Colman Byrne

Head of Analytical Services

Core Competencies

- Method Development
- Troubleshooting
- Agency Meeting Advice
- Strategic Planning
- Bioanalytical
- Investigations
- Regulatory Submissions
- Due Diligence
- Experimental Design/DOE
- Characterization

Professional Summary

Mr. Byrne has over thirty-five years of experience in analytical and bioanalytical method development and validation, troubleshooting, quality control (QC), analytical and stability testing. This also includes regulatory submission authoring, analytical support of pre-clinical and Phase I through IV small molecules, peptide and protein products at traditional, virtual and contract biopharmaceutical and veterinary companies. He has headed groups supporting active and finished product release, manufacturing, and stability programs; generated analytical modules of regulatory submissions such as INDs, DMFs/VMF, CTDs, NDAs, BLAs & INAD); and developed project plans for support of development activities.

Mr. Byrne leads our Analytical Services team through the utilization of his vast 36+ years of experience.

Education

M.S.	Natural Sciences	Trinity College - Dublin, Ireland
B.S.	Natural Sciences	Trinity College - Dublin, Ireland

Professional Experience

Design Space Inpharmatics, LLC **2007 – Present**

Head of Analytical Services **May 2020 - Present**

- Responsible for the oversight and management of Analytical Services,
- Works closely with our Analytical Services consultants at DSI (resourcing, strategic positioning of the group, business development support).

Senior Analytical Services Consultant **2007 – Present**

- Coordinates CMC analytical and bioanalytical activities (method development, validation, stability, outsourcing of testing on behalf of virtual companies in the pharmaceutical and veterinary fields,

- Generates regulatory submissions, and provide responses to post submission regulatory questions,
- Troubleshoot analytical problems and perform investigations in support of QA Out Of Specification SOPs,
- Evaluate test methods, stability and method validation protocols and reports, quality control systems, SOPs and specifications,
- Perform data, regulatory submission and site audits,
- Perform due diligence and compliance assessments for in- or out-licensing of new products,
- Perform gap analyses on the compliance status and submission readiness of pharmaceutical development and regulatory submission programs with respect to analytical and stability activities.

Cardiokine **2005-2008**

Director, Chemistry

- Responsible for all analytical and bioanalytical activities for a virtual pharmaceutical company,
- Project management, scheduling and review of release testing, methods development, validation and stability studies on starting materials, API and finished products for a Phase III pharmaceutical product,
- Generation and maintenance of analytical test methods, quality control systems SOPs and specifications for API, drug product, raw and reference materials,
- Qualification of contract analytical laboratories for pharmaceutical, bioanalytical and microbiological testing,
- Negotiation and review of contracts for analytical testing services; management of analytical group budgets,
- Performance of quality audits on contract laboratory and manufacturing facilities in order to ensure their cGMP compliance, in conjunction with CardioKine's QA group,
- Coordination of all bioanalytical testing activities for pre-clinical & Phase I-III clinical programs.

Eximias Pharmaceutical **2000-2005**

Director, Chemistry

- Coordinated release, methods development, validation and stability testing for a pharmaceutical product,
- Generated and maintained all analytical test methods and specifications for API, lyophilized drug product, raw and reference materials and instituted all quality control systems and API related manufacturing SOPs,
- Directed process development and pilot scale API manufacturing activities, including review of master and completed API and drug product batch records,
- Drafted budgets and spending forecasts for the manufacturing and quality control groups,
- Assisted the Regulatory Affairs group in preparing annual reports, briefing documents and the API and QC CMC sections of an aborted NDA filing for submission to regulatory authorities,
- Audited contract labs for pharmaceutical and bioanalytical testing and drug product and API manufacturers,
- Coordinated technology transfer of QC methods for a biochemical molecule, assessed of the state of its technical and regulatory compliance and selected analytical facilities to perform reference material characterization, process development support and bulk and finished product release and stability studies,
- Performed due diligence studies to assess the current state of compliance of potential in-licensed products,
- Took temporary responsibility (2003-2004) for EXIMIAS' QA group, including auditing of subcontractors, maintenance of controlled documents, and release of reference materials.

Impax Laboratories **1999-2000**

Lab Director

- Directed a QC laboratory performing raw material and finished product release and stability testing, cleaning validation support, and methods development and validation for a generic pharmaceutical manufacturer,
- Conducted an overhaul of laboratory systems and procedures in advance of FDA pre-approval inspections,
- Coordinated assay method development and validation, stability, product release and cleaning validation studies.

Charles River Labs **1990-1999**

Senior Technical Manager

- Directed and performed method development and validation studies for protein and peptide products, bioanalytical and stability studies, determination of trace components, routine analytical services and cleaning validation studies by HPLC, GC, TOC and other biochemical methods for a contract laboratory,
- Developed, maintained and approved SOPs, analytical methods, stability and validation protocols and reports,
- Consulted with clients, as a study director, to determine testing requirements, plan appropriate and time-efficient experimental strategies and generated proposals for work to be performed,
- Initiated a small molecule stability testing program, involving chromatographic, spectrophotometric and dissolution testing studies. Performed protein/peptide sequencing, amino acid and chromatographic analyses, peptide mapping, RIA and ELISA studies, water content, dissolution and disintegration testing.

Controlled Therapeutics **1988-1990**

Senior Chemist

- Assisted in startup of a new QC and development laboratory at a startup pharmaceutical company,
- Developed HPLC and GC test methods and performed raw materials and final product release testing.

Atlantic Pharmaceuticals **1984-1988**

Chief Chemist

- Supervised up to five chemists' raw materials and finished product release testing, manufacturing and raw material formulation work using Ph. Eur. and internal methods,
- Developed a formulation and process and assisted in set up of a pilot plant for manufacture of a raw material,
- Coordinated the manufacture, packaging and testing of a range of bulk formulated products.