

# Curriculum Vitae

## Personal information Sofia Trantza

## Work experience

- Employer: National Organization for Medicines
   Start date: 09/2021
  - - End date:
  - Position: Cosmetics Department
  - Activities: Part time learning of the procedures and legislation governing the Cosmetics' regulation
  - Country: Greece
- 2. Employer: National Organization for Medicines
   Start date: 11/2020

  - End date: 09/2021
    Position: Member of the Study Committee of the Regulatory Framework of Scientific Events Activities: Member of the Study Committee of the Regulatory Framework of Scientific Events of the National Organisation for Medicines through the Panhellenic Association of Pharmacists (PEF)
- Country: Greece
  3. Employer: National Organization for Medicines
  - Start date: 12/2020
  - End date:
  - Position: Member of the Committee for the Control of Medical Information Forms and Advertising of products
    • Activities:
- Country: Greece
   Employer: National Organization for Medicines
   Start date: 02/2021

  - End date: Position: Assessor at Evaluation's Division
  - Activities: Assessor at Evaluation's Division for several therapeutic areas (topical use, opthalmic use, corticosteroids etc) for national, MRP and DCP procedures (initial, renewals and variations) Secretary of the National Radiopharmaceuticals Authorization Council
- Country: Greece
   Employer: National Organization for Medicines (EOF)
  - Start date: 10/2016
  - End date: 01/2021
  - Position: Department of Adverse Reactions
  - Activities: Eudravigilance Deputy QPPV for EOF, Assessmet for Risk Management Plans (RMPs) for all procedures (DCP, MRP, National, Centralised), Assessment for Periodic Safety Update Reports (PSURs) for all procedueres, Signal Management assessment, Quality Manager for the Pharmaceutical Clinical Trials and Research Division, PRAC alternate member, EudraVigilance user, ICSR reporting in EV, PRAC communication expert and Rapporteur for centralised procedures, Member of the team for the update of the National Formulary update (2019, parts of cutaneous medicinal products and contrast medium agents)
- Country: Greece
   Employer: Creative Pharma Services SA
  - Start date: 07/2015

  - End date: 10/2016 Position: Pharmacovigilance Manager
  - Activities: XEVMPD and ICSR responsible, QPPV for 4 companies, Pharmacovigilance training for Pharmacovigilance Officers (team of 8 members), SOP writing and updating, PSUR and RMP writing and submission, PSMF writing and updating, Responsible for 1 Phase IV clinical trial (interventional type) and 1 Phase IV clinical trial for a medical device • Country: Greece
- 7. Employer: HEREMCO LTD

  Start date: 10/2014

  End date: 10/2016

  - Position: QPPV Activities: Building the PV system for the company and acting as QPPV
- Country: Greece
  8. Employer: Hospital Line SA
- Start date: 09/2014
  - End date: 06/2015
  - Position: QPPV, ISO 9001: 2008 and 13485 Manager, Responsible Pharmacist for the Warehouse
  - Activities: Build of the PV system, QPPV, ISO 9001: 2008 and ISO 13485 manual maitenance, Responsible pharmacist for the Warehouse

    Country: Greece

### Education and training

- 1. Subject: ETH Zurich
  - Start date: 05/2022
  - End date:

- Oualification: CAS in Radiopharmacy
- Organisation: Qualification in Radiopharmacy. Expected certification from EAMN 2024.
- Country: Switzerland
   Subject: University of Hertfordshire
  - Start date: 09/2014 End date: 09/2018
  - Qualification: MSc Pharmacovigilance
  - Qualification: MSc Pharmacovigilance
     Organisation: All aspects of Pharmacovigilance (Clinical trials, Pharmacoepidemiology, Risk Management Plan and Labelling, Major Body Systems (ADRs I), Regulations and Guidelines, Data Management in Pharmacovigilance, Principles of Pharmacovigilance) Dissertation thesis: "CAST analysis of the isotretinoin system for prevention of pregnancy in the UK with proposals towards its application as a global case study". CAST i.e Causal Analysis based on STAMP (Systems Theoretic Accident Model and Processes) Presentation on MIT on March 2018 Presentation in ESW conderence in Amsterdam on October 2018 Multiple presentations in D1A euromeeting Austria February 2019, poster presentation in ISOP conference Geneva 2018 Upcoming paper in high graded Journal Grade: Distinction
    - Country: United Kingdom
- 3. Subject: IFAPP Academy and Kings College
   Start date: 01/2018

  - End date: 02/2019

    Qualification: Medical Affairs

    Organisation: All the aspects of Medical Affairs, Awarded the international Fritz Buhler
  - scholarship. Ended on February 2019. Certification in Medical affairs.

     Country: United States
- Subject: National and Kapodistrian University of Athens
   Start date: 10/2009
  - - End date: 03/2012

    - $\label{thm:partial} \begin{tabular}{ll} Qualification: MSc in Industrial Pharmacy \\ Organisation: Pharmaceutical Technology, 1 year scholarship in the University of Parma \\ \end{tabular}$ (Dome matrix technology), Dissertation on transdermal pharmaceutical forms, teaching for the Pharmaceutical technology laboratories for the 5 year students of Pharmacy
    - Country: Greece
- 5. Subject: National and Kapodistrian University of AthensStart date: 09/2000
  - End date: 10/2009 Qualification: Pharmacy
  - Organisation: Bachelor Degree in Pharmacy
  - Country: Greece

#### Additional information

#### **Publications**

Trantza Sofia, Kraniou Giorgos, Tsapoga Dimitram, Mitropoulou Maria, A comparison of the three major worldwide pharmacovigilance systems (EU, USA and Japan). Do they remain harmonized?, ELEFI magazine, Issue 11, October

Brian D. Edwards, Bernard Bégaud, Esther Daemen, Ioannis Dokas, Jonathan M. Fishbein, Howard E. Greenberg, Alan Hochberg, Hervé Le Louet, Jytte Lyngvig, Nataliya Mogles, Kathryn Owen, Christine Prendergast, Martin Rejzek, Sophia Trantza, David J. Webb, Matthew Whalen and Simon Whiteley, "A call to incorporate systems theory and human factors into the existing investigation of harm in clinical research involving healthcare products", BJCP, Volume 83, Issue 11, November 2017, Pages 2339–2342 Andri Andreou,

Sofia Trantza, Demetrios Filippou, Nikolaos Sypsas, Sotirios Tsiodras, "COVID\_19:The potential role of copper and N\_acetylcysteine (NAC) in a combination of candidate antiviral treatments against SARS\_CoV\_2", In Vivo, 34: 1567\_1588 (2020)

Projects

CAST analysis of the isotretinoin system for prevention of pregnancy in the UK with proposals towards its application as a global case study". CAST i.e Causal Analysis based on STAMP (Systems Theoretic Accident Model and

Memberships

President of the Hellenic National Association of Pharmacists (December 2019\_ current) Member and former Treasurer for the NGO "World Pharmacists" Member of the Editorial Board of Annals of Clinical Trials and Vaccines Research

Other Relevant Information

ECDL certificate holder Greek: Mother tongue English: excellent (Cambridge Proficiency Certificate) German: very good (Mittelstuffe Göethe Universität), Oberstüffe current lessons French, Italian: moderate