

SOFIA POULOU

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PERSONAL INFORMATION

Date of Birth 27/05/1980

FIELDS OF INTEREST

Preclinical & Clinical Drug development, Clinical trials, Regulatory Affairs, Pharmacovigilance

EDUCATION

Biologist (Department of Biology, School of Natural Sciences, University of Patras, Greece)

WORK EXPERIENCE

2004-2009 **Freelance drug development and regulatory consultant, medical writer**

2009-present **Manager of InSciSol, a company providing scientific consultancy services in the fields of clinical trials, drug development & registration and pharmacovigilance**

Within the context of my professional experience both as a freelance consultant and as manager of InSciSol, I have provided and supervised the following services:

- Writing of expert reports
 - Modules 2.4 and 2.5 of the dossier (Non-clinical and Clinical Overview)
 - Addendum to the Clinical Overview and the Non-Clinical Overview (where necessary) for renewal applications
 - Risk management plans
 - Biowaivers
 - Environmental Risk Assessment Reports
 - Toxicology assessments of excipients or impurities
 - Assessment of adverse events within the context of clinical trials or pharmacovigilance procedures.
 - Reports for the change in classification/legal status from prescription to non-prescription drugs
 - Safety report for cosmetics and food supplements
- Support for EMA Scientific Advice
 - consultancy,
 - compilation of all relevant documents and presentations
 - physical presence of scientific consultants to the meetings.
- Study design and protocol preparation (Clinical studies, Preclinical studies)
- Compilation/Amendment of Product Information (SmPC, PIL)
- Readability Testing (User Testing) of Package Leaflets
- Medical Writing
- Advertising and marketing materials
- Training materials
- Advisory board preparation
- Technical & Scientific Translations (Protocols, SmPCs, PILs, Labelling, Advertising & training materials, Medical books etc.)
- Literature research

Clientele:

- | | |
|--------------------------------------|---------------|
| • Actavis | • Verisfield |
| • Glenmark | • TERIX |
| • Pharmathen | • Gerolymatos |
| • Genepharma | • PharOS |
| • Galenica & Minerva pharmaceuticals | • Pharmassist |
| • DEMO | • Pharmadata |
| • Rafarm | |

SEMINARS

I have attended various seminars relative to drug development, regulatory affairs and pharmacovigilance

LANGUAGES

Greek (Native), English (Fluent), French (Good), Spanish (Basic)