



Curriculum Vitae

PERSONAL INFORMATION

Address: 69, Via Voltorno, 00042, Anzio (RM), Italy
Name/Surname: **FEDERICA SFORZA**
Mobile: 335-6844847
E-mail: federica.qma@gmail.com;
Nationality: Italian and American
Date of birth: May 8th, 1986

I am certified Quality Assurance and GCP Auditor in compliance with DM 15/11/2011
*"Definizione dei requisiti minimi per le organizzazioni di ricerca a contratto (CRO)
nell'ambito delle sperimentazioni cliniche di medicinali".*

GCP EXPERIENCE

Dates: From 24 March 2010 to December 2013
Position Held: QA and GCP Auditor in training/Co-Auditor
Main activities: GXP Audits performed in EU and in US together with
Dr. Valentine Sforza who is the Lead Auditor
Name of employer: Quality Management Associates Valentine Sforza &Co. s.a.s.,
Rome

Dates: From January 2014 to date
Position Held: QA and GCP Auditor
Main activities: GXP National and International Audits
Name of employer: Quality Management Associates Valentine Sforza &Co. s.a.s.,
Rome

Dates: From March 2024 to date
Position Held: Quality Assurance Responsible for full service CRO and also for
two phase I Units
Main activities: Management of GCP Quality System,
Name of employer: Studio di Consulenza Farmacologica – Full service Italian CRO,
Catania

Dates: From 2023 to date
Position Held: Auditor GCP
Main activities: GCP Audits for Phase I Units, Site, Local Lab and Central Lab
Name of employer: Phase I Units – Ospedale Santa Maria della Misericordia – Perugia

Dates: From July 2022 to date
Position Held: QA and GCP Auditor
Main activities: GCP Audits and management of GCP Quality System, Phase I-II of pediatrics studies on rare diseases and also phase III and IV
Name of employer: Ospedale Pediatrico Bambino Gesù – Centro Studi Clinici Sviluppo Farmaci Pediatrici, Rome.

Dates: From January 2021 to date
Position Held: QA and GCP Auditor
Main activities: GCP Audits and management of GCP Quality System
Name of employer: Hippocrates Research – Full service Italian CRO, Genova

Dates: From 2017 to date
Position Held: Auditor GCP
Main activities: GCP Audits for Phase I Unit (hematology and healthy Volunteers)
Name of employer: Phase I Unit – Policlinico San Matteo di Pavia

Dates: From November 2022 to April 2025
Position Held: QA and GCP Auditor
Main activities: GCP Audits and management of GCP Quality System, for Italian Network for Pediatric Clinical Trials
Name of employer: The Italian Network for Pediatric Clinical Trials. Ospedale Pediatrico Bambino Gesù, Rome

Dates: From January 2014 to July 2022
Position Held: QA and GCP Auditor
Main activities: GCP Audits and management of GCP Quality System, Phase I-II of pediatrics studies on rare diseases and also phase III and IV
Name of employer: Ospedale Pediatrico Bambino Gesù - Contract Research Organization – Area del Farmaco, Rome

Dates: From November 2021 to June 2023

Position Held: QA Manager and GCP Auditor
Main activities: GCP and ISO Audits and management of GCP Quality System
Name of employer: Opera CRO (Romania), subsidiary of Tigermed CRO (China) – International CRO

Dates: From January 2019 to August 2022
Position Held: QA and GCP Auditor
Main activities: GCP and ISO Audits and management of GCP Quality System
Name of employer: FULLCRO – Full service Italian CRO, Rome

Dates: From January 2017 to December 2018
Position Held: QA GCP
Main activities: Implementation and Management of GCP Quality System Phase I studies (Determina 809/2015) and responsible for the training activities of internal QA
Name of employer: Centro Studi Early Phase – IFO - Rome

Dates: From January 2017 to December 2018
Position Held: QA GCP
Main activities: Implementation and Management of GCP Quality System Phase I studies
Name of employer: Hematology Department, Study specific phase I (ALF Study) and Pediatric-Onco-hematology Department- Le Molinette – Turin

Dates: From 2015 to 2016
Position Held: QA and AuditorGCP
Main activities: GCP Audits and Management of Quality System Phase I on healthy volunteers
Name of employer: Clinical Trial Unit - Università Campus Bio-Medico, Rome

GCP EXPERIENCE: please refer to the attached GCP audit records as evidence of experience performed and the days of audit performed

GLP EXPERIENCE:

Dates: 27th and 28th April 2016
Position Held: QA Auditor
Main activities: Mock FDA Inspection Animals Facilities

Name of employer: QMA for Pharmaceutical Company
Dates: 16th June 2014
Position Held: QA Auditor
Main activities: Evaluation of GLP Quality System
Name of employer: Laboratorio di Farmacologia Sperimentale dell'Università Federico II in Naples, Italy.

Dates: 30th October 2013
Position Held: QA Auditor
Main activities: Evaluation of GLP Quality System
Name of employer: Laboratorio di Farmacologia Sperimentale dell'Università Federico II in Naples, Italy

Dates: 3rd and 4th June 2013
Position Held: QA Auditor
Main activities: Process for implementation of GLP Quality System
Name of employer: Laboratorio di Farmacologia Sperimentale dell'Università Federico II in Naples, Italy

Dates: 19th and 20th December 2012
Position Held: Assistant QA Auditor
Main activities: GLP System Audit
Name of employer: Kedrion BioSC, Italy

Dates: 29th and 30th November 2012
Position Held: Assistant QA Auditor
Main activities: GCLP System Audit
Name of employer: Analytical Laboratory Dompè S.p.A. in Aquila, Italy

GMP EXPERIENCE:

Dates: 10th July 2013
Position Held: QA Auditor
Main activities: Participation to simulation of FDA GMP Inspection for medical devices
Name of employer: BIOS S.r.l. in Milan, Italy

GVP EXPERIENCE:

Dates: 28th October 2013
Position Held: QA Auditor Assistant
Main activities: System Audit for the Pharmacovigilance Quality System
Name of employer: Menarini I.F.R in Florence, Italy

Dates: 9th and 10th December 2013
Position Held: QA Auditor Assistant
Main activities: System Audit for the Pharmacovigilance System
Name of employer: Menarini I.F.R in Florence, Italy

EDUCATION AND TRAINING

Dates: 8th February 2014
Title of qualification awarded: Master II level "Sistemi di Qualità GXP & ISO"
Name and type of organization providing education: Università Cattolica del Sacro Cuore Rome (Italy)

Dates: March 2012
Title of qualification awarded: Laurea specialistica in Psicologia Clinica e di Comunità
Name and type of organization providing education: Università Europea di Roma, Rome (Italy)

Dates: March 2010
Title of qualification awarded: Laurea triennale in "Scienze e tecniche psicologiche"
Name and type of organization providing education: Università Europea di Roma, Rome (Italy)

Dates: 2006
Title of qualification awarded: Stage as QA in the Quality Assurance Unit (6 months)
Name and type of organization providing education: Research Toxicology Centre S.p.A. Rome (Italy)

Dates: 2005
Title of qualification awarded: Liceo Linguistico
Name and type of organization providing education: Istituto Linguistico Nostra Signora della Mercede, Anzio Rome (Italy)

TRAINING: All training activities performed are documented in the training records attached.

PERSONAL SKILLS and COMPETENCE

Mother Tongue: Italian

Other Languages: English
Understanding Skills: Good
Speaking Skills: Good
Writing Skills: Good

Other Languages: Spanish
Understanding Skills: Good
Speaking Skills: Good
Writing Skills: Good

Other Languages: Franch
Understanding Skills: Good
Speaking Skills: Good
Writing Skills: Good

SOCIAL AND ORGANIZATIONAL SKILLS

Good communication and interaction with colleagues as well as with professionals encountered during execution of work assignments

COMPUTER SKILLS

I have a good knowledge of Microsoft Office Programs (Word, Excel, Power Point) and Computer System Validation as per 21 CFR Part XI, GAMP V and Annex 11 GMP.

I hereby authorize the processing of my personal data above, pursuant to the Personal Data Protection Code – Italian Legislative Decree n° 196/2003, GDPR and updates.

17/10/2025

