

OFERTA PRACY

REGULATORY SPECIALIST/JUNIOR REGULATORY SPECIALIST



Lokalizacja: Kraków, Małopolskie

SZCZEGÓŁY:

Jesteśmy firmą rekrutacyjną. Dla naszego klienta, firmy KCRI, poszukujemy kandydatów na stanowisko: Regulatory Specialist/Junior Regulatory Specialist.

Join Our Team as a Regulatory Specialist!

We are a full-service clinical research and education organization with over 18 years of experience in clinical research of medical devices and medical algorithms. We manage around 85 long-term clinical projects per year and conduct daily operations in 20+ countries on 5 continents. We are looking for a Regulatory Specialist to join our team.

Company Overview

At our organization, we pride ourselves on being a leader in the clinical research industry. We are dedicated to conducting clinical research that advances medical knowledge and improves patient care. Our company is located in Krakow, Poland, and we offer a modern and comfortable office environment.

KEY RESPONSIBILITIES:

- Preparing, coordinating or reviewing regulatory submissions for domestic or international projects
- Obtaining and distribute updated information regarding domestic or international laws, guidelines, or standards
- Review of the clinical study documents to ensure their completeness for regulatory submissions
- Timely clinical studies application, amendment and notification
- Communication with the regulatory bodies in different countries
- Activities related to the study submission to the EC and CA for domestic or international projects
- Regular updates and alerts to the study team about upcoming periodic reports, expiring documents and current needs based on EC/CA requests
- Taking care of the submission packages in the General Trial Master File and Current Submissions Table

REQUIREMENTS:

- University degree
- Excellent English skills (verbal and written)
- Strong organizational and management skills
- Excellent verbal and written communication skills
- Decision making skills
- Knowledge of ICH-GCP
- Demonstrated knowledge of relevant domestic regulatory requirements
- Demonstrated knowledge of relevant international regulations and guidelines
- Experience in clinical trials will be an advantage

WHAT WE OFFER:

We believe in fostering a supportive and inclusive work environment that encourages personal and professional growth. When you join our team, you can expect:

- Stable job in a professional team
- Development opportunity (internal and external training)
- Encouragement to grow your expertise, take on new challenges and reinvent yourself
- Benefits package, including private health care, Multisport card, language classes and individual psychological support
- Friendly atmosphere
- A modernly designed, comfortable office

We thank all applicants for their interest, however, only those candidates selected for interviews will be contacted.

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Oferta ważna do 30 maja.