COMPLIANCE ENGINEER: OUTLINE JOB DESCRIPTION

Location of work: Bucks/Herts/Berks, some UK travel. Hybrid working home & office & client site.

Person Specification

- **Attention** to detail to ensure systems are meeting the requirements and documentation is complete
- **Communication skills,** with the ability to put technical concepts into non-technical language and communicate with internal and external stakeholders
- **Experience** in quality systems and / or current Good Manufacturing Practice (cGMP)
- **Knowledge** of pharmaceutical equipment and processes
- **Perform** diagnostic procedures and troubleshooting and analyze findings.
- **Proven** Information Technology (IT) and mathematical skills
- **Protocols and Governance** following a client process and strict sign-off procedure.
- **Structured** approach, ability to work to deadlines, ability to manage version control and change controls

Compliance Engineer: Job Description

The work covers compliance of equipment and systems in pharmaceutical manufacturing sites.

It includes but is not limited to: Periodic Validation Reviews; Access Control Lists;

Reviews of Deviations and Exceptions; Compliance Determination; Risk Assessments;

Audit Trails Reviews; Project Change Control; Back-Up's and Data Integrity.

- **Collaborate** with stakeholders to ensure all processes are compliant and no issues arise.
- **Cope** with the conflicting priorities in a manufacturing environment.
- **Investigate** and analyse current processes to design compliant systems and ways of working.

- **Liaise** with the stakeholders to resolve any issues on the system and / or documentation.
- **Maintain** compliance knowledge as requirements change by tracking and researching emerging practices.
- **Resolve** any discrepancies / deviations encountered during the review process.
- **Prepare and execute** documentation reviews and risk assessments, following the client's procedures.
- **Present** compliance reports with analysis of measurements, statistics, and other data.
- **Skills** in change control and version management.
- **Win buy-in** from a complex network of stakeholders.
- **Use** problem-solving skills and analysis to overcome obstacles.
- **Work** in a highly regulated environment where pharmaceutical/medical device manufacturing is taking place.

Skills and Qualifications

- Bachelor's degree in one of the following: Engineering, Chemistry, Computer Science, Life Sciences
- Technical writing: experience in relevant areas, including queries, reports, and presentations
- Good computer skills to develop documentation
- Good standard of written English.

About J P Hildreth Ltd

We are one of the UK's leading manufacturing consultancies and employ 35 engineers, technologists, and validation specialists. We work for major companies like Mars & GSK. We help define capital investment projects, deliver them and track benefits with certainty. Our engineers install and validate advanced manufacturing technology from around the world.
We are a positive, look-ahead company. People like to work for us. We react swiftly to opportunities and make the most of good ideas. www.jphildreth.com