



REDICA
Systems

Redica Systems Comparison Report Lonza & Catalent



REPORT

IN THIS REPORT WE IDENTIFY

- FY2018-FY2020 GMP data for Lonza & Catalent
- Top GMP primary citations
- Top FDA 483 observations

PUBLISHED BY

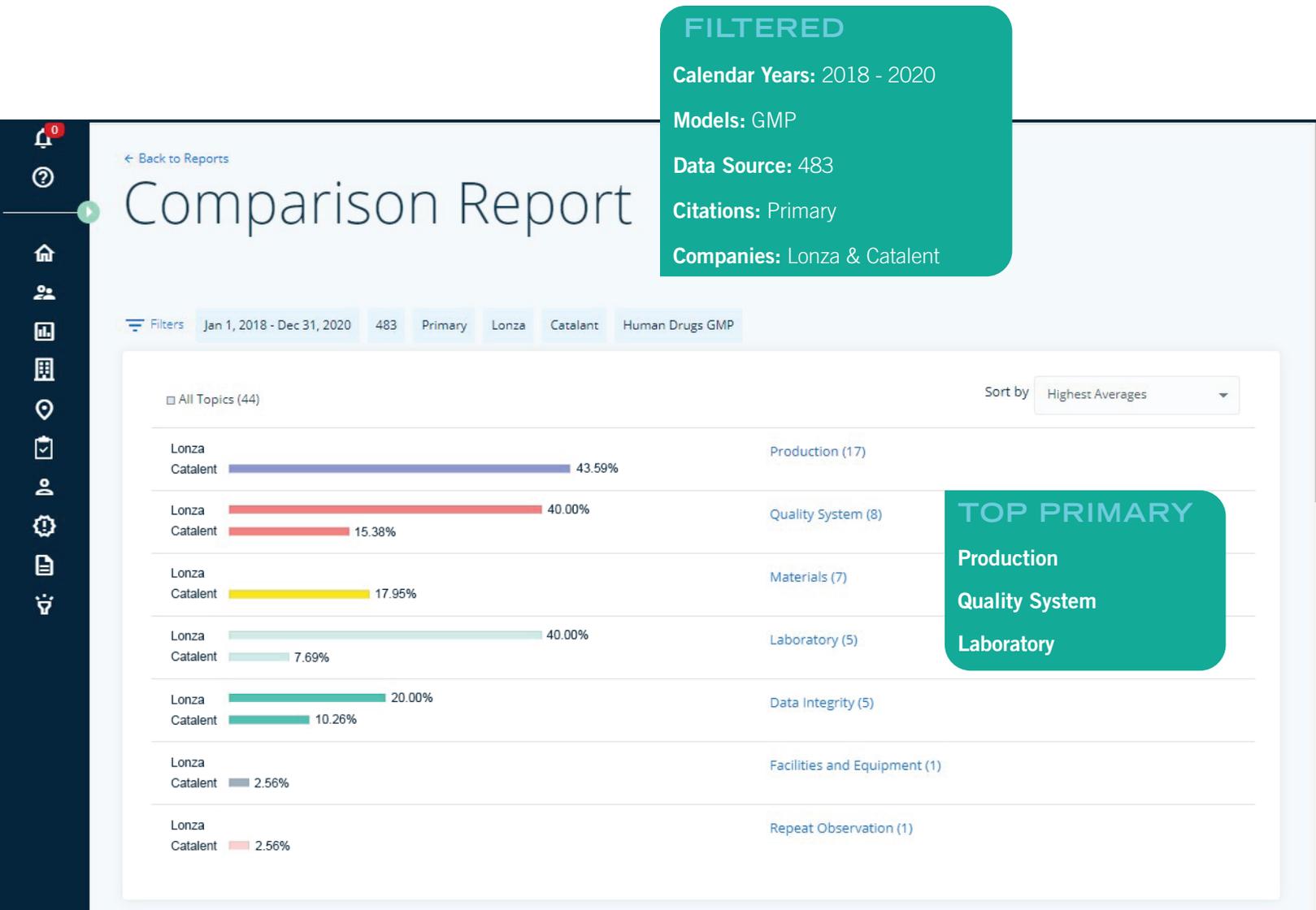
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REDICA | COMPARISON REPORT | LONZA & CATALENT

Primary Citations

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

The Comparison Report is used to compare and contrast two groups, giving you insight into historical 483 Observations issued and trends associated with them. Customers utilize this report to compare their site's inspection history to a competitor or group of competitors, and for inspection preparation.



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).

Below are the 483 Observations for Lonza and Catalent for their primary citations.

SORT
Sort by Date Issued, Industries, or Associated Events

FILTER
Filter by Topic Tags or Observations containing specific keywords

Organization	Site	Date Issued	GxP	Industries	Associated Events	Topic Tags	Observation Content
Catalent	Catalent Maryland [Baltimore / United States of America] 801 W Baltimore St #302, Baltimore, MD 21201, USA	Nov 4, 2019	GMP	Human Drugs Biologics	2	Production	OBSERVATION 1 Procedures designed to prevent microbiological contamination of drug products p... More
Catalent	Catalent Maryland [Baltimore / United States of America] 801 W Baltimore St #302, Baltimore, MD 21201, USA	Nov 4, 2019	GMP	Human Drugs Biologics	2	Quality System	OBSERVATION 2 Written records are not always made of investigations into unexplained discrepanc... More
Catalent	Catalent Indiana, LLC [Bloomington / United States of America] 1300 S Patterson Dr, Bloomington, IN 47403, USA	Oct 18, 2019	GMP	Human Drugs Medical Devices	2	Materials Data Integrity	OBSERVATION 1 Storage of drug products under appropriate conditions of temperature, hum... More
Catalent	Catalent Indiana, LLC [Bloomington / United States of America] 1300 S Patterson Dr, Bloomington, IN 47403, USA	Oct 18, 2019	GMP	Human Drugs Medical Devices	2	Production	OBSERVATION 2 Written production and process control procedures are not followed in the... More
Catalent	Catalent Indiana, LLC [Bloomington / United States of America] 1300 S Patterson Dr, Bloomington, IN 47403, USA	Oct 18, 2019	GMP	Human Drugs Medical Devices	2	Production	OBSERVATION 3 Procedure designed to prevent microbiological contamination of drug prod... More
Catalent	Catalent Indiana, LLC [Bloomington / United States of America] 1300 S Patterson Dr, Bloomington, IN 47403, USA	Oct 18, 2019	GMP	Human Drugs Medical Devices	2	Production	OBSERVATION 4 Equipment shall be cleaned and maintained at appropriate intervals to pre... More
Catalent	Catalent Indiana, LLC [Bloomington / United States of America] 1300 S Patterson Dr, Bloomington, IN 47403, USA	Oct 18, 2019	GMP	Human Drugs Medical Devices	2	Facilities and Equipment	OBSERVATION 5 Written procedures shall be established and followed for cleaning and maintena... More
Catalent	Catalent Nottingham Ltd. [Nottingham / United Kingdom of Great Britain and Northern Ireland] 8 Orchard Pl, Nottingham NG8 6PX, UK	Oct 11, 2019	GMP	Human Drugs	3	Data Integrity Production	OBSERVATION 1 A written record of the program along with appropriate validation data has not been... More
Catalent	Catalent Nottingham Ltd. [Nottingham / United Kingdom of Great Britain and Northern Ireland] 8 Orchard Pl, Nottingham NG8 6PX, UK	Oct 11, 2019	GMP	Human Drugs	3	Production Data Integrity	OBSERVATION 2 The batch production and control records are deficient in that they do no... More
Catalent	Catalent Pharma Solutions, LLC [Woodstock / United States of America] 2210 Lake Shore Dr, Woodstock, IL 60098, USA	Jun 25, 2019	GMP	Human Drugs Biologics	2	Production	Observation 1: Environmental monitoring (EM) for the Suite (b) (4) BPS fill machine, System 1. More

Organization	Site	Date Issued	GxP	Industries	Associated Events	Topic Tags	Observation Content
Catalent Catalent family tree	Catalent Pharma Solutions, LLC [Woodstock / United States of America] 2210 Lake Shore Dr, Woodstock, IL 60098, USA	Jun 25, 2019	GMP	Human Drugs Biologics	2	Production	Observation 2: Standard Operating Procedures (SOPs) are not followed. More
Catalent Catalent family tree	Catalent Pharma Solutions, LLC [Woodstock / United States of America] 2210 Lake Shore Dr, Woodstock, IL 60098, USA	Jun 25, 2019	GMP	Human Drugs Biologics	2	Production	Observation 3: The visual inspection process is inadequate. More
Catalent Catalent family tree	Catalent Pharma Solutions, LLC [Woodstock / United States of America] 2210 Lake Shore Dr, Woodstock, IL 60098, USA	Jun 25, 2019	GMP	Human Drugs Biologics	2	Materials	Observation 4: Utilities and equipment are not adequately maintained. More
Catalent Catalent family tree	Catalent Pharma Solutions, LLC [Woodstock / United States of America] 2210 Lake Shore Dr, Woodstock, IL 60098, USA	Jun 25, 2019	GMP	Human Drugs Biologics	2		Observation 5: The production batch record for a yield discrepancy is inadequate. More
Catalent Catalent family tree	Catalent Pharma Solutions, LLC [St. Petersburg / United States of America] 2725 Scherer Dr, St. Petersburg, FL 33716, USA	Feb 22, 2019	GMP	Human Drugs	3	Laboratory	OBSERVATION 1 The written stability testing program is not followed. More
Catalent Catalent family tree	Catalent Pharma Solutions, LLC [St. Petersburg / United States of America] 2725 Scherer Dr, St. Petersburg, FL 33716, USA	Feb 22, 2019	GMP	Human Drugs	3	Laboratory Production	OBSERVATION 2 Laboratory controls do not include the establishment of scientific... More
Catalent Catalent family tree	Catalent Pharma Solutions, LLC [St. Petersburg / United States of America] 2725 Scherer Dr, St. Petersburg, FL 33716, USA	Feb 22, 2019	GMP	Human Drugs	3	Data Integrity Quality System	OBSERVATION 3 Written production and process control procedures are not followed in the executio... More
Catalent Catalent family tree	Catalent Pharma Solutions LLC [Winchester / United States of America] 1100 Enterprise Dr, Winchester, KY 40391, USA	Dec 21, 2018	GMP	Human Drugs	3	Quality System Data Integrity	OBSERVATION 1 There is a failure to thoroughly review any unexplained discrepancy whether or not... More
Catalent Catalent family tree	Catalent Pharma Solutions LLC [Winchester / United States of America] 1100 Enterprise Dr, Winchester, KY 40391, USA	Dec 21, 2018	GMP	Human Drugs	3	Data Integrity	OBSERVATION 2 Appropriate controls are not exercised over computers or related systems to... More
Catalent Catalent family tree	Catalent CTS (Kansas City), LLC [KC/MO / United States of America] 10245 Hickman Mills Dr, Kansas City, MO 64137, USA	Oct 23, 2018	GMP	Human Drugs	2	Quality System Laboratory Production Data Integrity	OBSERVATION 1: There is a failure to thoroughly review any unexplained discrepancy whet... More

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Organization	Site	Date Issued	GxP	Industries	Associated Events	Topic Tags	Observation Content
Catalent Catalent family tree	Catalent CTS (Kansas City), LLC [KC/MO / United States of America] 10245 Hickman Mills Dr, Kansas City, MO 64137, USA	Oct 23, 2018	GMP	Human Drugs	2	Data Integrity Packaging and Labeling Laboratory	OBSERVATION 2: Appropriate controls are not exercised over computers or related systems... More
Catalent Catalent family tree	Catalent CTS (Kansas City), LLC [KC/MO / United States of America] 10245 Hickman Mills Dr, Kansas City, MO 64137, USA	Oct 23, 2018	GMP	Human Drugs	2	Materials	OBSERVATION 3: The flow of in-process materials through the building is not designed to... More
Lonza Lonza Group family tree	Lonza Walkersville, Inc. [Walkersville / United States of America] 8830 Biggs Ford Rd, Walkersville, MD 21793, USA	Jul 3, 2018	GMP GVP	Human Drugs Medical Devices	3	Laboratory Production Quality System Data Integrity	OBSERVATION 1 Process control procedures that describe any process controls necessary to ensure c... More
Lonza Lonza Group family tree	Lonza Walkersville, Inc. [Walkersville / United States of America] 8830 Biggs Ford Rd, Walkersville, MD 21793, USA	Jul 3, 2018	GMP GVP	Human Drugs Medical Devices	3	Laboratory Facilities and Equipment	OBSERVATION 2 Procedures to ensure equipment is routinely calibrated, inspected and maintained ha... More
Lonza Lonza Group family tree	Lonza Walkersville, Inc. [Walkersville / United States of America] 8830 Biggs Ford Rd, Walkersville, MD 21793, USA	Jul 3, 2018	GMP GVP	Human Drugs Medical Devices	3	Quality System Production Data Integrity	OBSERVATION 3 Procedures for corrective and preventive action have not been adequately ... More
Lonza Lonza Group family tree	Lonza Walkersville, Inc. [Walkersville / United States of America] 8830 Biggs Ford Rd, Walkersville, MD 21793, USA	Jul 3, 2018	GMP GVP	Human Drugs Medical Devices	3	Data Integrity	OBSERVATION 4 Procedures to ensure that all purchased or otherwise received product ... More
Catalent Catalent family tree	Catalent Pharma Solutions, LLC [St. Petersburg / United States of America] 2725 Scherer Dr, St. Petersburg, FL 33716, USA	Jun 14, 2018	GMP	Human Drugs	3	Production	OBSERVATION 1 Procedures designed to prevent objectionable microorganisms in drug prod... More
Catalent Catalent family tree	Catalent Pharma Solutions, LLC [St. Petersburg / United States of America] 2725 Scherer Dr, St. Petersburg, FL 33716, USA	Jun 14, 2018	GMP	Human Drugs	3	Production	OBSERVATION 2 Written procedures are not followed that describe the examinations to be... More
Catalent Catalent family tree	Catalent Pharma Solutions, LLC [St. Petersburg / United States of America] 2725 Scherer Dr, St. Petersburg, FL 33716, USA	Jun 14, 2018	GMP	Human Drugs	3	Quality System Production Laboratory	OBSERVATION 3 Drug product production and control records, are not reviewed by the qua... More
Catalent Catalent family tree	Catalent Pharma Solutions, LLC [St. Petersburg / United States of America] 2725 Scherer Dr, St. Petersburg, FL 33716, USA					Repeat Observation	OBSERVATION 4 The responsibilities and procedures applicable to the quality control un... More

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WANT TO SEE MORE?
Contact us to see the complete list of top secondary citations for Lonza and Catalent or a comparison of two companies of your choice.

CONTACT US FOR MORE INFORMATION | SALES@REDICA.COM | 844-332-3320