

### PERSONAL INFORMATION

Sofia Trantza

### WORK EXPERIENCE

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October 2016- Present

#### Department of Adverse Reactions

National Organization for Medicines (EOF) (Greece)

Eudravigilance Deputy QPPV for EOF, Assessment for Risk Management Plans (RMPs) for all procedures (DCP, MRP, National, Centralised), Assessment for Periodic Safety Update Reports (PSURs) for all procedures, 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)

July 2015-October 2016

#### Pharmacovigilance Manager

Creative Pharma Services SA (Greece)

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

October 2014-October 2016

#### QPPV

HEREMCO LTD (Greece)

Building the PV system for the company and acting as QPPV

September 2014-June 2015

#### QPPV, ISO 9001: 2008 and 13485 Manager, Responsible Pharmacist for the Warehouse

Hospital Line SA (Greece)

Build of the PV system, QPPV, ISO 9001: 2008 and ISO 13485 manual maintenance, Responsible pharmacist for the Warehouse

### EDUCATION AND TRAINING

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September 2014-September 2018

#### MSc Pharmacovigilance

University of Hertfordshire (United Kingdom)

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 conference in Amsterdam on October 2018

Multiple presentations in DIA euomeeting Austria February 2019, poster presentation in ISOP conference Geneva 2018

Upcoming paper in high graded Journal

Grade: Distinction

January 2018-February 2019 **Medical Affairs**  
IFAPP Academy and Kings College (United States)  
All the aspects of Medical Affairs, Awarded the international Fritz Buhler scholarship.  
Ended on February 2019. Certification in Medical affairs.

October 2009-March 2012 **MSc in Industrial Pharmacy**  
National and Kapodistrian University of Athens (Greece)  
Pharmaceutical Technology, 1 year scholarship in the University of Parma (Dome matrix technology), Dissertation on transdermal pharmaceutical forms, teaching for the Pharmaceutical technology laboratories for the 5 year students of Pharmacy

September 2000-October 2009 **Pharmacy**  
National and Kapodistrian University of Athens (Greece)  
Bachelor Degree in Pharmacy

## ADDITIONAL INFORMATION

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**Expertise** STAMP user (method of MIT) - risk hazard analysis  
CAST user (same as above and a part of STPA)

**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 2016.  
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 23392342  
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 Processes)

**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 (Mittelstufe Goethe Universität), Oberstufe current lessons  
French, Italian: moderate