Rachel Walmsley

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Work Experience

2018-March 2023 (redundancy) Quotient Sciences;

Analytical Scientist (2 years) to Senior Excipient and Veeva Analytical Coordinator (3 years)

This role was primarily to coordinate all QC testing for raw materials/packaging/API analytical testing to cGMP for the manufacturing site at Reading. I was responsible for ensuring that the incoming materials are sampled, tested and internal CoA's progressed to QA release for all solid dose and inhalation projects that progress to clinical trial manufacture on site. I performed testing (mainly following methods taken from BP/EP/USP monographs/pharmacopeia's) when prioritisation required expedited or investigational testing. I supervised external testing from quotations/ PO's/despatch/results receipt. This involved motivating and co-ordinating the team to complete work following the schedules I built to support other departments requirements and evolving timelines. I initiated and carried through to completion all departmental innovations for the documentation and quality event system – Veeva. I provided all the training/troubleshooting within the department for use of the Veeva system. As required, I performed a significant amount of the documentation initiation, editing and version changes, through to QA (and where appropriate client) approval for SOP's and work instructions, templates, method transfer/validation protocols and reports, stability documents, equipment qualification documents (OQ/IQ/PQ/requalification), test methods, specifications and CoA's. For the quality event/QA side of the Veeva system I work on, deviations, change controls, CAPA, out of specifications/ out of trends, and continuous improvement. I scheduled the stability team for sample management/ set downs/ pulls/ termination of studies, in addition to performing these stability activities myself. For the first two years of working in this company as an Analytical scientist I was doing analytical final product testing including HPLC – QC, validation and method transfer. Also, dissolution, Karl-Fisher water content, UV-spectroscopy, Fourier-Transform Infra-red, identification and appearance. I was a trainer on most of these methods.

2011-2018 Lonza Biologics;

Scientist in Quality Control Grades 3 to 7

My role was to schedule, perform or check write ups of all internal raw materials testing. I was responsible for ensuring that the testing performed by the team was completed in a timely manner to accommodate the needs of the competing plant/manufacturing schedules. My function involved chemistry testing/checking and equipment calibration including Karl-Fisher water content, UV-spectroscopy, Fourier-Transform Infra-red, Raman spectroscopy, Specific Optical Rotation, Loss On Drying, Immunodiffusion, assay titrations, identification and appearance. I was the main trainer for each of these methods. I provided on-site weekend cover primarily including HPLC and TOC analysis. This employment was

initially in the biochemistry section, performing a broad range of analyses from purely chemistry to IEF, SDS-PAGE, ELISA, GP-HPLC/SEC-HPLC and DNA by hybridisation.

2007-2011 Reading Scientific Services Limited;

Analyst - Scientist I - Scientist II in Pharmaceutical Department

My activities here developed from pharmacopeial analysis in both gas chromatography and wet chemistry techniques to GMP into organising the workflow in the wet chemistry area (team varying between 7-15 people), and training and troubleshooting for my colleagues. I carried out cGMP level checking of my colleagues' analysis and laboratory reports. I also regularly dealt directly with customers, using my communication skills to establish requirements and assist with projects or queries directly.

2006-2007 Bodycote Limited;

Research Assistant

My responsibilities here included testing raw materials, final products and environmental water samples according to the BP, PhEur and US Pharmocopias and individual company methods. My role focused on wet chemistry and GC/ GC-MS.

Education

1999- 2006;

MPhil in Organic Chemistry graduated 2006

University of Reading;

Title : Synthesis of Furan-2(5*H*)-ones for use in Palladium-Catalysed Cross-Coupling including Partial Synthesis of Digitoxigenin. Techniques : HPLC, NMR, IR, synthesis optimization and development.

1995 – 1999;

Degree MChem Hons. (4 year chemistry course) Grade 2:1

University of Reading;

Activities outside my working role

I very much enjoy maintaining my network of diverse and interesting friends. I currently spend lots of time on home improvements and assisting my family by entertaining and supervising my nephew with his additional needs.

Other skills

Practical Training Certificate with People 1st training company. Error Prevention Courses and 6S white/yellow belt trained as I enjoy organising /participating in continuous improvement projects, which I believe would be of benefit to a start-up, as having worked in large and small sites, startups can benefit most from agile thinking. I am proficient in a variety of computer applications; LIMS (Laboratory Information Management System), Empower for chromatography systems, Veeva (Documentation and quality event software), DMS (document management) and TrackWise Quality Management System Software and most Microsoft applications for laboratory and tracking level use. I am enthusiastic to use these skills and develop new ones focusing on startup activities.