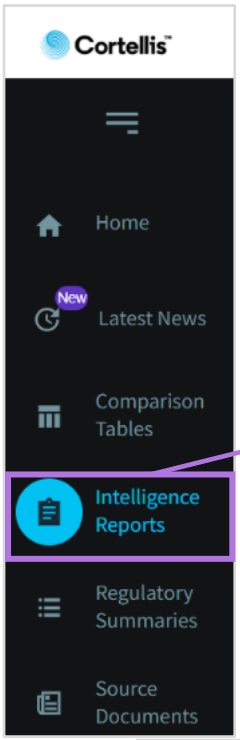
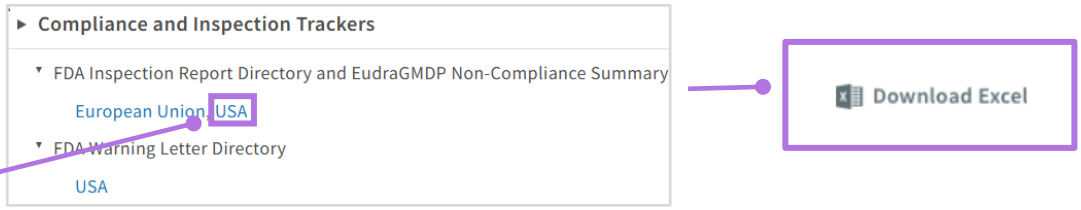
Finding FDA Inspection Documents – EIR's and 483's

This guide shows how use the FDA Inspector's Table and Quick Search to find FDA Inspection Documents. Cortellis also has inspection documents from the EU, Canada and South Korea.

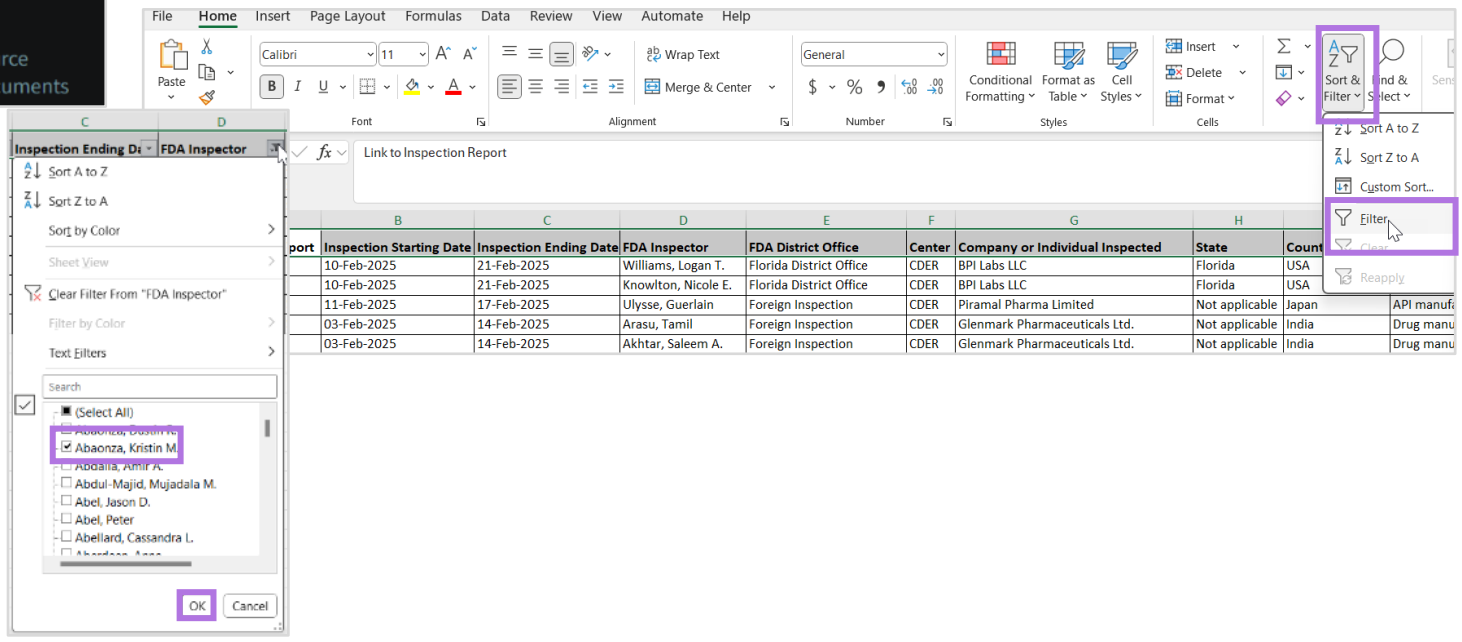
Example: Find Inspection documents for an inspector using the FDA Inspector's Table.



1. From the left-hand **Navigation bar** in Cortellis Regulatory Intelligence select **Intelligence Reports**
2. Scroll down the page to **Compliance and Inspection Trackers** and **select USA** under FDA Inspection Report Directory
3. Once the report is open you can read about the scope of inspection document coverage for the USA in the Abstract
4. Click the **Download Excel** icon underneath the abstract to open the attached Excel table



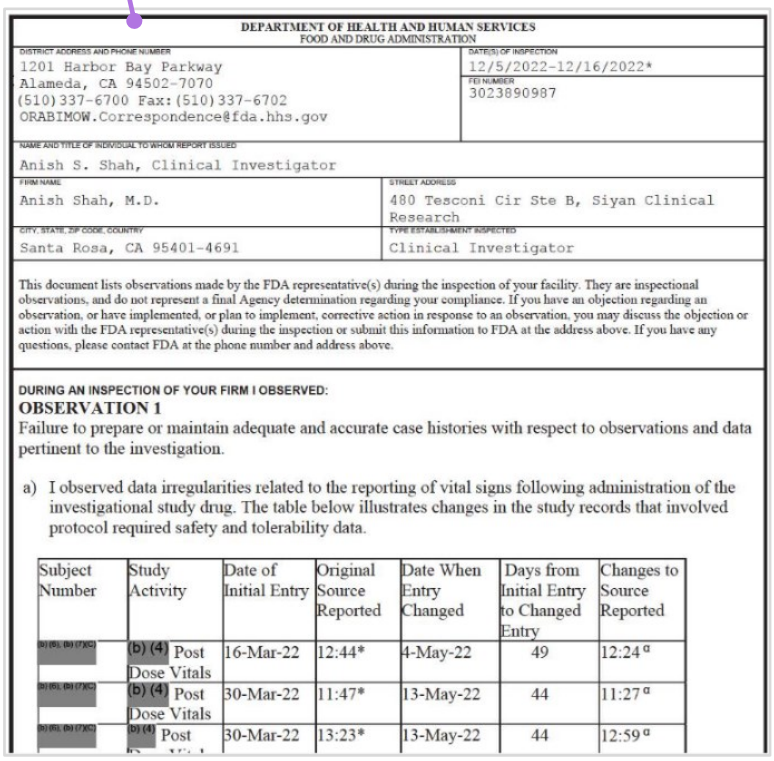
5. In the downloaded table **select the top row** and **Sort & Filter** in the Excel tool bar. You can now filter on any of the criteria in the headings across the top.
6. To filter by Inspector, **sort by column D, FDA Inspector and select the desired inspector's name**. Let's choose Kirsten M. Abaonza. Click OK.



7. You now have a table filtered to only include data and links to inspection documents for your inspector.
8. Click the links under **Link to Inspection Report in Column A to open 483, EIR reports and correspondence** and click the links under **Related Letters in Column O to open Warning and Untitled Letters**.

	A	B	C	D	E	F	G
1	Link to Inspection Report	Inspection Starting Da	Inspection Ending Da	FDA Inspector	FDA District Office	Cente	Company or Individual Inspect
685	380150	05-Dec-2022	16-Dec-2022	Abaonza, Kristin M.	San Francisco District	CDER	Shah, Anish, MD
1310	388406	29-Nov-2021	13-Dec-2021	Abaonza, Kristin M.	San Francisco District	CDER	Goodman, Daniel Fred, MD
1829	329555	24-Aug-2020	02-Sep-2020	Abaonza, Kristin M.	San Francisco District	CDER	Norman, Daniel, MD
2057	319999	29-Jan-2020	04-Feb-2020	Abaonza, Kristin M.	San Francisco District	CDER	Aazami, Hessam, MD
2474	307402	09-Apr-2019	16-Apr-2019	Abaonza, Kristin M.	Seattle District Office	CDER	Geneva Woods Pharmacy
2508	301602	11-Mar-2019	20-Mar-2019	Abaonza, Kristin M.	San Francisco District	CDER	MOM Enterprises Inc.
2667	286760	04-Sep-2018	14-Sep-2018	Abaonza, Kristin M.	San Francisco District	CDER	White House Pharmacy Inc.
3207	257772	17-Jul-2017	19-Jul-2017	Abaonza, Kristin M.	San Francisco District	CDER	One Way Drug
4006	226435	18-Mar-2016	29-Mar-2016	Abaonza, Kristin M.	San Francisco District	CDER	Reliable Rexall-A Compounding

	H	I	J	K	L	M	N	O
	State	Country/Regio	Type of Establishment Inspected	Project Area	District Decision	Inspection Type	Available Recor	Related Lette
	California	USA	Clinical investigator	Bioresearch	Official action indicated	Not available	483	376565
	California	USA	Clinical investigator ; Sponsor	Bioresearch	Official action indicated	Not available	483	350743
	California	USA	Clinical investigator	Bioresearch	Voluntary action indicated	Not available	483	
	California	USA	Clinical investigator	Bioresearch	Voluntary action indicated	Not available	483	
	Alaska	USA	Compounding pharmacy	Drug quality assurance	Voluntary action indicated	Not available	483	
	California	USA	Distributor ; Drug labeler	Drug quality assurance	Voluntary action indicated	Not available	483 ;	
	California	USA	Compounding pharmacy	Drug quality assurance	Not available	Not available	483	
	Nevada	USA	Compounding pharmacy	Drug quality assurance	Official action indicated	Not available	483	292367
	California	USA	Compounding pharmacy	Drug quality assurance	Official action indicated	Not available	483	245036



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER
1201 Harbor Bay Parkway
Alameda, CA 94502-7070
(510)337-6700 Fax:(510)337-6702
ORABIMOW.Correspondence@fda.hhs.gov

DATE(S) OF INSPECTION
12/5/2022-12/16/2022*
FEI NUMBER
3023890987

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Anish S. Shah, Clinical Investigator

FIRM NAME
Anish Shah, M.D.

STREET ADDRESS
480 Tesconi Cir Ste B, Siyan Clinical Research

CITY, STATE, ZIP CODE, COUNTRY
Santa Rosa, CA 95401-4691

TYPE ESTABLISHMENT INSPECTED
Clinical Investigator

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

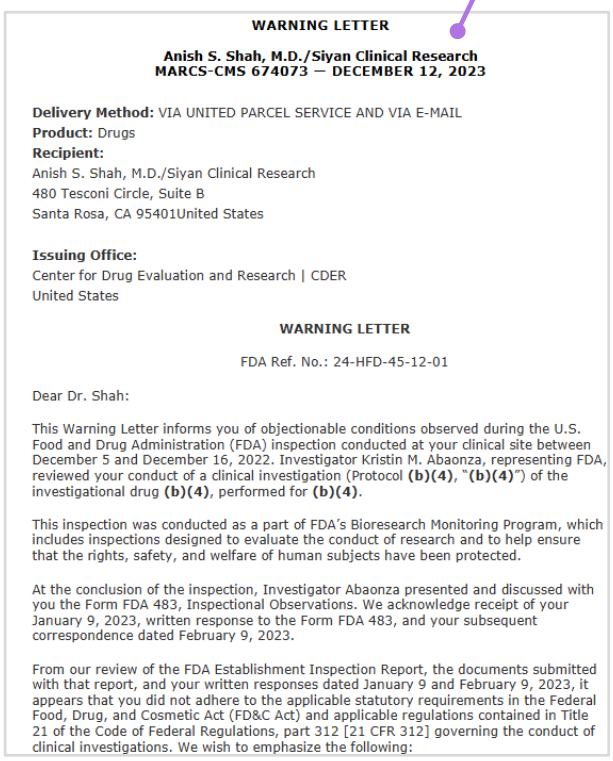
DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Failure to prepare or maintain adequate and accurate case histories with respect to observations and data pertinent to the investigation.

a) I observed data irregularities related to the reporting of vital signs following administration of the investigational study drug. The table below illustrates changes in the study records that involved protocol required safety and tolerability data.

Subject Number	Study Activity	Date of Initial Entry	Original Source Reported	Date When Entry Changed	Days from Initial Entry to Changed Entry	Changes to Source Reported
[redacted]	(b) (4) Post Dose Vitals	16-Mar-22	12:44*	4-May-22	49	12:24 a
[redacted]	(b) (4) Post Dose Vitals	30-Mar-22	11:47*	13-May-22	44	11:27 a
[redacted]	(b) (4) Post	30-Mar-22	13:23*	13-May-22	44	12:59 a



WARNING LETTER

Anish S. Shah, M.D./Siyan Clinical Research
MARCS-CMS 674073 — DECEMBER 12, 2023

Delivery Method: VIA UNITED PARCEL SERVICE AND VIA E-MAIL
Product: Drugs
Recipient:
Anish S. Shah, M.D./Siyan Clinical Research
480 Tesconi Circle, Suite B
Santa Rosa, CA 95401United States

Issuing Office:
Center for Drug Evaluation and Research | CDER
United States

WARNING LETTER

FDA Ref. No.: 24-HFD-45-12-01

Dear Dr. Shah:

This Warning Letter informs you of objectionable conditions observed during the U.S. Food and Drug Administration (FDA) inspection conducted at your clinical site between December 5 and December 16, 2022. Investigator Kristin M. Abaonza, representing FDA, reviewed your conduct of a clinical investigation (Protocol **(b)(4)**, "**(b)(4)**") of the investigational drug **(b)(4)**, performed for **(b)(4)**.

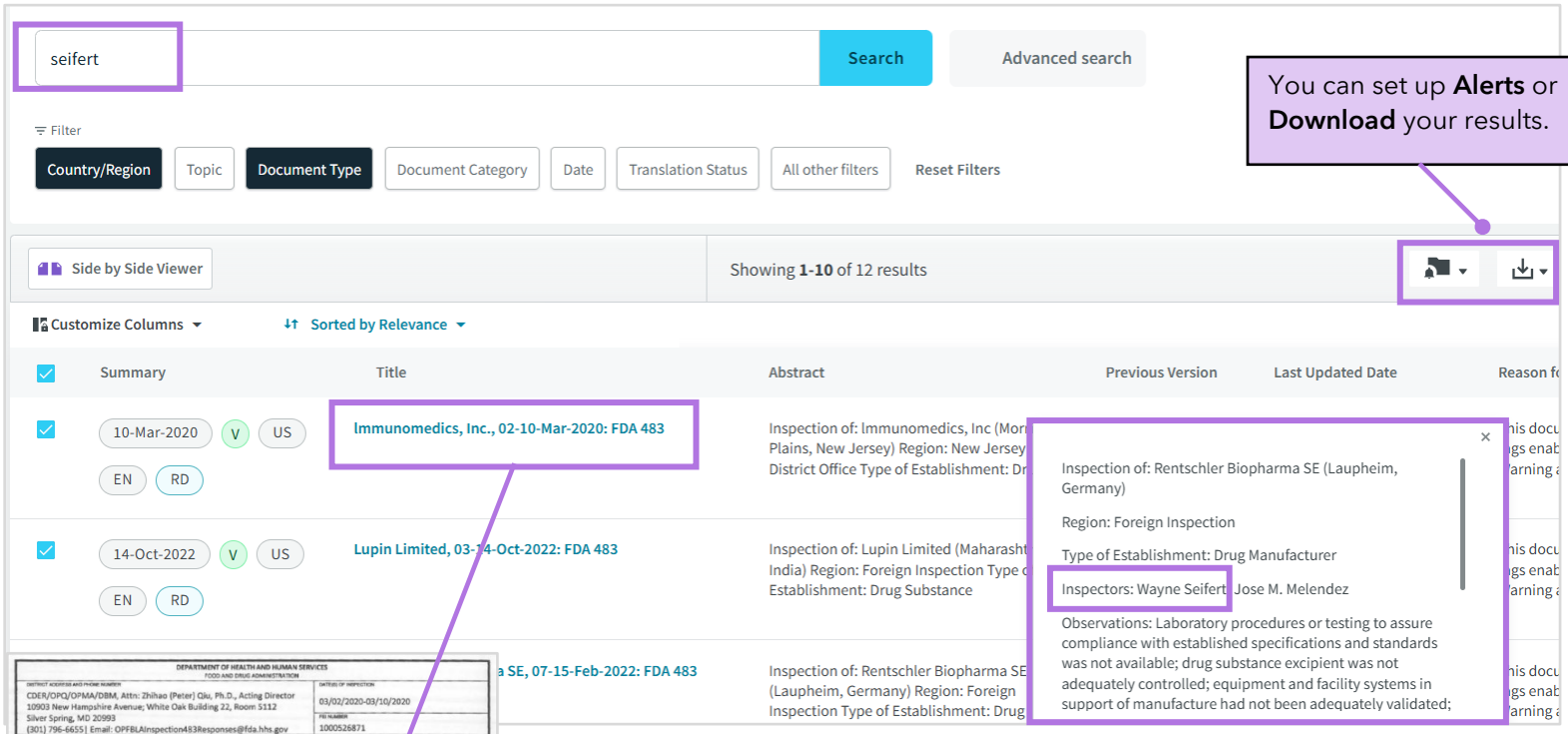
This inspection was conducted as a part of FDA's Bioresearch Monitoring Program, which includes inspections designed to evaluate the conduct of research and to help ensure that the rights, safety, and welfare of human subjects have been protected.

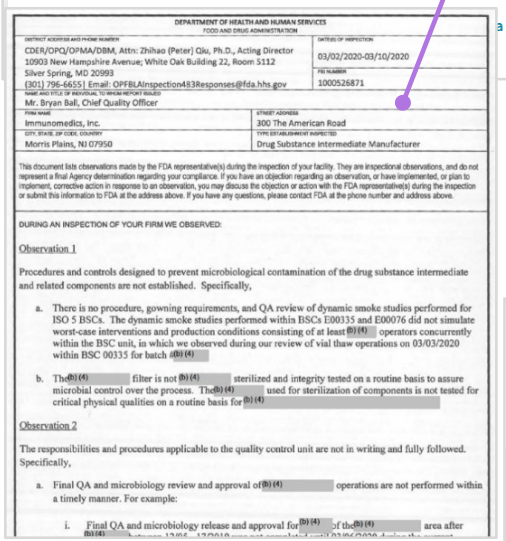
At the conclusion of the inspection, Investigator Abaonza presented and discussed with you the Form FDA 483, Inspectional Observations. We acknowledge receipt of your January 9, 2023, written response to the Form FDA 483, and your subsequent correspondence dated February 9, 2023.

From our review of the FDA Establishment Inspection Report, the documents submitted with that report, and your written responses dated January 9 and February 9, 2023, it appears that you did not adhere to the applicable statutory requirements in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and applicable regulations contained in Title 21 of the Code of Federal Regulations, part 312 [21 CFR 312] governing the conduct of clinical investigations. We wish to emphasize the following:

Example: Use Quick Search to find FDA inspection documents issued by inspector Wayne E. Seifert.

1. In the **keyword field enter the last name of the inspector: seifert**. If searching a common name, enter the full name: Wayne E. Seifert. It's best to start simply and add more keywords if you retrieve irrelevant documents
2. If you have many results you may want to filter to just US Inspection Documents. Use the **Country/Region filter and select USA and Document Type Filter and Inspection Report**. Click Apply before closing each filter. Click the Search button to refine your search results




DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CDER/OPQ/OPMA/DBM, Attn: Zhihao (Peter) Qiu, Ph.D., Acting Director
10903 New Hampshire Avenue; White Oak Building 22, Room 5112
Silver Spring, MD 20993
(301) 796-6655| Email: OPFBLAInspection483Responses@fda.hhs.gov
Mr. Bryan Ball, Chief Quality Officer
Immunomedics, Inc.
300 The American Road
Morris Plains, NJ 07950
Drug Substance Intermediate Manufacturer
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:
Observation 1
Procedures and controls designed to prevent microbiological contamination of the drug substance intermediate and related components are not established. Specifically,
Observation 2
The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed. Specifically,

3. Quick Search allows you to search the titles, abstracts and reasons for update in the reports. By using any keywords in these fields, you can find all inspection documents for an inspected party, for example Immunomedics. Or other keywords, like the date: 02-10-Mar, or process controls or computers.

For more information contact Customer Service at **LSH.support@clarivate.com.**