



Curriculum Vitae

Personal information **Maria Katsimpoula**

Work experience

10/2018 – present

ASSESSOR, ADVERSE REACTIONS DEPARTMENT, PHARMACEUTICAL STUDIES AND RESEARCH DIVISION – National Organization for Medicines (EOF) - Greece

- Monitoring of manufacturers actions subsequent to submission of healthcare professionals / users / patients incident reports involving medical devices
- Incidents recording
- Evaluation of Manufacturer Incident Reports (MIRs)
- Preparation, compilation and review of SOPs, records, etc. documentation associated with incidents management

01/2017 – 10/2018

ASSESSOR, MEDICAL DEVICES ASSESSMENT SECTION, PRODUCT ASSESSMENT DIVISION – National Organization for Medicines (EOF) - Greece

- Registration of Class I, Custom-made & In vitro diagnostic medical devices
- Assessment of the qualification of products as medical devices and the classification of medical devices
- Exchange of information between medical device Competent Authorities on borderline or classification issues (Helsinki Procedure)
- Issuance of Free Sales Certificates
- Entering New actors and registering Certificates in Eudamed
- Participation in the project team set up for the development of a national electronic register of medical devices (GREMDIS)

01/2016 – 12/2016

REGULATORY AFFAIRS OFFICER – DMP Dental Industry S.A. - Greece

- Supporting compliance of company products (medical devices for dental application) to European and FDA requirements
- Keeping abreast of international legislation and guidelines for countries the company exports products to (EU, USA, Canada etc.)
- Liaising with regulatory authorities
- Participation in Notified Body and FDA audits
- Preparation, compilation and review of SOPs, records, etc. documentation of the Quality Management System according to ISO 13485, ISO 9001 and FDA requirements
- Reviewing company practices and providing advice on changes to system

11/2003 – 05/2015

SENIOR ASSOCIATE, TECHNICAL SERVICES & COMPLIANCE – S.C. Johnson Hellas LTD - Greece

- Ensuring regulatory compliance of company products (insecticides, cleaners, disinfectants, air fresheners)
- Coordination of artwork development for local versions of products sold in Greece & Cyprus
- Consumer complaints management
- Contribution to creation & maintenance of local standard operating procedures (SOPs)

05/2000 – 10/2003

CHEMIST – SOYA MILLS S.A. - Greece

- Monitoring of the processing of soya beans (production of soybean meal and soybean oil) and refining of crude seed oils (soybean oil, sunflower oil, corn oil)
- Quality control of finished products and raw materials in line with the Quality Management System ISO 9002

12/1999 – 04/2000

CHEMISTRY TEACHER SECONDARY SCHOOL – High School, Vrachati - Greece
Teaching Organic and Inorganic Chemistry

08/1994 – 08/1994

CHEMIST (INTERNSHIP) – Motor Oil Hellas - Greece

Education and training

10/2001 – 07/2003

MASTER OF SCIENCE (M.SC.) IN PHARMACOGNOSY OF BIOACTIVE NATURAL PRODUCTS – National & Kapodistrian University of Athens, Faculty of Pharmacy - Greece

EQF level 7 <https://www.pharm.uoa.gr/>

10/1993 - 09/1999

CERTIFICATE OF OENOLOGICAL EDUCATION – National & Kapodistrian University of Athens, Department of Chemistry - Greece

<http://www.chem.uoa.gr>

10/1993 – 09/1999

BACHELOR OF SCIENCE (B.SC.) IN CHEMISTRY – National & Kapodistrian University of Athens, Department of Chemistry - Greece

EQF level 6 <http://www.chem.uoa.gr>

Additional information

Publications

Projects

Memberships

12/2018 - present

Member/Observer of MDCG WORKING GROUP ON POST-MARKET SURVEILLANCE AND VIGILANCE (PMSV)

12/2018 - 02/2021

Member/Observer of MDCG WORKING GROUP ON CLINICAL INVESTIGATION AND EVALUATION (CIE)

Other Relevant Information

HONOURS AND AWARDS

Scholarships for the 1st and 2nd year of postgraduate program (M.Sc.) – State Scholarships Foundation

COURSES

13/09/2019 – 13/09/2019

“MedDRA: Safety Data Analysis and SMQs” - MedDRA Maintenance and Support Services Organization (MSSO)

12/09/2019 – 12/09/2019

“Coding with MedDRA” - MedDRA Maintenance and Support Services Organization (MSSO)