



Is your Environmental Monitoring Annex 1 Compliant?



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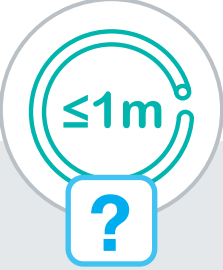


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Key EMS Points from Annex 1



“Tube length should typically be no longer than 1m unless justified and the number of bends should be minimized.”†



“Review of ongoing monitoring data should be carried out to identify any adverse trend in system performance.”†



“The monitoring programme should be considered in the overall context of the trend analysis and the CCS for the site.”†

The new version of EU GMP Annex 1 comes into force on 25 August 2023 and could have a major impact on existing Environment Monitoring System installations. With this date fast approaching it is important to assess your current EMS installation and ensure a robust plan is in place to move to compliance.

Some areas of particular concern are the new requirement to ensure that particle count tube length should be no longer than 1m unless justified, and the number of bends should be minimized. The new revision also introduces the need for a contamination control strategy (CCS) in which the monitoring programme and associated data plays a key role.

To assist our customers in achieving Annex 1 readiness, Pharmagraph are offering an **Annex 1 Site Survey** by one of our expert EMS engineers.

This survey covers a documented procedure which reviews both key hardware and software status, with the **findings and key risk areas published in a summary report** within 5 days of our visit.

Contact your local Sales Manager or sales@pharmagraph.co.uk for a survey quote today.*



† The Rules Governing Medicinal Products in the European Union Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use Annex 1.

* Survey chargeable based on number of fixed particle count locations.

