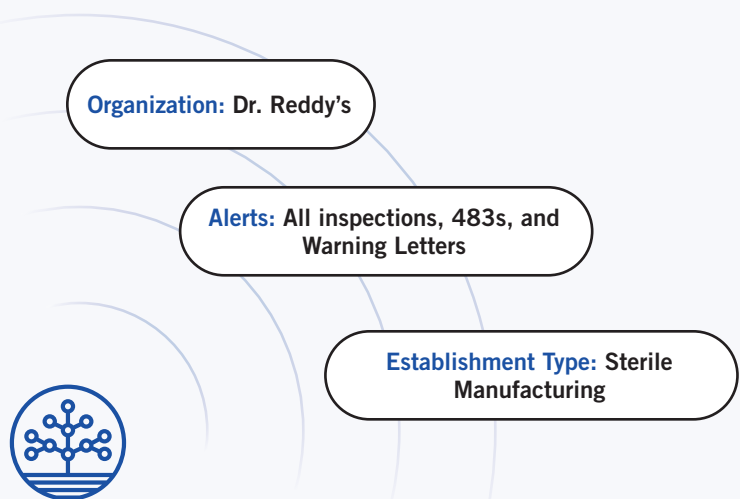

Redica Insights for Vendor Quality

Data analytics for a complete picture on suppliers and CMOs.

How can you be sure your vendors are adhering to Quality Agreements? Do you know the inspection history for your contract manufacturing organization (CMO)? With Redica Systems, our platform can help you ensure your vendor quality.

ASSESS AND MONITOR VENDOR COMPLIANCE PROFILES USING THE LATEST DATA INTELLIGENCE FROM AROUND THE GLOBE

We'll help you search, analyze, and derive valuable insight from thousands of data points covering all FDA and EMA registered CMOs and excipient suppliers.



THE REDICA DIFFERENCE

At Redica, we create actionable data intelligence that empowers global quality and compliance teams. Our Enforcement Analytics (EA) module addresses your deepest concerns around vendor quality, providing you the peace of mind to move your business relationships forward. Our database includes inspection history for hundreds of CMO 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!

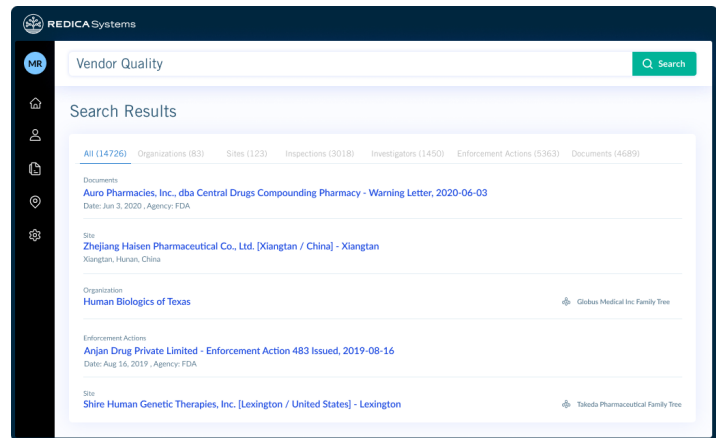
A RESOURCE FOR VENDOR QUALITY

- Data on all FDA inspected and registered sites since 2000, with more than 350,000 sites and 800,000 inspections.
- 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.
- Over 13,000 organization trees that link all sites to organization to parents.

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.



Vendor Quality Search

Search Results

All (14726) Organizations (83) Sites (123) Inspections (3018) Investigators (11450) Enforcement Actions (5363) Documents (4689)

Documents

- Auro Pharmacies, Inc., dba Central Drugs Compounding Pharmacy - Warning Letter, 2020-06-03**
Date: Jun 3, 2020, Agency: FDA
- Site: Zhejiang Haisen Pharmaceutical Co., Ltd. [Xiangtan / China] - Xiangtan**
Xiangtan, Hunan, China
- Organization: Human Biologics of Texas**
Globe Medical Inc Family Tree

Enforcement Actions

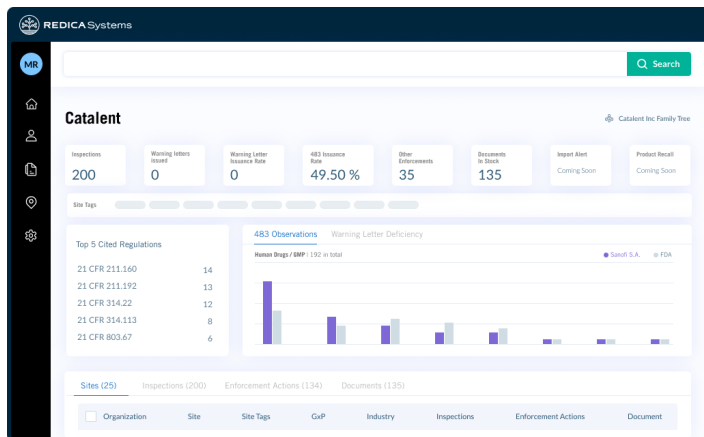
- Anjan Drug Private Limited - Enforcement Action 483 Issued, 2019-08-16**
Date: Aug 16, 2019, Agency: FDA
- Site: Shire Human Genetic Therapies, Inc. [Lexington / United States] - Lexington**
Takeda Pharmaceutical Family Tree

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.

INDUSTRY TRENDS

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



Catalant Catalant Inc Family Tree

Inspections: 200 | Warning Letters Issued: 0 | Warning Letter Issuance Rate: 0 | 483 Issuance Rate: 49.50% | Other Enforcement: 35 | Documents in Stock: 135 | Import Alert: Coming Soon | Product Recall: Coming Soon

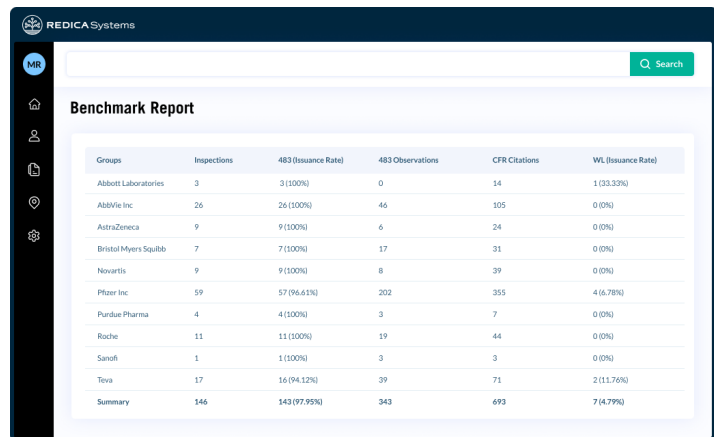
483 Observations | Warning Letter Deficiency

Human Drugs / BMP: 192 in total

Top 5 Cited Regulations

21 CFR 211.160	14
21 CFR 211.192	13
21 CFR 314.22	12
21 CFR 314.113	8
21 CFR 803.67	6

Sites (25) | Inspections (200) | Enforcement Actions (134) | Documents (135)



Benchmark Report

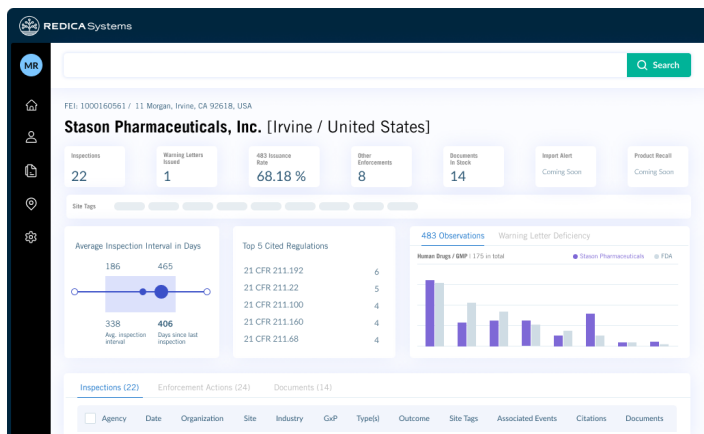
Groups	Inspections	483 Issuance Rate	483 Observations	CFR Citations	WL Issuance Rate
Abbott Laboratories	3	3 (100%)	0	14	1 (3.33%)
AbbVie Inc	26	26 (100%)	46	105	0 (0%)
AstraZeneca	9	9 (100%)	6	24	0 (0%)
Bristol Myers Squibb	7	7 (100%)	17	31	0 (0%)
Novartis	9	9 (100%)	8	39	0 (0%)
Pfizer Inc	59	57 (96.6%)	202	355	4 (6.78%)
Purdue Pharma	4	4 (100%)	3	7	0 (0%)
Roche	11	11 (100%)	19	44	0 (0%)
Sandoz	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.



Stason Pharmaceuticals, Inc. [Irvine / United States]

FEI: 1000160561 / 11 Morgan, Irvine, CA 92618, USA

Inspections: 22 | Warning Letters Issued: 1 | 483 Issuance Rate: 68.18% | Other Enforcement: 8 | Documents in Stock: 14 | Import Alert: Coming Soon | Product Recall: Coming Soon

483 Observations | Warning Letter Deficiency

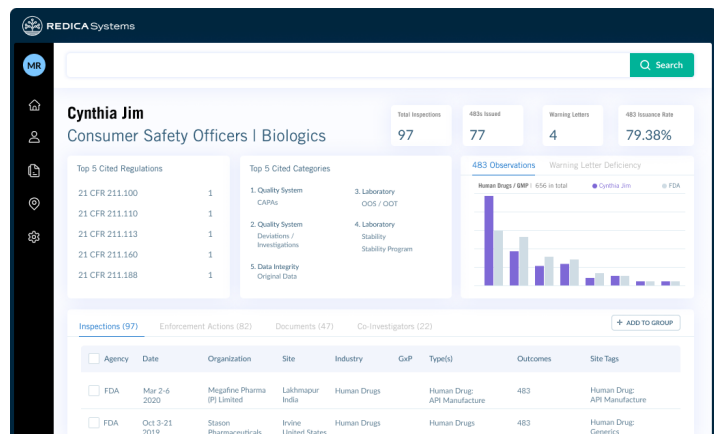
Human Drugs / BMP: 175 in total

Top 5 Cited Regulations

21 CFR 211.192	6
21 CFR 211.22	5
21 CFR 211.100	4
21 CFR 211.160	4
21 CFR 211.68	4

Average Inspection Interval in Days: 186 (336 since last inspection) | 465 (406 days since last inspection)

Inspections (22) | Enforcement Actions (24) | Documents (14)



Cynthia Jim
Consumer Safety Officers | Biologics

Total Inspections: 97 | 483s Issued: 77 | Warning Letters: 4 | 483 Issuance Rate: 79.38%

Top 5 Cited Regulations

21 CFR 211.100	1
21 CFR 211.110	1
21 CFR 211.113	1
21 CFR 211.160	1
21 CFR 211.188	1

Top 5 Cited Categories

- Quality System CAPAs
- Quality System Deviations / Investigations
- Laboratory OOS / OOT
- Laboratory Stability Program
- Data Integrity Original Data

483 Observations | Warning Letter Deficiency

Human Drugs / BMP: 656 in total

Inspections (97) | Enforcement Actions (82) | Documents (47) | Co-Investigators (22)

Agency	Date	Organization	Site	Industry	GxP	Type(s)	Outcomes	Site Tags
FDA	Mar 2-6 2020	MagnePharma (P) Limited	Lalhapur India	Human Drugs	Human Drug API Manufacture	483		Human Drug API Manufacture
FDA	Oct 9-21 2019	Stason Pharmaceuticals	Irvine United States	Human Drugs	Human Drugs	483		Human Drug Generics