Description du poste

INTERNSHIP: Regulatory Clinical Trials Submissions (6 months)

Rennes (as a priority) or Lausanne

Responsibilities:

Main task: participate in the preparation, submission and maintenance of the clinical trial application (CTA) package up to the submission of the clinical study report to competent authorities (CA) and Ethics Committees (EC).

During the course of a project, you will be asked to:

- Draft all documents pertaining to the CTA package in accordance with local requirements for the initial CTA submission as well as for any further notification,
- Assist the project manager with the regulatory review (as per Voisin specific procedures) of the study core documents (e.g. protocol, Investigator's Brochure, patient information leaflet/informed consent form),
- Create and update the study status tracking tool exchanged with client, and other internal tools such as memos,
- Check requirements with CA/EC and/or other service providers when appropriate.

Personal attributes and skills:

- Pharmacy or Master degree in Life Sciences and Technologies,
- Ease in English, oral and written,
- Team spirit,
- Proactive, rigorous, detail-oriented, ability to work in a multicultural environment.

Niveau hiérarchique

Stagiaire

Secteur

- Biotechnologie
- Industrie pharmaceutique
- Hôpitaux et centres de soins

Type d'emploi

Stagiaire / Alternant

Fonctions

- Sciences
- Stage
- Management de projet