Our client is an internationally active and fourth-generation owner-managed pharmaceutical group specializing in the development, approval and marketing of generic drugs.
Physicians, pharmacists and nursing staff in more than 55 countries value and trust the know-how and experience in the field of parenteral dosage forms.

To lead the Quality Management department and perform Quality Assurance tasks we are looking for our client for a

Director Quality Assurance (m/f/d).

Major Duties of Position

- You will have a comprehensive and detailed knowledge of Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP), ideally gained in a generic injectable drug environment.
- You will have a clear and demonstrable understanding of the CMC aspects of regulatory matters and their relevance to product development and lifecycle sustainment.
- Use this technical and regulatory knowledge to mitigate risk.
- Ensure that marketing authorization requirements related to product safety, quality and efficacy are systematically incorporated into all manufacturing, control and release activities for all finished products.
- Demonstrated experience implementing/managing quality systems in a GxP environment, including continuous quality improvement.
- Drive effective management of quality investigations and CAPAs and make decisions that may involve complex quality and technical issues.
- Ensure that: Deviation reports are investigated; information is documented with sound scientific justification; appropriate impact assessments are provided; the appropriate root cause is identified; and meaningful corrective/preventive actions are proposed and implemented.
- Support the EU QPPV and Staged Plan Officers by actively participating in the management of product recalls and reporting of quality defects and OOS findings/deviations to the appropriate authorities.

Your Profile

- At least ten years of relevant experience in QA, CAPA management, GDP and GMP
- Experience with injectable drug products
- A demonstrated understanding of the CMC aspects of regulatory affairs
- A clear understanding of current and evolving legislation
- Experience in organizing and managing a quality department
- Willingness to travel (between locations and to contract manufacturers) is expected (mainly Europe)

Do you feel attracted by this position? We kindly ask you to apply in full confidentiality in English, with resumee and list of key competences.

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Your application will be treated with strict confidentiality.