

PERSONAL INFORMATION

Valentina Di Giovanni

WORK EXPERIENCE

October 2017- Present

Senior Pharmacovigilance Assessor

Agenzia Italiana del Farmaco (Italy)

Alternate PRAC Member

Signal detection and management

Benefits-risks evaluation

Monitoring and analysis of adverse drug reaction in National Network for Pharmacovigilance (RNF) and

Eudravigilance (EV) database

Writing/Editing/Translation of Safety Communication Documents

Evaluation of renewals of Marketing Authorisations

May 2018- Present

Junior GVP Inspector

Agenzia Italiana del Farmaco (Italy)

Pharmacovigilance inspections

December 2007-September 2017

QPPV

Istituto Biochimico Italiano Giovanni Lorenzini S.p.A. (company belonging to the IBIGEN group) (Italy)

Implementation and management of the Company's pharmacovigilance and quality system.

Pharmacovigilance contact point in EU and extra EU countries

Direct involvement in signal management, preparation and approval of safety documents (such as PSUR,

RMP, ACO, PADER), population of XEVMPD, case report management, pharmacovigilance contracts and

agreements, screening of literature, risk-benefit assessment, implementation of risk minimisation measures, standard operating procedures (SOPs), management of third parties and affiliates, pharmacovigilance audit, pharmacovigilance training.

Contact person for OsSC (Osservatorio Nazionale sulle Sperimentazioni Cliniche, AIFA)

June 2004-November 2007

Medical Department Specialist

Istituto Biochimico Italiano Giovanni Lorenzini S.p.A. (company belonging to the IBIGEN group) (Italy)

Involvement in clinical trials, medical information, sales force training, standard operating procedures (SOPs)

Scientific support to the Export and Marketing Department

Cooperation with Regulatory Affairs Office (writing of 2.4, 2.5, 2.6 e 2.7 Modules of eCTD)

Pharmacovigilance activities

April 2002-May 2004

Biologist

La Madonna della Fiducia, Clinical analysis laboratory (Italy)

microbiological and chemical analysis

March 2001-March 2002

Internship

Department of Internal Medicine, Policlinico Umberto I, University of Rome La Sapienza (Italy)

Internship as a volunteer at a cell biology laboratory

February 2000-March 2000

Internship

Department of Clinical Science, Policlinico Umberto, University of Rome La Sapienza (Italy)

Internship as a volunteer at a molecular biology laboratory

January 1999-October 1999

Internship

Department of Clinical Physiopathology, Policlinico Umberto I, University of Rome La Sapienza (Italy)

Internship as a volunteer at a reproduction immunology laboratory

EDUCATION AND TRAINING

2002- 2005

Post graduated in Pharmacology

University of Rome La Sapienza (Italy)

1995- 2000

Biology Science Degree, Physiopathology specialization

University of Rome La Sapienza (Italy)

December 2019-December 2019

Internal Auditor for Quality System

AICQ SICEV (Italy) (Italy)

UNI EN ISO 9001:2015 and UNI EN ISO 19011:2018

2002- 2002

Registration in the National Council of Biologists (State Exam passed)

University of Rome La Sapienza (Italy)

ADDITIONAL INFORMATION

Expertise

Publications

Andrea Conte, Valentina Di Giovanni "Management and reporting of post-marketing adverse events to medicinal products: the US requirements and their differences with the European ones" - Giornale Italiano di Farmacoconomia e Farmacoutilizzazione 2017; 9 (3): 57-69.

Crisafulli S, Cutroneo PM, Verhamme K, Ferrajolo C, Ficarra V, Sottosanti L, Di Giovanni V, Spina E, Trifiro G. Drug-induced Urinary Retention: An Analysis of a National Spontaneous Adverse Drug Reaction Reporting Database. Eur Urol Focus. 2021 Jul 15:S2405-4569(21)00180-2. doi: 10.1016/j.euf.2021.07.001.

"Medicinali Biosimilari - Analisi di sicurezza", a cura di AGENZIA ITALIANA DEL FARMACO (AIFA), ROMA - Area Vigilanza Post-Marketing: A. R. Marra, G. Pimpinella, C. Santuccio, S. A. Barnaba, M. Conte, V. Di Giovanni, P. Felicetti, R. Ranalli, F. Renda, L. Sottosanti. Published on 12 luglio 2019.

Niccolo Lombardi, Giada Crescioli, Valentina Maggini, Eugenia Gallo, Ilaria Ippoliti, Francesca Menniti-Ippolito, Valentina Di Giovanni, Nicoletta Luxi, Laura Augusta Gonella, Ugo Moretti, Gianluca Trifiro, Emanuel Raschi, Fabio Firenzuoli, Alfredo Vanna. Valutazione delle reazioni avverse a farmaci e integratori contenenti Serenoa repens. XXXI Seminario Nazionale di Farmacoepidemiologia. Abstract, published on 16/12/2022.

Projects

Memberships

Other Relevant Information