



**REDICA**  
Systems

# Redica Systems Top 10 CRO Group Report



REPORT

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## IN THIS REPORT WE IDENTIFY

- Enforcement trends for the top 10 CROs (total of 129 sites)
- Top 5 cited regulations
- Top 483 observations

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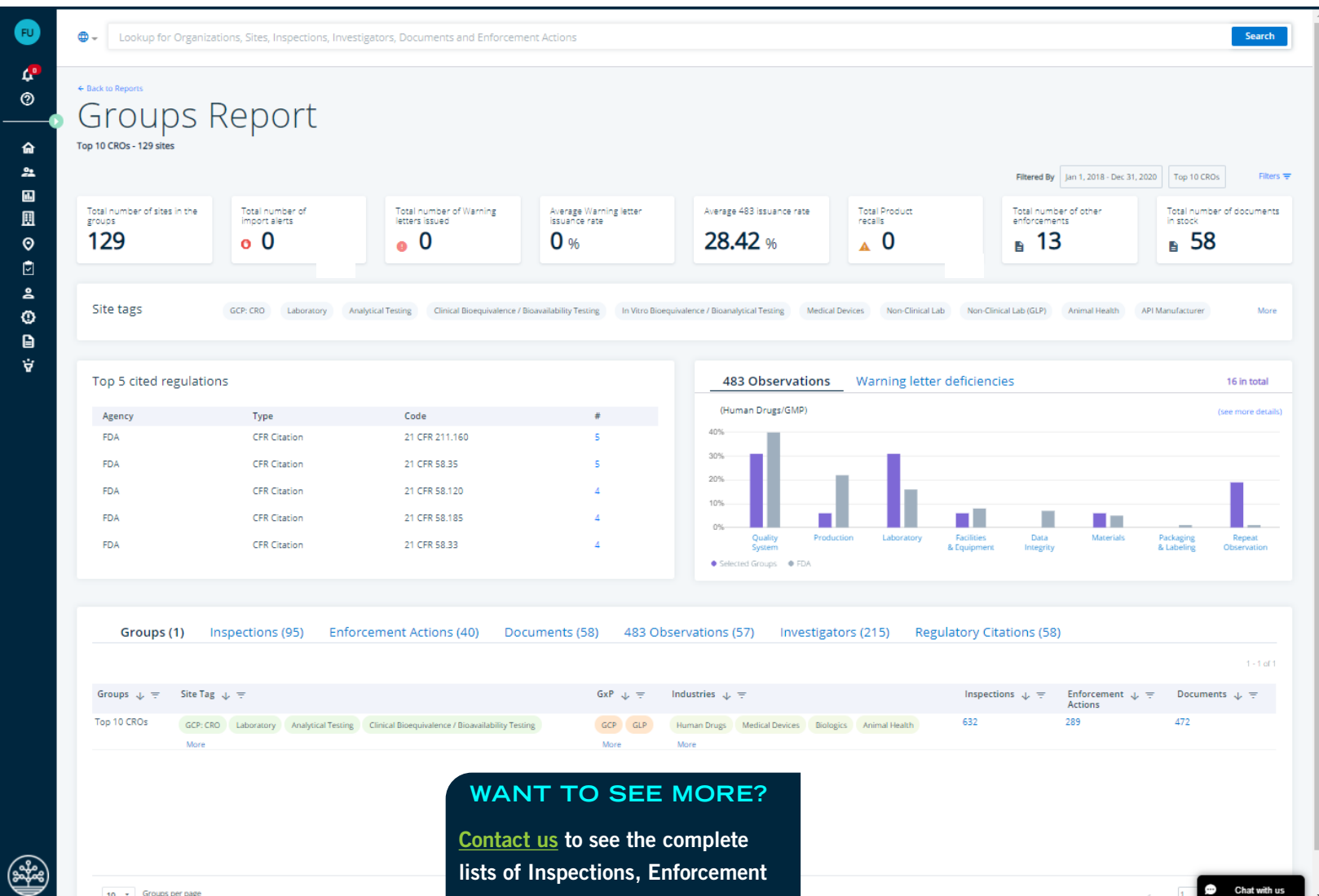
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## REDICA | TOP 10 CRO GROUPS REPORT

We developed proprietary automation and tags to augment data, giving Redica Systems customers the power to access information in seconds.

The Redica Systems Groups Report is used to compare and contrast historical enforcement trends for a set of organizations and/or sites. This is helpful if you are creating a report that compares inspection histories among CRO sites or preparing for an inspection.

In this example, we created a report that compares the inspection histories among sites of the top 10 CROs. Group Reports can also be used to help you prepare for an inspection or gain competitive intelligence.



The screenshot shows a dashboard for 'Groups Report' for 'Top 10 CROs - 129 sites'. It features a search bar at the top, a navigation sidebar on the left, and a main content area with several key metrics and charts.

**Key Metrics:**

- Total number of sites in the groups: 129
- Total number of Import alerts: 0
- Total number of Warning letters issued: 0
- Average Warning letter issuance rate: 0%
- Average 483 issuance rate: 28.42%
- Total Product recalls: 0
- Total number of other enforcements: 13
- Total number of documents in stock: 58

**Site tags:** GCP: CRO, Laboratory, Analytical Testing, Clinical Bioequivalence / Bioavailability Testing, In Vitro Bioequivalence / Bioanalytical Testing, Medical Devices, Non-Clinical Lab, Non-Clinical Lab (GLP), Animal Health, API Manufacturer, More

**Top 5 cited regulations:**

Agency	Type	Code	#
FDA	CFR Citation	21 CFR 211.160	5
FDA	CFR Citation	21 CFR 58.35	5
FDA	CFR Citation	21 CFR 58.120	4
FDA	CFR Citation	21 CFR 58.185	4
FDA	CFR Citation	21 CFR 58.33	4

**483 Observations - Warning letter deficiencies (16 in total)**

(Human Drugs/GMP)

Bar chart showing percentages for: Quality System, Production, Laboratory, Facilities & Equipment, Data Integrity, Materials, Packaging & Labeling, Repeat Observation. Legend: Selected Groups (purple), FDA (grey).

**Summary:** Groups (1), Inspections (95), Enforcement Actions (40), Documents (58), 483 Observations (57), Investigators (215), Regulatory Citations (58)

Filters: Groups (1), Site Tag (1), GxP (GCP, GLP), Industries (Human Drugs, Medical Devices, Biologics, Animal Health), Inspections (632), Enforcement Actions (289), Documents (472)

**WANT TO SEE MORE?**  
 Contact us to see the complete lists of Inspections, Enforcement Actions, Documents, and Observations for this group.