

SIMONA E. TEODOSIU, M.S. PHARM.

145 Rue d'Aguesseau, 92100 Boulogne-Billancourt
Téléphone : 01 46057916 ; simona.teodosiu@gmail.com

Austrian citizen
Born: June 7th, 1973

OBJECTIVE

To utilize and enrich my experience acquired in the US; to obtain a job in an analytical development or regulatory affairs department.

EXPERIENCE

Analytical chemistry:

HPLC, GC; NIR, FT-IR, and UV-visible Spectroscopy; Karl Fischer; Dissolution, Disintegration

Regulatory Affairs and Quality Control:

Knowledge of cGMP and GLP systems, US, European, and ICH regulatory guidelines
Regulatory documentation (CTD, IND, IMPD); GLP laboratory set-up and management
Project management; team leadership

Computer skills:

Windows, Microsoft Office XP, Agilent Chemstation, Dionex Chromeleon, Foss Vision

WORK HISTORY

01.2008 – 02.2008

Analytical Development Specialist

Steba Biotech, France

Defined and wrote the analytical and quality related sections (drug substance and drug product) of an IMPD dossier. Collected all relevant information and ensured data compliance with current European regulatory guidelines.

Managed the analytical transfer for several projects. Provided technical and quality control expertise, facilitated communication between laboratories, and approved the reports.

Defined quality standards and the stability study program for drug substances and drug products according to their stage of development.

07.2002 – 08.2006

Quality Control Associate IV, Analytical Development

ICOS Corp., Bothell, WA, USA

Managed the analytical method transfer:

Evaluated and optimized HPLC methods for transfer to a GMP environment; generated method qualification protocols; supervised protocol execution; reviewed and approved qualification reports.

As CMC representative managed several projects, coordinating resources, demonstrating ability to prioritize, multi-task, and complete assignments on time.

Reported non-conformances, conducted laboratory investigations, established and implemented corrective actions.

Trained, mentored, and supervised a team of analysts.

Method development and validation:

Developed, qualified, and validated multiple HPLC methods for raw materials, process intermediates, drug substances, and drug products in support of preclinical and clinical trials (phase I and II).

Developed and validated the first in-house GC methods for the determination of residual solvents.

Defined and conducted reference standard characterization and API forced degradation studies.

Managed the counterfeit analysis laboratory:

Set up laboratory systems, implemented and validated laboratory procedures for the analysis of suspect counterfeit Cialis® tablets.

Trained, supervised, and provided technical expertise to the team.

Reviewed and approved technical reports and communicated them to Eli Lilly's GPPTT team.

GLP Analytical Study Director:

Set up the GLP laboratory for the first in-house Test and Control Article characterization and stability studies; supervised test article release and stability in support of several pre-clinical studies.

Set up the GLP training program; trained and supervised the laboratory personnel; communicated with other departments.

Regulatory documentation:

Wrote the analytical and quality related sections of a CTD and an IND dossier.

Generated and revised multiple compliance documents: program and laboratory SOPs, test methods, GLP study protocols and reports, validation protocols and reports, investigation reports, certificates of analysis, training records.

Was awarded two Icosahedron Awards for distinguished contributions in 2004 and 2006.

Presented at the Icos Research Advance event in 2003 and 2004.

01.2001 – 06.2002

Chemist, Analytical Chemistry Department**SRI International, Menlo Park, CA, USA**

In a contract quality control GMP laboratory environment, led a project through planning, method development and validation, and analytical support for drug formulation.

Responsible for stability studies, raw materials inventory and release according to specifications.

Reference Standard characterization; instrument calibration, maintenance, and troubleshooting.

Trained other chemists; supervised a summer intern.

Demonstrated ability to prioritize and multi-task.

Generated SOPs, test methods, validation protocols and reports.

Was awarded a Spot Award for exceptional contributions in 2001.

1998 - 1999

Resident Pharmacist**Sahia Hospital, Bucharest, Romania**

Drug dispensing and in-house drug compounding; provided information and advice on the recommended use and side-effects of drugs to the medical staff.

1996 - 1998

Pharmacist**Minesan Pharmacy, Bucharest, Romania**

Dispensing prescriptions and pharmaceuticals; advising patients; administrative duties (inventory and book-keeping for the pharmacy).

1991 - 1992

Registered Medical Nurse**Municipal Hospital, Cîmpina, Romania**

Provided patient care in the Internal Medicine department and managed patient records.

EDUCATION

1997 **M.S. Pharmacy, Carol Davila University, Bucharest, Romania** (GPA: 3.8/4.0)

1991 **R.N., Ploiești Medical High School, Romania**

OTHER TRAINING

2006 Communicating with professionalism and diplomacy, Seattle, WA

2005 Management and Leadership, Seattle, WA

2005 Scientific Presentations; Writing Technical Reports, Seattle, WA

2005 XDS Instrument Operation and Method Development, Foss NIR Systems, MD

2004 Introduction to FDA Good Laboratory Practices, GLP in the Bio-analytical Laboratory, WA

2003 Headspace Theory and Technology; 6890 Agilent GC Maintenance and Troubleshooting, GA

2001 HPLC Chemstation Software, Agilent Technology, CA

PERSONAL

Fluent in English, French, and Romanian