

Curriculum Vitae

Personal information **Luca Santi**

Work experience

1. Employer: Agenzia Italiana del Farmaco _ AIFA
 - Start date: 10-2019
 - End date:
 - Position: Pharmacist at AIFA _ Innovation and Pharmaceutical Strategy Division
 - Activities: _ PK/PD assessor on CAPs; _ Technical/scientific support to EMA_CHMP Italian Members in the procedures where Italy is involved as (Co) Rapporteur or Non (Co) Rapporteur; _ Strategic setting of innovativeness grade and reimbursement modalities; _ Alternate Member of AIFA HTA Secretariate; _ Regulatory activity focusing on the EU _licensed medicines' national lifecycle (i.e. post _authorisation surveillance, variations, national requirements etc.). _ GMP inspector under training_ Project Management
 - Country: Italy
2. Employer: Agenzia Italiana del Farmaco _ AIFA
 - Start date: 012018
 - End date: 092019
 - Position: Pharmacist at AIFA _ Innovation and Pharmaceutical Strategy Division
 - Activities:
 - _ Pre _authorisation technical/scientific support assessment on Centralised MAAs submitted to EMA;
 - _ Technical/scientific support to EMA_CHMP Italian Members in the procedures where Italy is involved as (Co) Rapporteur or Non (Co) Rapporteur;
 - _ Strategic setting of innovativeness grade and reimbursement modalities;
 - Regulatory activity focusing on the EU _licensed medicines' national lifecycle (i.e. post _authorisation surveillance, variations, national requirements etc.).
 - Country: Italy
3. Employer: Pharmaceutical/Consultancy Company
 - Start date: 112015
 - End date: 122017
 - Position: CMC Senior Associate
 - Activities:
 - _ Chemistry Manufacturing and Control (CMC) maintenance of products licensed within the EMEA area;
 - _ Development and evaluation of regulatory strategies;
 - _ Implementation of ICH and c_GMP guidelines;
 - _ Planning & Monitoring Regional activity for submissions carried out in EMEA area.
 - Country: Italy
4. Employer: Agenzia Italiana del Farmaco _ AIFA
 - Start date: 032014
 - End date: 032015
 - Position: Pharmacist at AIFA _ Products Quality and Pharmaceutical Crime Counteracting Office
 - Activities:
 - _ Reception and assessment of quality complaints for human medicines; root cause analysis, cGMP compliance;
 - _ Management of Rapid Alert System and implementation of healthcare measures (withdrawals, batch recalls etc.);
 - _ Post _marketing surveillance activities (Annual Surveillance Program on nationally _authorised medicines; Centrally Authorized Products Sampling & Testing Programme;
 - _ Shortages monitoring and database maintenance;
 - _ Management of import and marketing of immunological and plasma/blood derived medicines.
 - Country: Italy
5. Employer: Hospital Policlinico Umberto I
 - Start date: 042012
 - End date: 022014
 - Position: Hospital/Clinical Pharmacist
 - Activities:
 - _ Oncologic Unit: sterile preparation of anticancer therapies; HTA; SOPs and risk management;
 - _ Artificial Nutrition Unit: preparation of nutritional mixtures destined to children and adults;
 - _ Logistic Unit: Pharmacovigilance, warehouse management and medicines/medical devices

distribution to the hospital departments; management of investigational medicinal products;

- Country: Italy
6. Employer: Università Sapienza _ Dept. of Chemistry and Drug Technologies
- Start date: 112011
 - End date: 032014
 - Position: Part_time Researcher in Organic Chemistry
 - Activities:

_ Basic research in organic and pharmaceutical chemistry: molecular design, synthesis, purification and characterization of natural or natural_derived substances with a potential anti_neoplastic activity.

- Country: Italy

Education and training

1. Subject: GEMA Business School
 - Qualification: Executive Master in Project Management
 - Organisation: Project Management
 - Country: Italy
2. Subject: Catholic University of Sacred Heart _ Medical School
 - Start date: 2017
 - End date:
 - Qualification: Second Level Postgraduate Master: Pre_clinical and Clinical Drug Development: regulatory, technical_scientific and ethical aspects
 - Organisation:
 - Country: Italy
3. Subject: Università Sapienza
 - Start date: 2016
 - End date:
 - Qualification: Postgraduate Specialisation in Hospital and Clinical Pharmacy
 - Organisation:
 - Country: Italy
4. Subject: Università Sapienza
 - Start date: 2014
 - End date:
 - Qualification: Higher Education Annual Course in Economics and HealthCare Management _ Diploma
 - Organisation:
 - Country: Italy
5. Subject: Italian Society of Hospital Pharmacy (SIFO)
 - Start date: 2014
 - End date:
 - Qualification: Clinical Pharmacist Diploma
 - Organisation:
 - Country: Italy
6. Subject: Università Sapienza
 - Start date: 2011
 - End date:
 - Qualification: State Qualifying Examination Certificate as a Pharmacist
 - Organisation:
 - Country: Italy
7. Subject: Università Sapienza
 - Start date: 2011
 - End date:
 - Qualification: Master Degree in Pharmacy
 - Organisation:
 - Country: Italy

Additional information

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