



## Curriculum Vitae

Personal information Paola Aita

### Work experience

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1. Employer: Italian Medicines Agency (AIFA)
  - Start date: 012005
  - End date:
  - Position: Pharmacist
  - Activities: Clinical Trials Unit (National Clinical Trials Monitoring Center and e-submission platform for Clinical Trials Applications / substantial amendments: collection, analysis and evaluation of pharmacologic clinical trials conducted in Italy; national report on clinical trials of drugs; training of representatives from local ethics committees and pharmaceutical companies/no commercial sponsor/CROs with regard to the use of the national electronic system for clinical trials and clinical research; Safety Monitoring of clinical trials conducted in Italy; VHP; CTIS MT for Italy); CTIS MS Master Trainer for NCA
  - Country: Italy
2. Employer: Ministry of Health, Directorate General for Medicine Evaluation and Pharmacovigilance
  - Start date: 061999
  - End date: 122004
  - Position: Pharmacist
  - Activities: Clinical Trials and Special Uses of Unauthorized Medicinal Products Office (National Clinical Trials Monitoring Center: collection, analysis and evaluation of data with regard to pharmacologic clinical trials conducted in Italy; national report on clinical trials of drugs; training of representatives from local ethics committees and pharmaceutical companies/no commercial sponsor/CROs with regard to the use of the national electronic system for clinical trials and clinical research; data validation and transmission to the EudraCT Data Base)
  - Country: Italy
3. Employer: National Cancer Institute of Aviano (PN)
  - Start date: 101994
  - End date: 061999
  - Position: Post\_graduate researcher (Funding from the National Research Council – CNR – and Ministry of Health)
  - Activities: Laboratory of Experimental and Clinical Pharmacology (pharmacokinetic and pharmacodynamic monitoring of new anticancer drugs in phase I\_II clinical studies of Early Clinical Trials Group (ECGT) of the European Organization for Research and Treatment of Cancer (EORTC) and therapeutic strategies optimization by biomolecular/pharmacokinetic monitoring of antineoplastic chemotherapy; development and validation of HPLC methods for the measurement of anticancer drug plasma concentration, pharmacokinetic analysis of concentration data and pharmacokinetic\_pharmacodynamic correlation)
  - Country: Italy
4. Employer: University of Trieste
  - Start date: 091991
  - End date: 091992
  - Position: Pre\_graduate student
  - Activities: Laboratory of Medicinal Chemistry (organic synthesis of new chemical entities with potential pharmacological activity and related qualitative/quantitative assays in the context of the experimental thesis in Medicinal Chemistry)
  - Country: Italy

### Education and training

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1. Subject: University of Milan
  - Start date: 111997
  - End date: 111999
  - Qualification: Post\_Graduate Specialization in Pharmacological Sciences
  - Organisation: Pharmacology, Molecular Pharmacology, Pharmacogenetics, Biostatistics
  - Country: Italy
2. Subject: University of Varese
  - Start date: 101995
  - End date: 101995
  - Qualification: Post\_Graduate Course in Pharmacokinetics for the pharmacist and the pharmaceutical scientist
  - Organisation: Clinical Pharmacokinetics
  - Country: Italy
3. Subject: University of Trieste
  - Start date: 111993
  - End date: 111993
  - Qualification: Qualification as Professional Pharmacist
  - Organisation: Pharmacology, Pharmaceutical Technology and Legislation, Qualitative and Quantitative Analysis
  - Country: Italy
4. Subject: University of Trieste
  - Start date: 121992
  - End date: 071993
  - Qualification: Degree in Pharmacy

- Organisation: Mathematics, Physics, Human Anatomy, Physiology, Biopharmaceutics, Inorganic Chemistry, Organic Chemistry, Biological Chemistry, Pharmaceutical Chemistry and Toxicology, Pharmaceutical Botany, Pharmacology and Pharmacognosy, Essays and Drug Dosages, Plants of the Pharmaceutical Industry, Pharmaceutical Technology and Legislation
  - Country: Italy
5. Subject: University of Trieste
- Start date: 101987
  - End date: 111992
  - Qualification: Degree in Medicinal Chemistry and Technology
  - Organisation: Mathematics, Physics, Human Anatomy, Physiology, Biopharmaceutics, Inorganic Chemistry, Organic Chemistry, Physical Methods in Organic Chemistry, Biological Chemistry, Applied Biochemistry, Pharmaceutical Chemistry and Toxicology, Applied Pharmaceutical Chemistry, Food Chemistry, Physical Chemistry, Pharmaceutical Botany, Pharmacology and Pharmacognosy, Essays and Drug Dosages, Plants of the Pharmaceutical Industry, Pharmaceutical Technology and Legislation, Microbiology and Hygiene, Chemotherapy, Qualitative and Quantitative Analysis of Chemicals and Pharmaceuticals, Chemical\_Pharmaceutical Analysis of Medicinal Products, Preparation of Extractive and Synthetic Drugs
  - Country: Italy

## Additional information

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### Publications

Regulatory activity of clinical trials (National Report on clinical trials of drugs, ed. 2001\_2015) Scientific activity of pharmacological research in oncology (Journal of Chromatography B: Biomedical Applications, Clinical Pharmacology & Therapeutics, Cancer Chemotherapy & Pharmacology, Clinical Cancer Research, Anticancer Drugs, Chemotherapy, Haematologica, **Reviews on Recent Clinical Trials**)

### Projects

e\_submission platform for Clinical Trials Applications / substantial amendments

clinical trials authorization regulatory procedures

clinical pharmacology

### Memberships

Professional list of pharmacists of Province of Udine (Italy) (since 1994), European Medicines Agency (EMA) expert (CHMP Efficacy Working Party 2002-2010, Multidisciplinary Drafting Group for the revision of "CHMP Guideline on Risk Assessment on Medicinal Products on Human Reproduction and Lactation: from Data to Labelling" 2006-2008, EudraVigilance Telematics Implementation Group - Clinical Trial Module 2005-2013, Clinical Trials Facilitation Group 2012-2016), AIFA Project Team "WHO Audit on Vaccines", AIFA Secretariat for Support and Coordination of Clinical Trials Unit (clinical trials on Advanced Therapy Investigational Medicinal Products and special uses of unauthorized medicinal products)

## Other Relevant Information