CHILL Talent Office – Environmental Monitoring Specialist - Basic Pharma

Will you be our new Environmental Monitoring (EM) Specialist at Basic Pharma?

Basic Pharma is a unique Dutch pharmaceutical company that is growing rapidly, continuously building its organization, and further specializing and developing. The company focuses on the full breadth of the pharmaceutical industry: from product development, registration, production, and commercialization of (bio)pharmaceutical products to pharmaceutical services, Basic Pharma serves an ever-growing circle of national and international clients, from startups to multinationals.

Have you always had a passion for the pharmaceutical sector, and would you like to work in a dynamic, innovative environment? Or are you looking for a career switch and ready for a new challenge? At Basic Pharma, you will have the opportunity to develop as Environmental Monitoring Specialist and play an important role in the production of medicines that improve the health of many people!

What will you be working on at Basic Pharma?

The Environmental Monitoring (EM) Specialist is a technical role that assists in the development and implementation of the site's environmental monitoring programs and provides technical guidance and expertise in sterility assurance, contamination control, aseptic process simulations, gowning/aseptic techniques, and cleaning/sanitization strategies. This position is also responsible for writing EM trend reports, giving advice on EM deviations, and providing first-line response related to aspects noted with Eudralex EU GMP Annex 1 Manufacture of sterile medicinal products.

Tasks:

- Lead or provide guidance for activities related to cleanroom programs, including but not limited to:
    - Environmental Monitoring Performance Qualifications (including execution activities)
    - Aseptic Process Simulations
    - Cleaning, Sanitization, and Disinfection
    - Gowning within GMP Classified Areas
    - Aseptic Processing Techniques
    - Contamination Control
- Assist in developing and implementing processes and facility environmental monitoring to ensure the correct establishment of contamination control strategies.
- Lead in evaluating EM data and authoring EM Trend Reports. Analyze microbial and manufacturing data to identify trends, process discrepancies, and opportunities for continuous improvements.
- Lead with support and provide technical expertise for developing the site's contamination control strategy (CCS) as required by Annex 1, as well as cleaning and sanitization program/strategy and disinfectant efficacy strategies.

- Lead/assist with support and/or provide technical expertise for the facility's cleanroom gowning and aseptic technique strategy/program.
- Assist with identifying facility environmental isolates and how to create and maintain environmental isolation cultures.
- Initiate and assist with introducing specific microbial techniques within the Basic Pharma Microbiology laboratory.
- Provide technical support for root cause investigations associated with cleanroom excursions.
- Participate and/or provide technical support during internal and external audits on topics related to environmental monitoring and aspects within the site CCS.
- Create, execute, review, and/or approve technical documents and change controls related to activities indicated within the site CCS.

Capabilities:

- Decide on identification testing of micro-organisms
- Initiating CAPAs in the event of deviations identified during environmental monitoring.
- Proposing improvements to SOPs and work instructions.
- Escalating serious deviations to supervisors or quality management.
- Requesting additional analyses or investigations in the case of suspicious results

Responsibilities:

- Primary site lead in CCS and Annex 1 knowledge.
- Responsible for the quality of work delivered.
- Responsible for ensuring the GMP level within Basic Pharma manufacturing environment
- Responsible for reviewing and interpreting site environmental monitoring data.
- Responsible for advising the line manager, Senior Manager Quality Affairs, Qualified person and manufacturing department managers on any adverse trends that could impact controls related to the site CCS.
- Responsible for conducting and reporting self-inspections and monitoring follow-up on CAPAs as a result of self-inspections, especially concerning aspects involving the CCS.
- Responsible for ensuring the timely completion and delivery of environmental investigations, deviations, changes and CAPAs.
- Responsible for conducting internal and external audits as scheduled.
- Responsible for maintaining the site CCS to reflect current practices and to align with industry updates.

What do you bring as an Environmental Monitoring (EM) Specialist?

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- Microbiological study would be preferred.
- Another related field (such as biomedical) with a background in microbial monitoring or proven experience in a pharmaceutical cleanroom environment.
- Knowledge of pharmaceutical microbiology. Recommendation to include aspects related to microbiological media, microbiological enumeration techniques, and microorganism isolation and identification.
- Knowledge of GMP and Quality Management Systems. In particular, GMP Annex 1. Exposure to pharmaceutical cleanroom environments in terms of related activities, coordination, monitoring, and investigation excursions.

- Analytical mindset and the interpretation of large volumes of data. Ability to identify trends/knowledge of statistical methods. Continuous knowledge update on topics related to Annex 1 and other environmental monitoring guides. A team player who can both drive and assist others in completing investigations and other quality system items where there are aspects related to Annex 1 activities.
- Environmental monitoring (viable and non-viable).

What we offer:

Basic Pharma offers a challenging position with excellent working conditions in a dynamic and inspiring work environment:

- We are constantly developing
- Flexible working hours
- Working in a team of enthusiastic colleagues
- We encourage our employees in their development by offering (internal) courses and training.

Your chance to grow!

Basic Pharma is a dynamic company that is continuously evolving. As Analytical Project Scientist, you will have the opportunity to further expand your knowledge and experience and grow in a field that is constantly changing! Ready to get started at a company that values quality and innovation? Don’t wait any longer and apply today!

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