CURRICULUM VITAE

PERSONAL INFORMATION

Last name: **Kafkala**
First name: **Stella**
Place of birth: **Athens**
Date of birth: **24/12/1977**
Address: **2, Pefkon st, 14565 Agios Stefanos**
Phone number: **6936200091**
Personal e-mail: **stellakafkala@gmail.com**

OVERVIEW:

- 16 years' experience in R&D laboratory management
- 19 years' experience in pharmaceutical analysis (solid dosage forms, oral liquids, oral suspensions, injectables), method development and validation
- 4 years' experience in lectures on pharmaceutical analysis topics in postgraduate course of Industrial Pharmaceutics, University of Thessaloniki (as an external partner)
- Excellent knowledge of chromatographic technics (HPLC/GC/UPLC), analytical method development, validation and troubleshooting
- Use of the principles for QbD approach in analytical methods development, setting up of the lifecycle management
- Chemistry degree (4 years course) and a Master's degree in Food Chemistry (2 years course)
- Excellent knowledge of the English language (verbal and written)

WORK EXPERIENCE

2006-today: **GENEPHARM SA, GENERICS PHARMACEUTICAL COMPANY**
March 2014-today: **Analytical Development Director**

- General management of the R&D laboratory
- Coordination with the subordinate responsible scientists within the laboratory for the planning of the analysis, execution of method development and validation for the new methods. Overviewing the flow of analytical results of development analysis, of requested data for the submission dossier and of stability analysis of submission batches
- Coordination with the formulation development department and regulatory affairs department for the planning of development activities, bioequivalence studies, submission timelines and development/submission strategy
- Communication with client companies for the arrangement of method transfer activities, organizing the procedure and needed documentation
- Communication with partners in the frame of projects codevelopment, regarding the analytical issues

- Organizing and/or presenting training courses for the laboratory team (in-house seminars, webinars or international training courses) and other departments/ companies within the company group
- Designing and implementing systems for the electronic data integrity conformity through procedures, audit trail implementation in R&D files and electronic signatures system

September 2006
-March 2014: **Head of Analytical Development, R&D Laboratory:**

- Responsible for planning, supervising, evaluation of results and troubleshooting on the lab analyses. Compilation of summarizing reports for the presentation of results
- Method development (HPLC/GC/dissolution) and design of the validation procedure
- Organizing the lab by preparing procedures (SOP), methods of analysis and electronic databases for recording the use of chromatographic columns, the consumption of reference materials and the distribution and logistics of stability samples in the ovens
- Training of the analysts on the lab procedures and on principles of good laboratory practice
- Preparation of seminars for the laboratory staff on analytical issues (liquid and gas chromatography, dissolution principles), on the guidelines that refer to analytical issues, on European pharmacopoeia chapters, on the analytical parts of the submission dossier, as well as safety principles and first aid measures
- Compilation of the analytical parts of the submission dossier and response to deficiency letters on analytical queries
- Participation in seminars abroad (poster presentation of developed methods in the lab) and publication of respective papers in scientific journals

March 2006
- September 2006: **Regulatory affairs department**

- Compilation of submission dossier in ctd format
- Response in deficiency letters to authorities in Greece, Europe, Australia, Canada and Third Countries
- Experience with DCP and MRP submissions

October 2005
-March 2006: **IMS HEALTH**: Codification of the pharmaceutical products and compilation of the report format depending on clients requests

2003-2005 : **DEMO pharmaceutical company**

October 2003
- August 2005: **R&D Laboratory**.

- Supervision of stability studies
- Design and execution of method validation
- Evaluation of results and compilation of stability and validation reports

January 2003
- October 2003: **Quality control analyst**.

- Analysis on dry powders for injection, tablets, solutions for infusion, syrups and lyophilized products
- Stability analysis and validation analysis for the R&D department

August 2000: Job training in the public laboratory of fuel and lubricants (ΔΕΗ)

EDUCATION

2000-2002: **Master in Science** in the Department of Food Chemistry of the National and Kapodistrian University of Athens
Subject : "Study of the effect of microwave heating on olive oil and corn oil"
Responsible professor: E. Melissari

Grade: Excellent

1996-2000: **BSc in Chemistry**

Grade: Very well
Certificate of participation in Oenology course
BSc Thesis in the Department of Food Chemistry
Subject: "Isolation and identification of triglycerides in plant foods"
Responsible professor: E. Melissari

Grade: Excellent

FOREIGN LANGUAGES

ENGLISH: Certificate of Proficiency in English, University of Cambridge, June 1997 .

Presentations and publications

2008, September: **Participation with poster** in "International Symposium on Chromatography 2008, Munster, Germany" Subject: "Development of a headspace GC method for the simultaneous determination of 19 organic solvents in active pharmaceutical substances".

2007, December: **Publication** in Journal of Chromatography A: "A New Gradient HPLC method for the determination of donepezil HCl assay and impurities content in oral pharmaceutical formulation"

2007, June: **Participation with poster** in "HPLC 2007 forum, Ghent, Belgium". Subject: "A New Gradient HPLC method for the determination of donepezil HCl assay and impurities content in oral pharmaceutical formulation"

2005, April **Publication** in Journal of Pharmaceutical and Biomedical Analysis, subject: "A novel gradient HPLC method for the simultaneous determination of ranitidine, methylparaben and propylparaben in oral liquid pharmaceutical formulation"

2001, May: Participation in the seminar « Design, application-certification and inspection of HACCP systems»

Training courses

- Masterclass on Data Analysis for the performance of Analytical Procedures, March 2022
- Advanced Stability Testing, February 2022
- Quality and Regulaatory requirements for Biosimilars in EU, October 2021
- Seminar on dissolution testing, September 2021
- Forced Degradation Studies, September 2021
- Statistics/ Chemometrics in analytical method validation, February 2019
- Data Integrity, February 2018
- Practical Solutions for establishing In Vivo In Vitro Correlation, London , April 2014
- QbD and lifecycle management for analytical procedures, Scotland, June 2013
- Bioavailability and pharmacokinetic studies, Athens, November 2012
- The current state of dissolution testing, London, December 2008
- Metrology in Chemistry, Athens, May 2008
- Generic registrations and product development, Athens, September 2006
- Designing, application-certification and inspection of HACCP system, Athens, May 2001

OTHER QUALIFICATIONS

- Very good collaboration with subordinates and other departments colleagues. Team spirit, motivation of the laboratory members by allowing initiatives and assigning responsibilities
- Very good organizational skills on the workload handling, analysis planning and development procedures establishment
- Setting up ready to use templates for automatic calculation of results and compilation of respective reports. Automation of activities like generation of analysis program, through Access databases
- Set up of the excel templates validation activity, validation of access databases, electronic signatures set up and validation of the process, establishment of the electronic files data integrity procedure

- Excellent knowledge in gas and liquid chromatography principles and application as well as dissolution technique. Familiar with UPLC analysis, basic knowledge of LCMS analysis
- Excellent knowledge of pc programs of MS office, including setting up and using Access databases and VBA, as well as internet programs, and scientific instruments software (Empower, Chemstation, Class VP). Use and validation of scientific applications like DDSOLVER and R
- Piano degree and certification of teaching
- Driving license available