

Curriculum Vitae

NIKOLAOS GREKAS, B.Sc., Ph.D. in Chemistry

Personal details

Place and date of birth: Athens, Greece, 23rd of August 1962

Marital status: married

Nationality: Hellenic

Professional address: ELPEN Pharmaceutical Co. Inc.

95 Marathonos Av., 190 09 Pikermi Attica, Greece

tel: (+30)2111865360 / Fax : (+30)2106039300

e-mail : n.grekas@elpen.gr

Professional appointments

May 2009 – present: Clinical QA Manager, ELPEN Pharmaceutical Co. Inc.

Specific assignments

- QA in clinical research (Phase I-IV clinical trials, BEs, PASS, DUS and PMSS)
- Biostatistics and clinical study reports
- Internal and external GLP/GCP quality audits
- e-CRF/EDC Quality Management
- Publication of study results (scientific & medical writing)

Jan. 1999 – April 2009: Quality&Compliance Manager, ELPEN Pharmaceutical Co. Inc.

Specific assignments

Pharmaceutical Quality System Operations

- GMP and regulatory compliance. Implementation of ICH & EMA guidelines
- SOPs writing
- Implementation of pharmacopoeial quality specifications for APIs, packaging materials and drug products
- Qualification of suppliers

Technical & scientific support to the Regulatory Affairs and Exports departments

- Preparation of the module 3 of technical dossiers for registration for marketing authorization of generic pharmaceuticals (CTD format)
- Follow up according to the authorities and customer requirements

Stability studies

- Organization, assessment and follow-up of on-going stability studies for generic medicinal products
- Data management, presentation and reporting.

Jan 91 – Dec 98: Scientist and Head of R&D Diagnostics Lab., FARMALEX S.A.

Specific assignments

- Formulation development and industrial scale production of commercial in-vitro diagnostic reagent kits for clinical chemistry and immunology
- Planning, implementation and assessment of the QA program

- Laboratory and production management
- Technical support and training of the sales personnel
- Execution and leadership of national and international research projects

Sep 92 – Dec 92 : **Research fellow**, National Institute of Biological Standards and Control, Endocrinology Division, London UK. Training on immunochemical methods of analysis and quality control of r-DNA derived proteins.

1989 – 1990: Military Service, Analyst of the Clinical Biochemistry Laboratory, 251 HAF General Hospital, Athens, Greece. Routine assays, pharmacokinetic measurements, planning and execution of internal and external quality assessment programs.

Professional training

1991-2015: Regular attendance of scientific conferences, seminars and courses for the professional advancement.

Education

1984 – 1988 : Ph.D. thesis, Laboratory of Analytical Chemistry, Chemistry Department, University of Athens, Greece. During my post graduate studies and having a teaching assistantship I was participating in the laboratory training of the undergraduate students

1980 - 1984 : B.Sc. in Chemistry, Chemistry Department, University of Athens, Greece.

Other skills

- **Languages:** Greek, English, Italian
- **Computer literacy:** excellent command in the use of MS Office and other software programs (ERP, SPSS, IBM SPSS Data Collection Author, QUIS)
- **Human skills:** Strong and efficient interpersonal and social skills. Excellent technical skills.

Publications and other scientific activities

- Ph. D. Thesis, “*Analytical Applications of Molecular Emission Cavity Analysis*”
- 22 publications in international peer-reviewed scientific journals
- 39 presentations (poster & oral) in referred national and international conferences
- Contribution of the chapter “*Instrumentation and Automation*” in Vol. 129, “*Flame Chemiluminescence Analysis by Molecular Emission Cavity Detection*”, Series in Chemical Analysis, John Wiley and Sons, 1994
- Post Doc training on immunochemical methods of analysis and qc of r-DNA derived proteins (NIBSC, London)
- Member of the editorial board of the journal of the association of Greek chemists (Chimica Chronika). Period : 2007-2013.

List of publications at:

<http://scholar.google.com.au/citations?user=fMVQw0cAAAAJ&hl=en>