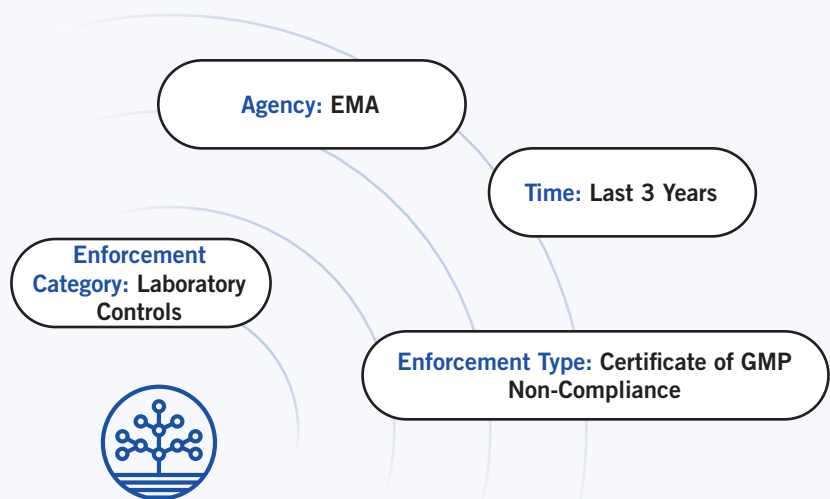

Redica Insights for Quality Assurance

How Can Redica Help Quality Assurance Personnel?

As a Quality Assurance leader, you face many challenges in your day-to-day activities. Evolving regulatory expectations. Health authority inspections. Concerns about vendor quality offsite. Fortunately, Redica Systems provides you with critical data to help you overcome these challenges.

SHARPEN YOUR INTERNAL AND EXTERNAL AUDIT FOCUS USING THE LATEST AGENCY INSPECTION AND ENFORCEMENT DATA INTELLIGENCE

We'll help you search, analyze, and derive valuable insight from thousands of agency enforcement data points. Leverage our expert classification models to quickly summarize macro trends in quality and compliance and detect changes in agency focus.



THE REDICA DIFFERENCE

At Redica, we create actionable data intelligence that empowers global Quality Assurance teams.

Our Enforcement Analytics module addresses your deepest concerns about compliance risk, providing you the peace of mind to move your business forward. Our database includes inspection history for sites, inspector profiles, and more!

Our Regulatory Intelligence provides routine surveillance and expert analysis in an easy-to-access section of our platform. You'll receive weekly summary emails listing recent Health Authority developments in addition to special reports drafted by our own GMP experts, all of whom have decades of industry experience.

Learn more about how Redica Systems can help you achieve your Quality Assurance goals.

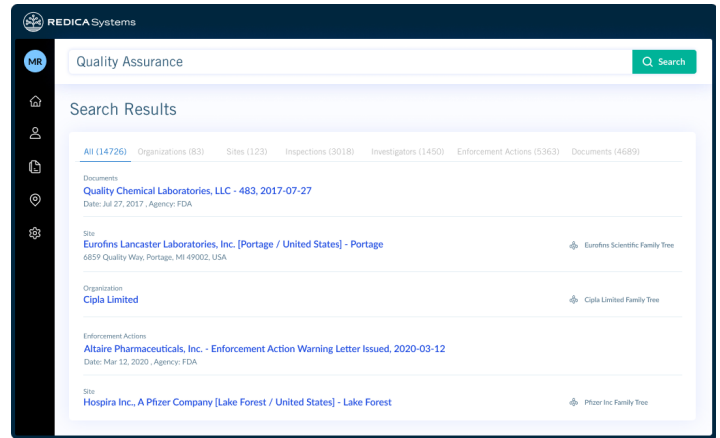
A RESOURCE FOR QUALITY ASSURANCE LEADERS

- Up-to-date, real-time notification of changes to global QA regulations
- Access to 483 site observations, including QA-related findings
- Intelligence on investigators and their common QA observations
- Reports from leading industry experts
- And much, much more!

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 vendor facilities, products, organizations, and enforcement.



Quality Assurance 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

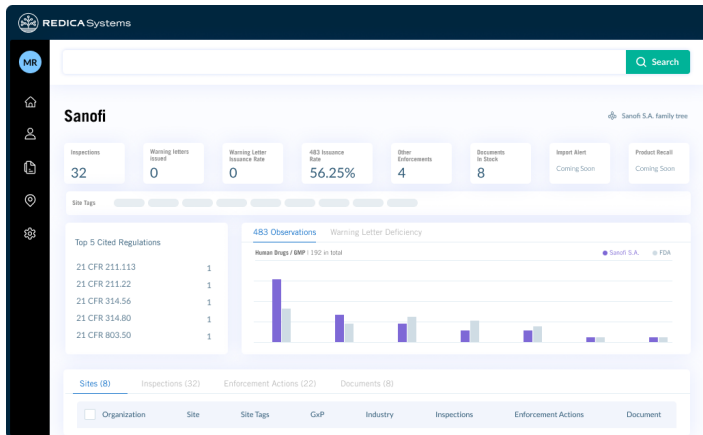
Organization:
Cipla Limited

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.



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 / BMP: 192 in total

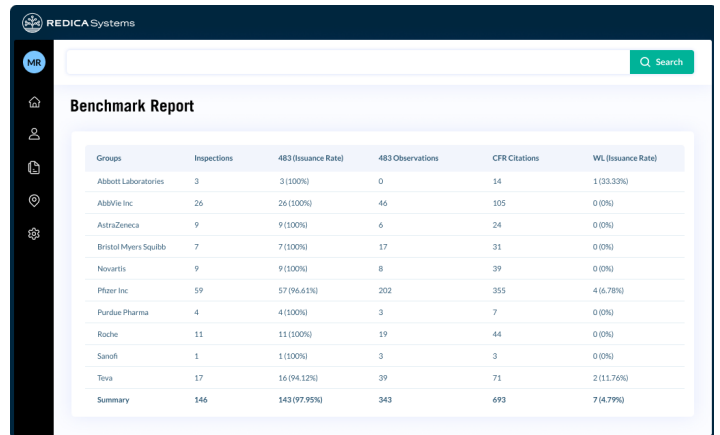
Top 5 Cited Regulations:

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)

INDUSTRY TRENDS

Use our intelligence and data to see the latest regulatory trends for your industry.

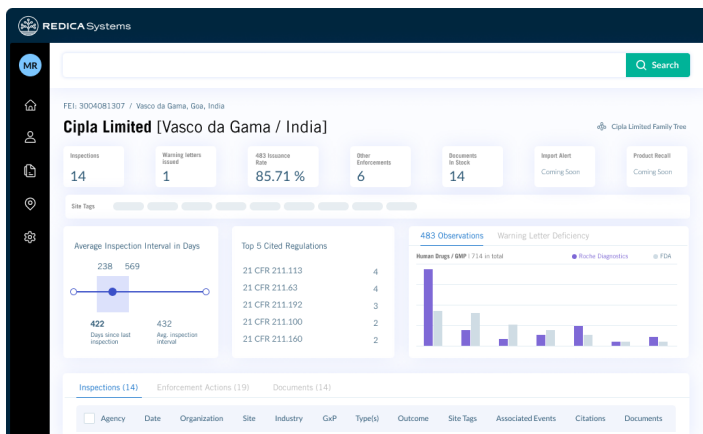


Benchmark Report

Groups	Inspections	483 (Issuance Rate)	483 Observations	CFR Citations	WL (Issuance Rate)
Abbott Laboratories	3	3 (100%)	0	14	1 (33.33%)
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 (11.76%)
Summary	146	143 (97.95%)	343	493	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.



Cipla Limited [Vasco da Gama / India] Cipla Limited Family Tree

FEI: 3004081307 / Vasco da Gama, Goa, India

Inspections: 14 | Warning Letters Issued: 1 | 483 Issuance Rate: 85.71% | Other Enforcement: 6 | Documents in Stock: 14 | Import Alert Coming Soon | Product Recall Coming Soon

483 Observations | Warning Letter Deficiency

Human Drugs / BMP: 714 in total

Average Inspection Interval in Days: 238 - 569

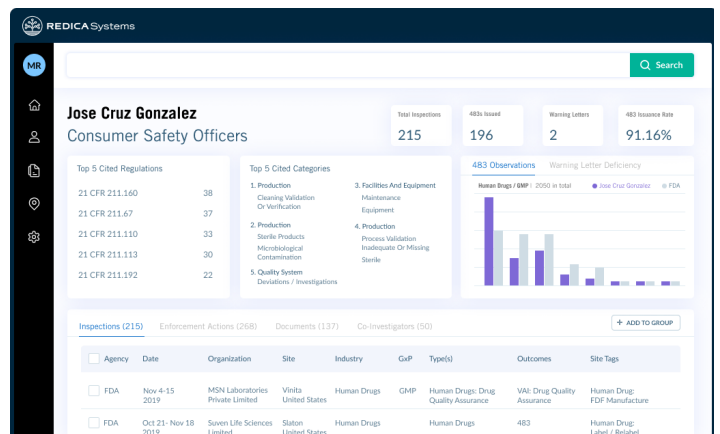
Top 5 Cited Regulations:

21 CFR 211.113	4
21 CFR 211.63	4
21 CFR 211.192	3
21 CFR 211.100	2
21 CFR 211.160	2

Inspections (14) | Enforcement Actions (139) | Documents (14)

INSPECTOR PROFILES

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



Jose Cruz Gonzalez | Total Inspections: 215 | 483s Issued: 196 | Warning Letters: 2 | 483 Issuance Rate: 91.16%

Consumer Safety Officers

Top 5 Cited Regulations:

21 CFR 211.160	38
21 CFR 211.67	37
21 CFR 211.110	33
21 CFR 211.113	30
21 CFR 211.192	22

Top 5 Cited Categories:

1. Production: Clearing Validation Or Verification Equipment
2. Production: Sterile Products Microbiological Contamination
3. Facilities And Equipment: Maintenance Equipment
4. Production: Process Validation Inadequate Or Missing Sterile
5. Quality System: Deviations / Investigations

483 Observations | Warning Letter Deficiency

Human Drugs / BMP: 2056 in total

Inspections (215) | Enforcement Actions (268) | Documents (137) | Co-Investigators (50)