Curriculum Vitae

ALESSANDRO MINIATI

PERSONAL INFORMATION	Alessandro Miniati 12/04/1984 Phone: +39 3293566890 Email: alessandro.miniati@live.com Residence: Milan (MI), Francesco Cilea 64, 20151
Who I am	**Alessandro Miniati** is an experienced **Quality Assurance System Specialist** with a strong background in **analytical development and validation** within the **pharmaceutical industry**. Currently working at **Grünenthal S.p.A.**, he specializes in **process validation, change control management, and regulatory compliance**. With over 15 years of experience, he has developed expertise in **analytical method validation, technology transfer, and equipment qualification**. Alessandro holds a **Master's degree in Chemistry and Pharmaceutical Technologies** and is a certified **Qualified Person**. His skills include **cGMP compliance, data integrity, statistical analysis, and chromatographic techniques**. Fluent in **Italian and English**, he thrives in dynamic, high-pressure environments.
PROFESSIONAL EXPERIENCE	**From January 2024** Permanent contract at Grunenthal S.p.A (Farmaceutica Formenti), Origgio (Varese) **Position**: **QUALITY ASSURANCE SYSTEM** Cooperation in the drafting/management/approval/review documentation concerning the following topics: - **Process validation** - **Product quality review topics** - **Management of change control** - **Notifications to health authorities** - **Equipment qualifications** - **Statements drafting** Collaboration for the global quality pillars related to the creation of both process validation and equipment qualification standards. Reviewing documents related to analytical validation activities. Collaboration into technical project team for insourcing products in the facility.

	From October 2, 2017 to January 2024 Permanent contract at Grunenthal S.p.A (Farmaceutica Formenti), Origgio (Varese) **Position**: **ANALYTICAL DEVELOPMENT SENIOR EXPERT** Main duties: - Technology transfer of products to the site. Evaluation of documentation, material order, drafting of protocols and analytical validation reports, execution of analytical validations or analytical transfers, and review of results. - Development and validation of analytical methods for raw materials and/or finished products according to ICH guidelines in compliance with cGMP regulations. Verification of compendial methods (EP USP JP etc.) and internal method validations for non-compendial methods. - Introduction of new analytical technologies in the laboratory. - Process validation. - Transfer of analytical methods. - Cleaning validation. - Evaluation and application of requirements defined in pharmacopoeia chapters (EU USP JP BP etc.). - Writing of validation protocols and reports. - Statistical analysis. - Troubleshooting laboratory methods and processes. - Management of processes in compliance with cGMP regulations. - Application of Data Integrity rules. - Development and validation of specific Excel spreadsheets for laboratory activities. **From February 1, 2017 to September 29, 2017** Permanent contract at Icrom S.p.A, Concorezzo (Monza) Position: **RESEARCH & DEVELOPMENT ANALYST** Main duties: - Development and validation of analytical methods for Drug Substance according to ICH guidelines in compliance with cGMP regulations. Development of internal methods for Starting material, Intermediates, and Finished products. Verification of pharmacopoeia methods and internal method validations for non-compendial products. - Cleaning validation. - Evaluation and application of requirements defined in pharmacopoeia chapters (EU USP JP BP etc.). - Creation of validation protocols and reports. - Statistical analysis of validation data. - Troubleshooting laboratory methods and processes. - Management of processes in compliance with cGMP regulations.

	- Application of Data Integrity rules. - Development and validation of specific Excel spreadsheets for laboratory activities. - Analytical support to synthetic chemists for the release of R&D products. **From November 1, 2015 to February 1, 2017** Temporary contract at Pharmanalytica SA – Novartis, Locarno (Switzerland) Position: **METHOD DEVELOPMENT SPECIALIST** Main duties: - Development, validation, and transfer of analytical methods for Drug Product both for Release and Stability studies according to ICH guidelines in compliance with cGMP regulations. - Evaluation and application of requirements defined in pharmacopoeia chapters (EU USP JP BP etc.). - Creation of validation protocols and reports. - Statistical analysis of validation data. - Troubleshooting laboratory methods and processes. - Management of processes in compliance with cGMP regulations. - Application of Data Integrity rules. - Development and validation of specific Excel spreadsheets for laboratory activities. **From October 1, 2008 to October 15, 2015** Permanent contract (4th Level CCNL Commerce) at ChelabSilliker S.p.A. - Mérieux NutriSciences, Chemical and Microbiological Laboratory - Services Sector, Food Analysis Position: **CHEMICAL ANALYST - METHOD SPECIALIST** Main duties: - Development and validation of new methods for the chemical determination of environmental contaminants, bromatological and environmental analysis using chromatographic techniques (gas chromatography and liquid chromatography) coupled with main detection systems (mass spectrometry, UV/visible spectrometry, conductometry, FID, ECD, NPD, PFPD) as well as gravimetric and volumetric techniques. - Validation of internal normative and standardized analytical methods. - In-depth knowledge of statistical data analysis. - Technical update of the laboratory based on current regulations. - Resolution of issues related to particular analytical conditions. - Update and development of the Visual LIMS 2005 system. - Development of electronic sheets for faster, correct, and effective quality/data management of the laboratory.

	- Participation in internal/external audits (Accredia, clients...). **From March 10, 2008 to September 10, 2008** Training internship at Silliker Italia S.p.A. - Mérieux NutriSciences, Prato Position: **CHEMICAL ANALYST - RESEARCH AND DEVELOPMENT** Main duties: - 6-month training internship in the company for the development and drafting of the experimental thesis to complete the university studies. - Technical training alongside laboratory technicians aimed at inclusion in the Research and Development department. **From September 15, 2003 to January 10, 2006** Full-time fixed-term contract (5th Level CCNL Commerce) at Progetto Natura S.p.A., later Silliker Italia S.p.A., Prato Position: **CHEMICAL ANALYST** Main duties: - Chemical analysis for the determination of contaminant residues (pesticides, PAH, PCB, dyes, mycotoxins, sulfur dioxide, dithiocarbamates), water analysis, bromatological analysis (sugars, dry residue, wet residue, fats, proteins, ashes, analysis of vegetable oils), environmental analysis.
EDUCATION AND TRAINING	**January 2025** Obtained licence from health authority as Qualified Person **2022 / 2023** Participation in "Lean six sigma" courses for yellow belt **January 10th, 2019** Agilent course for the use of RAMAN spectroscopy equipment (RAMAN specialist) **October 19th, 2016** Agilent training course on “Fundamentals of GC and troubleshooting”. **June 21th, 2016** Agilent training course on “Fundamentals of HPLC and troubleshooting”. **January 21th, 2015** Qualification as a Chemist after passing the state exam at the University of Florence **December 2-3, 2014** Participation in the training course “PR2 How to achieve optimal performance in UHPLC: practical course” at Phenomenex - Bologna. **May 20th, 2014**

	Participation in the training course “Analytical strategies in lc-ms/ms for the determination of algal biotoxins and mycotoxins” at IZSLER in Bologna **October 30th, 2008 - October 29, 2013** Master's degree in Chemistry and Pharmaceutical Technologies at the University of Florence. Graduation with a score of 101/110, discussing the experimental thesis titled: "Determination of Marine Biotoxins in seafood". **October 1st, 2005 - October 30, 2008** Bachelor's degree in Quality Control in the Pharmaceutical Industrial Sector at the University of Florence. Graduation with a score of 110 and honors/110, discussing the experimental thesis titled: "Validation of the extraction and determination method of 'Growth Regulators' with liquid chromatography - mass/mass on food matrices". **2005** Obtained ECDL certification: European Computer Driving License. **07/2003** Diploma in Industrial Chemistry from ITIS Tullio Buzzi in Prato with a score of 82/100.
LANGUAGES	**ITALIAN** Native **ENGLISH** Reading: good Writing: good Oral expression: good
SKILLS AND COMPETENCIES ➢ Relational ➢ Organizational ➢ Technical	 - Ability to work in a team with good time and resource management even in stressful situations with tight deadlines. - High organizational and coordination skills. Organization of activities coherently with the required deadlines based on short/medium-term projects. - Good knowledge in the use of technical equipment for gas chromatography, liquid chromatography, mass spectrometry (single quadrupole, triple quadrupole, ion trap in chemical ionization, electron impact, electrospray (ESI), atmospheric pressure chemical ionization (APCI)), UV/VIS detectors, ECD, NPD, PFPD, FID. - Use of automatic titrator.

	- Use of spectrophotometer. - Use of FT-IR. - Use of RAMAN. - Ability to optimize instrumental conditions. - Knowledge of main software for instrumental management (Chromeleon, Empower, Analyst, Multiquant) and high ability to learn new ones. - Knowledge of main extraction, purification, separation, and derivatization systems. - Knowledge of ISO 9001:2008 standard. - Knowledge of UNI CEI EN ISO/IEC17025:2005 standard.
➢ IT	- Excellent knowledge of Office software package (especially WORD, EXCEL, and POWER POINT). - Excellent knowledge of Empower software for chromatographic analysis. - Excellent knowledge of Chromeleon software for chromatographic analysis. - Basic knowledge of HTML and CSS programming languages. - Basic knowledge of XML programming language.
➢ DRIVING LICENSE	Category B - car owner

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