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Martina Giorgio Gaggia
Responsabile QA Clinico

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I'm graduated in CTF at the university of Florence in 2014, and then I've started to work in Pharmaceutical company as Quality Assurance. In 2015 I entered the clinical research world for supporting Sponsors and CROs, becoming QA Responsible Person according to Italian Decree 15.11.2011 and managing Clinical QA staff in national & international projects.

Experience

Position: *Quality Assurance Senior Consultant & Team Leader – Responsabile QA Clinico*
Date: November 2020 – Ongoing
Company: JSB Solutions
Activities:
Review of Standard Operating Procedures for the conduct of a Clinical Trial and GxP/ISO Quality System Management activities ; Support to other Business Unit for the Quality Compliance; Project Management of GxP/ISO Quality projects; Internal/External Audit conduct; Position of QA Manager for external companies; QA Manager according to DM 15.11.2011.

Position: *Clinical Quality Assurance Specialist and QA Responsible person*
Date: March 2019 – November 2020
Company: JSB Solutions
Activities:
See acitivities for current position.

Position: *Clinical Quality Assurance Consultant and Responsible person*
Date: January 2018 - March 2019
Company: JSB Solutions
Activities:
Review of Standard Operating Procedures for the conduct of
a Clinical Trial and Quality System Management activities; Support to other Business Unit for the Quality Compliance.

Position: *Responsable person for ISO and internal QA*
Date: February 2017 – Ongoing
Company: JSB Solutions
Activities:
Preparation and review of Standard Operating Procedures for the ISO 9001:2015 Certification (Regulatory, Quality and Clinical SOPs) and ISO 9001:2015 process management.

Position: *Quality Assurance Consultant*
Date: March 2015 – Ongoing
Company: JSB Solutions
Activities:
Suppliers' qualification (Auditing management, Follow Up
and CAPA Plan management, Quality Agreement preparation); Preparation and review of SOPs for the conduct of a Clinical Trial; Preparation of Quality Overall Summary of CTD, research of applicable regulatories for management of changes, clinical trial of pharmaceutical products, clinical trial on food, pharmacovigilance procedures, Start Up activities data publication of Clinical Trial results in EU database; trainee Auditor for GCP Audit to Sponsor, CROs and on site Audit

Education

Degree: Master in "Management and Marketing of Pharmaceutical Industry-Medical Division"
Date: 19/11/2015
University: Alma Laboris
Thesis: n/a

Key skills

Technical Skills:

- Auditor for internal Audit
- Third parties qualification
- GCP/GMP
- Quality Assurance GMP/GCP
- Batch Release
- Regulatory Affairs
- Auditing (GCP trainee Auditor)
- Third parties qualification
- GCP/GMP
- Quality Assurance GMP/GCP
- Batch Release
- Auditor for internal Audit

Soft Skills:

- Project management
- Problem solving
- Versatility

Languages: Italian, English