Better Data. Better Decisions.

The leading platform for GXP inspection analytics

CMO Risk Mitigation

CMO Risk Mitigation

Work with the Right People

- A. Eliminate Surprises
- B. Zoom Out!
- C. Not All CMOs Are Created Equal

Trust, but Verify

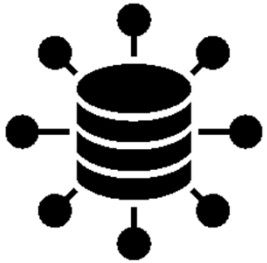
- A. Monitor Everyone
- B. Risk-Based Audit Schedule: >Risk?
- C. Risk-Based Audit Schedule: <Risk?

What we do

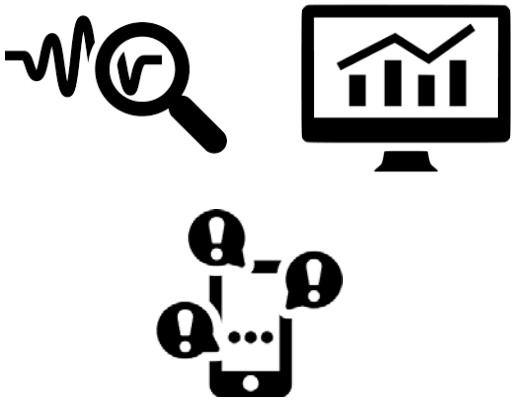
Continuously Acquire | Extract Data

Transform | Load Data

Search | Analyze | Alert



- *Model / Persist*
- *Combine / Separate*
- *Clean / Dedupe*
- *Tag*



Our data

What we have now

- FDA Inspection data since 2000
- 21 CFR Citations (211, 820 and everything in between)
- 9,500+ 483s
- 3,000+ EIRs and 483Rs
- 15,000+ Warning Letters
- 200k FDA inspected sites
- MDSAP inspections and NC Reports
- CLIIL Inspections & Citations

The most complete and easy to use FDA inspection database in existence (including the FDA's database)

More FDA sources

- FDA Import Alerts (all categories)
- FDA Product Recalls
- Untitled Letters
- Complete Response Letters
- Inspection Types (e.g. PAI)
- Site Registrations (API, Sterile etc.)
- Drug Shortages
- Debarment List / DQ Proceedings

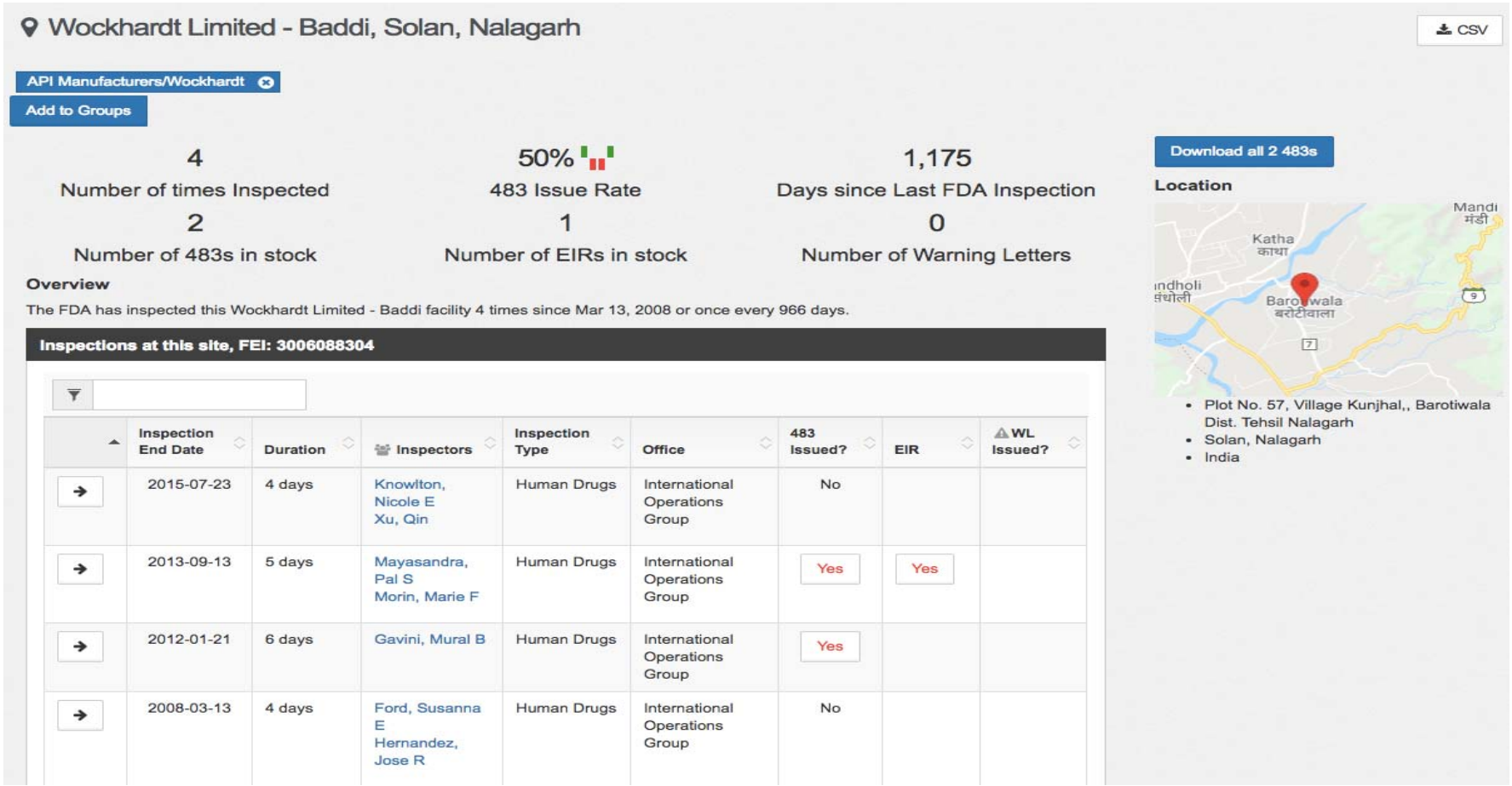
Other International & Domestic Health Agencies

- EUDRA GDMP Inspections
- EU RASSF Alerts & Site Registries
- Health Canada Recalls
- MHRA Inspections and NC Reports
- State inspection logs (e.g. Texas)
- Other International agencies…

Other Sources of Data

- EPA inspections and violations
- OSHA inspections and violations
- Department of Justice
- USDA inspections and violations

Eliminate Surprises & Zoom Out!



Wockhardt Limited - Baddi, Solan, Nalagarh

CSV

API Manufacturers/Wockhardt

Add to Groups

4	50%	1,175
Number of times Inspected	483 Issue Rate	Days since Last FDA Inspection
2	1	0
Number of 483s in stock	Number of EIRs in stock	Number of Warning Letters

Overview

The FDA has inspected this Wockhardt Limited - Baddi facility 4 times since Mar 13, 2008 or once every 966 days.

Inspections at this site, FEI: 3006088304

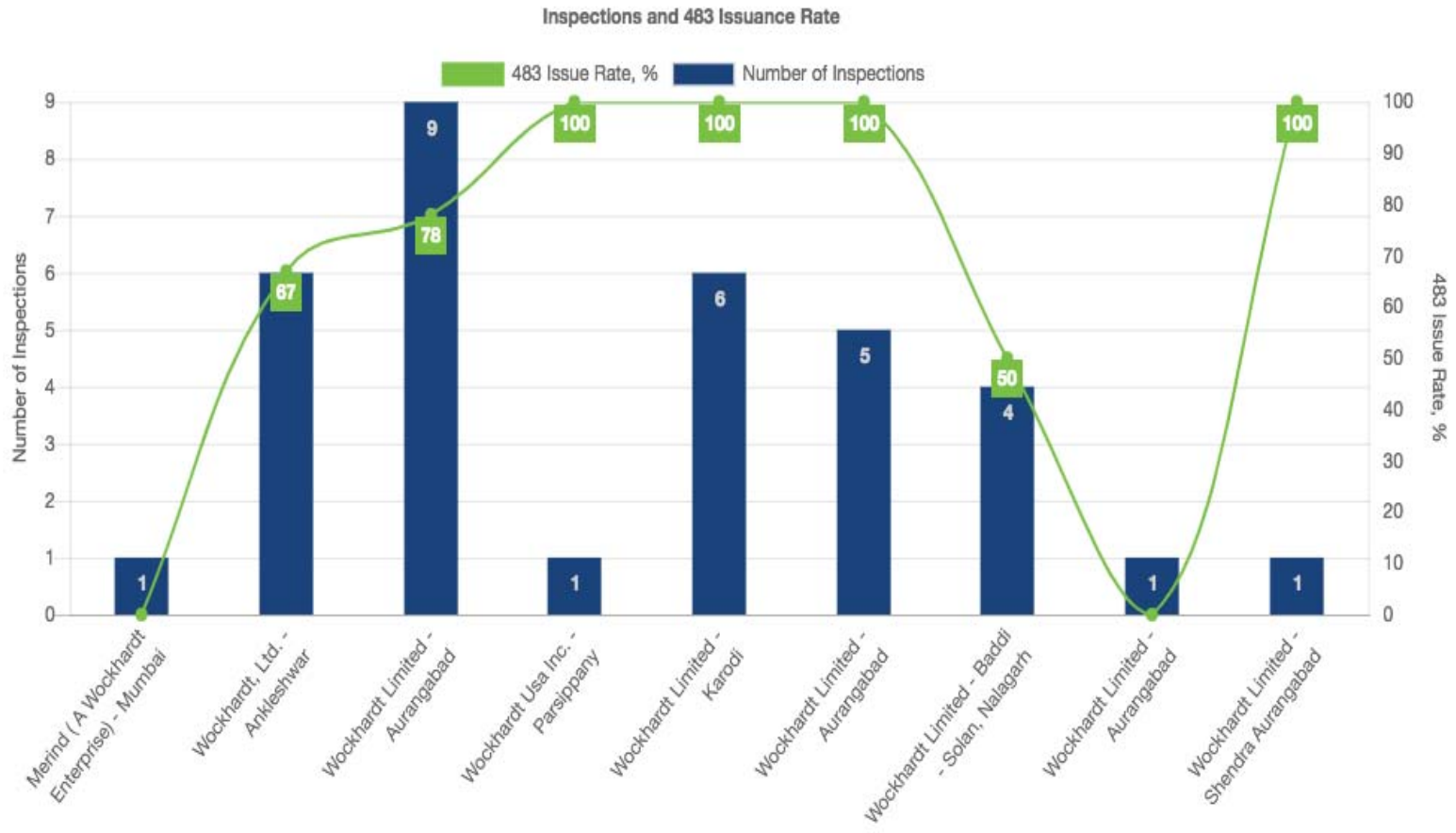
	Inspection End Date	Duration	Inspectors	Inspection Type	Office	483 Issued?	EIR	WL Issued?
→	2015-07-23	4 days	Knowlton, Nicole E Xu, Qin	Human Drugs	International Operations Group	No		
→	2013-09-13	5 days	Mayasandra, Pal S Morin, Marie F	Human Drugs	International Operations Group	Yes	Yes	
→	2012-01-21	6 days	Gavini, Mural B	Human Drugs	International Operations Group	Yes		
→	2008-03-13	4 days	Ford, Susanna E Hernandez, Jose R	Human Drugs	International Operations Group	No		

Download all 2 483s

Location

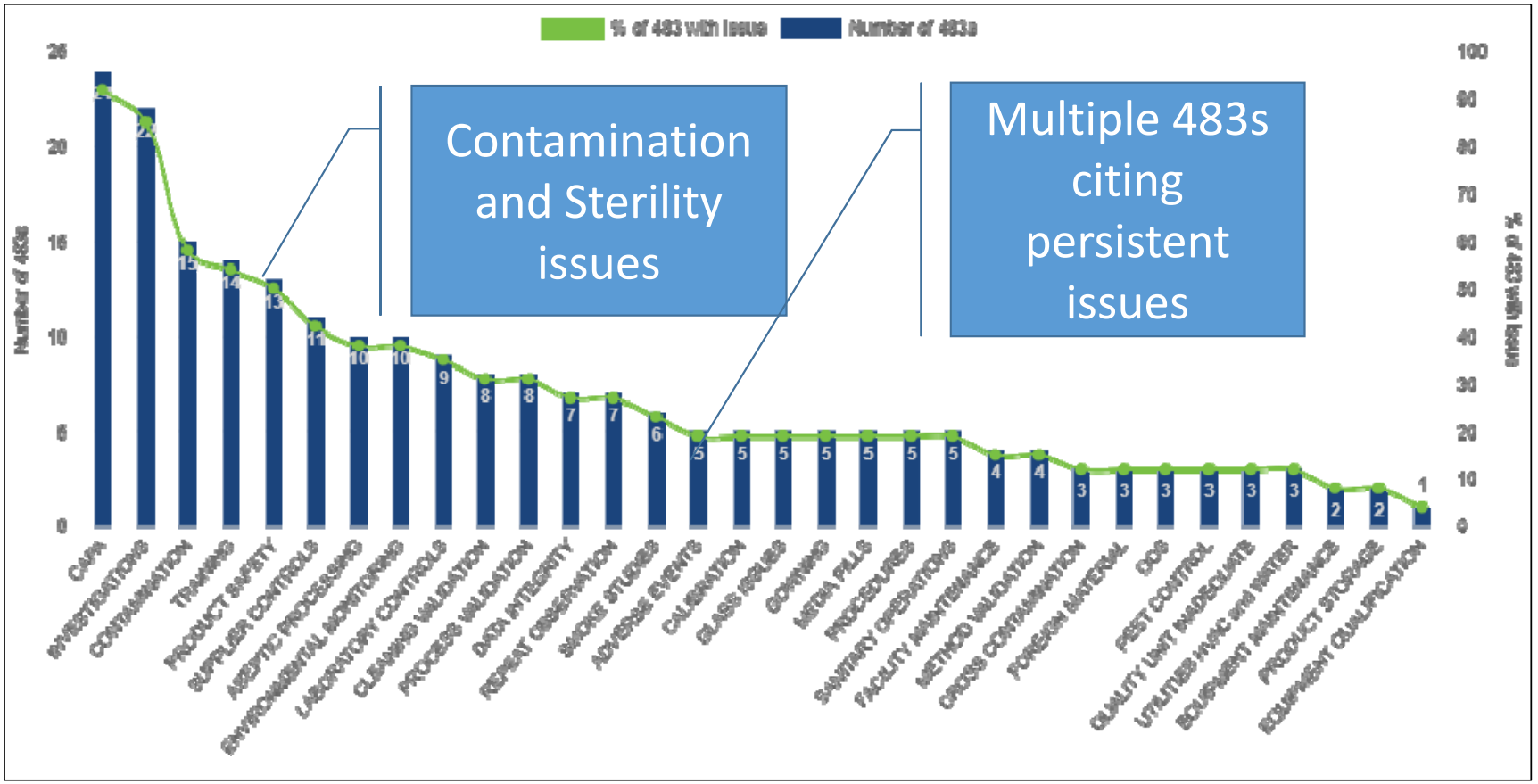
- Plot No. 57, Village Kunjhal,, Barotiwala Dist. Tehsil Nalagarh
- Solan, Nalagarh
- India

Zoom Out!


Inspections and 483 Issuance Rate
483 Issue Rate, %
Number of Inspections
Number of Inspections
483 Issue Rate, %
0
1
2
3
4
5
6
7
8
9
0
10
20
30
40
50
60
70
80
90
100
1
67
9
78
1
100
6
100
5
100
4
50
1
100
1
100
Merind (A Wockhardt Enterprise) - Mumbai
Wockhardt, Ltd. - Ankleshwar
Wockhardt Limited - Aurangabad
Wockhardt Usa Inc. - Parsippany
Wockhardt Limited - Karodi
Wockhardt Limited - Aurangabad
Wockhardt Limited - Baddi - Solan, Nalagarh
Wockhardt Limited - Aurangabad
Wockhardt Limited - Shendra Aurangabad

Zoom Out! Clearly Hospira Was Going To Pose Issues For Pfizer

26 483s analyzed – last 5 years



Not All CMOs Are Created Equal

Comparison of Selected API Manufacturers: Last 5 Years

	Number of Sites	Number of Inspections	Inspections/ Site	Number of 483s	483 rate percent	Number of Warning Letters	WL rate percent
Teva	49	295	6.0	151	51.2%	1	0.30%
Mylan	38	193	5.0	77	39.9%	4	2.1%
Dr. Reddy's	21	83	4.0	42	50.6%	1	1.2%
Sandoz	20	113	5.5	67	59.3%	2	1.8%
Wockhardt	9	34	3.8	26	76.5%	4	11.8%
Cipla	8	41	5.1	26	63.4%	0	0.0%
Divi's Labs	2	12	6.0	7	58.3%	1	8.3%

There are major differences between API manufacturers and even Sponsors

Source: FDAzilla analysis
Notes: Human Drug and Biologics inspections only. Last 5 years

Monitor Everybody: Stay Proactive

June 2017

FDA Inspection of Celltrion

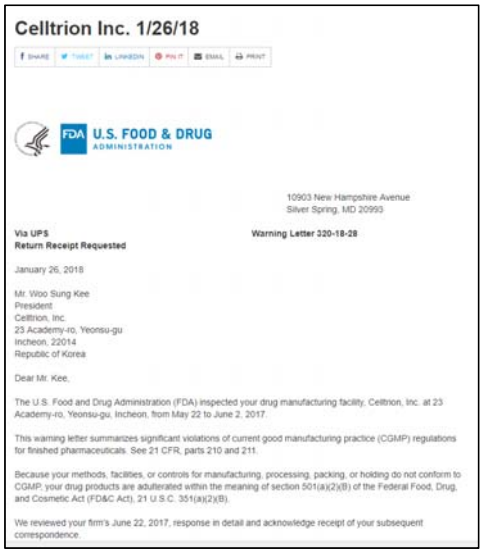
July 2017

FDAzilla Analysis – very high likelihood of Warning Letters

1. The FDA inspector is *very* tough.
2. The FDA found major issues
   a. Sterility concerns (particles, contamination)
   b. Poor process controls
   c. Poor lab controls
   d. Untrustworthy data

January 2018

FDA Issues Warning Letter



Celltrion Inc. 1/26/18

U.S. FOOD & DRUG ADMINISTRATION

10903 New Hampshire Avenue
Silver Spring, MD 20993

Via UPS
Return Receipt Requested

Warning Letter 320-18-28

January 26, 2018

Mr. Woo Sung Kee
President
Celltrion, Inc.
23 Academy-ro, Yeonsu-gu
Incheon, 22014
Republic of Korea

Dear Mr. Kee,

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Celltrion, Inc. at 23 Academy-ro, Yeonsu-gu, Incheon, from May 22 to June 2, 2017.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 21 CFR, parts 210 and 211.

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

We reviewed your firm's June 22, 2017, response in detail and acknowledge receipt of your subsequent correspondence.

February 2018

Broader Market Knowledge

BioPharma-Reporter.com

Celltrion FDA warning causes headache for Teva's biologics ambition
13-Feb-2018 By Dan Stanton

A warning letter at manufacturing partner Celltrion could delay approvals

Monitor Everybody: Stay Proactive

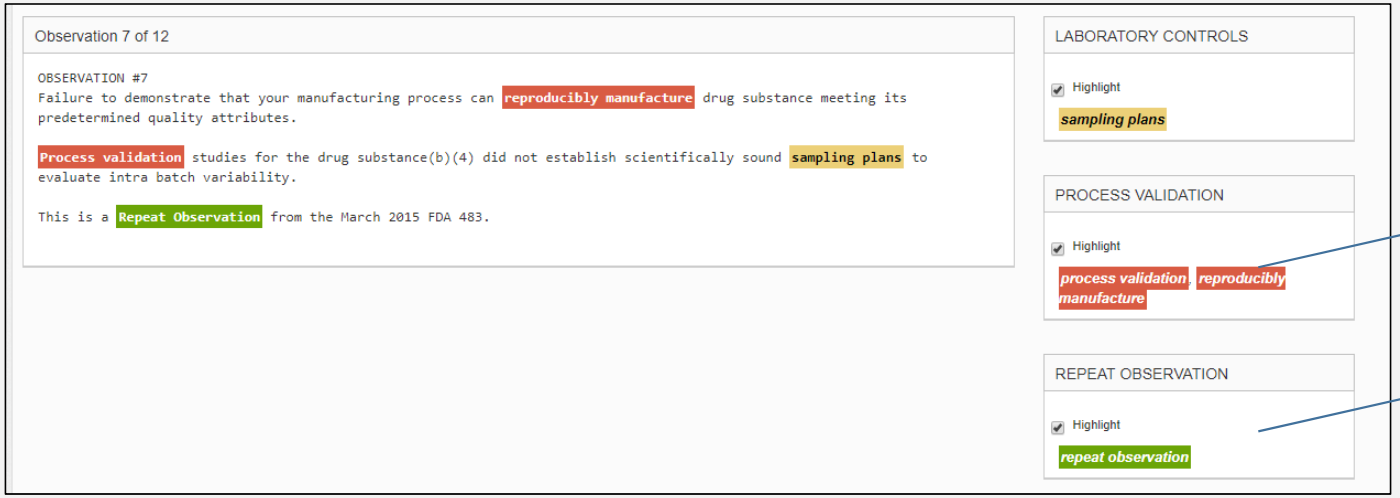
June 2017 — FDA Inspection of Celltrion

July 2017 — FDAzilla Analysis – very high likelihood of Warning Letters

January 2018 — FDA Issues Warning Letter

February 2018 — Broader Market Knowledge

Sample Analysis: Observation 7 of 12 – 483s re-typed and tagged for key issues

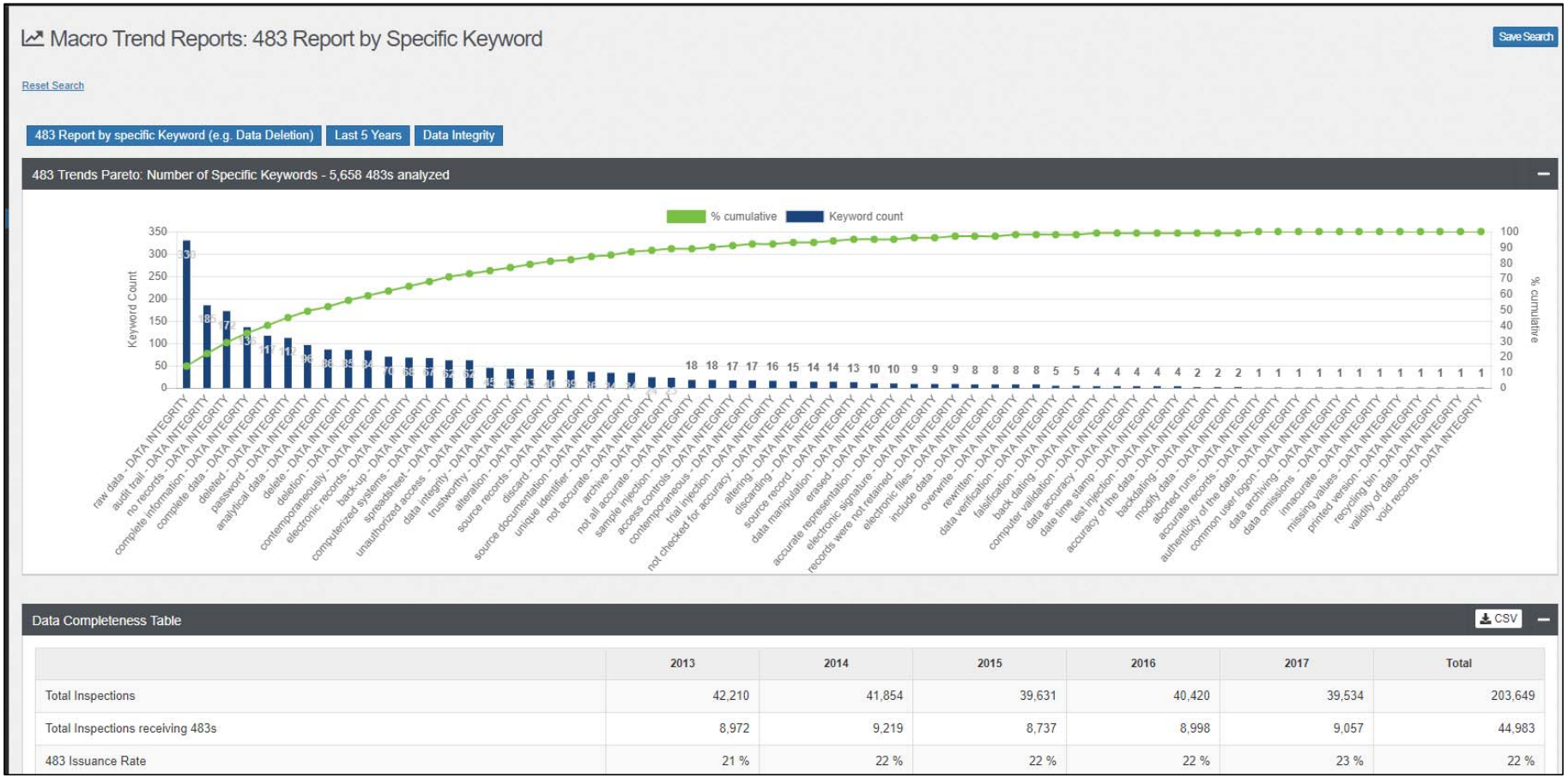


Major red flag

Major red flag

Data-Driven & Risk-Based Audits: Pareto Charts for Keywords

Example: from Data Integrity Citations last 5 years



	2013	2014	2015	2016	2017	Total
Total Inspections	42,210	41,854	39,631	40,420	39,534	203,649
Total Inspections receiving 483s	8,972	9,219	8,737	8,998	9,057	44,983
483 Issuance Rate	21 %	22 %	22 %	22 %	23 %	22 %