Assistant Manager/Manager-QA

About Bluefish Pharmaceuticals

Founded in Sweden, with its long tradition of industrial entrepreneurship, Bluefish Pharmaceuticals has become one of the most progressive generics pharmaceuticals companies. At Bluefish, we strive to make quality medicine accessible to more people.

Bluefish creates value in the full pharmaceutical value chain from developing to manufacturing and successfully marketing generic pharmaceuticals and we take pride in doing this in an innovative, responsible and cost-efficient way. Bluefish currently conducts operations in 19 countries in Europe and, over the next few years, will also expand outside Europe with the aim of becoming a global player.

Our corporate culture and close collaboration with development and manufacturing partners are integral parts of our effort to deliver quality products at affordable prices.

We offer a product portfolio consisting of a broad range of high-quality generics for all major therapeutic areas. It is part of our long-term strategy to expand the product portfolio of off-patent blockbusters while at the same time offering a broader range of niche products within more narrow disease areas.

Bluefish products all originate from a generic substance, where the efficacy and safety are well documented. Through our many collaborating partners, we have access to a vast range of technology platforms, enabling us to develop and enhance the intellectual property of our product portfolio.

Our strategy of developing products based on well-known substances with an improved value to patients results in a product portfolio with a significant market potential. We achieve this with a relatively short development time, low risk, and limited investment.

By focusing on innovation and simplicity in both thought and action, and by taking responsibility on all markets and cost efficiency in all stages, we are creating a strong and vibrant brand that offers quality pharmaceuticals at prices affordable to all.

Bluefish provides quality generic pharmaceuticals at affordable prices. Its product portfolio contains a wide range of products within all major therapeutic areas.

Since its inception, Bluefish has developed the platform and know-how to participate in and to be an integral part of all major steps of the value chain in the offering of generic pharmaceuticals. With the vision of offering quality pharmaceuticals at prices affordable to all, we have to be innovative and at the same time cost-efficient in all stages. This includes operational excellence in departments such as product development, quality assurance, pharmacovigilance, IP and supply chain as well as marketing and sales.

Profile Description

Bluefish is looking for profiles to fill the position of Assistant Manager/Manager-QA, contributing to the accomplishment of the QA function objectives. The position will report to Senior Manager-QA. The role would be involved in the below mentioned areas:

- Responsible for Internal and External Audits
- Schedule, prepare, conduct, document, and follow-up of assigned GxP audits in accordance with Bluefish and regulatory standards.
- Initial assessment of audit deficiencies, corrective and preventive actions, and overall vendor/site compliance status based on regulatory GMP requirements.
- Communication to stakeholders on potential risk and product impact from observations and GMP deficiencies found during audits.
- Communicates audit results to management and auditees through written audit reports.
- Escalates any compliance issues.
- Monitor the Regulatory Nonconformance reports issued by regulatory authorities and its impact on Bluefish business.
- Provide support with supplier qualification issues and supplier risk assessment based on audit result when required/requested.

- Regular participation in GMP trainings (internal/external)
- Review audit reports from outsourced or external agencies in line with Bluefish and regulatory requirements
- Yearly Supplier evaluation and Bona fide checks.
- Support QPs in preparing the QP declarations after reviewing the support documents.
- Actively participation in Product Launch process and ensure all required prerequisite with respect QA function.
- Represent Quality Assurance during Technology Transfer of products. Review technology Transfer Package, Master documents and Specification before and during Technology Transfer Process.
- To draft and negotiate Technical Agreement with Suppliers.
- Building Supplier relations
- Interprets policies, standards, and regulations, and its implementation in Key area.
- Meet the KPI requirements
- Represent the BAU process in periodic assessment meeting (Internal/External)
- Ensures that written procedures are followed, and exercises judgment in evaluating quality systems, processes, procedures, and protocols for compliance.
- Assists with training/orientation for new Quality Auditing staff.
- Identifies and drives process improvements.
- Actively engages in discussions to determine impact of changing needs of the regulatory environment.
- Supervises junior auditors, coaches colleagues, and leads training for routine and non-routine site and process audits.

Candidate Specifications

Education and Experience

- Graduate/Post Graduate Degree in any life sciences or Pharmaceutical sciences
- Lead Auditors (GMP/GDP) Certification from reputed EU certification agency is mandatory.
- Professional experience of 8-10 years, with minimum 5 years of experience required as a Quality Auditor in a regulated pharmaceutical environment with a minimum of 30+ audits performed in a Lead Auditor role
- GxP audits of pharmaceutical manufacturing, packaging/ labeling, laboratory controls, storage & distribution, and quality systems for non-sterile APIs & drug products.
- Experience of working with Sterile Formulation will be an added advantage.
- Excellent computer skills, including Word and Excel in a Microsoft Windows environment
- Excellent interpersonal skills

Skills & Abilities Requirements

- Must have good communication skills
- Safety of the workforce
- Personal development thru' self-learning
- Demonstrates advanced knowledge in ICH and global regulations (e.g., EU, PICs, EMA,) and international standards (e.g., ISO, WHO)
- Ability to identify trends within data and apply insights to make recommendations and decisions.
- Ability to bring recommendations to stakeholders for discussion and input.
- Exhibits good project management capabilities.
- Experience evaluating and understanding quality standards or their application.
- Uses and interprets qualitative/quantitative data to drive decision making,

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