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Interim QA Director and QP

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Company: Pharmaron

Location: Hoddesdon

Category: other-general

We are looking for: Interim Director of Quality Assurance/QP position to develop, manage and implement quality strategies within Pharmaron Hoddesdon across its CMC activities to ensure that the strategies are aligned with corporate and regulatory authority requirements. The role will entail maintaining the Hoddesdon Quality Assurance function, as stated in the regulatory guidelines, as a separate independent function of manufacturing activities. Monitoring the compliance of site activities, establishing and reporting the compliance level to site management as Quality Metrics.This role will further develop overall Pharmaron capabilities and enhance the reputation of Pharmaron with its scientific and commercial stakeholders. At Pharmaron we offer:Vibrant and dynamic employment – we are a highly specialised, growth company operating in a critical sector of the economy – our future is strong and exciting! Opportunities to develop your skills and yourself – our rapid growth brings greater opportunities for you to learn and grow faster!A great team where we all support each other – enjoy your work – after all you spend about a third of your time here! Key roles and responsibilities:To ensure that all GMP activities are adequately covered by S0Ps or appropriate documentation. Ensuring that all S0Ps are aligned with corporate expectations and regulatory guidance's. To recommend any updates to SOPs that may be required as a result of QA review. To ensure the effectiveness of the Quality Management System be performing independent internal audits of systems and procedures to endure their adherence to S0Ps and regulatory expectations. To follow up on internal audit observations with all appropriate personnel to see that effective CAPAs are established and implemented. To act as the primary contact at the Pharmaron Hoddesdon site for Quality Assurance

enquiries as appropriate and to support Pharmaron globally as required and directed by the QA Director UK Operations and the VP of Quality CMC.To host any Regulatory Authority Inspections or Client/ Sponsor audits or Quality visits as appropriate. To establish, maintain and communicate to all staff Quality Metrics that give an accurate and honest view of the state of the Quality Management System and in particular to ensure that the Senior Management Team are aware of any significant deficiencies in the Quality Management System.Authorisation of written procedures and other documents, including amendments.To undertake the release of manufactured API and DP batches at Hoddesdon ensuring that all registered parameters and regulatory expectations are met. To provide European advice and input on Quality issues, trends or areas for improvements principally at the Hoddesdon site that may have applicability globally across the CMC group. Preparation of reports for the UK Director QA and VP Quality CMC on key KPIs, Quality Metrics and QA matters as appropriate. Requirements: BSc degree in science or a related field. Higher qualification in science desired. Ideally 10 years' experience in a Quality Assurance Management role. GMP experience of Quality in an API / Drug Product environment.Knowledge of current GMP guidelines and industry trends regarding data integrity. Be familiar with any changes that are introduced into legislation that would affect the Quality Status of the site. Able to work independently and leads groups without direction.Demonstrates leadership qualities in the field of Quality.Leads by example. Our Company: “We are a dynamic, fast-growing company, with an enviable reputation for leading edge science, offering contract research services to some of the world’s leading pharmaceutical companies, solving what were believed to be unsolvable scientific challenges”.We believe in our ability to relentlessly push forward the boundaries of scientific excellence, delivering solutions for our clients, always operating ethically and with integrity. We take pride in our professionalism and commitment to always deliver our very best work. We offer a competitive salary and a progressive and comprehensive suite of employee benefits. We offer state of the art working environment across our sites. We offer the opportunity for growth and development and will support funding for relevant training and development programmes. Why Should You Apply? This is an opportunity for you as a Quality Assurance Director/QP to make a real impact in a highly scientific and dynamic environment, demonstrate leadership, ambition and the desire to drive forward and embed PBPK into the business.Continue to build and shape your career in an environment that sets and commits to the highest standards of DMPK science. To be part of a team who support each other, embrace and solve technical challenges and put excellence at the heart of all that we do.

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