

Giampaolo CARDUCCI **Environmental Engineer**

Engineer with over 9 years of experience in utilities CQV and construction supervision.

I've established a trusty and respectful relationship with several pharmaceutical companies supporting in black and clean utilities commissioning, validation and construction projects. I've improved skills in GMPs, in team coordination and project permitting.

SUMMARY SKILLS

GMP/GDP OOO

CE CERT. - 2006/42/EC • • • •

ENGLISH ••••

COV (Utilities)

CLEAN UTILITIES 0000



RISK ANALYSIS ISO 12100:2010

OOOO

CONSTRUCTION SUPERVISION OOOO



PERSONAL DATA Professional

Environmental Engineer (Italian Association of Engineers - N° 3507)

PLACE AND DATE OF BIRTH / NATIONALITY PHONE / EMAIL/SOCIAL/

Arpino (FR) 23.AUG.1989 | Italian

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CURRENT LOCATION

Lyss (BE) - Switzerland (CH)

WORK EXPERIENCE May 2023 -

ONGOING

Website

Plant and CAPEX engineer / Lonza BioAtrium (Visp) - CH bloatrium

Key responsibilities:

- Production (USP and DSP) and clean utilities maintenance planning.
- CAPEX management till 500K CHF
- Requalification and qualification activities (IQ-OQ) for USP/DSP/Clean Utilites equipment/process

- Campaign readiness and PPQ for production support.
- Daily use of SAP, Kneat, TrackWise, DMS, COMOS

FEBRUARY 2022 -APRIL 2023

Advanced consultant Engineer / Life science division at Capgemini engineering

Key responsibilities:

- Solution Architect for C&Q projects (Lonza Singapore Lonza Belgium)
- Technical support for C&Q activities related to lab equipment, process equipment (DSP)
- Qualification document preparation execution and review (IQ-OQ) for utilities equipment
- Lonza/Sanofi BioAtrium: Technical Change Request coordinator (daily use of SAP, Excel, COMOS, DMS, TrackWise, GMP standards. Daily and weekly alignment with Department stakeholders to discuss Technical Changes related to all BioAtrium department.

November 2016 -**JANUARY 2022**

Project engineer at Ingegno P&C S.r.l. LNGEGNO

March 2020 -DECEMBER 2021 Project: CSL – Behring – Lengnau (BE) – CH (1,5 billions project investment) Civil-Structural-Architectural Handover Engineer – Construction coordination and final building handover: (administrative, Labs, production and classified clean room (E-D-C) areas).

- QA/QC civil department. Definition of GMP standard documentation for clean rooms and labs.
- Work and contractor supervision. Direct interface with client for revamping/change requests and local contractors' management and internal QA/QC audit on executed works.
- **Integral test planner** and executor for final building occupancy.
- Responsible for quality, schedule, costs of all assigned CSA sub-systems. CSA completion walkdowns and safety walk-downs execution.
- Inspections with GVB for final building acceptance (fire protection approval for the building
- Fire protection requirements construction supervisor

AUGUST 2018 -March 2020 Project: NGM – Biogen – Luterbach (SO) – CH (2 billions project investment) Biogen Project management/field engineer - Key responsibilities:

Responsible for quality, schedule, costs of all assigned sub-systems, provide equipment and

system mechanical completion walk-downs, safety walk-downs.

- Coordination of all process relevant activities incl. review and approve process engineering specifications, process piping & instrumentation diagrams (P&IDs), datasheets, and procurement packages for equipment and systems.
- Close collaboration with all project discipline (incl. Contactors), key Project & Site stakeholders and project manager.
- Interface with stakeholders to ensure the design execution and delivery are in accordance with Global Engineering, Quality, Environmental and Safety procedures.
- Compliance supervision according to local and European fire protection directives (VKF/AEAI). TUV Sud Basel support on machine directive procedures for documental compliance with MD 2006/42/EC and 2014/68/EU and EKAS requirements. Vendor and supplier's installation supervision. Scheduler and coordinator for cantonal inspections (AWA, SUVA, SGV, FM global, AfU). Lightning protection system coordination for final cantonal approval.

NOVEMBER 2016 – AUGUST 2018

Project: GSK Vaccines S.r.l. Rosia (SI)

Engineering process consultant



- URS definition for clean utilities production plant revamping (Ultrafiltration system, Softened water system, Purified water system (double stage reverse osmosis equipment), Water for injection (5 stages distillator equipment), clean steam generator. Clean gasses (CO2, O2, N2, He) storage and distribution.
- Responsibility for all Process related activities, Engineering and the process discipline of **CAPEX** projects to ensure that GSK standards and requirements as well as the site standards are correctly incorporated within the discipline specifications
- Clean utilities installation (FAT/SAT) and qualification (IQ, OQ) execution and supervision.
- Instrument calibration planning and supervision (support to relevant project manager)- KAYE validator for temperature mapping.
- Ensure compliance with legal regulations on energy supply, technical guidelines, and standards (GSK standards, ATEX and Machinery Directive, SOPs, ASME, etc.).
- Handle **deviations**, **CAPAs** and **change controls** and troubleshoot system failures and interruptions on clean utilities maintenance department.
- Performance qualification (PQ) supervision, GMP deviations and gap assessment execution for all
 the equipment and relevant mechanical interconnections related to the clean utilities mentioned
 above according to GMP, FDA and AIFA requirements.
- **Commissioning supervision**. PW (purified water), WFI (water for injection) loops sanification process tuning during IQ-OQ using Delta-V and OSI PI software.
- Monitor external service providers, participate in internal audits, and serve as SME for production issues. Capture and maintain consistent data on technical systems (spare parts lists, operating instructions, clean utilities **SOPs creation**, technical documentation request and revision)
- Clean utilities maintenance department: activity planner, Start-up/shut down scheduler, spare
 part list creation and client support with vendors'/suppliers' contact for ordinary and notordinary maintenance.

January 2016 – October 2016 Safety engineer at A.M. Engineering & industrial research s.r.l



Several projects for different Pharmaceutical, Chemical, Food and Mechanical companies.

- Pressurized equipment compliance with D.M. 329/2004, 97/32/CE (P.E.D.) and D.Lgs. 26/2016.
- Equipment and Assembly putting in service according to D.Lgs. 17/2010 documental checks.
- Compliance, design and revamping of pressurized equipment (ASTM e ISPESL directives).
- Operation manuals for equipment according to local machine directive (D.Lgs 17/2010) and 2006/42/ European directive.
- Risk analysis according to local D.Lgs. (81/2008) and EN 12100.

EDUCATION AND TRAINING

Master degree on Environmental engineering [LM-35]

University of Study in L'Aquila (AQ), Italia.

www.ing.univaq.it

January 2015

DECEMBER 2015

Trainer . Tech Training Course

Microcontrollers programming (ARDUINO UNOTM)

Programming in C, C++

Final degree 110/110

ITALIAN Mother tongue

ENGLISH Fluent Written and spoken (C1)

GERMAN Beginner (A2)

INFORMATIC SKILLS

- **Writing, managing and computing programs**: Latex Microsoft™(Word, Excel, Access, Outlook).
- **Technical Software:** Excel; Autocad[™] + 3D, Matlab[™]ArcMap,ArcGis[™], ArduinoHec-Ras[™], Intergraph[™] PV Elite; Intergraph[™] Caesar II, SAP (ERP), OSI PI, DeltaV, DCS, Kneat.
- Programming languages known: HTML (5), CSS (3), Javascript (5), Python, VBA, C++.

DRIVING LICENSE

Type A, B (Car owner)

ADDITIONAL INFORMATION

Courses - Seminaries

- Certificate of attendance - "The treatment of water in heating systems and sanitary circuits according to current legislation as a tool for energy efficiency"

- Registration in the Register of Engineers of Pisa on 28/02/2017.

PUBLICATIONS

CERTIFICATES -

- Master degree "Numerical model for the characterization of the downstream jet of ski jump spillways (2015)".
- Bachelor degree "River transport of pollutants. Case of study: Sacco river in Colleferro (RM) (2013)".

INTERNATIONAL FIRMS/COMPANIES

During my working activities I had the opportunity to get in contact and collaborate with international companies like:

Food and drink company

- CESARE FIORUCCI
- CUKI FRESCO
- FINDUS

Engineering company

- JACOBS
- TUV SUD BASEL
- WOOD/AMEC FOSTER WHEELER
- GRUNER AG
- AMSTEIN+WALTHERT AG
- PHARMATEC
- CTP System
- TECHNICONSULT

Chemical and Pharmaceutical company

- LONZA
- BIOGEN
- GSK VACCINES
- CSL BEHRING
- PFIZER CONSUMER MANUFACT. ITALY SRL
- CORDEN PHARMA LATINA
- BSP Pharmaceutical S.r.l.
- MENARINI BIOTECH S.r.l.

Mechanic and Electromechanic companies

- ABB SPA
- FCA ITALY
- ISOPAN SPA
- SIAPRA (FIAMM SPA)
- SKF INDUSTRIE SPA

