Better Investigations – Using Appropriate and Accurate Data to Expedite and Enhance Root Cause Analysis

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Abstract

Most Quality Control (QC) labs are aware of the need for monthly and quarterly trend reports, but those reports, even if they are easy to generate, do not maintain your cleanrooms in a state of control. So, what does? Timely data analysis, automated trend alerts, real time trends and rapid investigations allow you to react to events in a more meaningful manner. Having access to good data allows you to analyse your own existing data for clues that can lead to better root cause analysis and reduce the cycle time associated with these investigations as well. This presentation covers some of the strategies involved in managing investigations which will allow you to be more in control of the state of your cleanroom. These strategies will also lead to more meaningful routine trend reporting.

Digital Transformation to Enable Faster and More Robust Investigations

Throughout the industry transformation into a digital workspace, definitive rules and practices were not always immediately available. The result was that as platforms matured, a lot of changes were mandated and often retroactively provided as guidance and standards were formed. Industry buzzwords like “data integrity” dominated conversations and, sometimes, could seemingly make the science involved in your Environmental Monitoring (EM) and Testing programs take a back seat to coming to grips with which direction the industry was headed towards. There was pressure to ensure that your system(s) were “adequate.” Unfortunately, having a platform that can answer the call to things like data integrity and audit reviews does not necessarily mean that it can adequately and sufficiently answer the pressing questions that are urgently required during quality events.

The Right Solution to Capture Your Data

Context is critical. Environmental Monitoring programs should be designed with purpose and allow for associations with inherent “metadata,” that allows information to be attributed to your transactions. This can lead to accomplishing compliance and enhanced data retrieval benefits. Without foresight into how laboratories are executing their sampling and testing, platforms can miss the mark when it comes to ease of use and achieving the true goal of providing data and support that can properly inform a decision.

A platform developed specifically for QC Microbiology will include the ability to leverage its data structure to enable flexible reporting and querying. The platform should include a framework that is easily identifiable to the target audience (Laboratory Personnel) and facilitates the translation of site requirements and operating procedures into a digital workflow. This translation of procedures must conform with the planned data standard of the platform and allow for scalability. When a platform is purposefully built, customization is rarely, if ever, required within the application core and this homogenous approach can lend itself well to scrutiny from regulatory agencies.

Considerations for Selecting a Digital EM Platform

- **Configuration over customization –** a turnkey solution developed to meet the business needs
- **Ad Hoc Data Retrieval and Metadata Analysis –** to facilitate more dynamic and useable reporting
- **Integration Capability –** It is structured to seamlessly share data across systems
- **Workflow Adherence –** Build compliance into your system

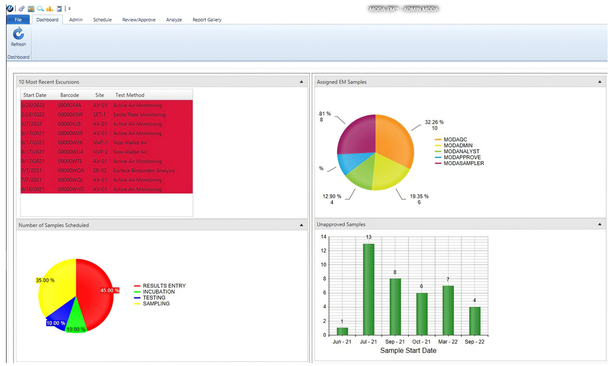

Figure 1. Dashboards

When you can progress from a platform that meets minimum standards to one that meets or exceeds requirements and provides meaningful data, there is a beneficial impact to your laboratory workflow. Within the Environmental Monitoring space, it can be far too easy to be reactionary. When quality events occur, there can often be a de facto response. The response may include additional sampling, additional cleaning and disinfection activities, and confirmation of “resolution” through a predetermined number of passing EM samples following an excursion. **When fast and reliable data is available, you can take the next steps toward not just reactive monitoring but start a proactive approach.**

Real Time Data Retrieval

Digital platforms can provide rapid visualization and feedback to users of the system. Dashboards, KPIs, and status updates should be readily available to allow for someone to quickly understand issues and workloads. (Figure 1 and Figure 2) Being able to move from printed reports to interactive displays of information can also be critical differentiators. As mentioned above, hierarchical associations are easy to understand, but being able to see an overlay of samples and recoveries against a room or site map can provide impact when relaying information or providing the context and significance of events. Having multiple ways to view and analyse data is a significant differentiator for your digital laboratory system.

The Importance of Data Structures

Solutions that are purpose built will assist their users with recurring issues. In the quality event space, this will include the ability to quickly aggregate data related to investigations. Easy access to dynamically selected area and room trend reports can allow you to contextualize recoveries over variable periods of time and over varying tests and locations. The manner in which data is structured can create relative hierarchies and bring along intrinsic data associations that are beneficial when reviewed. Being able to group data by collection method, site, room, suite, corridor, building, etc… becomes possible when a platform’s data setup models real-world relationships and is easy to translate into the digital workflow. Having a mechanism to identify critical data parameters and elements is critically important when it comes to standardizing the approach to data review and reporting. With configurable software and workflows, a platform must be able to account for variations across the client base and allow users to identify their reporting requirements.

Making your data work for you

When your data platform allows you to translate your processes into a digital workflow and identify critical areas of data, the next step is providing answers without the need to customize a solution or report. Data requirements for an investigation requires an overview of multiple activities. (Fig 3) Real-time notifications of recurring recoveries, alert level, or action limit excursions must be available through the system, due to the amount of data generated during environmental monitoring being too high to solely rely on a retrospective review. When excursions occur, the data system should be capable of highlighting events that happened prior to the deviation as well as any samples that have occurred following the event (allowing for a pre and post-event review). **The system should be capable of quickly and easily providing details on who was involved in each phase of the sample’s workflow.** Any equipment or media associated with the sample from the event should automatically be identified as well as other related deviations that occurred within a specified period. By collating and providing this information, the system allows the quality personnel who would normally be consumed with hunting down this information to instead focus on analysing and consuming the data. Between the ease of data retrieval and a workflow engine that can aid in enforcing compliance to a site data standard, a digital platform must enable your Environmental Monitoring Program rather than hinder it.

Critical elements like product and batch association should be easy to identify and aggregate against. Pharmaceutical manufacturing can include both “routine” as well as batch related samples associated to manufacturing activity. How your platform handles this information can be the difference between concise reports versus multiple report and attachments being required for batch release. Having the ability to associate samples with multiple production batches and having a data structure that allows that to be easily handled is necessary. When the metadata associated with a sample is standardized and easily retrievable, your platform can provide the answers to time critical questions. The metadata allows you to expand your impact assessment scope to multiple locations, rooms, operators affected batches. It helps frame your investigation rapidly and more importantly, appropriately. Dedicated solutions and platforms leverage their customer base to better understand the trials and tribulations that are encountered. There can be a significant benefit provided by the platform when learning and understanding from the client base is used to bolster the system and the answers it can provide.

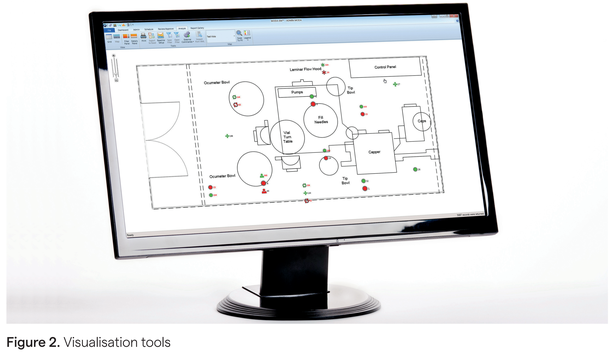

Figure 2. Visualisation tools

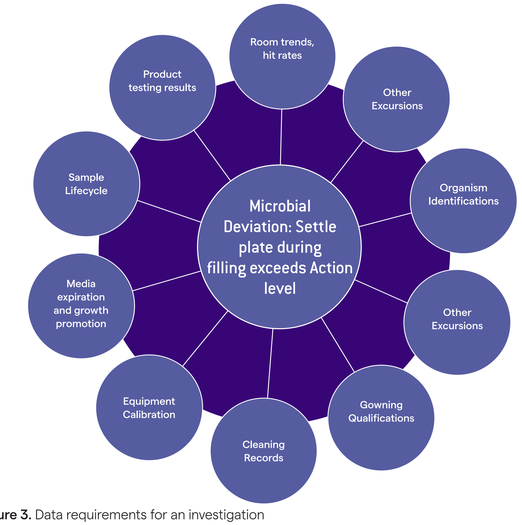

Figure 3. Data requirements for an investigation

Conclusion

The creation and maintenance of a compliant Environmental Monitoring Program is labor intensive. The systems and tools that are used toward this effort should help to ensure compliance with regulatory expectations and can assist with the timely turnaround of information so that appropriate action can be taken quickly. Through a combination of real-time notification(s), standard reporting, and workflow controls, your Environmental Monitoring platform can provide quality responses to ensure your success.