# Understanding the new EU GMP Annex 1 environmental monitoring. And how the BioTrak® could be the ARMM you need.

## Real-Time Continuous Monitoring

The BioTrak is a viable and non-viable particle counter providing data in real time, allowing you to monitor the entire critical process from the installation of equipment to aseptic production and batch release. This allows you to make use of combined real-time monitoring data for improved process automation, accelerated decision making and improved process analytics.

*"9.24 Continuous viable air monitoring in Grade A (e.g. air sampling or settle plates) should be undertaken for the full duration of critical processing, including equipment (aseptic set-up) assembly and critical processing."*

## Minimised interventions = increased productivity

Replacing compendial methods, including settle plates and active air sampling in the process area, can reduce interventions for changing plates, which reduces risk and product waste. It also allows for early detection of excursions to enable line stoppage and segregation of products. An integrated viable particle collection filter can be changed without interventions in the process area.

*"9.17 The grade A area should be monitored continuously (for particles ≥0.5 and ≥5µm) and with a suitable sample flow rate (at least 28 litres (1ft$^3$) per minute) so that all interventions, transient events and any system deterioration are captured."*

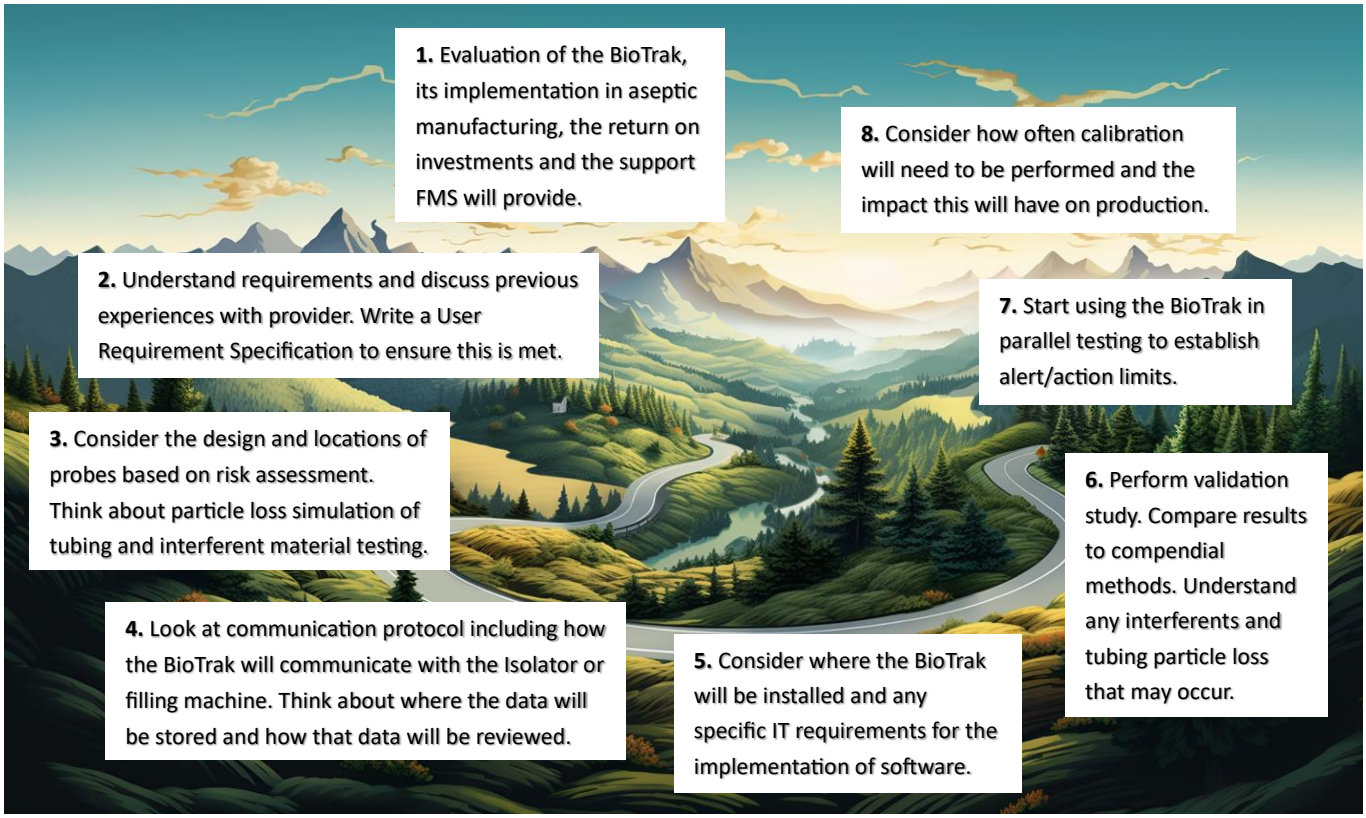
## Measure the risk at the risk

Because the BioTrak sits outside of the filling line but will be connected via tubing and an Isokinetic probe, you can position the probe optimally, at the highest point of contamination risk. Additionally, BioTrak can scan for increased viable particle concentration through a handheld probe, allowing for targeted investigations to determine specific microbiological contamination source locations in a problem area.

*"4.28 For the aseptic processing area and the background environment… all critical processing areas such as the point of fill and container closure feeder bowls should be evaluated. Critical processing locations should be determined by documented risk assessment and knowledge of the process and operations to be performed in the area."*

## What does the BioTrak® Implementation Roadmap look like?

**FMS has created a Roadmap enabling companies to implement Real-time Viable Particle monitoring in their Grade A aseptic production spaces.**

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