P01 Digitalization in Environmental Monitoring – An opportunity to gain efficiency and improve data integrity and investigations

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Introduction

Environmental monitoring is a mandatory yet non-value adding task in aseptic production, especially in grade A and B environments. A lot of laboratories are doing it still paper based with data transcription risks and Excel or similar non-validated systems for reporting and trending, thus lacking readily available validated data and processing tools. This leads to delays and significant overheads to in reporting, monitoring and trending, as well as limitations and delays in investigations. We want to show strategies on how digitalization could mitigate these limitations and increase efficiency.

Materials and methods

We analyzed discussions from the past year with >10 companies doing environmental monitoring in Annex 1 regulated QC and are not digitalized yet for how they are currently doing it and their biggest challenges in the process. We conducted interviews with subject matter experts how digitalization could address those issue.

Results and discussion

All companies not using digitalization used paper based documentation and reporting and trending in Microsoft Excel. Out of the challenges we identified the following with compliance issues and efficiency gains being the most popular ones:

- Issues with sampling plan (samples not scheduled according to sampling plan)
- Missing data points (Forgetting to take samples, loosing plates, overincubation, etc.)
- Data integrity/process execution (Lack in enforcing the process, improper sampling, etc.)
- Compliance issues (e.g. reporting and trending using Excel)
- Efficiency gains (faster sampling plans, more sample with same number of people, faster reporting and trending, more regular trending reports)

In addition, we discussed with subject matter experts the potential of digitalization to improve the situation. Digitalization of environmental monitoring processes has the potential to enable significant improvements in the execution of the process and avoids errors, such as issues with the sampling plan, proper sampling and incubation, making sure all the data is entered correctly in the system. However, proper digital data collection is key. It enables significant efficiency gains especially around reporting and trending as well as audits, as all the data is readily available and can be analyzed in real time. In addition, we identified investigations and root cause analysis as another major area of improvements of digitalization.