Pauline L McGregor PhD CChem MRSC

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Career Objective

To contribute to the compliance of the Pharmaceutical and related industries by means of training, problem solving, QA and technical support, creating internal, external and global partnerships whilst assuring the highest level of quality and integrity.

Core Competencies

- **30 + years in the Pharmaceutical Industry**
- **Analytical procedures/Laboratory Support**
- **Pre and Post Inspection GMP Audits**
- **Global GMP compliance**
- **SOP and technical document writing**
- **Excellent written and oral communication skills**
- **Quality System Management**
- **Validation**
- **Training**
- **Project Management**
- **Document and Data review**
- **QbD and enhanced approach to analytical methods**

BUSINESS EXPERIENCE

2006 -Present **Consultant/Owner – PM^{c}G Consulting**

- Auditing of GMP and associated quality systems (Europe, Canada and US regulations)
- Analytical Method Development, Validation, Transfer
- Analytical QbD (Enhanced approach for method lifecycle)
- Data integrity for Laboratories
- Document and Data review
- Training Specialist (Presented customised training courses in Canada, UK, Europe, US, Jordan and China)
- Member of USP Validation and Verification Expert Panel 2011-2019
- USP expert committee member
- Validation Master Plans
- Validation activities (Analytical procedures, equipment, cleaning, facilities, process, protocols, reports)
- Analytical Support Specialist
- Write technical documents (SOPs, Protocols, Investigations, Reports)
- Technical Consulting
- Quality Investigations to determine root cause and corrective and preventative actions
- Quality System set up and management
- External auditor for company self- inspection programs (QA departments)

2003-2006 **Manager Method Development, Validation, SGS Life Science Services (Division of global company -Pharmaceutical Contract Testing Laboratory). Also fulfilled the roll of temporary QA Manager**

- Hired to develop and grow an R & D, Analytical Validation group within the Company to bring in new business.
- Managed projects and staff related to R&D, validation and transfers
- Authored protocols, technical reports and quotations
- Reviewed technical data, documents and proposals
- Responsible for growth and development of group, staff and new business
- Represented the company by giving external/internal customers training courses/seminars
- SOP writing
- Prepared for and participated in Quality audits (Internal and external)
- Provided technical support to customers and North American Sales team
- Client consultant on behalf of SGS (Analytical Services)
- Monitored financial position of group
- Troubleshooting of technical issues/ difficulties with methods/formulations
- Prepared relevant quality documentation for R & D group and instrumentation

2002-2003 **Senior Scientist, Bodycote Materials Testing Canada, Inc. (Pharmaceutical Contract Testing Laboratory – left for better opportunities at SGS)**

- Provided technical support to pharmaceutical and biomedical customers
- Wrote and reviewed protocols, reports and methods
- Developed and validated analytical methods to cGMP, FDA and ICH guidelines for various pharmaceutical formulations.
- Wrote and executed SOPs, instrumentation protocols including IQ/OQ and PQ's
- Provided client/customer relations through troubleshooting, problem solving and project management
- Prepared for and participated in Quality audits (Internal and external)

1999 - 2002 **Analytical Services Consultant, Novocol Pharmaceuticals of Canada Inc. (Contract position)**

- Ensured GMP compliance in the laboratory
- Developed and presented Training sessions for staff in method development and validation of HPLC methods.
- Provided technical direction towards investigations and problem solving issues relating to formulations, solubility, laboratory methods, instrumentation and regulatory requirements
- Maintained and executed a master validation plan for the analytical laboratory including calibration and preventative maintenance schedules for all laboratory related equipment
- Wrote protocols and technical reports
- Advised on cleaning validation and wrote and executed protocols
- Assisted Quality Department in preparation for and execution of audits from a laboratory perspective (FDA, Health Canada)

2000 - 2001 **Professor, Fanshawe College, London, Ontario (Temporary Position)**
- Lectured in Instrumental Analysis (HPLC, GC, UV/Vis, IR, AA) and Organic Chemistry

1997-1998 **Method Validation Specialist with Pfizer AHG, London, Canada (Site closed- layed off due to closure of plant)**
- Participated in Corporate/plant teams to share knowledge and expertise within Pfizer. Maintained and executed a plan for method validation, and transfer of analytical methods in conjunction with the Quality Department
- Assisted Quality Department and trained staff in SOP's relating to Validation of HPLC/UV methods
- Planned, coordinated and performed in-house method development and validation including graphical and statistical review of data within a set operating budget.
- Coordinated and tested cleaning validation studies with QA from an analytical perspective
- Coordinated outside consultants to complete tasks within set timelines and budget.
- Provided technical direction and guidance towards investigations and problem solving issues relating to formulations such as solubility and stability

1996-1997 **Research Chemist**, **Labatt Brewing Company Ltd (1 year contract)**
- Investigated stability of beer formulations
- Developed analytical methods for trace elements

1995-1996 **Post Doctoral Fellow, University of Western Ontario in collaboration with Labatt Brewing Company Limited (1 year contract)**
- photochemistry of organics in beer
- product analysis at ppt level using various GC/MS

1992-1995 **Postgraduate Research Assistant, Napier University, Scotland**
Ph.D. qualification
- Achieved PhD qualification for research entitled "Photodegradation of Organic Pollutants in Water"
- Presented work at international conferences
- Lectured undergraduate students in analytical chemistry techniques

1990-1992 **Scientific Officer, The Medicines Testing Laboratory, Edinburgh (Associate of the British Pharmacopeia)**
(Left to pursue PhD qualification)
- Performed routine analyses on various pharmaceutical formulations
- Analytical Chemistry techniques.
- Developed analytical methods and wrote scientific reports

1988-1990 **Laboratory Technician, University of Edinburgh, Geology Dept.**
- Supervised and trained staff/postgraduate students in the setting up of and use of electron microprobe

- Provided technical assistance in sample preparation

1982-1988 **Trainee to Analytical Chemist, Syntex Research Centre, Edinburgh (left to pursue Graduate degree part time)**

- Analysed pharmaceutical preparations during stability studies
- Predicted shelf life drugs using kinetic equations
- Received training in GMP and quality systems
- Applied dissolution profiling information to pre-clinical drugs
- Developed chromatographic methods for novel formulations
- Performed routine analytical testing on pre-clinical formulations
- Investigated preformulation characteristics of candidate drugs including solubility, structure and physical testing.

EDUCATION

1995 – 1996 Post-Doctoral Studies at University of Western Ontario in collaboration with Labatt Brewing Company

1992-1995 PhD, Analytical, Photo-organic Chemistry, Napier University, Edinburgh

1991 GRSCII (2:1) Napier University, Edinburgh

1982-1992 Part time studies while in full time employment.

COURSES (attended)

- People Skills Course at the Canadian Management Centre of AMA
- Small Business Diploma – SBC – London, ON, Canada
- Attended various FDA/ ICH Regulatory Issues, GMP, Validation and Instrumentation seminars to keep training up to date
- Computing - certificate in elementary computing
- Excel Computer course (intermediate)
- Familiar with various software packages for graphics and word processing
- Certificate in SPME (Solid Phase Micro Extraction)

PROFESSIONAL MEMBERSHIPS

July 2015 to present Member of the USP Chemical Medicines 5 expert committee

Oct 2011 to Dec 2019t Member of USP Validation and Verification Expert Panel

Oct. 1993 to present Member of the Royal Society of Chemistry
Chartered Chemist (CChem MRSC)

Jan 2004 to present Pharmaceutical Sciences Group (PSG) and Calibration and Validation Group, Toronto (CVG)

Jan. 1998 Member of the Global Technical Quality Improvement Team (A Pfizer Spheres of Activity Team - Represented Canada AHG)

Mar. 1994 Member of the Young Chemists Advisory Committee to the Chief Government Scientist (Represented University and Scotland)

REFERENCES - Available on request