



Regulatory Affairs Scientist

Focus: Paediatric Field

Description

The Regulatory Scientist will have the responsibility in the scientific management and coordinating/administrative activities related to the paediatric studies, clinical trials and research projects carried out by INCIPIT.

In particular she/he will be responsible for:

- Support in scientific consultancy activities (Protocol writing, Paediatric Investigational Plan and Scientific Advice procedures, etc..).
- Clinical trial design, review/medical writing of clinical study documents.
- Contacts with National Competent Authorities (AIFA, EMA) and Ethic Committees (es: preparation and follow-up of submission packages for clinical trials).
- Participating in evaluation of feasibility studies and sites selection.
- Budget and Agreement (related to clinical trials) negotiation.
- Research Project management and scientific activities (H2020, IMI2, etc..).
- Activating and maintaining contacts with Sponsors, INCIPIT clinical Sites, thematic networks, Scientific Societies.

Qualifications

- University degree in scientific fields (Pharmacy, Chemistry and pharmaceutical technology, Biology, Pharmaceutical Biotechnology, Biostatiscian).
- Good Knowledge of Good Clinical Practices, ICH guidelines, ethics, EU and country legislation related to clinical trials.
- Good knowledge of concepts and understanding of clinical research and drug development process (preferable knowledge in paediatric drug development).
- Ability to handle and prioritise multiple therapeutic areas and projects simultaneously.
- Ability to work effectively in a team/matrix environment.
- Advanced computer skills.
- Experience of at least 2 years in Regulatory Affairs field.
- Proficiency in English (spoken and written).

Type

Research Fellow

Entry level and salary

To be evaluated based on the real experience of the candidate.



INCIPiT Italian Network for
Paediatric Clinical Trials

Job location

Roma (Italy)- INCIPIT coordinator centre (Paediatric Hospital Bambino Gesù-Gianicolo)

Applications

All candidates can send their applications including their resume and letter of presentation to info@incipit-ped.net