Curriculum Vitae

Personal information

Anna Westin

Work experience

Present:

June 2021: GCP Inspector at Medical Products Agency Läkemedelsverket, Sweden

Past:

May 2021 - Jun 2022: Global QA GCP Manager at Sobi - Swedish Orphan Biovitrum AB, Sweden

The purpose of my role was to provide GCP quality oversight and QA support to the global clinical organisation and related departments in compliance with applicable GCP requirements and provide support in the development and improvement of the Quality Management System (QMS). I supported and gave advice in risk assessments, CAPAs, deviations, change control and training. I was the QA approver for SOPs, deviations and CAPAs in the QMS system. For the Global GCP audit program, I was accountable and responsible to plan, create and complete the program including leading cross functional risk assessments. I planned and participated in external audits. I performed document/desktop-based qualifications of third parties including risk assessments. In my responsibility for third parties, it additionally included review of contracts, to ensure inclusion of GCP sections (such as, regulations, standards, audits rights, subcontracted vendors, serious breach etc). In the GCP Regulatory Surveillance team I was responsible to ensure released documents was reviewed and assessed in time to identify required updates to our processes. I represented Global QA GCP in QMS KPI meetings and Quality Management Review meetings.

Aug 2007- Mar 2021: Study Manager Nordics, CRO Manager, Clinical Trials Manager at GlaxoSmithKline AB, Sweden

Between 2016 - 2021 I worked as a Study Manager in the Nordics. I had overall responsibility for studies allocated to me, in Sweden, Denmark and Norway. Main therapy areas: oncology and respiratory. I led study teams in start up, maintenance and close out in phase IIa- IV studies. I planned and evaluated study budgets, negotiated study agreements (internal/external) with sites and vendors (like pharmacies). I led feasibilities together with medical advisers. In respiratory and oncology studies I was the chair for the monthly cross functional meeting with Medical Affairs, Regulatory, Clinical Operations, Market Access and Pharmacovigilance. I participated in strategic planning together with other Study Managers, Head of Clinical Operation and Quality Manager, as risk management (risk plans, analysis and mitigation plans) quality control (management monitoring of processes at the department, investigational drug shipment logistics etc) on a department and country level, including align and develop new processes. I have participated in several site audits and company audits as an auditee.

During 2018- 2019 I led a pilot project, as part of building a Nordic clinical trials cluster. I was project leader of the first pilot study- for Denmark. This involved all parts of a new pilot project, as planning, goal setting, milestone planning, regulation review, map new landscape of stakeholders, build network, feasibility, risk plan, submissions to authorities, training of teams, lead study team, negotiate contracts for sites and vendors etc. I was accountable and performed study feasibilities (country/site level) to evaluate their possibilities to participate and recruit in a study.

Between 2015- 2016 I worked as an acting CRO Manager (approx. 15 consultants reporting to me), with both Clinical Research Associates and Clinical Trial Assistants in my team. I had oversight responsibility of CROs, negotiated contracts and was first point of contact for the CROs. GSK changed preferred partner during this period and I became process lead for Sweden, for implementation.

During 2013-2015 I led a pilot project as Scandinavian Project Leader in a hematology study. In my team I had (CRAs from Denmark and Norway).

During my time as Clinical Trials Manager I acted as mentor for junior CRAs, planned and initiated studies mainly in oncology and respiratory, been responsible for all start up activities (incl planning, recruitment strategies, communication plans, risk analysis, budgets, pre- study- and initiation visits at sites, site training, GCP training etc). Negotiated and completed study country budgets, pharmacy and sites, writing submissions to the ethics committee, regulatory authority, bio banks, radiations committees etc.

Jan 2006- Jul 2007: Clinical Research Associate at PharmaNet GmbH (CRO), Sweden

Worked as a CRA in oncology and cardiology studies in the Nordics, with several sponsors.

Jun 2005- Dec 2005: Pharmacist (Leg. Apotekare) at several pharmacies for Apoteket AB, Sweden

Worked as a licensed pharmacist in several pharmacies.

Education and training

Aug1999- Jun 2004: Apotekare, Master of Pharmacy (Msc) at Uppsala University, Sweden

Additional information

Publications

Projects

Memberships

Other Relevant Information