According to Italian D.P.R. 445 of 28.12.2000

SUMMARY

I carried out my first 30+ years as Quality Director (GxP-ISO) in several life sciences companies. I spent my first 5 years in the academic research, in chemical synthesis, and in the industrialization of new production techniques. Since 1992, I held the role of GxP Quality Director/Qualified Person in various manufacturing and distribution life sciences companies, where I have always dealt with projects, such as the construction of a new plant for injectables, the creation of the GDP quality in a Distributor, the creation of the GMP culture in medical device company and analytical laboratory, the selection and training of the quality team for a Chinese manufacturing company, the improvement of the GxP EU and USA quality culture in several manufacturing sites.

Since 2010, I cover role of Quality Director/Qualified Person in GLP-GCP-GVP companies.
Since 2018, I work as independent Quality Director and Qualified Person in GxP companies in Italy and EU.

Authorized Qualified Person for pharma drugs in EU.
Authorized PR/PRRC Person Responsible for Regulatory Compliance as per EU MDR 2017/745.
Authorized Pharmacist to operate in Italy and in Switzerland.

Multi-years' experience as Quality Site Director and Qualified Person in pharmaceutical, medical device, food supplements and cosmetic companies certified GxP or ISO.

GCP and GLP Quality Assurance Manager in CRO and Laboratories authorized against GCP and GLP guidelines for preclinical and clinical study.

As GxP Auditor, I conducted about 300 audits to providers of the Health Life Science field according to GLP, GCP, GMP, GVP, ISO 9001: ISO 13485, ISO 22716. The audited company were manufacturer of API, Excipients, Pharma Drug, medical devices, cosmetics, machines, utilities, or operating as distributor, CRO, analytical laboratories.

Team Leader in inspections by Regulatory Authorities, Notified Body, Certification Company (FDA, AIFA, ANVISA, ISS, Swissmedic, Italian Health Ministry, Kiwa, Certiquality, ISS, TUV, Eurofins).

Quality Validation Expert in charge to prepare and/or to approve Validation Project Plan, Risk Assessment (FMECA methodology), User Requirements, IQ/OQ/PQ/PV protocols and reports.

Compliance Quality Assurance Director for the quality system remediation: CAPA, deviation investigations, complaints, stability, FDA 483 response writing, supplier management; selection, qualification, audit, evaluation, approval.

Team Head for the supplier management; selection, qualification, audit, evaluation, approval.

Responsible of the Quality Control department, in charge of the physical, chemical and microbiological analysis of primary packaging materials, raw materials, bulks, semifinished and finished products.

EXPERTISE

GxP Quality Compliance to EU and USA Regulation for application in pharma, medical device, food supplement and cosmetic
Validation: facility, equipment, instrument, computer, method
Auditor to thirdy parties, Mock Audit, Due Diligence
Developer and Assessor of Quality System Management according to GMP, GLP, GCP, GVP and ISO
Chemical analytical techniques such as FTIR, NIR, HPLCs, GCs, MASS, AAS, NMR, TOC
Microbiological analytical techniques, such as sterility test, LAL test, bioburden, identification
Risk Assessment Method, such as FMECA, Hazop, HACCP, FTA

LANGUAGES

Italian	Mother tongue	English	Very Fluent, both written and spoken
French	Very Fluent, both written and spoken	Spanish	Good, both written and spoken

CERTIFICATION - AUTHORIZATION

Responsible Person according to the article 15 of the MDR Regulation 2017/745
Qualified Person in Europe and in Switzerland
Pharmacist in Italy and in Switzerland
Qualified Auditor for ISO 9001, ISO 13485, ISO 22716, ISO 15378

EDUCATION AND CERTIFICATION

November 2019	Qualification as Responsible Person according to MDR 2017/745.
March 2011	Authorization as a Qualified Person by AIFA
October 2010	Authorization as Pharmacist in Switzerland, no. GLN7601003216127
November 2006	Authorization as Auditor/Lead auditor for ISO 9001 and ISO 13485 Norm
November 2005 June 2006	Post graduate Master in Classical Homeopathy
January - June 1995	Post Graduate Master in management of Technology, University of Milan
September 1990 November 1992	Doctorate in Chemical Synthesis, Vote 62/70, Faculty of Chemistry, University of Milan, Thesis: “Synthesis of 1-methyl-3-hydroxitetralins and stereochemistry study”.
November 1991	Qualification as Pharmacist.
September 1985 July 1990	Bachelor, Honors degree in Chemical and Pharmaceutical Technologies with a Vote of 110/110 cum Laude, Course of 5 years at the Faculty of Pharmacy at the University of Pavia, Thesis "Synthesis of antimicrobial products".
September 1980 July 1985	Graduate High School in classic literature, Vote 52/60

PROFESSIONAL EXPERIENCE

Actual (projects and roles ongoing) ALL OF THEM IN PART-TIME
Free-lance in health life science companies, In Italy and in Europe
Quality Assurance - Qualified Person – Responsible Person - Auditor

- Qualified Person for IMPs Release in EU: EU-QP, IMP GCP Clinical Studies. Dublin, Ireland. (since 2022)
- Quality Assurance Manager: GLP and GCP Laboratory, Analysis of samples from preclinical and clinical trials. LC-MS/MS, HPLC. Milan, Italy (since 2017)
- Quality Assurance Manager: CRO GCP Clinical Trial, Italy (since 2022)
- Quality Assurance Manager: CRO GCP Statistical, Statistical and Data Management of clinical trials. Genova, Italy (since 2020)
- Quality Assurance Manager: ISO Engineering Service, Instruments calibration and validation. Milan, Italy (since 2020)
- Quality Assurance and Responsible Person: Medical Devices manufacturer, Medical Device Class III. Italy. (since 2020)

- GCP auditor for IRCCS Bologna S. Orsola (since March 2022)
- GCP auditor for IRCCS Reggio Emilia (since June 2022)
- Auditor. Italy, Europe, Worldwide
  GLP, GCP, GMP, GDP, GVP, GAMP + ISO Norms 9001, 13485, 22716, 15378

- Coach for personnel on QA topics, i.e. Internal Audit, Validation, GMP, FDA requirements.
- Quality and FMECA Expert to assess Design and Lay out for engineering companies.
- Quality Assessor for a Nitrosamine Project in drug medicine for about 100 items.
- Quality Assurance Expert to develop, built and implement the QMS and Validation documentation for a new virtual company for producing a sterile MD in France.

July 2017 – 2022 (Contracts already closed)

- **Free-lance in health life science companies, In Italy and in Europe, for the following role, that are closed.**

- Qualified Assurance and Responsible Person: GMP distributor of Medical Device and Pharma drug products. Lugano Switzerland (since 2017)
- Qualified Person for Pharmacovigilance. GMP distributor of pharma drug products and Medical Device. Lugano Switzerland (2020, 2021, 2022)
- Quality Assurance Manager. GCP CRO Verona, Italy (2021-2022)
  Clinical Studies, Project specific activities, Assessment and improvement
- Qualified Assurance – Qualified Person. GMP manufacturer, USA (12 months-2022)
  Pharma drug products.
- Quality Assurance Manager and Responsible Person. MD Manufacturer. Lugano, Switzerland. Medical Device Filler products.
- Quality Operation Director. GLP Laboratory. Lugano, Switzerland.
  Tissue Engineering and Absorption test for MD, ISO 10993-OECD guides
- Quality Assurance Expert. Food Supplements and OTC products. Milan, Italy
  GMP improvement and construction of a new facility for liquid oral products
- Quality Assurance Expert
  Cosmetics for USA, Medical Device for Italy, France and EU.

Quality Site Director – Qualified Person – Responsible Person
Dec. 2014 – July 2017
TUBILUX PHARMA S.p.A., in Rome (IT)
Private pharmaceutical company, CDMO. Manufacturer of ophthalmic drug product & medical device through aseptic process.

- Lead 40 people
- QA compliance, QA validation, QA sterility, QC department, Qualified Person
- Approval and Release of drug product and medical device, as QP.
- To drive and to prepare the company to the first FDA inspection for OTC and ANDA products (pre- approval inspection).
- To assess and review the entire Quality System through all departments to follow US guidelines. To implement the highlighted CAPAs (remediation plan).
- To train all the company's staff about the FDA GMP requirements.
- To act as Quality expert in the R&D developing activities for new products for USA.
- Leader during the FDA inspection for OTC during December 2016.
- To drive all the routine activities related to the Quality aspects, as the GMP compliance (CC – Complaints – Deviation – Documents – regulatory compliance), the sterility assurance of the production environment and equipment, the validation of machine/equipment/utilities.
- QA approver of documents related to validation (VPP, RA, URS, Protocol, Report) of utilities (as HVAC, PW, WFI, pure steam), equipment (tanks, autoclaves, ovens, filling machine), IT systems (ERP, Quality Plus) and analytical chemical methods (HPLC, GC, IR, UV, TOC), microbiological methods (bioburden, sterility, LAL), sterilizing methods (gamma, beta, ETO)

Quality Assurance
July 2014 – December 2014
Free-lance in health life science companies, In Italy and in Europe

- Auditor. Italy, Europe, Worldwide
  GxP + ISO Norms 9001, 13485, 22716, 15378
- Trainer. Italy, Europe, Worldwide
  GMP topics, FDA requirements, Validation
- Quality Assurance Expert. Cosmetic, Lodi, Italy
  FDA inspection.
- Quality Assurance. GMP Laboratory, Bologna, Italy (2010-2012)
  FDA inspection.
- Quality Assurance Manager. engineering company
  Technical reviewer and QA expert in the FMECA study.

Quality Site Director – Qualified Person – Responsible Person
November 2012 – July 2014
MIPHARM S.p.A., in Milan (IT)
Private pharmaceutical company, CDMO. *Drug Forms:* Liquid and solid form (solution, sachet, tablets, capsules, granulated); topic and mucosa's creams; nasal spray; suppository; secondary packaging of bottles and vials. *Categories*: high potent, psychotropic.

- Lead 70 people
- QA compliance, QA validation, RA department, QC department, Qualified Person
- Approval and Release of drug product and medical device for EU and USA, as QP.

- Quality Assurance compliance/validation and Quality Control of all activities according to EU and USA GMP as well as any other Regulation.
- To plan and conduct activities in compliance with Marketing Authorization (MA) of customers.
- Leader for the HAs Inspections (FDA, AIFA, ANVISA, Kenya, and Uganda) and customer's audit.
- Quality expert during the Technology Transfer project for new projects.
- To implement the serialization for China (good distribution): first company in Italy to get this result.
- To prepare and approve all validation documents (VPP, RA, URS, Protocol, Report) related to:
  - product's processes and equipment (powder/liquid mixers, liquid/powder filling machine, semi-solid/ointment filling machine, spray filling machines, tableting and capsuling machine, granulates mixer and dryer, suppositories melters and filling),
  - utilities (as HVAC, Nitrogen, PW),
  - computer systems (LIMS, ERP, Material Warehouse Management system, SAP, Intranet net, Quality documentation system, Serialization)
  - method validation (chemical and microbiological).

Quality Assurance Manager - Qualified Person
November 2011 – November 2012
POLYCRYSTALLINE Srl, in Bologna (IT)
GMP Analytical Laboratory

- Lead 10 people
- QA compliance, QA validation, Qualified Person
- Approval and Release of GMP analysis for EU, as QP
- Project leader to obtain the authorization to the Good Manufacturing Practices (AIFA)
- QA approver of QMS documents
- Trainer of the staff on GMP and GLP.

Quality Assurance (ALL OF THEM IN PART-TIME)
January 2010 – March 2013Free-lance in health life science companies, In Italy and in Europe

- Quality Assurance Manager. GCP CRO. Milan, Italy (12 months)
  Clinical Studies, Project specific activities, assessment and improvement, training courses, regulatory inspections, customer audit, external audit to Investigational Centers

- Auditor. GCP CRO. EU-AstraZeneca (10 months)
  Execution of GCP audits to investigational centers in East Europe for clinical studies.

- Auditor. Italy, Europe, Worldwide
  GxP + ISO Norms 9001, 13485, 22716, 15378

- Coach for personnel on QA topics, i.e. Internal Audit, Validation, GMP, FDA requirements.

- Quality Assurance Consultant. Cosmetic-ISO 22716. Lodi, Italy (36 months)
  Quality compliance of the QMS, QC and Manufacturing activities to GMP-ISO 22716

- Quality Assurance Consultant. Food Supplement. Lodi, Italy (18 months)
  Quality compliance of the QMS, QC and Manufacturing activities to GMP-ISO 22716

- Quality Assurance Consultant. Sterile Medical Device. Verona, Italy (12 months)
  Quality compliance of the QMS, QC and Manufacturing activities to EU and USA GMP.

- Quality Assurance Consultant. Primary Packaging. Milan, Italy (12 months)
  Quality compliance of the QMS, QC and Manufacturing activities to EU GMP.

- Quality Assurance Consultant. Drug pharma. Novartis Milan, Italy (8 months)
  Quality compliance of the QMS, QC and Manufacturing activities to EU GMP.

Pharmacist Part Time
July 2010 – December 2012
Farmacia PORRO, in COMO (IT), Private Pharmacy store

October 1999 – Dec 2009 Quality Site Director
APTAR S.P.A. (VALOIS), in Lugano (CH) and in Suzhou (China).
Manufacturer of primary packaging and medical device for inhalation and nasal application.

- Lead 30 people in Lugano and 20 in China
- Head of Quality Assurance and of Quality Control (physical, chemical and microbiological)
- To Release the primary packaging and medical devices
- To lead the validation, change control (raw materials, processes and products), corrective and preventive action (CAPAs), and continuous improvement
- Senior Auditor for internal audits and that ones to the suppliers/subcontractors
- To approve Quality/Technical agreements with customers
- To assure continuous compliance of QS to Norms ISO 9001, ISO 13485 and ISO 15378
- To approve of documents related to validation (VPP, RA, URS, Protocol, Report) of utilities (as HVAC, deionized water, nitrogen), equipment (assembling machine and molds), IT systems (LIMS, ERP, Material Warehouse Management system, SAP, Intranet net, Quality documentation system) and analytical methods.
- To train for the GxP and ISO regulations for the internal, Chinese and suppliers' people.
- Quality Expert during the implementation and qualification of IT SAP & MES systems; reviewer and approver of validation documents (VPP, RA, URS, Protocol, Report).
- Project technical leader for the transfer of a production line from Lugano to the production plant in China and Quality Responsible of the Quality System Implementation (3 years).
- Promoter for studying and implementing the continuous improvement of manufacturing processes, (Operations Excellence) by applying the Lean Manufacturing and 6-Sigma methodology.

Quality Assurance - Qualified Person
January - September 1999
CHEMO GROUP, in Lugano (CH)
Import and export of chemicals, pharmaceuticals and foodstuffs materials.

- Lead 5 people
- To release drug products for EU and USA, as QP
- To implement and approve the GMP & GDP Quality System.
- To lead the GDP inspections of Swissmedic.
- QA compliance manager for complaints and technical service support to the customer.
- QA expert in the developing projects of new formulations of drug for nasal application (ANDA).

Quality Site Director – Qualified Person
November 1995 - Nov 1998
BIGMAR PHARMACEUTICALS SA, BARBENGO
Manufacturer of injectable oncology medicines for US Market, with aseptic process by using isolator.

- Lead 10 people in QC and QA
- To release drug products for EU and USA, as QP
- To promote the improvement of GMP in order to qualify this new facility.
- To lead Swissmedic and FDA inspection for GMP authorization and approval of the site and of the herein produced products for export to USA.
- To train QA and laboratory personnel.
- To approve QS documents in compliance with European and USA GMP.
- To approve documents related to validation (VPP, RA, URS, Protocol, Report) of utilities (as HVAC, PW, WFI, pure steam), equipment (tanks, autoclaves, filling machine, lyophilizer), analytical methods.

QC Chemical Analyst
May - October 1995
LAGAP SA
Manufacturer of oral drug pharma

- To execute chemical routine analysis for the release of medicinal products.
- To validate new chemical analytical methods, according to the current Pharmacopeia.

Project leader and QC Chemical Analyst
November 1992 - April 1995
CURT GEORGES SpA.
Manufacturer of flavor for food and essences for perfumes.

- Project leader of the project "New food flavorings and extracts from plants transformed by microorganisms"; co-operation with the Departments of Organic Chemistry and Biology, University of Milan.
- Development of new methods for the extraction of flavor and consequently scale-up.
- Coordinator during the transfer of the extraction method from the pilot equipment to the industrial ones.
- Developer and validator for the new analytical methods for product's quality control.
- As QC Analyst, I performed the routine chemical analysis of daily produced flavor batches.
- Representative QA in the group for the implementation of the ISO 9001 Norm; writer of the SOPs for the quality control laboratory.

Researcher for the Nutrition Foundation, F.lli Branca
September 1990 - October 1992
University of Milan, Faculty of Chemistry, Department of natural organic substances. In Milan (IT)

- To study the extracts from natural products and their chemical characterization.
- To test new methods for processing and synthesis of molecules through fermentation.

KNOWLEDGE OF THE REGULATIONS APPLIED TO CARRY OUT THEIR FUNCTION IN THE REALITIES WHERE I WORKED	
Code	**Title**
EP	European Pharmacopoeia
USP	US Pharmacopeia
US CFR 21	part 11, 111, 210, 211, 800
ICH	ICH Guidelines, group E, group Q
OECD	OECD Guidelines
GAMP	GAMP Guidelines for computerized system
EudraLex - Volume 4	Good Manufacturing Practice (GMP) guidelines and Annexes
EudraLex - Volume 3	Scientific guidelines for medicinal products for human use - EMA Scientific Guidelines
MDR	MDR 2017/745
ISO 22716	Cosmetici - Pratiche di buona fabbricazione (GMP) - Linee guida sulle pratiche di buona fabbricazione
ISO 15378	Imballaggi Primari
ISO 14971	Risk Analysis
ICH Q9	Risk Analysis
Serie ISO 14644	Camere bianche ed ambienti associati controllati
Serie ISO 14698	Camere bianche ed ambienti controllati associati
Serie ISO 10993	Valutazione biologica dei dispositivi medici
EN 14885	Disinfettanti chimici ed antisettici - Applicazione delle Norme Europee per i disinfettanti chimici e gli antisettici
EN 556-1:2001	Sterilizzazione dei dispositivi medici - Requisiti per i dispositivi medici che recano l'indicazione "STERILE" - Requisiti per i dispositivi medici sterilizzati terminalmente
EN 556-2:2015	Sterilizzazione dei dispositivi medici - Requisiti per i dispositivi medici che recano l'indicazione "STERILE" - Parte 2: Requisiti per i dispositivi medici preparati asetticamente
EN ISO 11737-1	Sterilizzazione dei dispositivi medici - Metodi microbiologici - Parte 1: Determinazione di una popolazione di microrganismi sui prodotti
EN ISO 11737-2	Sterilizzazione dei dispositivi medici - Metodi microbiologici - Parte 2: Prove di sterilità eseguite nel corso della definizione, della convalida e del mantenimento di un processo di sterilizzazione
EN ISO 17665-1	Sterilizzazione dei prodotti sanitari - Calore umido - Parte 1: Requisiti per lo sviluppo, la convalida e il controllo di routine di un processo di sterilizzazione per dispositivi medici
EN ISO 11135-1	Sterilizzazione dei prodotti sanitari - Ossido di etilene - Requisiti per lo sviluppo, la convalida ed il controllo sistematico di un processo di sterilizzazione per dispositivi medici
EN ISO 11137-1	Sterilizzazione dei prodotti sanitari - Radiazione - Parte 1: Requisiti per lo sviluppo, la convalida e il controllo sistematico dei processi di sterilizzazione per i dispositivi medici
EN ISO 11137-2	Sterilizzazione dei prodotti sanitari - Radiazione - Parte 2: Definizione della dose sterilizzante

KNOWLEDGE OF THE REGULATIONS APPLIED TO CARRY OUT THEIR FUNCTION IN THE REALITIES WHERE I WORKED	
Code	**Title**
Serie ISO 11138	Sterilizzazione dei prodotti sanitari - Indicatori biologici
Serie ISO 11140	Sterilizzazione dei prodotti sanitari - Indicatori chimici
Serie ISO 13408	Trattamento asettico dei prodotti per la cura della salute
EN ISO 14937	Sterilizzazione dei prodotti sanitari - Requisiti generali per la caratterizzazione di un agente sterilizzante e per lo sviluppo, la convalida ed il controllo sistematico di un processo di sterilizzazione per dispositivi medici
EN ISO 20857	Sterilizzazione di prodotti per la sanità - Calore secco - Requisiti per lo sviluppo, la convalida e il controllo sistematico di un processo di sterilizzazione per dispositivi medici
EN 1422	Sterilizzatrici per uso medico - Sterilizzatrici a ossido di etilene - Requisiti e metodi di prova
EN ISO 11607-1	Imballaggi per dispositivi medici sterilizzati terminalmente - Parte 1: Requisiti per materiali, sistemi di barriera sterili e sistemi di imballaggio
EN ISO 11607-2	Imballaggi per dispositivi medici sterilizzati terminalmente - Parte 2: Requisiti di convalida per il formato, la tenuta e i processi di assemblaggio
ASTM F1980 – 07	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM D4169	Standard Practice for Performance Testing of Shipping Containers and Systems
EN ISO 10112	Sistemi di gestione della misurazione - Requisiti per i processi e le apparecchiature di misurazione