60° Pharmaceuticals LLC

Global Quality Manager:
60 Degrees Pharmaceuticals LLC (60P) and its subsidiaries develop and commercialize small molecule therapeutics for the treatment and prevention of tropical diseases. Target markets are disease endemic countries and travel medicine. 60P is seeking to hire a Global Quality Manager who will be responsible for leading the implementation and execution of the Corporate Quality System globally for development and commercial stage products. The candidate will be the primary Quality contact for 60P, and will have strong experience in GXP's, quality systems and Pharmacovigilance areas as well as proven ability to lead Quality functions independently in a globally matrixed environment.

Major Responsibilities:

Quality Strategy:
· Ensure that a coherent quality management system is set up for all key processes across the company that meets GMP (and/or other regulatory) requirements under which all sites operate
· Develop and implement operational strategies to meet Company's long term goals and objectives; including upscaling of production capacity and the establishment of a cost effective global operations footprint
· Define the strategy for the quality management system resulting from industrial strategic plans, in a manner consistent with all standards and certifications, and promotes them across sites.
· Ensure that the contacts and relationships with GMP administrative authorities, GMP auditors, certification and Notified Bodies are professional
· Manage (regulatory/quality) audit coordination and the resolution of findings for internal, external and 3rd party (suppliers)
· Ensure Company is kept fully informed of new or emerging GXP and regulatory changes in their region and assesses impact of regulatory change on corporate policies and procedures

Quality Assurance:
· Ensure that Key QA Systems exist and meet regulatory, corporate and GMP requirements. Key QA Systems include: change control, investigations (deviations, Out of Specifications and complaints), CAPA management, annual product reviews, vendor management (including supplier audits), internal audits, site quality council, recall procedure, stability program, documentation control and good documentation standards
· Ensure that key performance indicators exist for each system and are reviewed on a regular basis for adverse trends.
· Ensure independent members of QA approve all installation, operational, performance qualifications and process validation
· Facilitate GMP inspections and audits to be carried out internally and by external organisations
· Oversee and provide direction for the validation program(s), ensuring that commitments are met, new product, new methods and new equipment are introduced on time and that the overall compliance of the facility is increased

Quality of Products:
· Ensure that Product Disposition processes exist which cover: in-process and finished products; 3rd party manufactured products, incoming goods including raw materials, packaging and imported finished products and the disposition of returned goods
· Ensure that all products released for use or sale meets quality specifications, regulatory compliance and are released based on customer demand. Ultimately responsible for Release to supply
· Organise quality control, standardisation of the analysis and data monitoring across all manufacturing sites
· Supervise the deployment of all quality assurance projects across the sites that drive continuous improvement in the quality and / or manufacturing processes
· Drive risk assessments for product quality, manufacturing processes and regulatory compliance

Regulatory Compliance:
· Identify required and desirable changes required for regulatory compliance and drives the required changes in the quality and manufacturing systems

· Initiate recall of non-conforming product if necessary and manage recalls in accordance with the applicable regulatory and company requirements
· Responsible for pharmacovigilance (adverse event) reporting

Validation:
· Manage the validation team to ensure all compliance projects are completed on time and provide assurance that processes are consistent and compliant
· Ensure all new capital purchases are validated appropriately to ensure equipment functions as per specification
· Ensure the validation master plan is up to date, comprehensive, meets compliance goals and is followed consistently

Continuous improvement:
· Will lead and be a participant in the company's Continuous Improvement program
· Is permanently looking at developing a "different" and "innovative" effective way of doing business
· Challenge processes, procedures, systems, and proposes improvements in order to improve the efficiency and to focus teams on continuous progress
· Ensure an on-going monitoring and evaluation of the performance

Key performance indicators/ Measures of success:
· Results versus goals
. Feedback from internal and external stakeholders regarding implementation of quality strategy and assurance programs
· Results of third party audits of 60P, and 60P's suppliers, distributors and research partners
. Quality of adverse event reporting to regulatory agencies and third parties
. Cost-effectiveness of Quality programs
. Ability to expeditiously, efficiently, and skillfully implement and maintain Quality programs

Capabilities/Experience:
· Languages: Fluent in written and spoken English (essential)
· Citizenship/Residency: U.S. citizen or green-card holder
. 10+ years of Quality Assurance / Compliance management experience in pharmaceutical/ biotech/medical device industry, with small pharmaceutical company experience being highly desirable
. Thorough knowledge of applicable local and global regulatory requirements, regulations and guidelines required for GXP compliance and pharmacovigilance
. Strong knowledge of pharmacovigilance AE reporting systems and regulations required
. Extensive knowledge in a broad range of pharmaceutical activities and Quality Systems
. Proven capacity to develop and implement Quality Systems from scratch
. Candidate must demonstrate proven capacity to be a strong leader, with strong organizational skills and ability to work effectively across functional lines in a globally matrixed organization
. Candidate must demonstrate exceptional communication and interpersonal skills
. Candidate must be a 'self starter' with proven capacity to work independently and provide practical, action-oriented solutions to management
. Candidate must have proven capacity to prioritize work without senior management input

Education: Appropriate tertiary degree in scientific / technical field

Location: Full time/Washington DC. Ability to travel interstate and internationally as required

Next Steps: Please send CV to **geoffdow@60degreespharma.com**