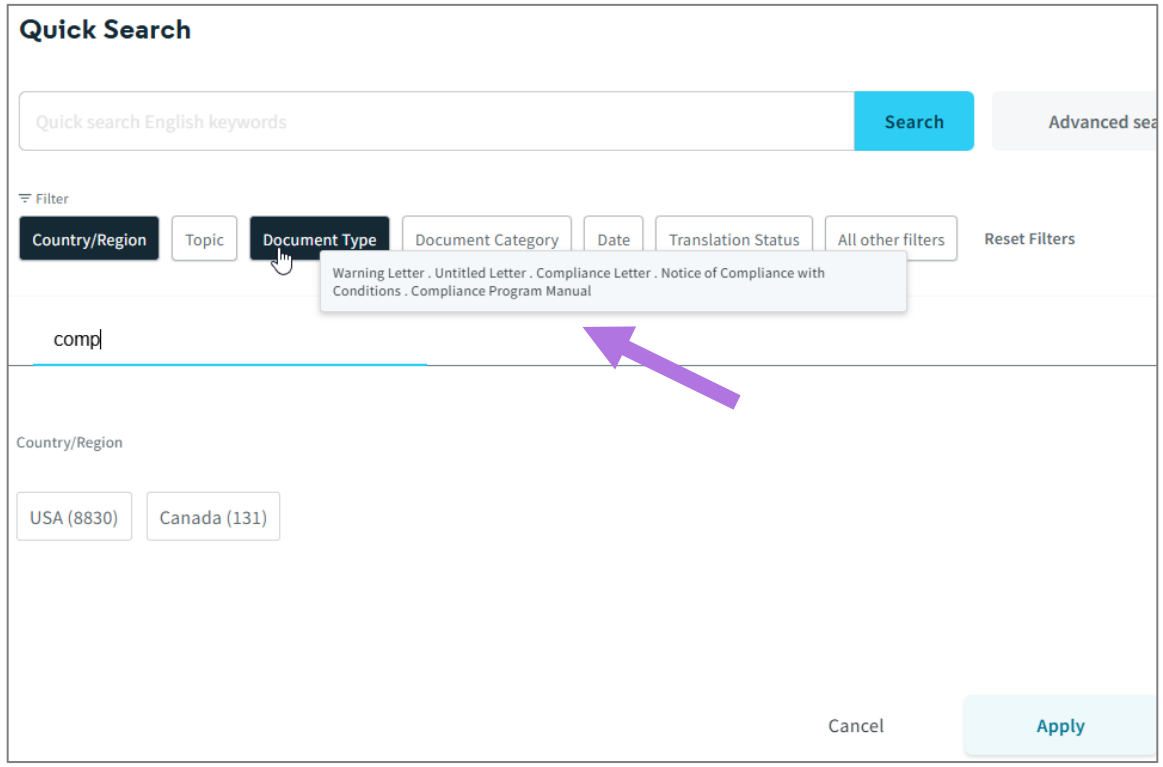
13. Click the blue Search button to update your results



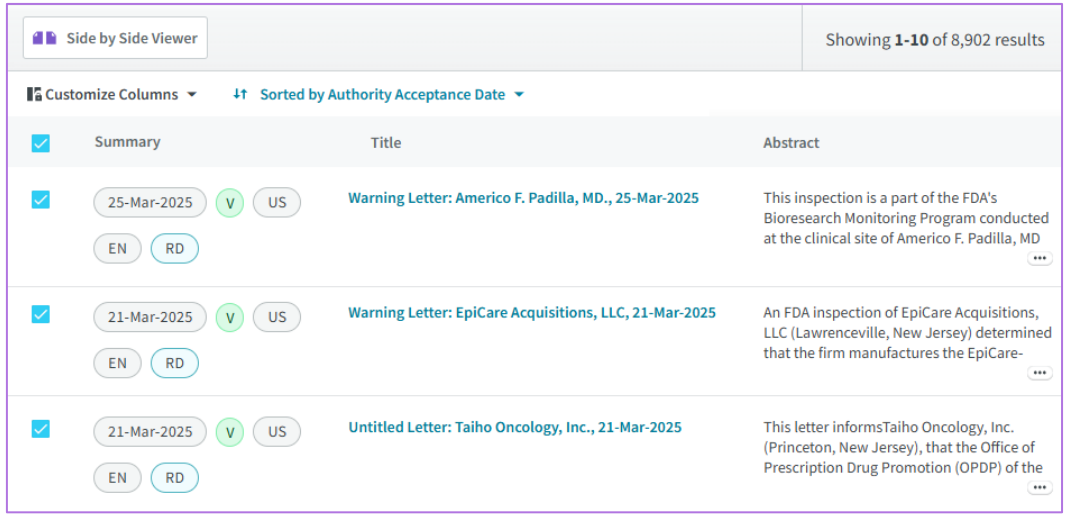


Use Case 1: Quickly locate warning letters and other compliance letters

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



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

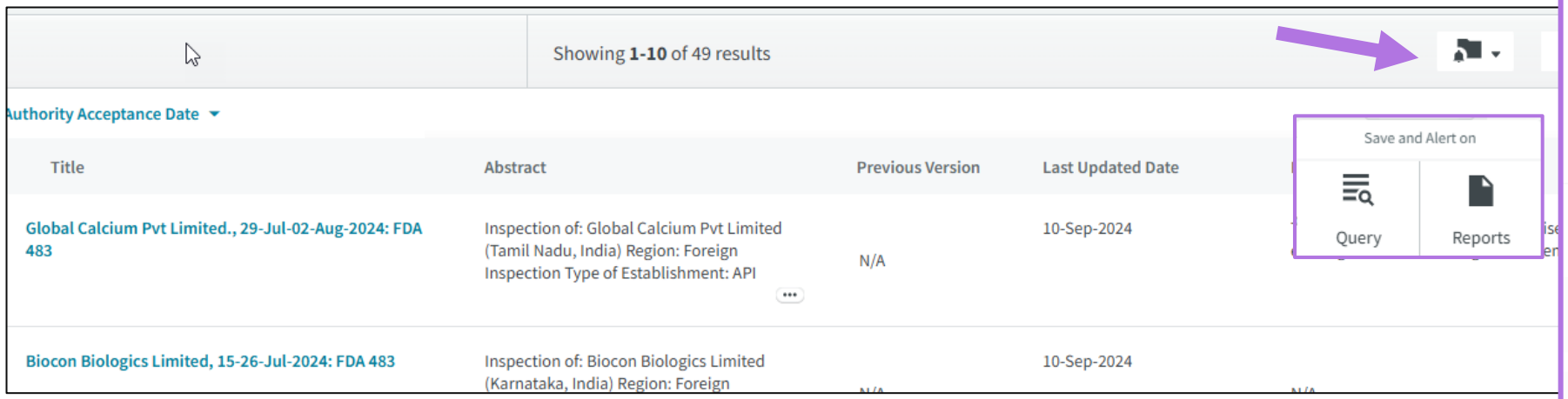


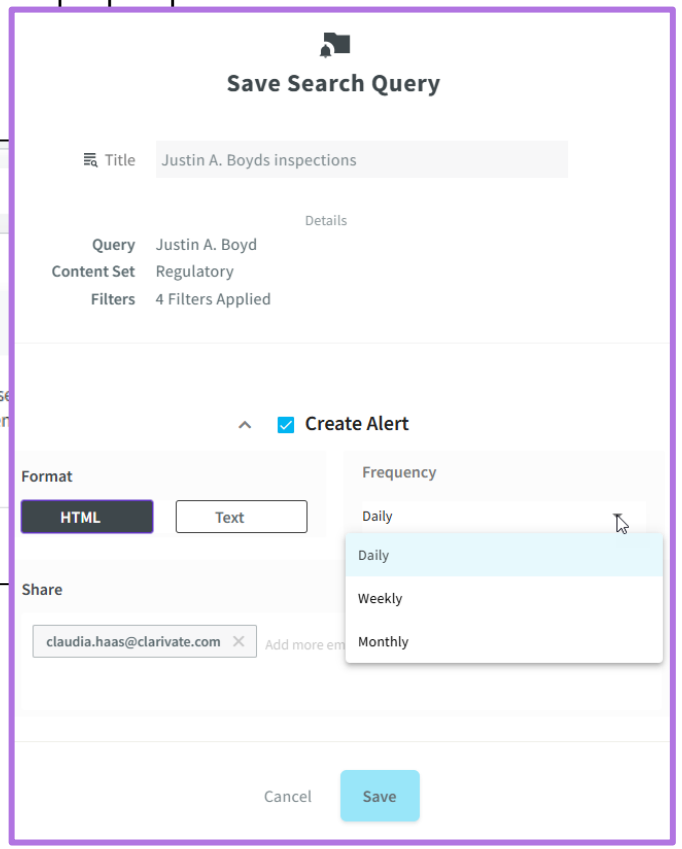
Use Case 1: Quickly locate recent or specific inspection reports

Set up Alerts to ensure you don't miss future inspection/compliance documents

1. On the results list click the Alert bell icon, use Query to get your search monitored and fill in the pop-up form

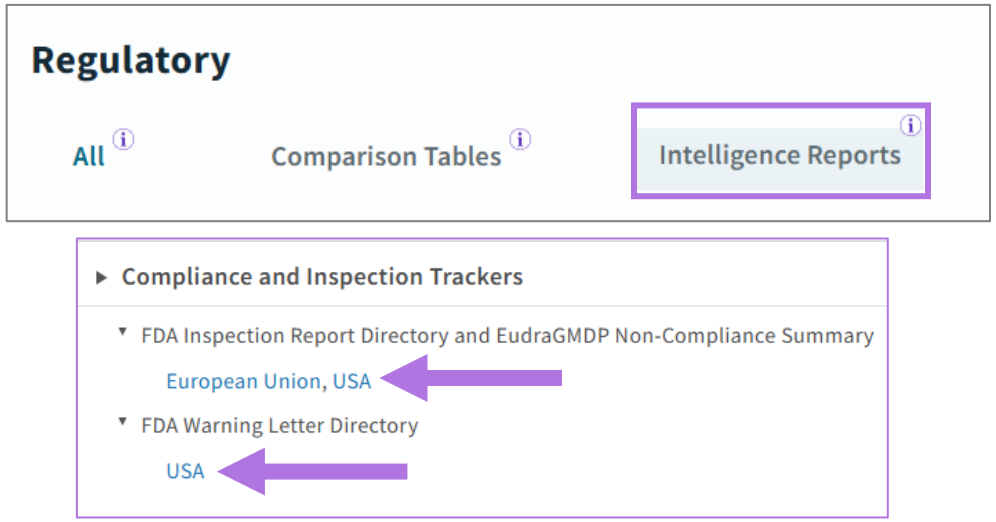
2. Change alert title and settings if desired, then click Save



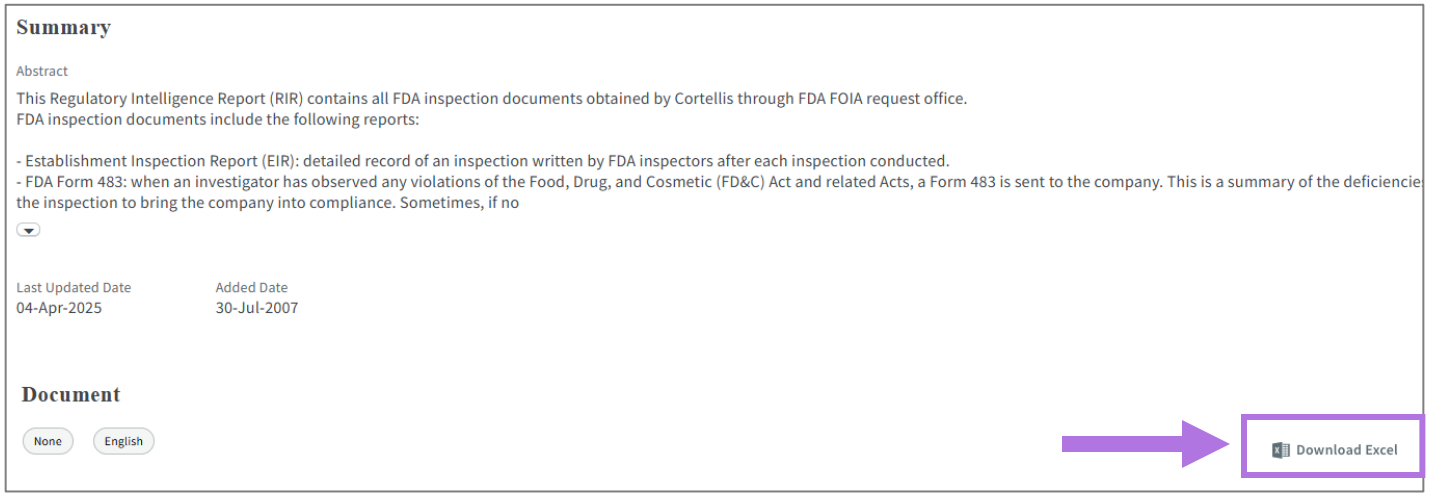


Use Case 2: Better prepare for upcoming inspections and learn from precedence

Consulting the Cortellis Compliance & Inspection Excel Trackers

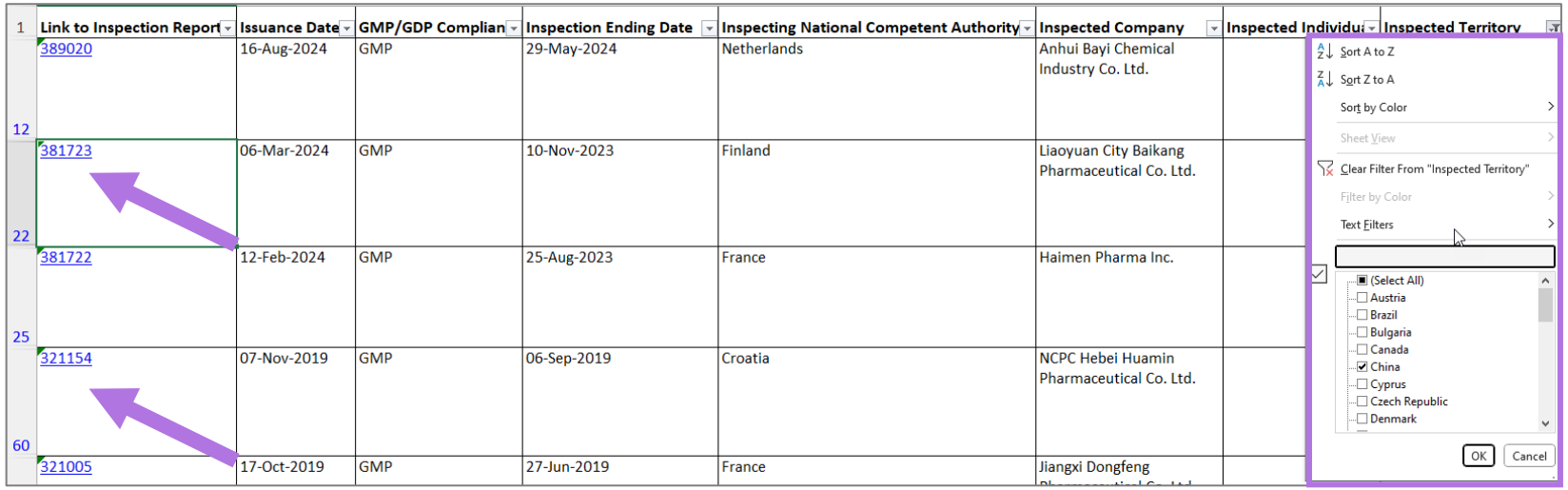


1. Go to Intelligence Reports
2. Scroll down to Compliance and Inspections Trackers listed on the left (drugs & biologics) and right (devices: USA only)
3. Select the desired tracker (inspections or warning letters)
4. Click European Union or USA
5. On the document page scroll down and click Download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

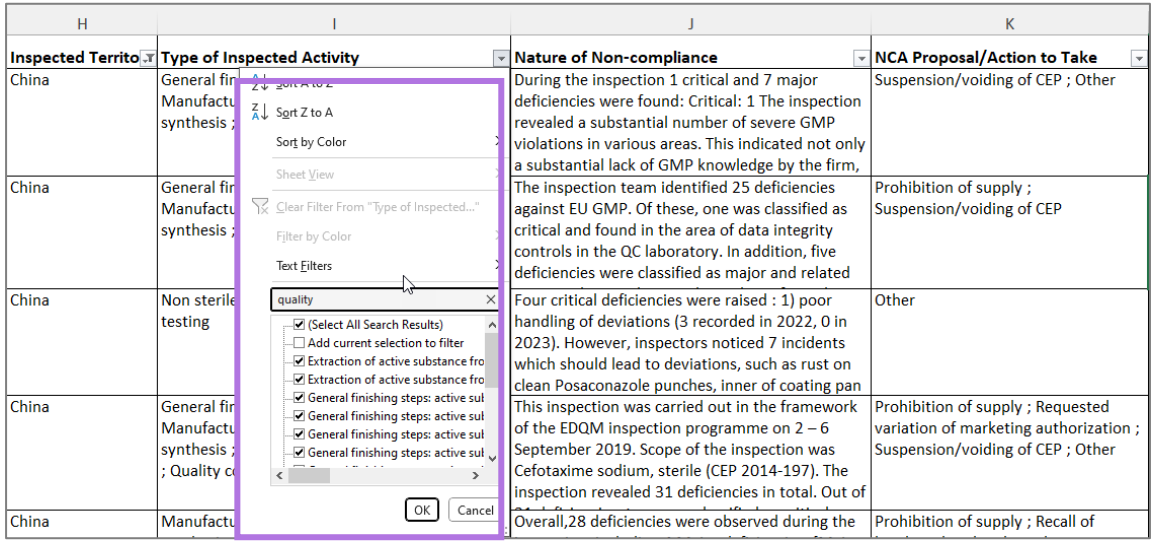


Use Case 2: Better prepare for upcoming inspections and learn from precedence

EU Excel Tracker: EudraGMDP Non-Compliance Summary



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



Inspected Territo	Type of Inspected Activity	Nature of Non-compliance	NCA Proposal/Action to Take
China	General fin Manufactu 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 fin Manufactu 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 fin Manufactu synthesis ; ; Quality c	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	Manufactu	Overall,28 deficiencies were observed during the	Prohibition of supply ; Recall of

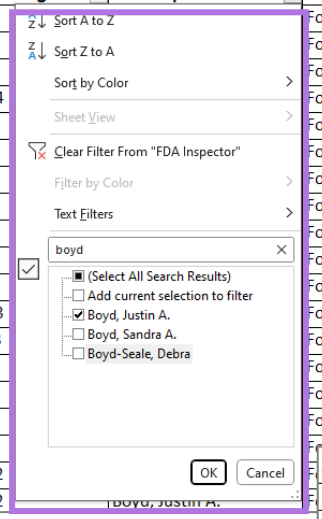
6. Sort and/or apply filters as desired (e.g. date, territory, activity type etc.)

7. Link out to associated inspections reports from column A

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

USA Excel Tracker: FDA Inspection Report Directory

	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		Foreign Inspection	CDER	Biocon Sdn Bhd
96	389555	29-Jul-2024	02-Aug-2024		Foreign Inspection	CDER	Global Calcium Pvt Limited
107	390138	15-Jul-2024	26-Jul-2024		Foreign Inspection	CDER	Biocon Biologics Ltd.
173	383774	25-Apr-2024	03-May-2024		Foreign Inspection	CDER	Eugia Pharma Specialities Ltd.
184	383132	15-Apr-2024	23-Apr-2024		Foreign Inspection	CDER	Zydus Lifesciences Ltd.
291	378888	22-Jan-2024	02-Feb-2024		Foreign Inspection	CDER	Eugia Pharma Specialities Ltd.
303	387796	15-Jan-2024	19-Jan-2024		Foreign Inspection	CDER	Brassica Pharma Pvt. Ltd.
382	375295	12-Oct-2023	20-Oct-2023		Foreign Inspection	CDER	Kilitch Healthcare India Ltd
391	373169	03-Oct-2023	12-Oct-2023		Foreign Inspection	CDER	Panacea Biotec Pharma Ltd.
394	395689	03-Oct-2023	10-Oct-2023		Foreign Inspection	CDER	Fresenius Kabi Oncology Limited
464	402531	07-Aug-2023	15-Aug-2023		Foreign Inspection	CDER	Amman Pharmaceutical Industries
533	367441	01-May-2023	12-May-2023		Foreign Inspection	CDER	Intas Pharmaceuticals Ltd.
606	394819	06-Mar-2023	14-Mar-2023		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 Pharmaceuticals 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				



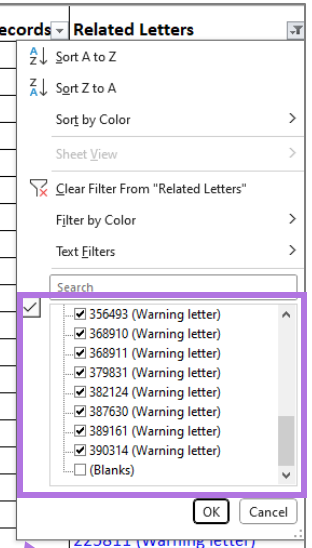
6. Sort and/or apply filters as desired (e.g. date, inspector, company, country/region, inspection, available records etc.)

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/Regio	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	
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	Drug quality assurance	Official action indicated	Not available	483	
Jordan	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	Drug quality assurance	Official action indicated	Not available	483	
India	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	483	
India	Drug manufacturer	Drug quality assurance	Not available	Not available	483	
South Korea	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	EIR ; 483	
Germany	API manufacturer	Drug quality assurance	Official action indicated	Not available	483	
Japan	API manufacturer	Drug quality assurance	Official action indicated	Not available	483	
Japan	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	483	
Hungary	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	483	
Italy	Drug manufacturer	Drug quality assurance	Official action indicated	Not available	483	
United Kingdom	API manufacturer	Drug quality assurance	Official action indicated	Not available	483	
Italy	API manufacturer	Compliance: devices	Official action indicated	Not available	483	
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	217894 (Warning letter)
Italy	Drug manufacturer	Drug quality assurance	Not available	Not available	483	211114 (Warning letter)



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

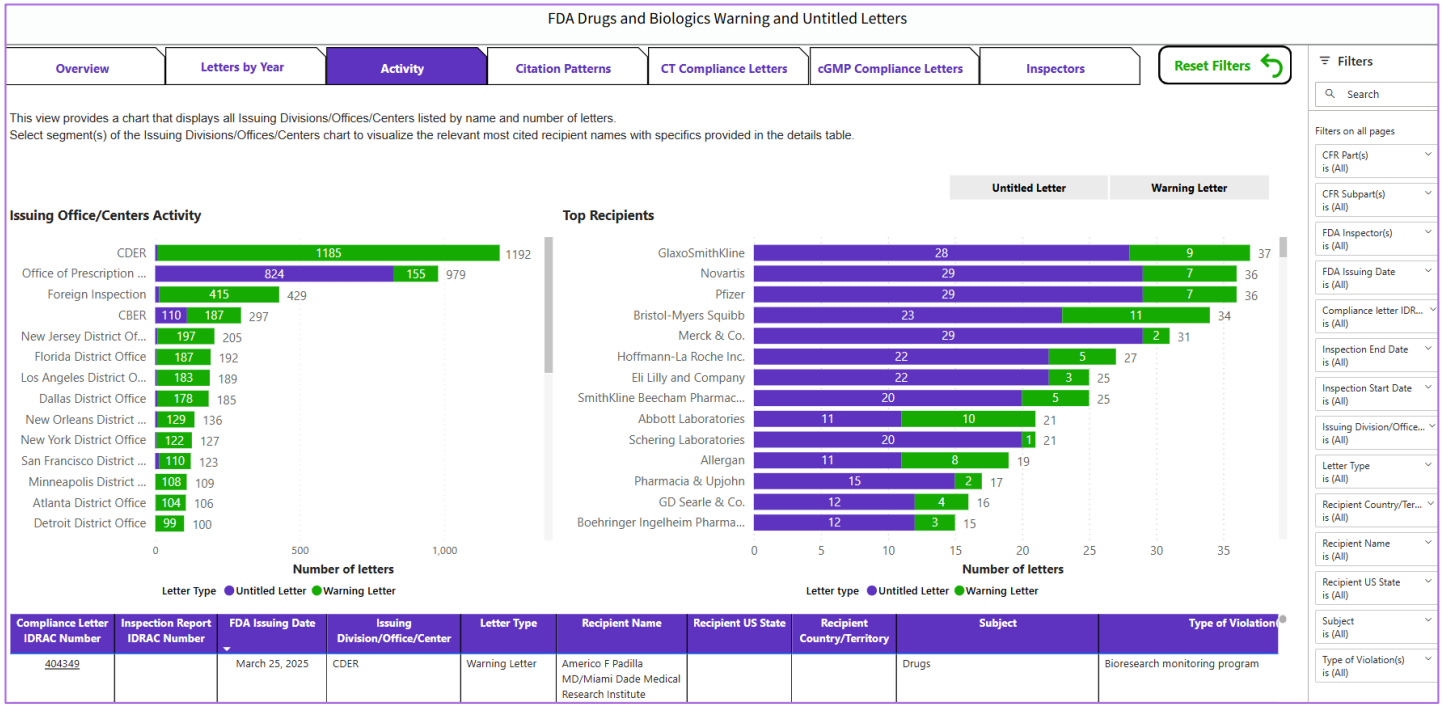
3. To quickly find recent or specific FDA inspections or warning letters you
   - Use Quick Search
   - Consult the trackers
   - Both options will work

Clarivate™

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

Gain deeper insights, make informed decisions

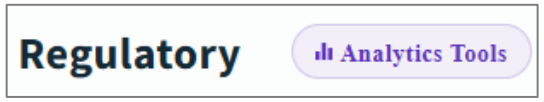
- Quickly draw conclusions from the data with easy-to-use analytics and save time preparing for FDA inspections
- Easily pinpoint Warning and Untitled Letters by inspector, citation, date, recipient, type, location, and more.
- Hyperlinks to original compliance letters and inspection reports
- Understand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



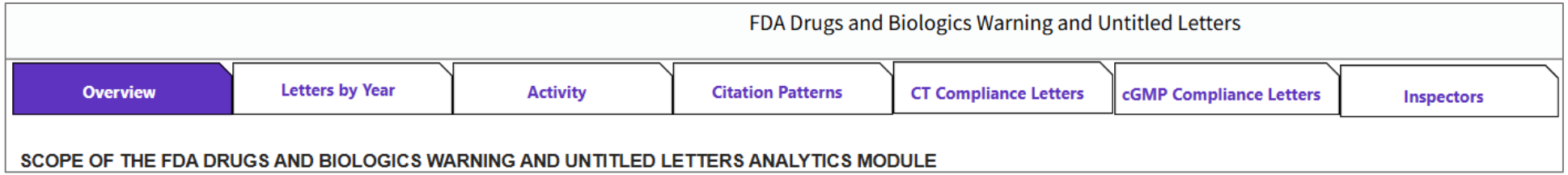
** Please note: Cortellis FDA Analytics are add-on modules, Access depends on your subscription.*

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

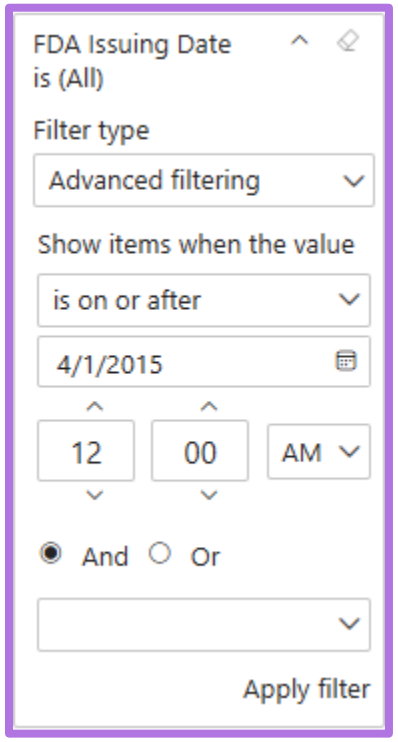


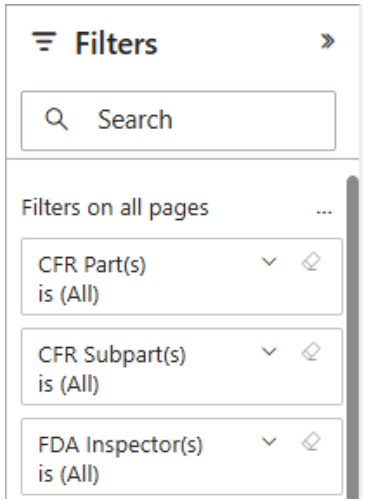
** Please note: Cortellis FDA Analytics are add-on modules, Access depends on your subscription.*

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

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

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





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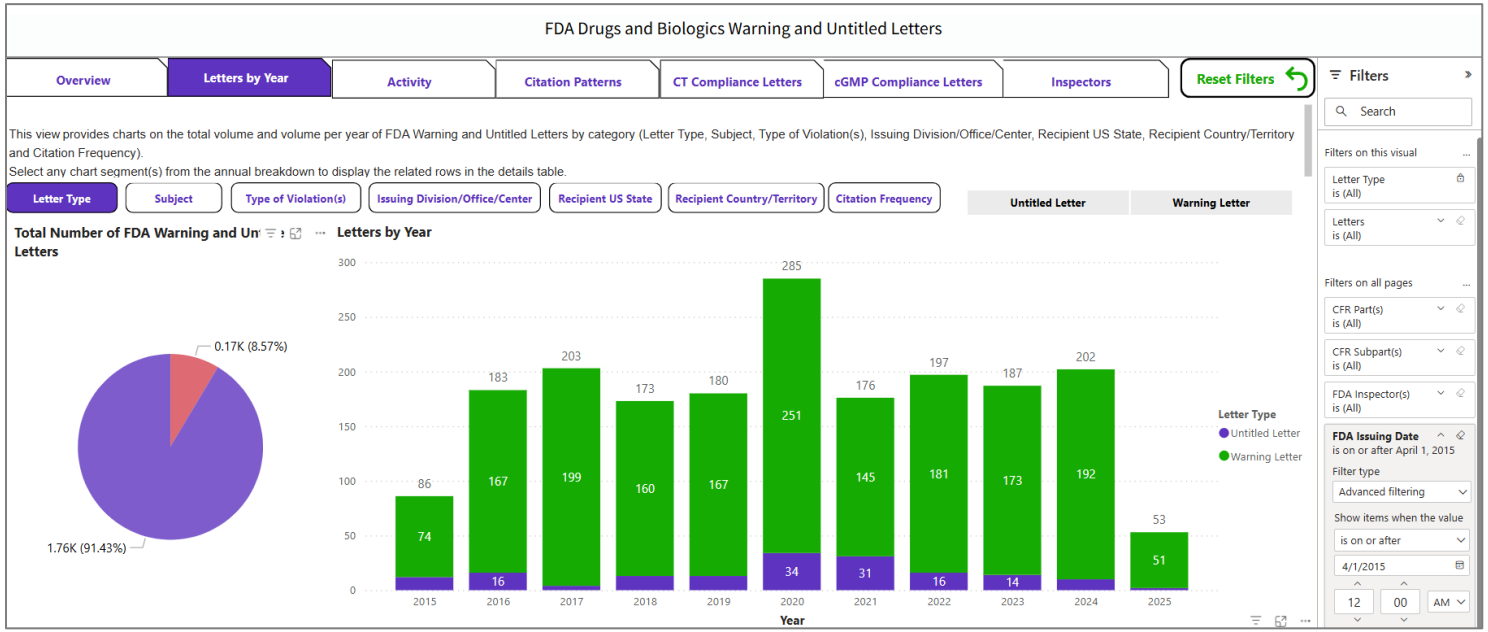
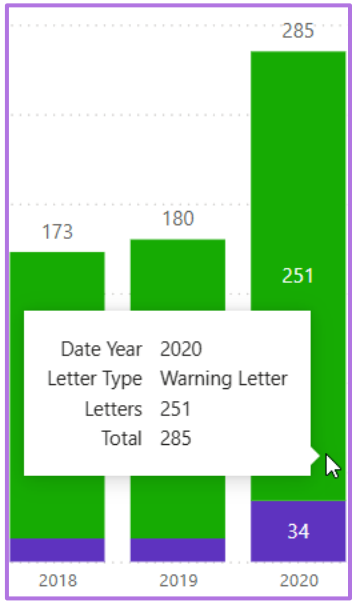
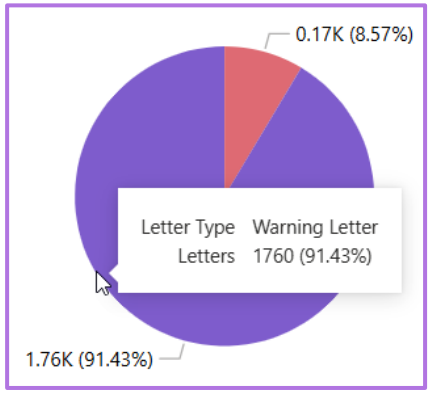
Use Case 3: Cortellis FDA Warning & Untitled letters Analytics (Drugs & Biologics)*

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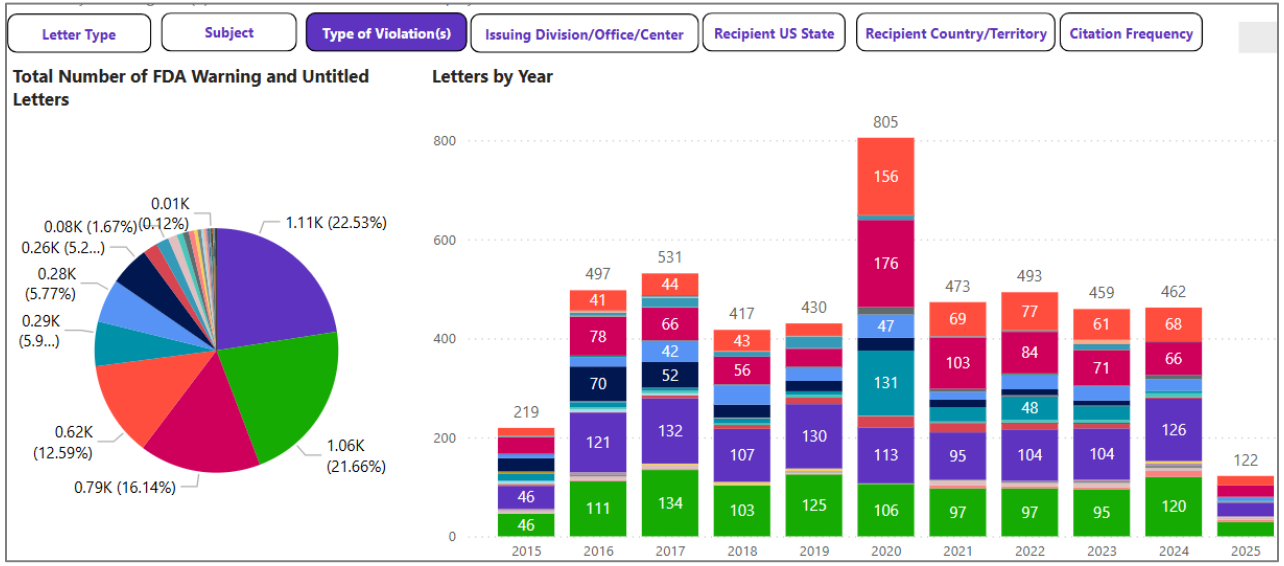
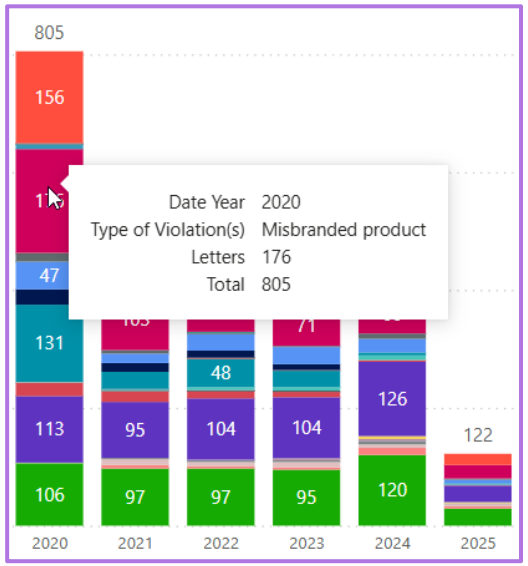
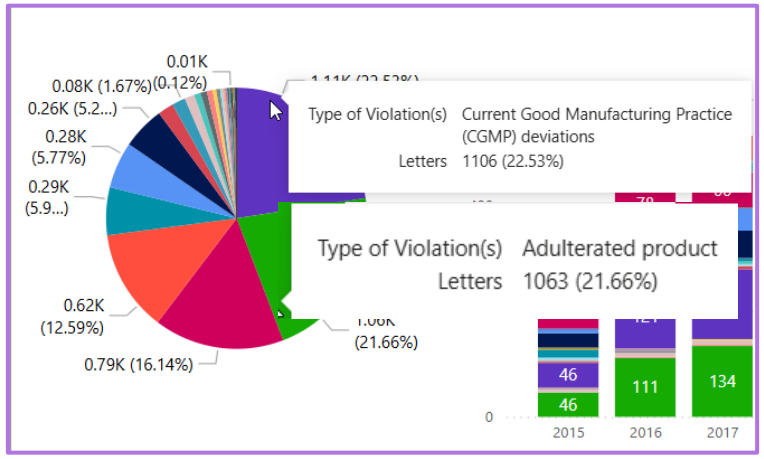
Use Case 3: Cortellis FDA Warning & Untitled letters Analytics (Drugs & Biologics)*

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

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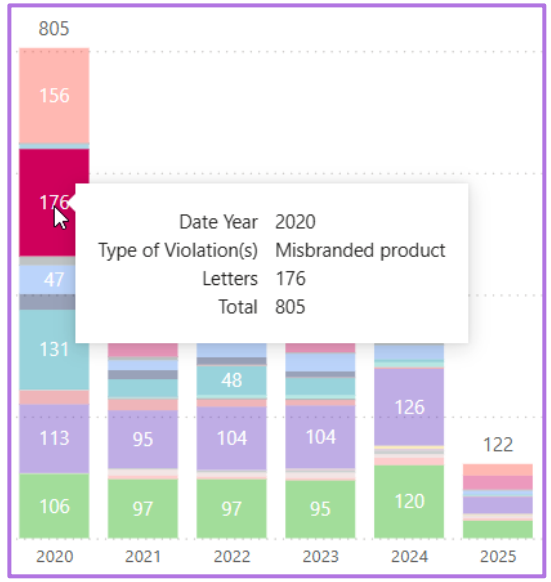
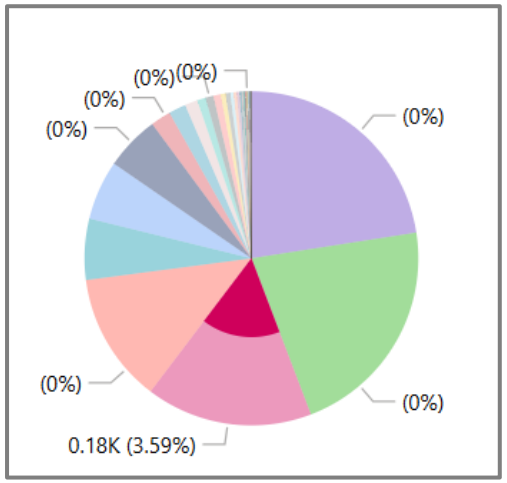
Use Case 3: Cortellis FDA Warning & Untitled letters Analytics (Drugs & Biologics)*

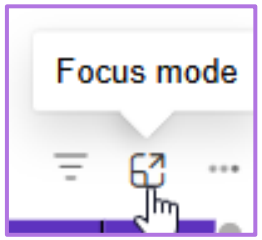
Example: What violations are most prevalent in the compliance letters? What were the main concerns of the FDA?





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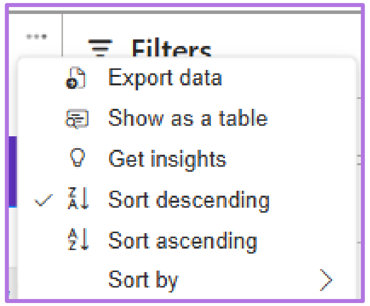
Use Case 3: Cortellis FDA Warning & Untitled letters Analytics (Drugs & Biologics)*

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.*

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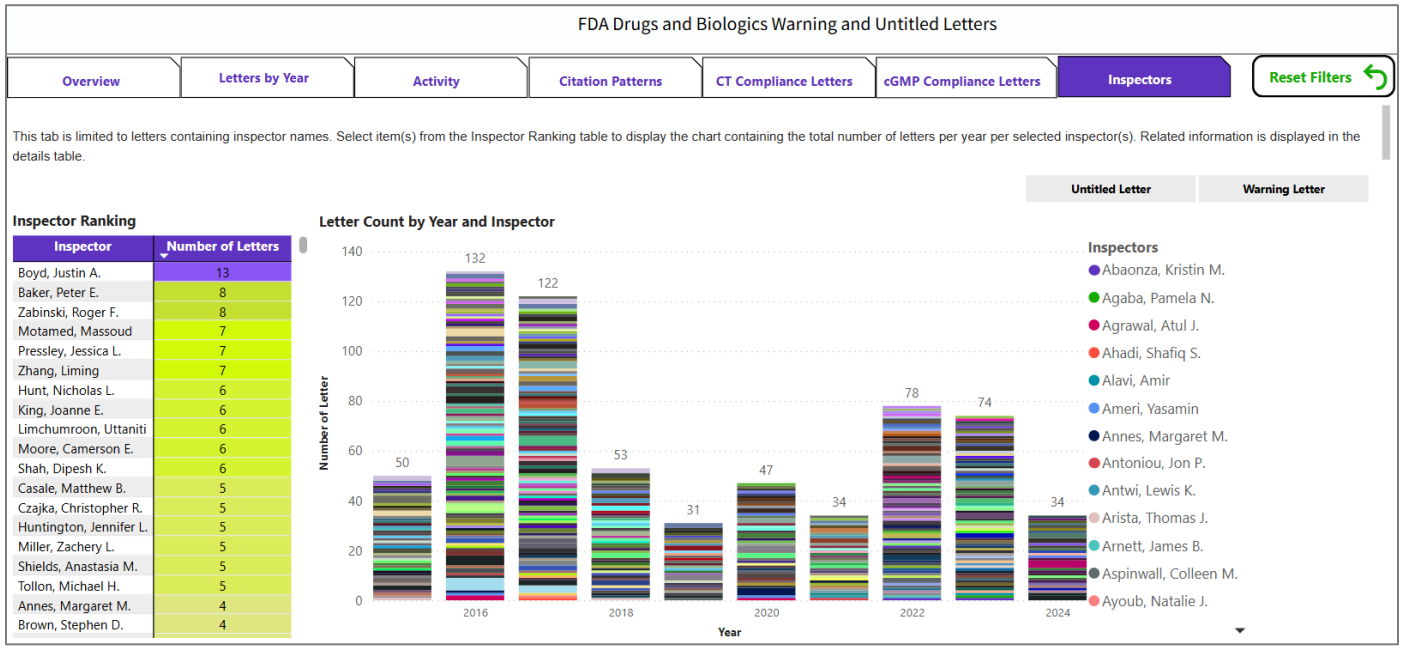
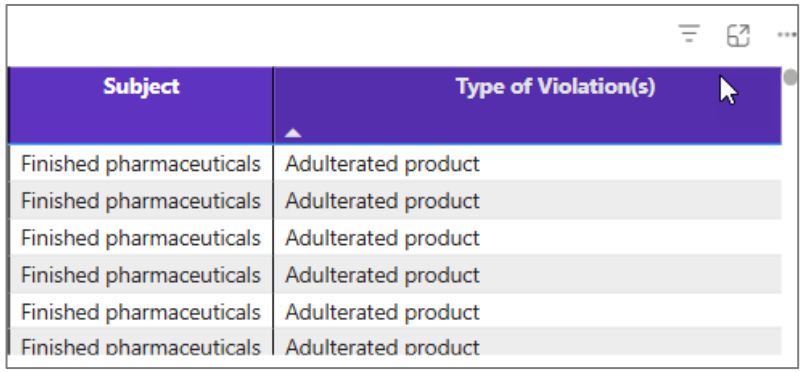
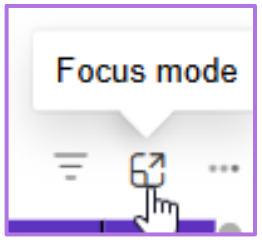
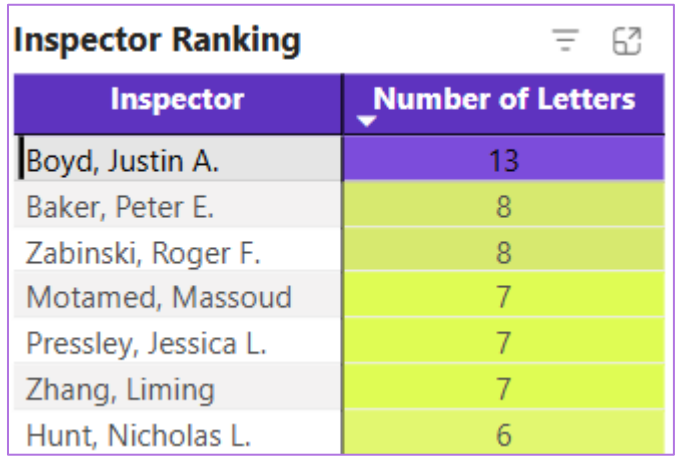
Use Case 3: Cortellis FDA Warning & Untitled letters Analytics (Drugs & Biologics)*

Example: What are inspectors citing in their compliance letters?









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

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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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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**.

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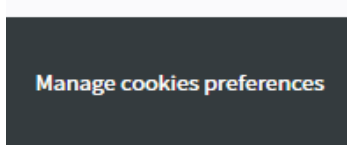
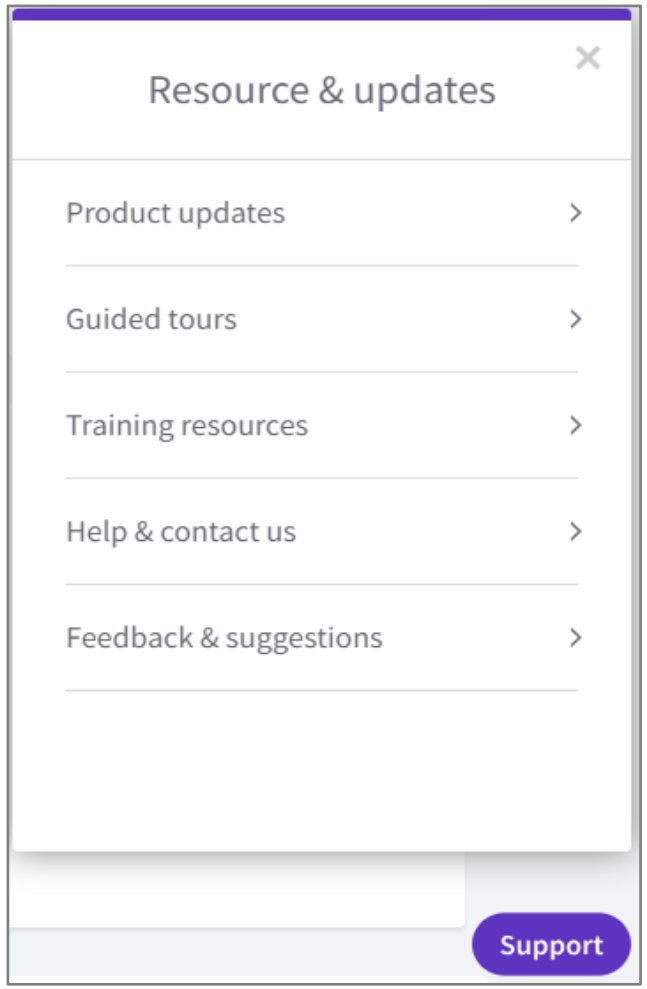
Get assistance with Cortellis

In-product guidance to assist you with your questions

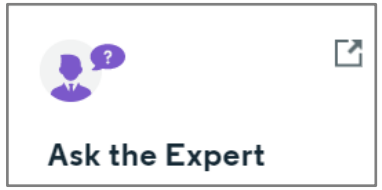
- Click the Support button in the bottom right corner

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





- 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)



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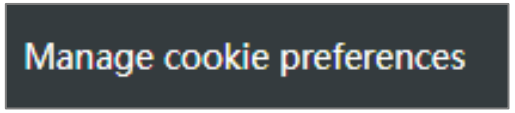
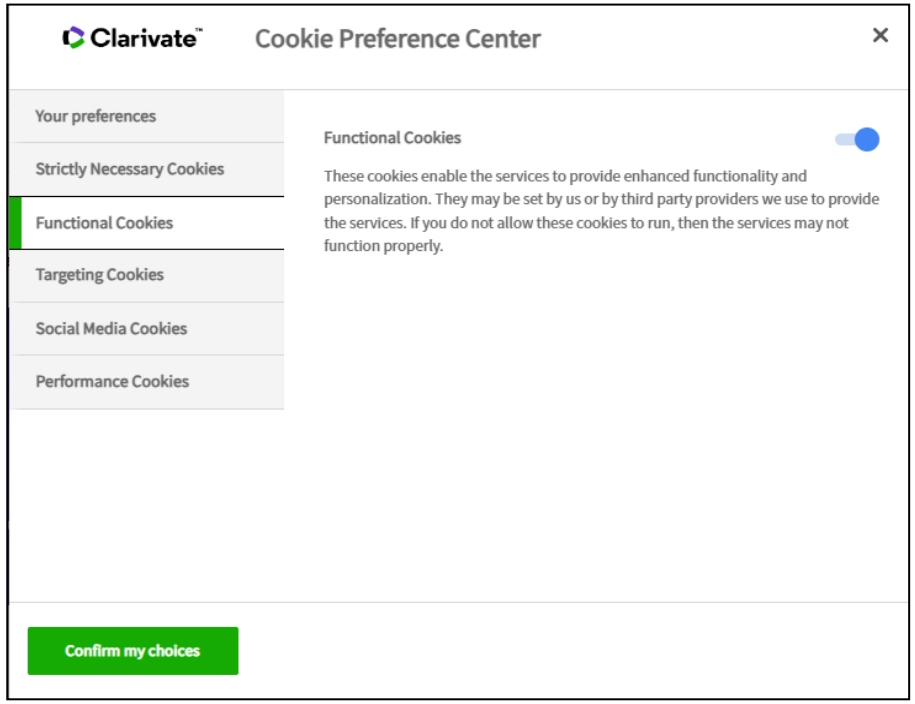
- We recommend accepting all cookies when you login for the first time or when you login again after clearing cache or cookies.

- Alternatively, scroll down to the bottom of the page in Cortellis and click on '**Manage cookie preferences**'.



- 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.



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

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About Clarivate

Clarivate is the leading global information services provider. We connect people and organizations to intelligence they can trust to transform their perspective, their work and our world. Our subscription and technology-based solutions are coupled with deep domain expertise and cover the areas of Academia & Government, Life Sciences & Healthcare and Intellectual Property. For more information, please visit clarivate.com