Pauline L McGregor PhD CChem MRSC

Canada Office: 221 Ross Lane, Oakville, ON, L6H 5K6, Canada
UK Office: BioCity Scotland, Bo'Ness Road, Lanarkshire, ML1 5UH
Email: pauline@pmcgconsulting.com, Website: www.pmcgconsulting.com

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.

Core Competencies

- **30 + years in the Pharmaceutical Industry**
- **Quality System Management**
- **Analytical procedures/Laboratory Support**
- **Validation**
- **Pre and Post Inspection GMP Audits**
- **Training**
- **Global GMP compliance**
- **Project Management**
- **SOP and technical document writing**
- **Document review**

BUSINESS EXPERIENCE

2006. -Present **Consultant/Owner – PMᶜG Consulting, www.pmcgconsulting.com**

- Auditing of GMP and associated quality systems (Europe, Canada and US regulations)
- Analytical Method Development, Validation, Transfer and QbD
- Member of USP Validation and Verification Expert Panel
- USP expert committee member - Chemical Medicines Monographs 2015 - 2020
- 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)
- Equipment and Cleaning Validation
- Validation Master Plans
- Documentation review
- Project and Quality management

- Training Specialist (Presented customised training courses in Canada, UK, US, Jordan and China)

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

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

1982- **Trainee to Analytical Chemist, Syntex Research Centre,**
1988 **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)

- Interpersonal 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 Member of USP Validation and Verification Expert Panel

to present	
Oct. 1993	Member of the Royal Society of Chemistry
to present	Chartered Chemist (CChem MRSC)
Jan 2004	Pharmaceutical Sciences Group (PSG) and Calibration and Validation
to present	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

Presentation Highlights – see Attachment 1

PRESENTATION HIGHLIGHTS

Jan 2007 to present	Various client training/consulting on good documentation practices for production, GMP compliance, quality systems inspection and site validation, laboratory techniques.
Nov 2008 to present	"Working in a GMP Environment" PSG, Toronto and Montreal
Oct 2011	"Current Handling of OOS/OOT Results and Introduction of the QbD and Lifecycle Approach for Future Analytical Methods", Dr.Naji Najib Center for Pharmaceutical Advancement (NNC), Amman, Jordan
May 2011	"Writing Effective SOPs" -2 day course – PSG, Toronto
April 2011	EU-GMP requirements for API and associated Quality Systems, Nottingham, UK
Dec 2010	IPA course on Analytical Method Transfer with GSK and Novartis in Philadelphia
Jul/Oct 2010	Global Compliance Webinars on Method Validation, Method Transfer and Verification, Quality by Design for Analytical Methods Webinar
March 2010 to present	Qualification of Analytical Methods and Application of QbD, Toronto, UK
Oct 2008	5 day onsite training course including: cGMP, Qualification of analytical instruments and personnel, Degradation Tests (Stress Studies) for Stability Indicating Assays , Laboratory Qualification of Analytical Test Methods, Evaluating Out-of-Specification Test Results, China
April 2008	PSG Full Day workshop "Investigating OOS Results in a GMP environment
October 2007	5 day onsite consulting and training USP methods and validation protocols, lab troubleshooting, Hangzhou, China
March 2007	5 day training course, "Method qualification in the Laboratory including GMP" – Winnipeg, Canada
March 2007	5 day training course, "Method qualification in the Laboratory including GMP", Haikou, China
Jan 2007	PSG Full Day workshop- "Standard Operating procedures" in Toronto, Montreal and Vancouver.
Oct 2006	PSG Full Day workshop – "HPLC methods – Development to Validation and the Stress in Between" Toronto, Montreal, Vancouver

2004 to present	Various technical customer and in –house presentations including analytical method transfers, method development and validations in Toronto
March 2007 to present	Various training courses, lecturing and laboratory sessions at AAPS, Toronto