



## Curriculum Vitae

Personal information **Adele Romani**

### Work experience

---

1. Employer: Adele Romani
  - Start date: 102002
  - End date: 102007
  - Position: Quality Assurance and Research and Development
  - Activities: Implementation of ISO 9001 and ISO 14001 standards. Managing audits by Certification Agency and from third parties. Internal Lead auditor. Trainer of internal auditors. Review the business statistics and determine areas requiring enhancement. Analysis on manufacturing and analytical processes. Writing procedures and following updates. Developing new products, testing of new raw materials, production scale\_up.
2. Employer: Adele Romani
  - Start date: 102007
  - End date: 102009
  - Position: Pharmacist
  - Activities: Keep administrative records (narcotics register) and checking medical prescriptions according to current legislation. Maintaining pharmaceutical stock, creating inventories and ordering. Able to advise patients on medication brands, medication storage, medical equipment and health\_care supplies. Dispensing drugs to patients according to a doctors prescription.
3. Employer: Adele Romani
  - Start date: 012010
  - End date:
  - Position: Senior GMP Inspector
  - Activities: Lead of regulatory and compliance inspections on drugs manufacturing sites (chemical and biological/biotechnological products), located in Italy (on behalf of AIFA) and on behalf of EMA\_European Medicines Agency. Filed in the European Medicines Agency (EMA) as an Expert. Expert on manufacturing process, marketing authorization examination, quality compliance with marketing authorization, sterility assurance, Contamination Control Strategy (CCS), quality control and quality management systems (QMS). Lead auditor and cooperation with other regulatory agencies during on site inspections ( joint inspection with FDA, MHRA, ANVISA). Follow up investigations to set GMP compliance. Assessment of CAPA plan provided as response to the observations' raised up during inspections. Release of Manufacturing Authorization on EUDRAGMDP database. Investigations on quality defects, complaints and recall from the market (evaluate potential health hazards for patients). Prepare accurate and complete written investigation reports. Cooperation with the national gendarmerie of Italy for health protection (Carabinieri NAS) for health issues linked to manufacturing processes of medicines (sterile and non sterile). Person in charge in AIFA GMP Inspectorate for the managing of internal activities of Quality Assurance (till 2017). Participation to BEMA audits. Training of new personnel for GMP standards and audit techniques. EMA HBEL Implementation Team Member Member of PIC/S Expert Circle on CCCISF (2019) Deputy Chair of PIC/S Working Group on CCCISF (2020)
4. Employer: Adele Romani
  - Start date: 032017
  - End date:
  - Position: Senior GMP Inspector and Training Account
  - Activities: Person in charge in AIFA GMP Inspectorate for the managing of training for all the inspectors. Conducting and organizing courses, administering training assessments, and evaluating the effectiveness of training programs.
5. Employer: Adele Romani
  - Start date: 062017
  - End date:
  - Position: Member of HBEL Implementation Team and PIC/S Coordinating Committee of CCCISF
  - Activities: Involved in the review of Q&A on implementation of risk based prevention of cross contamination in production and involved in the PIC/S Coordinating Committee of CCCISF (Cross Contamination in Shared Facilities)
6. Employer: Adele Romani
  - Start date: 122021
  - End date:
  - Position: Member of PIC/S Sub Committee on Training
  - Activities: Identify training needs; Co\_ordinate and monitor PIC/S training activities; Review the planning and organisation of annual training seminars, in particular: propose and validate the seminar topics Monitor the Joint Visits Programme and the Coached Inspection Programme and carry out a review of reports in order to identify divergences on GMP interpretation and inspection practices;

### Education and training

---

1. Subject: University of Bologna
  - Start date: 091995
  - End date: 062002
  - Qualification: Degree on Pharmaceutical Chemistry and Technology
  - Organisation:
  - Country: Italy
2. Subject: University of Ferrara
  - Start date: 012004
  - End date: 012006
  - Qualification: Master on Cosmetic Technology
  - Organisation: Manufacturing, quality control and applicable legislation on cosmetics
  - Country: Italy
3. Subject: University of Rome
  - Start date: 112014
  - End date: 112015
  - Qualification: Master on Regulatory Affairs
  - Organisation: Deep overview on all the activities applicable to manufacturing of pharmaceutical products, by a regulatory point of view.
  - Country: Italy

## Additional information

---

[Publications](#)

[Projects](#)

[Memberships](#)

\_ PIC/S Member in CCCISF (Cross Contamination in Shared Facilities) \_ HBEL EMA Subgroup Member \_ PIC/S Member of Sub Committee on Training, PIC/S Ad hoc group on soft skills, JAP auditor

## Other Relevant Information

Invited as speaker and moderator to different conference, seminars and at University. Person in charge for selecting, organizing training for GMP inspectors