FIRST NAME	Luca
LAST NAME	Mazzoni
NATIONALITY	Italian

RESOURCE RESUME

PROFILE SUMMARY

Over **10** years of experience in pharmaceutical, biotechnology and laboratory environments with broad experience in Equipment and Utilities Commissioning & Qualification and Computerized Systems Validation. Possesses wide knowledge of US , ALCOA+ Data Integrity Principles, GAMP 5 and main FDA Guidance(s) for Industry. Proven track record in enhancing staff performance, documentation technical writing and review (validation/qualification protocols and SOPs) and leading high-performing teams.

Great teamwork skills gained through the work experiences, with a natural attitude to cooperate and communicate with colleagues of all levels. Problem solving capacity and ability to reach the expected target when requested. Wide experience in planning and coordination of activities. Able to maintain high quality performances even under pressure.

EXPERTISE

Broad experience on **Pharmaceutical Processes Commissioning & Qualification** through development/review of validation plans, user requirements specifications, design qualification protocols/reports, risk assessment reports, critical aspects verification plans as per ASTM E2500, traceability matrixes, verification protocols, installation-operational-performance qualification protocols, validation summary reports, with focus on items below:

- Manufacturing equipment for Biotech facilities (Sterilizers, Autoclaves, fridge, freezers, Bioreactors & vessels, Thermal Mapping system, Incubators, filtering and ultra-filtering systems, chromatography system, vials-ampoules-syringes-cartridges washers, depyrogenation tunnels, filling machines, autoclaves, pass-boxes, media fills)
- Primary and Secondary Packaging equipment/lines
- Pharmaceutical water (WFI/PW/RO) Production, Storage and Distribution systems
- Clean Steam Production, Storage and Distribution systems
- Oxygen and Nitrogen Storage and Distribution systems
- HVAC Systems

Advanced experience on **Computer System Validation Projects** through the development/review of validation plans, user requirements specifications, configuration and design specifications, risk assessment reports, traceability matrixes, installation-operational-performance qualification protocols, validation summary reports for production and laboratory systems.

Advanced experience on **Computerized Systems Validation and related Electronic Records/Data Integrity Compliance** through the development of compliance assessment plans (at site or global campaign levels), execution of field assessment activities as assessor, organization of onsite workshops to share the outcome of site/s assessment activities and define all possible strategies to outline remediation action plans/projects.

Project management / coordination activities through development/review of project plans/Gantt, status update reports/presentation, project issues tracker and technical problem solving, resources workload plans, meeting agenda/minutes, budget monitoring.

EDUCATION

- **Degree in Biotechnology** University of Florence – Florence Italy

POST GRADUATE

- **Master Degree in Medical and Pharmaceutical Biotechnology** University of Florence – Florence Italy
- **PhD in Biomedical Sciences - Biochemistry and Applied Biology** University of Florence – Florence Italy

JOB EXPERIENCES

2017-today	PQE Group – Florence, Italy **Project Manager on Equipment/Utilities Commissioning & Qualification**
2016-2017	GSK Vaccines Srl – Siena, Italy **Quality laboratory analyst**
2012-2016	C.I.M.M.B.A. – Florence, Italy **Fellowship**
2010-2011	Department of Biochemical Sciences – Florence, Italy **Trainee**
2010	Department of Critical Medical Surgery – Florence, Italy **Trainee**

ATTENDED CONFERENCES & TRAINING COURSES

- Data Integrity Survey Vers2, Elearning platform, 2019
- Luca Neri, Utilizzo della suite kaye validator, HQ , 2019
- Federico Ceccarelli, Process Equipment vs computerized systems compliance, HQ , 2019
- Gilda D'Incerti , Computer System Assurance, Skype , 2020
- Quiz Cybersecurity, Elearning platform, 2020
- Data Integrity Survey ver 2, Elearning , 2021

LANGUAGES

Italian	Mother Language
English	Fluent

SUPPORTED CLIENTS

EMEA (BELGIUM, FRANCE, ISRAEL, ITALY, POLAND, SWITZERLAND):

Avara, Baxter, Bruschettini, Delta Med, Eli Lilly, Fresenius, Helsinn, Kedrion, Procos, Takeda, Teva

North America (UNITED STATES):

Akorn

DELIVERED SERVICES AT PQE

- Data Integrity Assessment
  - DI Assessment & CSV
- IT Technical Support (CS Upgrade, IT Migration, Gaps Fix)
  - CSV SOP's Creation
- Laboratory Application Systems Validation
  - Empower 3 Validation
  - Empower system validation
  - Support for CSV
- Process Control System Validation
  - ARGUS Safety v. 8.0.1 System Validation Turn Key Activities
  - Monster 2.0 upgrade validation
- Remediation Validation
  - CSV and DI Support for Laboratory and Production Systems
  - Systems Validation for FDA Inspection
  - Somerset CSV First 20 items (No TQ)
  - Data Integrity Assurance for GxP Computerized Systems

- DI Remediation
- Remediation Activity in Hechingen (Germany)

- Technical Qualification
  - Support for C&Q Activities PFS Project Ancillary Equipment
  - Support moving equipment Lab Device
  - Support to MICS department
  - 2021 Support
  - CSV Ancillary, Freezer e Bilance Addendum
  - Supporto spostamento equipment Lab
  - Validation Processes Assembly & Packaging
  - Validation Sterile Catheter Assembling and Packaging Processes
  - Plant Annual Requalification

DELIVERED SERVICES AT GSK

- Perform in vivo laboratory analysis to ensure the high quality of vaccines, in a Good Manufacturing Practice (GMP) environment, in accordance with; company procedures (SOPs), regulatory requirements and safety standards.
- To understand and respect the rules on Environment, Health and Safety (EHS) and proper use of Personal Protective Equipment (PPE).
- Demonstrate ability to work in full compliance with Data Integrity to ensure that data is: attributable, comprehensible, up to date, original, and accurate (ALCOA).
- Planning and coordination of daily and weekly lab activities.
- Carry out Rabbit Pyrogen Test (RPT) and competent in the use of CFR21 Pharmalab system.
- Drafting and modification of business procedures (e.g. SOPs).
- Qualification of a new analytical method and a new internal standard.
- Entering analytical results in laboratory management systems such as the Global Laboratory Information Management System (GLIMS).
- To ensure correct functionality of all laboratory equipment within GMP guidelines/requirements.
- Use of GMP compliant software to manage all aspects of departmental processes, e.g. deviations, CAPAs, investigations etc.
- Support the manager and supervisor during the conduct of internal inspections, AIFA and FDA.

DELIVERED SERVICES AT C.I.M.M.B.A.

- Characterization of Human Hypertrophic Cardiomyopathy (HCM).
- Perform cardiac electrophysiology.
- Carry out pharmacological studies in vitro and in vivo in; mice, rats rabbits and guinea pigs.
- Characterization and management of animal models.
- Studies and pharmacological tests on neuropathic pain.