



How Thermo Fisher Scientific Streamlined Inspection Management With AuditUtopia®

In highly regulated industries, you can count on the fact that your company will be inspected a time or two by regulatory agencies and/or your clients. Most companies manage these inspections using a mixture of programs for different aspects of the inspection. A leading problem with that approach is that these programs do not communicate with each other or update automatically.

Ridding Manual Processes During Inspections

Thermo Fisher Scientific's Viral Vector Services (VVS) division (formerly Brammer Bio) is a contract development and manufacturing organization (CDMO) with three cGMP facilities and over 100 successful client projects under their belt. The VVS division was sometimes handling up to two inspections per month. During each of the inspections, the team was using multiple tools to manage inspections requests and to communicate between the inspection room, support room, and strategy room.

Audits and inspections undoubtedly call for numerous teams working simultaneously to fulfill requests. When these teams are not in sync, opportunities for missed and incomplete request responses arise. This causes strain on the inspection process as well as on the employee's tasks.

For these reasons, Thermo Fisher brought on AuditUtopia®. Prior to AuditUtopia, Thermo Fisher managed the communication and requests surrounding the inspection using manual tools to communicate with those outside of the inspection room.

For example, the team would use a shared Microsoft OneNote folder to keep notes and track requests. The OneNote method required the team to enter basic information such as request number and type of request and track the progress of the request manually by refreshing the OneNote file. This made communication difficult and left notes unorganized.

ThermoFisher
S C I E N T I F I C

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The overall flow of the audit is smoother, and we have received compliments from our clients about how much our audit process has improved.

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Kayla Harris, Quality Assurance
Project Manager

The Cost of a Failed Regulatory Inspection

With the cost of a failed regulatory inspection approaching hundreds of thousands of dollars, the VVS division needed a dedicated solution to manage their regulatory and client inspections. Thermo Fisher's VVS division soon found that one software, AuditUtopia®, stood above the rest for its responsiveness, ease of use, implementation program, and single platform solution for all their inspection management needs.

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The training process was thorough. Our trainer was very knowledgeable and gave us a recording of the training so we could train future employees and off-site employees on the utility of the program.

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Cameron Jones, Head of VVS
Quality Compliance & Regulatory

Switching to AuditUtopia®

For most companies, the thought of implementing a new software to replace an established system is daunting. PSC Software™ aims to mitigate the stress and learning curve that often comes with the implementation of a new software by providing trainers who are subject matter experts on the program along with recordings of the same trainings as a reference documents for future employees.

Gaining Peace of Mind While Achieving Results

Following a seamless implementation process, the Viral Vector Service's inspection management team is able to stay organized and on top of the requests and inspection as a whole. Rather than playing “telephone”, the team is relying on first-hand, written accounts of what is being said in the inspection room.

The Thermo Fisher VVS team can now track the status of each request in real time and view metrics on where they struggle to answer requests in a timely, efficient manner. With the implementation successful, Thermo Fisher and PSC Software™ look forward to a successful long term partnership.

See how AuditUtopia® can improve your inspection readiness today!

[Free Demo](#)