Regulatory Trends, Insights, and Impact

Agilent
Trusted Answers

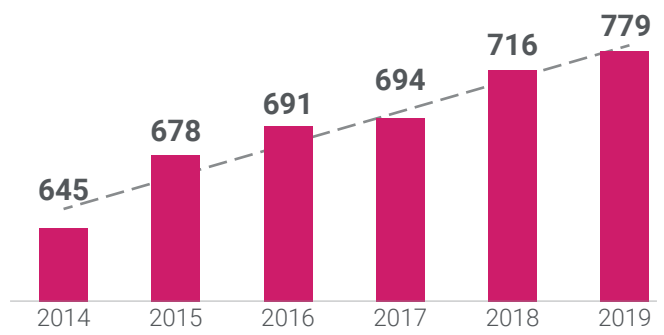
Globalization is leading to a paradigm shift in compliance and increased scrutiny on data and product quality

FDA Form 483 Observations

FDA enforcement continues to increase

Total number of observations issued by FDA (for drugs)*

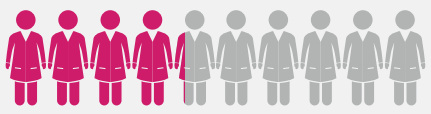
*As published in the FDA Inspection Observation Summaries.



70%

of all Form 483 observations are related to **Data Integrity**

The impact and challenges around data integrity



43% of lab leaders say data integrity is one of the **key pain points** in their labs

54% of lab leaders cite **data integrity as being very important** to their work

70% of lab leaders say **improving documentation** of the sample chain of custody and data integrity is a **key strategy** for **advancing drugs** through the pipeline quicker

This data comes from Pharma Lab Leaders#

#2019 Frost & Sullivan global survey of pharma laboratory leaders.

Warning letters

The number of drug GMP warning letters issued globally each year continues to climb

Impact of warning letters

> *Forced to delay the launch of a new product by two years.*

According to an article in The Wall Street Journal

> *One bad 483 cost our company $5 M.*

Former VP of Quality

> *Loss of business ranging from $270–600 M.*

According to a case study by McKinsey & Company

> *Time and resource allocation to fix the compliance and quality-related issues cost upwards of $200 M.*

According to an article in The Wall Street Journal

> *Forget about actual warning letters. The cost of us receiving a moderately bad 483 is roughly $250,000.*

Head of Manufacturing of Biopharma Company

Impact of consent decrees

A typical consent decree lasts three to five years and can result in significant financial loss

> $100 M
Spent on consultants and third-party auditors

> $100 M
Revenue loss due to product shortages

> $500 M
Costs to companies in fines, penalties, remediation expenses, and lost sales

~ 625 products
Recalled since 2011

Impact of consent decree data from: www.lachmanconsultants.com

Stock prices fall dramatically and companies immediately become takeover targets for other firms at a significantly reduced overall cost

Pharma company

Facilities in Puerto Rico and New Jersey

Impact
Sites remain open with third-party oversight

Cost/Penalties
- $500 M disgorgement penalty and potential for a maximum of $175 M in additional penalties if timelines were missed (did not occur)
- $40 M in lost sales due to termination of certain product lines
- Approval of popular antihistamine drug delayed by one year; loss of revenue not determined

Pharma company

Facilities in New York and Pennsylvania

Impact
Sites remain open with third-party oversight; one plant is decommissioned and sold

Cost/Penalties
- $30 M disgorgement penalty and $26 M in other fees and costs
- $267 M in fines paid in 2001
- Closure of two plants

Generic pharma company

Facilities in U.S. and India

Impact
The company relinquishes 180-day marketing exclusivity for three generic drug applications

Cost/Penalties
- Company to withdraw applications with data integrity issues
- Up to $10 M/year penalty if drugs distributed from consent decree sites
- Up to $30 M/year penalty if additional untrue statements were made to FDA

To learn how to mitigate data integrity challenges, please visit: Data Integrity Resource Center

DE.44301.4655671296

Published in the USA, April 22, 2021
5994-3229EN