Онуфриева Леся

РЕГУЛЯТОРНЫЙ СПЕЦИАЛИСТ

24 червня 2021 Місто: Київ

Вік: 42 роки
Режим роботи: повний робочий день, віддалена робота
Категорії: Медицина, фармацевтика

Опис

OBJECTIVE: to obtain position of Regulatory Specialist, Start up coordinator (remote, full-time, part-time)

Education: National Pedagogical University named after Mikhail Drahomanov (Institute of Correction Pedagogy and Psychology).

EXPERIENCE:

June 2017-May 2019 AstraZeneca LLC, Regulatory specialist:

Duties and responsibilities:

- Assist in coordination and administration of clinical studies from the start-up to execution and close-out.
- Collect, assist in preparation, review and tracking of documents related to Submissions to Expert Center MOH Ukraine. Interface with Investigators and Local Study Leaders during the collection process to support effective delivery of a study and its documents. Serve as local administrative main contact and work closely with Study Manager and/or the LSLs until finalization of the study.
- Download clinical regulatory documents to the Global Electronic Library according the Global Document List.
- Prepare ICF according local templates (initial and actual).
- Maintain regulatory documents, monitor and recommend improvements for tracking regulatory documents.
- Collaborate on development of standard operating procedures, trainings and documentation. Participate in delivering trainings.

January 2016-May 2017 AstraZeneca, LLC Clinical Trial Assistant-LEC Coordinator:

Duties and responsibilities:

- Ensuring overall project maintenance according project timelines and goals.
- Assisting with the creation and review of technical and administrative documentation
- Prepare and submit IRB/IEC application and follow up until final approval received (initial submission and amendments)
- Operational responsibility to set-up the local Trial Master File (eTMF) and ISF including tracking of documents. Maintain and close the local TMF (in electronic or paper form depending on study) ensuring International Conference of Harmonisation Guidelines for Good Clinical Practice (ICH/GCP) compliance and local requirements. Support the CRA in the maintenance and close out activities for the ISF.
- Contribute to the production and maintenance of study documents, ensuring template and version compliance. Translate or give the appropriate support with the translation of documents when required.
- Set-up, populate and accurately maintain information in AstraZeneca tracking and communication tools (e.g. IMPACT, SharePoint etc) and support others in the usage of these systems

- Manage and contribute to coordination and tracking of study materials and equipment
- Coordinate administrative tasks duringthe study process, audits and regulatory inspections, according to company policies and SOPs
- Prepare, contribute to and distribute presentation material for meetings, newsletters and web-sites
- Responsible for layout and language control, copying and distribution of documents. Support with local translation and spell checks in English to/from local language
- Responsible for printing and distribution of documents such as letters and meeting minutes, and for handling and archiving of study related e-mails
- Participation in internal study team meetings, organizing study-specific meeting for Investigators; planning and execution of local investigator meetings

April 2015-December 2015 AstraZeneca LLC, Labor Code Specialist

September 2009-September 2014 Istil Studios LLC, Labor Code Specialist

June 2008-February 2009- Favorit LVP, Labor Code Specialist

Duties and responsibilities:

- Work with department manager to fill internal positions
- Work with department managers update job descriptions and position requirements
- Work with managers to source and screen applicants
- Work with recruitment agencies to find ideal contractor candidates
- Work with staff to edit and maintain employee resume library
- Coordinate and scheduled interviews with interview panelists
- Develop employee health and safety policies

Skills:

- Good organizational and time management skills; ability to adhere to timelines
- Producing weekly and monthly regulatory reports for Managers
- Ability to solve practical problems and deal with a variety of concrete variables in situations where only limited standardization exists
- Very strong attention to detail
- Excellent communication and team leadership skills with strong managerial skills
- Excellent writing, communication and interpretive skills
- English-intermedia

Hobbies:

Yoga, travelling.