**Job Description – Quality Assurance Manager**
**Reports to: Director, Quality Assurance**
**Location: Cheadle Royal Business Park, Cheadle**

**Job purpose:**

We are seeking a highly experienced Quality Professional to Manage and lead the quality Assurance team at Seda's GMP manufacturing facility.
As Quality Assurance manager you will provide Quality oversight and leadership to the QA team and wider CMS division, to ensure that the products manufactured in our facility comply with GMP standards and meet appropriate quality, safety and efficacy standards.

**Key responsibilities:**
Lead and manage the Quality Assurance Team at Seda's IMP manufacturing site, focused on Phase I and Phase II clinical trial materials.

- Ensure full compliance with UK/EU GMP Regulatory Standards and Seda procedures.
- Maintain QA systems and processes, reviewing and supporting ongoing improvement activities.
- Ensure effective management of documents through lifecycle, ensuring compliance with regulations and industry best practices. This includes - creating, reviewing, and approving key documentation such as specifications, SOPs, protocols, and methods associated with all products and procedures.
- Support batch documentation review and provide quality oversight for the certification and release of IMPs by the QP.
- Investigating and approval of deviations, complaints and OOS to prevent future reoccurrences of nonconformance, providing support on SMART CAPA plans.
- Supplier Management: Managing supplier approval and ongoing performance.
- Assessing planned changes and their impact on the site through Change Control
- Evaluating site compliance and implementing improvements through the internal audit process, as an Internal Auditor and Report approver.
- Supporting Client projects as a Quality Assurance representative and Customer liaison
- Support maintenance of the site training process.
- Support generation and cascade of quality training packages, including but not limited to GMP induction and annual refresher.
- Assist with management of Regulatory inspections: inspection readiness, inspection and response.
- KPI monitoring and trending – Support Management Review and output.

**Qualifications & Experience:**

- Minimum of 5 years' experience in Quality Assurance within a Pharmaceutical (GMP) facility, preferably Investigational Medicinal Products (IMPs)
- Proven Leadership/ Management experience
- Degree or equivalent in a relevant scientific discipline desired
- Experience in working with analytical laboratories and/ or GMP production areas.
- An understanding of GMP and regulatory requirements within the pharmaceutical industry.
- Excellent communication skills, both written and spoken English, and computer literacy.
- Time Management: Ability to manage your own workload, meet deadlines & prioritise accordingly.
- Good attention to detail and high standards in all work output.

- Strong communication, and interpersonal skills, with experience working in cross functional environments and stakeholder management.
- Continuous Improvement