

Redica Insights for Inspection Readiness

How Can Redica Help You Prep for Your Next Inspection?

What if there was a way you could prepare for your next regulatory inspection? Imagine access to the latest enforcement data on 483 observations, profiles on inspectors, and a site's inspection history. Well, imagine no more! With our Enforcement Analytics, quality and compliance personnel now have access to actionable data intelligence to help you prepare for your next inspection.

PREPARE YOUR OWN MANUFACTURING FACILITIES, CMOS, AND CLINICAL TRIAL VENDORS WITH THE LATEST INSPECTION DATA INTELLIGENCE AND TRENDS FROM AROUND THE GLOBE

We'll help you search, analyze, and derive valuable insight from over 4,000 FDA investigator profiles and over 20 years of GxP-specific enforcement trends so that you always know what to expect from upcoming inspections.



THE REDICA DIFFERENCE

At Redica, we create actionable data intelligence that empowers quality and compliance teams.

Our Enforcement Analytics (EA) module addresses your deepest concerns around inspection readiness, providing you the peace of mind to move your business forward. Our database includes inspection history for sites, inspector profiles, and much more.

We've built the largest dataset of inspection and enforcement documents in the world. Then, we combined it with advanced machine intelligence delivered to you via an intuitive and easy-to-use platform. We source our data through thousands of unique Freedom of Information Act (FOIA) requests and agency monitoring tools, and our proprietary machine learning models combine industry expertise with modern data science approaches.

Learn more about how Redica Systems can help you prep for your next inspection.

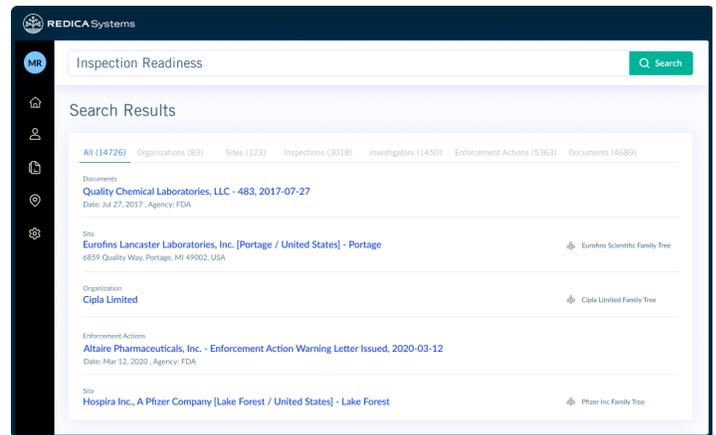
A RESOURCE FOR INSPECTION READINESS

- Data on all FDA inspected and registered sites since 2000, with more than 350,000 sites and 800,000 inspections.
- 20x more data than what has been released on FDA.gov—over 30,000 Form 483s, EIRs, Untitled Letters, MDSAP Reports, and 483Rs.
- All FDA issued Warning Letters since 2000.
- Inspection reason for inspections—including preapproval, routine, and for-cause inspections.
- EMA GDMP inspections and enforcement since 2005.
- Health Canada GMP and GCP inspections and enforcement since 2012.
- MHRA GMP post-inspection reports since 2005.

Tailor insights to your specific compliance and risk concerns

ONE SEARCH

We'll help you search, analyze, and derive valuable insights from thousands of global regulatory data points covering investigators, facilities, products, organizations, and enforcement.



Inspection Readiness Search

Search Results

All (14726) Organizations (83) Sites (123) Inspections (3018) Investigators (1450) Enforcement Actions (5363) Documents (4689)

Documents

Quality Chemical Laboratories, LLC - 483, 2017-07-27
Date: Jul 27, 2017, Agency: FDA

Site:
Eurofins Lancaster Laboratories, Inc. [Portage / United States] - Portage
6859 Quality Way, Portage, MI 49002, USA

Organization:
Cipla Limited

Enforcement Action:
Altaire Pharmaceuticals, Inc. - Enforcement Action Warning Letter Issued, 2020-03-12
Date: Mar 12, 2020, Agency: FDA

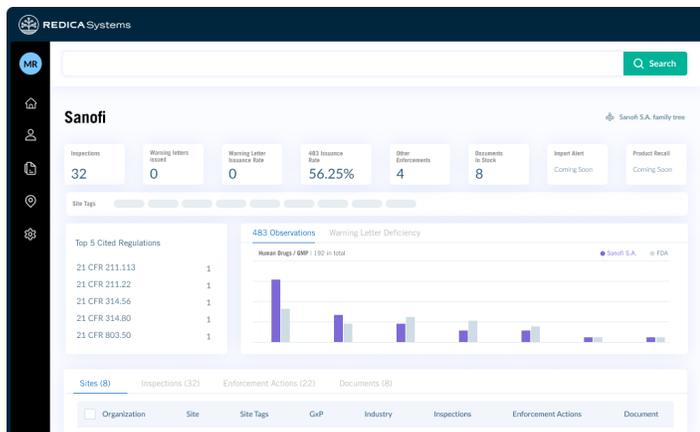
Site:
Hospira Inc., A Pfizer Company [Lake Forest / United States] - Lake Forest

ORG PROFILES

Our Family Tree allows you to see all sites, including suppliers and outsourcing facilities, associated with a particular organization in addition to inspection history, 483 observations, and Warning Letter citations.

BENCHMARKS AND TRENDS

Use our intelligence and data to see the latest regulatory trends for the group of investigators you are interested in.



Sanofi Sanofi S.A. family tree

Inspections: 32 | Warning Letters Issued: 0 | Warning Letter Issuance Rate: 0 | 483 Issuance Rate: 56.25% | Other Enforcement: 4 | Documents in Stock: 8 | Import Alert Coming Soon | Product Recall Coming Soon

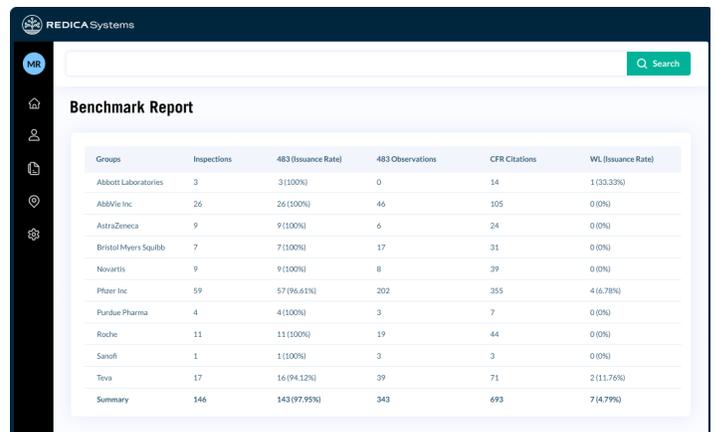
483 Observations | Warning Letter Deficiency

Human Drugs / OMP / 192 in total

Top 5 Cited Regulations:

21 CFR 211.113	1
21 CFR 211.22	1
21 CFR 314.56	1
21 CFR 314.80	1
21 CFR 803.50	1

Sites (8) | Inspections (32) | Enforcement Actions (22) | Documents (8)



Benchmark Report

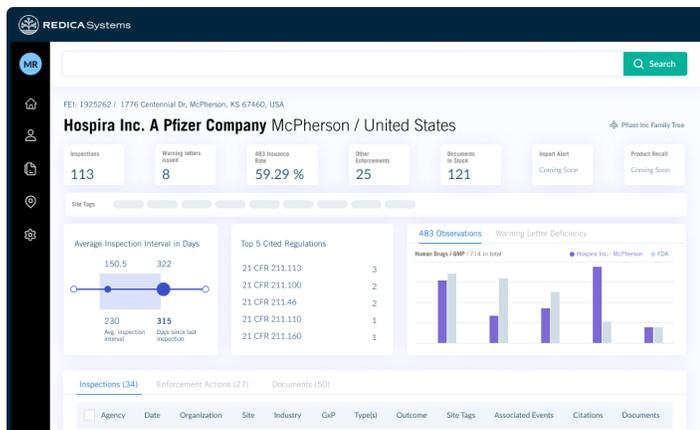
Groups	Inspections	483 (Issuance Rate)	483 Observations	CFR Citations	WL (Issuance Rate)
Abbott Laboratories	3	3 (100%)	0	14	1 (3.33%)
AbbVie Inc	26	26 (100%)	46	105	0 (0%)
AstraZeneca	9	9 (100%)	6	24	0 (0%)
Bristol Myers Squibb	7	7 (100%)	17	31	0 (0%)
Novartis	9	9 (100%)	8	39	0 (0%)
Pfizer Inc	59	57 (96.6%)	202	355	4 (6.78%)
Purdue Pharma	4	4 (100%)	3	7	0 (0%)
Roche	11	11 (100%)	19	44	0 (0%)
Sanofi	1	1 (100%)	3	3	0 (0%)
Teva	17	16 (94.12%)	39	71	2 (1.76%)
Summary	146	143 (97.95%)	343	693	7 (4.79%)

SITE PROFILES

Inspection data for thousands of global sites, including inspection history, 483 observations, and Warning Letters. Plus, our Family Tree allows you to see all sites, including suppliers and outsourcing facilities, associated with a firm.

INSPECTOR PROFILES

The latest intelligence on health authority inspectors—their 483 observations, Warning Letter citations, co-inspectors, and more.



FBI: 1925262 / 1776 Centennial Dr, McPherson, KS 67460, USA

Hospira Inc. A Pfizer Company McPherson / United States

Inspections: 113 | Warning Letters Issued: 8 | 483 Issuance Rate: 59.29% | Other Enforcement: 25 | Documents in Stock: 121 | Import Alert Coming Soon | Product Recall Coming Soon

483 Observations | Warning Letter Deficiency

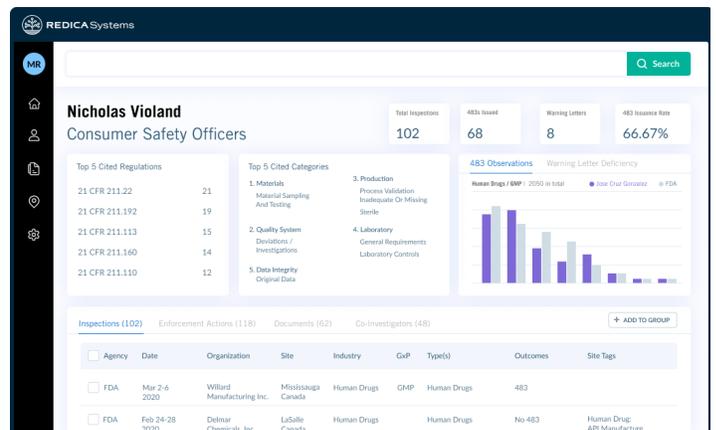
Human Drugs / OMP / 714 in total

Average Inspection Interval in Days: 150.5 (322) | 230 (315) Avg. Inspection Interval (Days since last inspection)

Top 5 Cited Regulations:

21 CFR 211.113	3
21 CFR 211.100	2
21 CFR 211.44	2
21 CFR 211.110	1
21 CFR 211.160	1

Inspections (34) | Enforcement Actions (27) | Documents (50)



Nicholas Violand Consumer Safety Officers

Total Inspections: 102 | 483s Issued: 68 | Warning Letters: 8 | 483 Issuance Rate: 66.67%

483 Observations | Warning Letter Deficiency

Human Drugs / OMP / 2050 in total

Top 5 Cited Regulations:

21 CFR 211.22	21
21 CFR 211.192	19
21 CFR 211.113	15
21 CFR 211.160	14
21 CFR 211.110	12

Top 5 Cited Categories:

1. Materials: Material Sampling And Testing
2. Quality System: Deviations / Investigations
3. Production: Process Validation Inadequate Or Missing Sterile
4. Laboratory: General Requirements Laboratory Controls
5. Data Integrity: Original Data

Inspections (102) | Enforcement Actions (118) | Documents (62) | Co-Investigators (48)

Agency	Date	Organization	Site	Industry	GxP	Type(s)	Outcomes	Site Tags
FDA	Mar 2-6 2020	Willard Manufacturing Inc.	Midisoupp	Human Drugs	GMP	Human Drugs	483	
FDA	Feb 24-28 2020	Delmar Chemicals, Inc.	LuSelle	Human Drugs		Human Drugs	No 483	Human Drug API Manufacture