



Curriculum Vitae

Personal information **Craig Connolly**

Work experience

1. Employer: Health Products Regulatory Authority
 - Start date: 092020
 - End date:
 - Position: Pharmaceutical Assessor
 - Activities: o Conducting scientific evaluation of quality data submitted in support of applications for marketing authorisation for human medicinal products containing new chemical entities or established active ingredients. Analysis of their risk/benefit profiles; reporting and forming conclusions in respect of their suitability for use as human medicinal products as well as consideration of the public health consequences of their use. o Conducting scientific evaluation of quality data submitted in support of: □ National applications for marketing authorisations, including Parallel Products □ Centralised applications to the EMA for marketing authorisations when the HPRA is acting as rapporteur, co_rapporteur or peer reviewer on behalf of the EMA □ EU applications when the HPRA is acting as Reference Member State in a mutual recognition or decentralised procedure o Preparation of assessment reports on applications for marketing authorisation for human medicinal products and submission of reports to other EU member states when the HPRA is acting as Reference Member State in a mutual recognition or decentralised procedure o Analysis in the context of public health, of risk_benefit profiles in respect of applications for marketing authorisation; making recommendations and preparation and presentation of reports to the Board, Advisory Committees and Sub_Committees or the Management June 2020 Committee of the HPRA, and/or the CHMP or their representative working parties, regarding the suitability of human medicinal products for marketing approval
 - Country: Ireland
2. Employer: Bristol Myers Squibb / SK biotek Ireland Limited
 - Start date: 052017
 - End date: 082020
 - Position: R&D Scientist
 - Activities: Subject matter expert in small molecule process development, crystallisation, particle engineering and materials science. Process optimisation lead, planning, executing and delivering on process optimisation and R&D projects. Working cross functionally with engineers, quality team members and multiple departments site wide to support manufacturing campaigns, Tech Transfers and New Product Introductions to Swords Laboratories. Preparing technical presentations and reports for client pharmaceutical companies, managing customer relationships through regular technical updates. Facilitating planning, preparation and technical meetings with a cross_functional team to support successful on_time execution of manufacturing campaigns. Technical support as a lead chemist across a range of products and campaigns for clinical, validation and routine manufacturing. Statistical process robustness monitoring. Completion of supporting documentation for manufacturing campaign preparations and closeouts (technical risk assessments, technical memos, campaign and verification reports, campaign reports, CAPAs, change controls). Trained Lead Investigator charged with leading and completing investigation reports. Agile campaign support, including real_time responses to issues in manufacturing and leading/participating in investigations and impact assessments. Safety Representative for the R&D department at SK biotek Ireland, championing safe work practices and driving improvements.
 - Country: Ireland
3. Employer: APC Ltd
 - Start date: 052015
 - End date: 052017
 - Position: Research Scientist
 - Activities: Working within a small molecule process development research team to plan, organise and deliver on R&D pharmaceutical research projects. Providing R&D laboratory support across the APC Process Development Group through collaboration with other scientists and engineers, both internally and externally. Operating to GLP standards within a R&D laboratory. Investigating, monitoring, developing and optimising pharmaceutical reaction and purification unit processes. Performing analytical characterisation of processes and isolated materials, both online and offline. Interpreting the outputs. Developing pharmaceutical scale_up and optimisation strategies. Based on needs, developing and introducing new techniques, methods and processes to improve business effectiveness. Preparing technical presentations and report material to high standard internally and for client pharmaceutical companies. Presenting the issues, results and project progress to client companies and management.
 - Country: Ireland

Education and training

1. Subject: University College Dublin
 - Start date: 092010
 - End date: 032015
 - Qualification: PhD (Chemistry)
 - Organisation: My PhD study was in the area of Bioorganometallic Chemistry. The focus of this work was on the synthesis of new organometallic compounds and the investigation of potential biological applications of these new compounds, including as cellular imaging agents, anticancer drugs and photodynamic therapeutics. Practical research skills and experience:

Synthetic skills: Extensive knowledge and 4 years of practical experience in chemical synthetic techniques, organic synthesis and purification of chemicals, including handling of air_ and water_sensitive chemicals. Inert Schlenk techniques expert. Experienced in the handling of hazardous chemicals, gas cylinders and vacuum distillations of air sensitive substances. Practical laboratory skills: Experienced in the use and maintenance of laboratory equipment and instrumentation, including the maintenance of dry solvent purification systems, rotary evaporators, vacuum pumps and LCs. Practical experience of laboratory running/organisation. Analytical skills: High level of experience with qualitative and quantitative analytical techniques and instrumentation including NMR spectroscopy, mass spectrometry, UV_Vis spectroscopy, FTIR and various chromatographic purification techniques among many others. Record keeping: Constant recording of data and maintenance of a comprehensive lab book, as part of a meticulous laboratory work habit analogous to GLP. Project supervision and teaching experience: Teaching and demonstration skills developed as a Senior Demonstrator in various undergraduate chemistry labs and tutorial sessions. Presentation skills developed through the delivery of small and medium class tutorial sessions, as well as oral presentations at major conferences. Supervision and direction of multiple final year research projects.

- Country: Ireland

Additional information

Publications

Projects

Memberships

Other Relevant Information