

Curriculum Vitae

Personal information **Valentina Di Giovanni**

Work experience

1. Employer: Agenzia Italiana del Farmaco
 - Start date: 10/2017
 - End date:
 - Position: Senior Pharmacovigilance Assessor
 - Activities: Alternate PRAC Member (from 24/06/2022 to 15/01/2024). 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. Quality System Management of the Signal Management Office.
 - Country: Italy
2. Employer: Agenzia Italiana del Farmaco
 - Start date: 05/2018
 - End date:
 - Position: Senior GVP Inspector
 - Activities: Pharmacovigilance inspections
 - Country: Italy
3. Employer: Istituto Biochimico Italiano Giovanni Lorenzini S.p.A. (company belonging to the IBIGEN group)
 - Start date: 12/2007
 - End date: 09/2017
 - Position: QPPV
 - Activities: 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)
 - Country: Italy
4. Employer: Istituto Biochimico Italiano Giovanni Lorenzini S.p.A. (company belonging to the IBIGEN group)
 - Start date: 06/2004
 - End date: 11/2007
 - Position: Medical Department Specialist
 - Activities: 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
 - Country: Italy
5. Employer: "La Madonna della Fiducia", Clinical analysis laboratory
 - Start date: 04/2002
 - End date: 05/2004
 - Position: Biologist
 - Activities: microbiological and chemical analysis
 - Country: Italy
6. Employer: Department of Internal Medicine, Policlinico Umberto I, University of Rome "La Sapienza"
 - Start date: 03/2001
 - End date: 03/2002
 - Position: Internship
 - Activities: Internship as a volunteer at a cell biology laboratory
 - Country: Italy
7. Employer: Department of Clinical Science, Policlinico Umberto I, University of Rome "La Sapienza"
 - Start date: 02/2000
 - End date: 03/2000
 - Position: Internship
 - Activities: Internship as a volunteer at a molecular biology laboratory
 - Country: Italy
8. Employer: Department of Clinical Physiopathology, Policlinico Umberto I, University of Rome "La Sapienza"
 - Start date: 01/1999
 - End date: 10/1999
 - Position: Internship
 - Activities: Internship as a volunteer at a reproduction immunology laboratory
 - Country: Italy

Education and training

1. Subject: University of Rome "La Sapienza"
 - Start date: 2002
 - End date: 2005
 - Qualification: Post graduated in Pharmacology
 - Organisation:
 - Country: Italy

2. Subject: University of Rome "La Sapienza"
 - Start date: 1995
 - End date: 2000
 - Qualification: Biology Science Degree (Physiopathology)
 - Organisation:
 - Country: Italy
3. Subject: AICQ SICEV (Italy)
 - Start date: 122019
 - End date: 122019
 - Qualification: Internal Auditor for Quality System
 - Organisation: UNI EN ISO 9001:2015 and UNI EN ISO 19011:2018
 - Country: Italy
4. Subject: AICQ SICEV (Italy)
 - Start date: 072021
 - End date: 072021
 - Qualification: Lead Auditor for Quality System
 - Organisation: UNI EN ISO 9001:2015 and UNI EN ISO 19011:2018
 - Country: Italy
5. Subject: University of Rome "La Sapienza"
 - Start date: 2002
 - End date: 2002
 - Qualification: Registration in the National Council of Biologists (State Exam passed)
 - Organisation:
 - Country: Italy

Additional information

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 Farmacoeconomia e Farmacoutilizzazione 2017; 9 (3): 57-69.
- Crisafulli S, Cutroneo PM, Verhamme K, Ferrajolo C, Ficarra V, Sottosanti L, **Di Giovanni V**, Spina E, Trifirò 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. Pubblicato il 12 luglio 2019.
- Cooperation in preparing the "Rapporto annuale sulla sicurezza dei vaccini covid -27/12/2020 - 26/12/2021", a cura di AGENZIA ITALIANA DEL FARMACO (AIFA). Published on February 9th, 2022.
- Niccolò Lombardi, Giada Crescioli, Valentina Maggini, Eugenia Gallo, Ilaria Ippoliti, Francesca Menniti-Ippolito, **Valentina Di Giovanni**, Nicoletta Luxi, Laura Augusta Gonella, Ugo Moretti, Gianluca Trifirò, Emanuel Raschi, Fabio Firenzuoli, Alfredo Vanna. Valutazione delle reazioni avverse a farmaci e integratori contenenti *Serenoa repens*. Atti del XXXI Seminario Nazionale di Farmacoepidemiologia. 16/12/2022.
- Crescioli G, Maggini V, Raschi E, Gonella LA, Luxi N, Ippoliti I, **Di Giovanni V**, Bonaiuti R, Firenzuoli N, Gallo E, Menniti-Ippolito F, Moretti U, Trifirò G, Vannacci A, Firenzuoli F, Lombardi N. Suspected adverse reactions to medications and food supplements containing *Serenoa repens*: A worldwide analysis of pharmacovigilance and phytovigilance spontaneous reports. *Phytother Res.* 2023 Nov;37(11):5289-5299. doi: 10.1002/ptr.7960. Epub 2023 Jul 18. PMID: 37463655.

Projects

Memberships

PRAC Alternate, from June 2022 to January 2024.

Member of SMART processes work stream group, from April 2022.

Other Relevant Information