

ALESSIA GOZZI



SKILLS AND COMPETENCES

ANALYTICAL SKILLS

- HPLC/UPLC and ionic chromatography (Waters, Agilent, Thermo Fisher)
- GC (Agilent and Thermo Fisher)
- LC-MS (Agilent)
- X-ray diffractometry (MiniFlex Rigaku)
- Laser granulometry (Malvern)
- Spectrophotometry
- Polarimetry
- IR (Thermo Fisher)
- SDS-PAGE
- Routine analysis of refractive index, melting point, titrations, KF, osmolality, sub-visible particles.

SCIENTIFIC COMPETENCES

- Analytical methods validations and transfers
- Drafting of protocols, reports and SOPs
- Review of analytical sheets and datas
- Deviations and CCP handling
- Supplier qualification
- Personnel planning and activities management

LANGUAGE SKILLS

English listening / reading comprehension level: advanced
level of interaction / oral production: autonomous

writing level: advanced

INFORMATIC KNOWLEDGE

Microsoft Office and Adobe Creative Suite packages

Specific software and platforms:

Empower 3, LIMS (Labvantage and Quality Plus), Trackwise, Binocs (planning), Chemstation

PROFESSIONAL PROFILE

Chemist with experience in pharmaceutical industry and proven analytical, data collection and processing skills, able to produce technical documentation in compliance with the scientific and regulatory requirements. Excellent interpersonal skills, spirit of initiative and teamworking, as well as flexibility, learning speed, adaptability and spirit of initiative. Eager to grow professionally in dynamic and consolidated realities. Meticulous, skilled in managing multiple activities at the same time and working under pressure.

PROFESSIONAL EXPERIENCES

Laboratory Excellence Support Consultant, 06/2022 - now

Support for the laboratories in reaching full potential through the principal QC and Microbiological lab and instrumentation tools, developing the best process roadmaps for smart solutions, from regulatory compliance to training, securing the best lab performances.

Part of the activities is the optimization of analytical methods and integration of digital systems with smart solutions.

Researcher Pharmaceutical Development, 03/2022 – 06/2022

Merck Serono - Guidonia, RM

- Execution of chromatographic, biological and generic tests planned by the analytical protocols on new formulations and process variations starting from the early phases to late stage controls on Drug Substances and Drug Products
- Validation of custom fields, creation of report methods and master sample sets for automatic calculations with the Empower software
- Collaboration with a team that manages the digitization and the implementation of new softwares of useful interface for laboratories

QC researcher Chromatographic lab (Market - Biotech), 04/2021 – 02/2022

Merck Serono - Guidonia, RM

- Stability studies of drug products and drug substances according to cGMP rules and ICH Guidelines
- Use of the Laboratory Information Management System (LIMS) software to upload stability data, to receive and/or retrieve stability samples for analytical tests, to download the stability weekly plan
- Collaborate with different company functions and departments (QC stability, QA, regulatory affairs, technology transfer, validation)
- Working in accordance with cGMP in the chromatographic team, using HPLC, UPLC and GC applying these methodologies to biomolecules such as proteins, and collecting and processing data through Empower 3
- Paper and electronic review of chemical laboratory analysis according to the ALCOA rules of Data Integrity.
- Drafting of laboratory investigations through Trackwise
- Data collection for Health Authorities requirements
- Deviation management, CAPA, CCP, updating and reviewing SOPs
- Contributing to internal/external reports, papers, presentations, regulatory documents
- Participating in department-wide support efforts such as safety,

committees including train staff and/or supervise others coordinating and organizing resources needed to complete the task

- 5S management to improve lab quality and helping colleagues with daily duties and support for troubleshootings
- As part of the digitization projects, planning activities were carried out for the team using Binocs software in accordance with the release needs and the head of the laboratory, ensuring adequate distribution of the analytical activities

Junior Supervisor in Raw Materials lab, 08/2019 – 04/2021

Alfasigma - Pomezia, RM

- Drafting of protocols/reports for the validation of analytical methods (HPLC, GC and LC-MS) and analytical transfers. Review of analytical sheets for raw materials, finished products and stability, management of investigations and deviations for OOS, OOT, atypical laboratory events and System Suitability Failures with particular attention to data integrity once the root cause of the event has been identified
- Execution of analytical tests on drug active ingredients, solvents, excipients and packaging materials according to the standards of the European (EP) and American (USP) Pharmacopoeia, and of all the related methods and instruments
- Drafting and revision of the standard operating procedures (SOP), in particular instrumental procedures (X-ray diffractometer) and protocol for the stability study of the reagents in use and prepared in the laboratories, as well as the Standard Texts for the analyses of raw materials
- Experience in planning analytical activities and management of the operators in the team according to planning needs, using the LIMS Labvantage platform.

QC Analyst, 05/2019 - 08/2019

IBI Lorenzini - Aprilia, RM

In-depth knowledge of sampling methodologies and techniques as well as methods of data analysis and processing. Ability to perform chemical tests - such as HPLC, UPLC, GC, IR, UV-VIS, potentiometry, polarimetry, pH, KF, content uniformity, mass variation - in the finished products sector. Skills in comparing the results obtained with the reference parameters according to GMP. Ability in the use of scientific softwares such as Empower 3, Totalchrom, Spectrum, Winlab and Quality Plus.

Chemist, 11/2017 - 11/2018

ISCR Istituto Superiore per la Conservazione ed il Restauro - Roma, RM

Specialized collaborator for the Istituto Superiore per la Conservazione ed il Restauro in Rome acquiring skills in the following techniques and analysis: micro-FTIR (transmittance and ATR), optical microscopy, SEM-EDS, colorimetry, DSC and TGA, preparation of samples and stratigraphic sections. The job mainly dealt with canvases and tables, painted wooden sculptures, textile materials and leather manufactures. Within the work experience, research was carried out on the aging of paints mainly used in the conservation of cultural heritage (especially in the restoration of canvases and tables) and the optimization of mixtures of the paints in study with UV-adsorbers and HALS (Hindered Amine Light Stabilizers). These materials have been subject to accelerated aging using QUV chambers and analyzed in micro-FTIR, colorimetry, thermogravimetric analysis (TGA) and glossmetry in order to characterize aging and chemical-physical properties.

Professor, 10/2018 - 10/2019

ABAMC Accademia di Belle Arti di Macerata - Macerata, MC

Professor of the course of Elements of chemistry applied to restoration of cultural heritage. As well as in previous work experience, developed teaching skills, including practical laboratory experiences.

Professor, 10/2017 - 10/2018

ABANA Accademia di Belle Arti di Napoli - Napoli, NA

Professor of the course of Chemistry Elements for Art Graphics.

Developed teaching skills, preparation of teaching material and practical exercises, through the use of specific computer platforms and software.

Preparation of the didactic program and of the examination and practice procedures.

EDUCATION AND TRAINING

Master's Degree in Industrial Chemistry: Polymeric Materials,
07/2016

Università degli Studi di Roma "La Sapienza" - Roma

Vote: 107/110

Title of the thesis: "F-moc gelogenic peptides for biotechnological applications"

Summary of the thesis: the tetrapeptide hydrogel Fmoc-Phe-Gly-Phe-Phe was biosynthesized for biomedical applications in the nanobiotechnology laboratory of Prof. Palocci. This material was characterized by HPLC, GC-MS, SEM, rotational rheometer, UV-VIS spectrometry and pH analysis. Finally, in order to verify the applicability of these biomaterials for tissue regeneration studies, cytotoxicity (MTT) and cell adhesion tests were performed in the presence of model human cell lines.

Skills acquired during the master's degree course:

in-depth knowledge of synthetic polymers and biomaterials. Use of the main techniques for the characterization of polymers: optical microscope for the observation of crystallization processes, dynamomechanical measurements to investigate the viscoelastic behavior of materials, conductivity measurements, static and dynamic measurement methods for the surface tension of solids and contact angle, FTIR characterization of polymeric materials.

Bachelor's Degree in Chemistry: Chemistry, 05/2012

Università degli Studi di Roma "Tor Vergata" - Roma

Vote: 104/110

Title of the thesis: "Molecular dynamics simulations of polyvinyl alcohol in water by force field OPLS-aa".

Suitability: Pedagogy-Psychology-Anthropology-Didactics,
06/2018

Università degli Studi di Roma "La Sapienza" - Roma

Qualification achieved at the University of Rome "La Sapienza" as part of the "24 CFU Teacher Training" course in the following modules:

- Individualized educational programming: reading and writing – Special Educative Needs and autism SSD: M-PSI/04 CFU: 6
- Experimental pedagogy SSD: M-PED/04 CFU: 6
- Cultural anthropology SSD: M-DEA/01 CFU: 6
- Didactics of animal biology SSD: BIO/05 CFU: 6

I authorize the processing of personal data contained in my CV pursuant to art. 13 of the legislative decree 196/2003 and art. 13 of EU regulation 2016/679 on the protection of individual citizens regarding the processing of personal data

Alessia Gozzi