IIio V. Durandis

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Experimented and highly motivated scientist with a Masters degree in molecular biology and Bachelors in Biological Sciences and Political Science. Previous experience in Quality Control, Analytical Development and Project Management in laboratory settings, currently my objective is to be in a position to support ongoing research and analytical analysis in the biotechnology, biomedical or pharmaceutical industries.

KEY EXPERIENCES

- Modern molecular biology techniques including PCR, transfection, transformation, cloning
- Western blotting, ELISA, RNA editing, SDS-PAGE. Gel-clot Endotoxin, LAL
- HPLC (SEC, IEX, RP) method development and troubleshooting
- Gas Chromatography (FID, TCD, Headspace), Total Organic Carbon (TOC), Water testing
- FT-IR spectroscopy, A280, AA, ICP-MS, Karl-Fischer, LC-MS, Environmental Monitoring
- LIMS, New Genesis, Lab Management
- AKTA, UPLC, Process development, 2AA, glycoprotein, Antibodies
- SOP, GMP, Method validation, Quality system PQ,IQ, OQ

EDUCATION

Central Connecticut State University 2010
Masters of Science: Cell & Molecular Biology
- Independent research in the lab of Barry Hoopengardner by focusing my research on RNA editing, a process by which the coding and stability of an RNA message can be changed post-transcriptionally.

Framingham State University 2008
Masters of Science: Nutrition science
- Part of the chemistry department, works in food analysis and nutrition biochemistry

University of Massachusetts-Lowell, MA 2000
Bachelor of Science: Biology/Biotechnology
- Emphasis in Cellular, and Molecular biology
- ***Political Science***

PROFESSIONAL/INDUSTRIAL EXPERIENCE

■ **Lantheus Medical Imaging** **04/12-07/13**
Quality Scientist (Contract)
Perform supplemental validation of current methods using laboratory notebook.
Perform supplemental validation activities for other identified assays.
Perform transfer and validation of improved Definity methods from R&D according to the validation protocols: Includes performing the PQ of 2 new ELSD (CAD) detectors for Agilent HPLC.
Perform Laboratory analysis using HPLC, GC, TLC, Gamma Spectroscopy, FT-IR, Karl

Fischer.
Coordinate the chemistry raw materials testing.
Troubleshoot and resolve non-routine issues with guidance from QCchemistry.
Coordinate activities to meet timelines and collaborate with cross-functional teams.
Follow current internal procedures and cGMPs for all documentation and analysis.
Utilize electronic documentation such as LIMS, Atlas, Excel, Word, and Document Management software.
Actively promote safety rules and awareness. Demonstrate good safety practices at all times including the appropriate use of protective equipment.

■ **Dyax** **10/10 – 01/12**
Developmental Scientist/Project Manager
Work as a consultant to support many of the company's ongoing research and Development analysis.
Develop and validate analytical methods and perform validation, such as CEX, SCX, SEC, for various drug substances and drug products.
Design and troubleshoot basic, HPLC, SDS-PAGE, ELISA protocol, PCR, peptide mapping protocols, Deamidation assay for analytical use.
Run analysis on iCE, DLS, UV-spec, plate reader, AKTA for separation and Process development to make sure that raw materials and formulation samples are within specificity.
Generate Laboratory reports and contribute to development report.
Work closely with CMO and clinical team.

■ **Biogen Idec** **11/09- 10/10**
Associate Scientist II (Contract)
- Method development, validation and data Analysis for Proteins and small molecules. Experience with protein quantification, labeling and purification techniques, using the AKTA purification system.
- Proficiency in immunochemistry assay, analytical and chromatographic techniques such as SEC, RP, HIC, IEC and electrophoresis techniques like SDS-PAGE, IEF and CE.
- Develop and validate new method for ELISA assay, and all kind of blotting techniques. Work closely with CMO and CRO. Set up Stability program.
- Experienced using Empower, E-Room, LIMS, NuGenesis, Trackwise, Lotus Notes.

■ **Eisai Research Institute (MGI Pharma)** **08/07- 07/09**
Bioanalytical Research Associate
- Duties include, but not limited to design study protocols for clients, responsible for method development, validation, and optimization on Agilent HPLC (RP, SEC, IEX), GC systems, UV-Spec, FT-IR. Experienced in GMP, ISO, ICH guidelines. Writing Standard Operating Procedures, ordering chemical supplies. Work independently on different analytical projects.
- Experienced in developing assays for ELISA, SDS-PAGE, RT-PCR, qPCR, Western-blots, Work with Proteins and small molecules.
- Support Process development team using AKTA purification chromatography system

■ **Advanced Magnetics, Inc.** **05/05-08/07**
Analytical Chemist/Microbiologist

- Performed wet chemistry, endotoxin (gel-clot method) on raw materials and finish products. Used AA spectrophotometer, FT-IR, magnetic susceptibility balance, Shimadzu TOC, GC, HPLC, LC-MS, UV-Spec, water testing for LAL, microbial identification and LLS particle sizer. Developed and validated analytical methods for QC used. Wrote SOPs, Reports for NDA, and Stability protocols. cGMP, GLP strictly followed.

■ **Pharmasol Corp** **05/04 – 05/05**
Lead QC Chemist/Supervisor

- Designed various stability protocols for small molecules. Developed analytical methods for client companies. Performed photostability using the Sunset instrument, Dissolution, and run HPLC based analytical methods.
- Write SOPs, Deviations, stage release forms. Follow cGMP and GLP guidelines.
- Establish data trending for water system, microbiological testing, and cleaning validation procedure.
- Performed Karl-Fishcer, Refractive Index, Titration, FT-IR, UV-spec, TOC and many more wet chemistry assays.

■ **Armstrong Pharmaceuticals an Andrx Division** **08/00 – 09/02**
Chemist II

- Performed various release testing such as Andersen Impactor for particle size and label claim. Total contents, Potency, Identification assay, Microscopy, Raw Materials, drug products, stability samples, Karl Fischer.
- Involved in out-of-specifications investigations, and product compliance
- Reviewed and written SOPs and Test Methods.
- Worked on new drug development. Experienced in method transfer and validation.
- Experienced in using Agilent HPLC, GC, Karl Fischer, FT-IR, TOC, pH meters.

■ **Internship/Temporary positions**

- **Control Delivery System** 01/03 – 02/03
  I Worked as a formulation chemist and provided support running Water HPLC instrument.
- **Acambis** 02/03 – 06/03
  As a QC microbiologist, helped with environmental monitoring, water testing, plating, microbial identification and endotoxin on raw materials.
- **Avatar Pharmaceuticals** 10/03 – 04/04
  As a research chemist, responsible for writing SOP, testing raw materials, method development on Waters HPLC (IEX, SEC, RP) for oligomers.
- **Toxikon** 08/07 to 04/08
  Analytical Chemist
  Performed various wet chemistry analysis, extraction of organic solvent, developed numerous HPLC based analytical methods.

References available upon request.