



Quality Metrics Report

The FDA issued new guidance to the Bio/Pharmaceutical industry regarding contractor management, which outlined that manufacturers are ultimately responsible for all operations of the supply chain, including contract vendors. The agency is seeking to have efficient, flexible and compliant firms without extensive regulatory oversight by developing meaningful quality metrics, not just for the firm itself, but for all involved supply chain partners.

In order to meet the desired state required by FDA, firms must establish an effective quality system through implementation of a strong quality culture and proactive management. Companies that abide by this guidance and successfully present quality metrics to the FDA would potentially be considered low risk, thus decreasing the frequency of required audits by the FDA.

Eurofins BioPharma Product Testing has taken proactive measures to help our clients meet this requirement with the development of our Quality Metrics Reports. The reports serves as a score cards to measure key quality and operational indicators throughout your projects with us.

Why Choose Eurofins BioPharma Product Testing?

- We are among the first laboratories to offer this report in response to the FDA's new guidelines.
- We maintain a strong regulatory profile through successful inspections by the most prominent domestic and international authorities, such as FDA, EMA and DEA.



Type of Data Reported

Our standard metrics are provided on a quarterly basis to allow for identification of performance trends.

The standard reports include key operational and quality indicators, such as:

- **Service Measures:** Total on time completion of tests and/or study activities
- **Quality Measures:** Investigation rate reported as a proportion of total tests completed

Service Measures

Regulatory Status	Time Period	Test/Study Activity Count	Test/Study Activity TAT (% on time)
GMP Commercial	Q1 2021	X	X.X
GMP Commercial	Q2 2021	X	X.X
GMP Non-Commercial	Q1 2021	X	X.X
GMP Non-Commercial	Q2 2021	X	X.X



Quality Measures

Regulatory Status	Time Period	EX Count	Test/Study Activity Count	% Exception/Test	% OOS/ Sample (Product)	% OOS/ Sample (Lab)	% Operator Error/Test	% Client Related/ Test	% PACF/ Study
GMP Commercial	Q1 2021	X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
GMP Commercial	Q2 2021	X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
GMP Non-Commercial	Q1 2021	X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
GMP Non-Commercial	Q2 2021	X	X.X	X.X	X.X	X.X	X.X	X.X	X.X

*The reports may be further customized to meet client needs for an additional charge. Contact your Business Development Representative or Project Manager to discuss options.

Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing
Cell Banking Services • Virology Services • Facility & Process Validation
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology
Stability Testing & Storage • Primary & Secondary Package Testing

Flexible Service Models

Fee For Service (FFS)
Full-Time-Equivalent (FTE)
PSS Insourcing Solutions®

Global Facilities

Australia	Denmark	Ireland	New Zealand	Switzerland
Austria	France	Italy	Spain	UK
Belgium	Germany	Japan	Slovakia	US
Canada	India	Netherlands	Sweden	