

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

Address: 7 Panagiotara st. Athens 114 75, Greece, email: nikolaos.d.grekas@gmail.com

mob.: +306972092437

Professional appointments

April 2025 - present: Consultant, Independent Researcher

September 2017 - March 2025: Senior Manager, Clinical Research, ELPEN

Specific assignments

- Supervision and support of the activities of the Clinical Research team within the Clinical Research Department

May 2009 – September 2017: Clinical QA Manager, ELPEN Pharmaceutical Co Inc

Specific assignments

- QA in clinical research (Phase I, IV clinical trials)
- 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 quality guidelines
- Implementation of pharmacopoeial quality specifications for APIs, drug products and packaging materials
- Qualification of suppliers - SOPs writing

Technical & scientific support to the Regulatory Affairs and Exports departments

- Preparation of 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
- Technical support and training of the sales personnel
- Participation in 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.

Education

1984 – 1988: Ph.D. thesis, Laboratory of Analytical Chemistry, Chemistry Department, University of Athens, Greece.

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

Other skills

- **Languages:** Greek (mother language), English (full professional proficiency), Italian (professional proficiency)
- **Computer literacy:** excellent command in the use of MS Office
- **Teaching experience:** 4 years teaching in undergraduate and post graduate university students (1985-1989). Guest lecturer in seminars and scientific events and post graduate courses.
- **Human skills:** Strong and efficient interpersonal and social skills.

Professional training

1991-2025: Regular attendance of scientific conferences, seminars and courses for professional advancement.

Publications and scientific activities

- Ph. D. Thesis, “*Analytical Applications of Molecular Emission Cavity Analysis*”
- 26 publications in international peer-reviewed scientific journals
- 52 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
- Member of the Committee for Clinical Trials - SFEE (Hellenic Association of Pharmaceutical Companies). Period: 2015 - 2017
- Member of the editorial team in SFEE edition: Bioequivalence Trials Manual, “A Short Guide for Sponsors and CROs”, 2016

List of publications at:

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