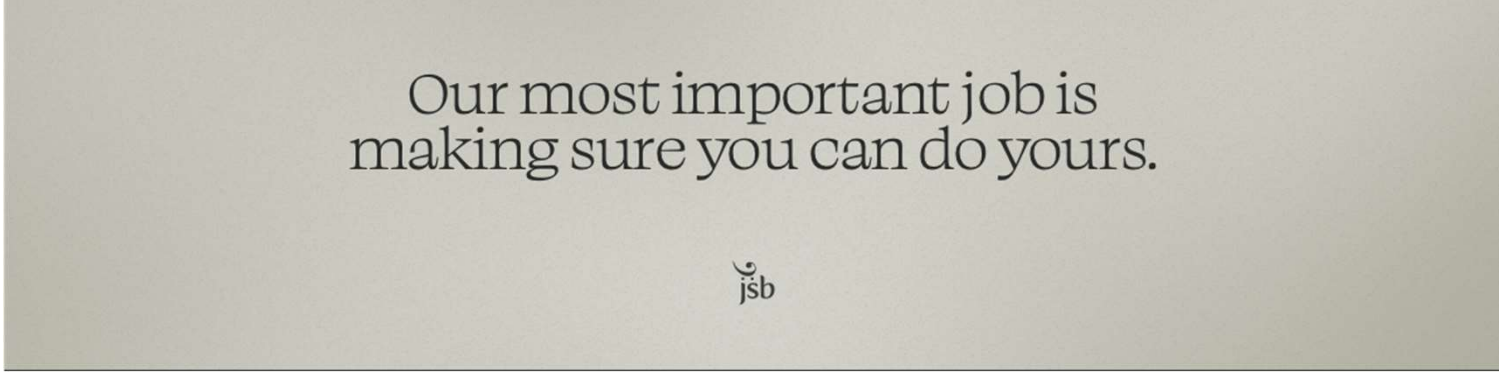


Angela Pedico

Regulatory Start Up Specialist

SUMMARY

Pharmacist specialized in drug technologies and regulatory activities at the University of Pavia.
Regulatory Start Up Specialist with 1,5 year of experience in the management of regulatory clinical trials activities and in the administrative activities of clinical trial management in according to GCP guidelines.

EDUCATION

Degree: Master's Degree in "Tecnologie farmaceutiche ed attività regolatorie"
Date: Jun 2023
University: Università degli studi di Pavia

Degree: Pharmacy
Date: Nov 2021
University: Università degli studi di Bari "A.Moro"

KEY SKILLS

Technical Skills:

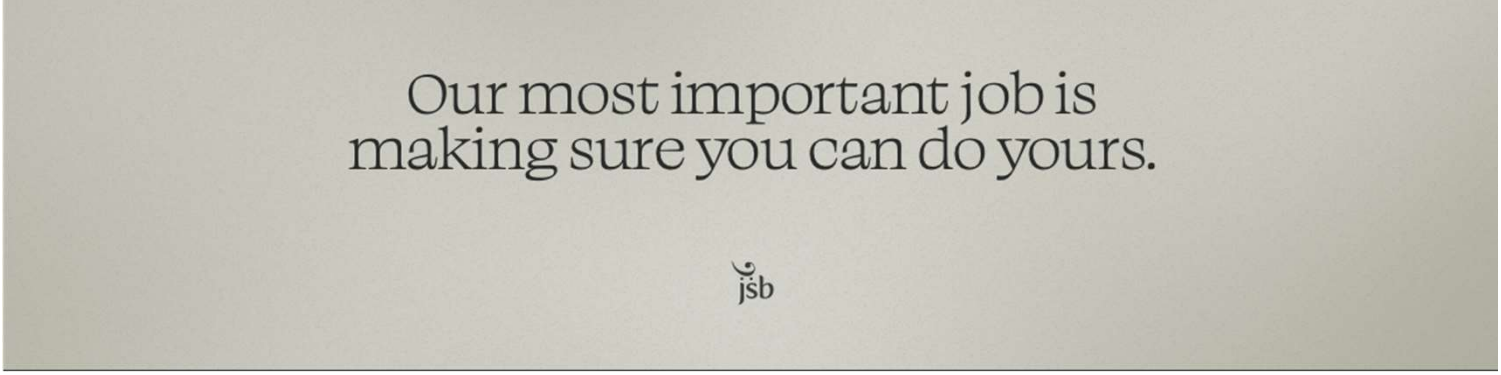
- GCP R2
- CTIS
- TMF
- StartUp
- Veeva
- Suite Office

Soft Skills:

- Communicational skill
- Interpersonal skills
- Problem Solving
- Teamwork
- Reliable

Languages:

- Italian (native speaker)
- English (B1)



Angela Pedico

Regulatory Start Up Specialist

COMPETENCIES

- Conducting clinical study/investigation submission activities to Competent Authorities and Ethics Committee
- Managing Translation Agencies
- Preparing/reviewing and assessing the completeness and compliance with current regulations of documents required for submission
- Adjustment of clinical study/investigation documents to site- and/or country-specific requirements
- Management of Follow-Up and Deficiencies Letters received from Ethics Committees and Competent Authorities
- Supporting clinical centers in the preparation of center-specific documentation
- Submission of a clinical study/investigation to the portals of Competent Authorities and Ethics Committees
- Supporting the registration of a clinical study/clinical investigation and publication of clinical data on international registries/portals
- Supporting the preparation of study files such as Trial Master File (TMF) and Investigator Study File (ISF
- Submission of the Final Report of a clinical study/investigation to Ethics Committees and Competent Authorities
- Variations, renewals and registrations in EU and extra UE countries.
- Submissions and follow up of national applications.
- Administrative regulatory affairs acts, according to national laws.
- Submission activities to Competent Authorities and Ethics Committees.
- Using software to record and manage regulatory activities and the life cycle of a pharmaceutical product
- Basic preparation in regulatory/ quality- affairs

COMPANIES & POSITIONS

Position: Regulatory Start Up Specialist
Date: May 2024 – On going
Company: JSB Solutions

Position: Regulatory affairs Consultant
Date: Aug 2023 – May 2024
Company: JSB Solutions

Position: Regulatory affairs Stageur
Date: Nov 2022 – Aug 2023
Company: JSB Solutions

Position: Pharmacist
Date: Feb 2022 – Nov 2022
Company: Gsm- Più Medical