



REDICA
Systems

Redica Systems Data Integrity 483 Observation Report



REPORT

IN THIS REPORT WE IDENTIFY

- FY2020 Data Integrity 483 Observations
- Data Integrity Observations for Human Drugs
- Observations Falling Under GMP

PUBLISHED BY

REDICA SYSTEMS

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REDICA | 483 OBSERVATION REPORT | DATA INTEGRITY

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

Our database of over 20,000 483s is retyped and tagged, making it easy to create a 483 Observation Report in seconds. Redica Systems customers can even create a report showing 483 observations for a specific area of focus, such as data integrity, using topic tags.

FILTERED

Calendar Year: FY2020

Models: GMP

Data Source: 483

Industry: Human Drugs

Topic Tag: Data Integrity

← Back to Reports

483 Report (Barb Report 2.0)

Observations / Deficiencies (169)

Source	Type	Date Issued	Site	Industry	GXP	Site Tags	Associated Events	Model	Tags	Content
US - FDA	483 Observation	Jan 27, 2020	Peripheral Visions, Inc. (Black Diamond / United States of America) 30741 3rd Ave #123, Black Diamond, WA 98010, USA	Medical Devices Human Drugs	GMP	Medical Devices FDF Manufacturer	3	Human Drugs GMP	Quality System > Complaint management Quality System > Deviations / Investigations > Investigation topic Data Integrity > Original Data	OBSERVATION 1 Procedures for receiving, reviewing, and evaluating complaints by a forma... See More
US - FDA	483 Observation	Mar 12, 2020	Medical Products Laboratories, Inc. (Philadelphia / United States of America) 9990 Global Rd, Philadelphia, PA 19115, USA	Medical Devices Human Drugs	GMP	Animal Health Human Drugs: Generics Medical Devices Manufacturer Repackaging	3	Human Drugs GMP	Data Integrity > Legible Production > Sterile products > Personnel Monitoring Facilities and Equipment > Design > Plumbing Quality System > Records and Reports > Annual Product Quality Review	OBSERVATION 1 The responsibilities and procedures applicable to the quality control unit are not... See More
US - FDA	483 Observation	Mar 12, 2020	CHEMATICS, INC. (Leesburg / United States of America) 4519 IN-13, Leesburg, IN 46538, USA	Medical Devices Human Drugs	GMP	Medical Devices FDF Manufacturer	3	Human Drugs GMP	Production > Process Validation inadequate or missing - non-sterile Production > Process Validation inadequate or missing - sterile Data Integrity > Original Data	OBSERVATION 2 Procedures for monitoring and control of process parameters for a validated process... See More
US - FDA	483 Observation	Feb 25, 2020	Hudson Scientific LLC (Hudson / United States of America)	Medical Devices Human Drugs	GMP	Medical Devices Repackaging Relabeling FDF Manufacturer	3	Human Drugs GMP	Data Integrity > Legible	OBSERVATION 2 Procedure for finished d...

1 - 10 of 169

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483 Observations

Comparison Reports show more than just a high level summary. Users can drill down further to view specific observations associated with each organization based on site, date issued, industries (Human Drugs, Biologics, etc.), view associated events, read the primary and secondary citations, and even refine their filter further to only view desired Topic Tags (Production, Quality System, Data Integrity, and more).

SORT
Sort by Timeframe, Industries, or Associated Events

FILTER
Filter by Topic Tags

← Back to Reports

483 Report (Barb)

Observations / Deficiencies (169)

Source	Type	Date Issued	Site	Industry	GxP	Site Tags	Associated Events	Model	Tags	Content
US - FDA	483 Observation	Mar 11, 2020	Light Age, Inc. [Franklin Township / United States of America] 500 Appar Dr, Somerset, NJ 08873, USA	Medical Devices Less	Human Drugs GMP More	Medical Devices: Radiological Health Medical Devices PDF Manufacturer	3	Human Drugs GMP	Quality System > Audit > Internal Audit Program Data Integrity > Original Data	OBSERVATION 4 Procedures for quality audits have not been adequately established. See More
US - FDA	483 Observation	Jan 30, 2020	Perahealth Inc [Charlotte / United States of America] 1616 Camden Rd #350, Charlotte, NC 28203, USA	Medical Devices Less	Human Drugs GMP More	Medical Devices PDF Manufacturer	3	Human Drugs GMP	Data Integrity > Original Data Quality System > Records and Reports > Management Review	OBSERVATION 6 The management representative has not reported on the quality system perf... See More
US - FDA	483 Observation	Jan 30, 2020	Perahealth Inc [Charlotte / United States of America] 1616 Camden Rd #350, Charlotte, NC 28203, USA	Medical Devices Less	Human Drugs GMP More	Medical Devices PDF Manufacturer	3	Human Drugs GMP	Quality System > Complaint management Data Integrity > Attributable > General	OBSERVATION 8 Service reports do not include the required information. See More
US - FDA	483 Observation	Feb 28, 2020	ISOVAC Products, LLC [Romeoville / United States of America] 1306 Enterprise Dr Ste C, Romeoville, IL 60446, USA	Medical Devices Less	Human Drugs GMP More	Medical Devices PDF Manufacturer	3	Human Drugs GMP	Production > Nonsterile products > Cross Contamination Laboratory > Stability > Stability Program Data Integrity > Original Data	OBSERVATION 2 Procedures for design validation have not been adequately established. See More
US - FDA	Warning Letter Deficiency	Nov 9, 2020	Tarmac Products, Inc. d.b.a. Avara Pharmaceuticals [Hialeah / United States of America] 16311 NW 52nd Ave, Hialeah, FL 33014, USA	Medical Devices Less	Human Drugs GMP More	Medical Devices Manufacturer Human Drugs OTC Dietary Supplements	1	Human Drugs GMP	Production > Sterile Products > Microbiological Contamination Data Integrity > Original	Your laboratory records did not include complete testing data. See More

11 - 20 of 169

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WANT TO SEE MORE?
Contact us to see the complete list of data integrity 483 observations for FY2020.

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