Employee Information

Full Name: Annette Brus, ?
Q Location: QUPP
Job Title: Sr CRA
Business Title: Sr CRA
Supervisor Name: Jannic Gasslander
Country of Residence: Sweden
Regular / Temp Status: Regular

Summary

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Formal Educational History

Last Date Attended	Institution Name, Country	Education Level/Degree	Area of Study	Completion Status
06/1975	Rudbeckskolan, Sweden	High school	Social programme	Completed
06/1977	Fridhemsplans gymnasium, Sweden	High school	Higher specialist course for medical secretaries	Completed
06/1994	Marknadsinstitutet, Sweden	Diploma	Market Economy	Completed
06/1998	Swedish Academy of Pharmaceutical Sciences, Sweden	Basic Course	Clinical Trial	Completed
06/2000	LIF - the research-based pharmaceutical industry in Sweden, Sweden	The LIF Course	Medical Basic Education	Completed
06/2010	Pharmacia, Janssen-Cilag, Serono plus SentoClone, Sweden	Internal rolebased	education in the field of medicine and GCP	Completed

Employment History

Quintiles Employment History

Date of Employment: 01/2015 - Present
Job Title: CRA
Business Title: CRA
Key Responsibilities: Working for Amgen
Theraputic areas.
Cardiology, onkology, neurology
Performing clinical trails in above areas as a sitemanager

Non-Quintiles Employment History

Date of Employment: 05/2011 - 12/2014
Name of Employer: Norma Cro
Job Title: CRA
Key Responsibilities: CRA Monitoring

Date of Employment: 05/2007 - 09/2010
Name of Employer: SentoClone AB
Job Title: Clinical Trial Manager
Key Responsibilities: Indication; Malignant Melanoma, Colorectal cancer,
Responsibilities:

·1 Involved in the protocol writing, planning and design of the eCRF and all other study documents

·2 Initial contact with investigator, negotiation of financial agreements with investigators

·3 Involved in the process of submission to authorities

·4 Overseeing the overall management of the tudy (timelines , budget, etc) and liaising with third party vendors

·5 Tracking of out of scope issues

·6 Monitoring

·7 Training the site personnel in the eCRF

·8 Conducting of regular investigator meetings

·9 Liaising with project managers within other departments

Date of Employment: 03/2005 - 05/2007
Name of Employer: Serono AB
Job Title: Clinical Research Scientist
Key Responsibilities: Indication: Neurology and Growth Hormones

·1 Initiating planning and conducting phase II - IV clinical studies in the Nordic Organization including the following steps in the process:

-initial contact with investigator
-negotiation of financial agreements with investigator and pharmacies
- submission to the ethics committees and the authorities
- organization of investigators meeting
- education of monitors and site initiation along with the monitor
- monitoring of the Swedish sites

·2 Cooperation with Corporate Clinical Trials at the headquarter in Geneva, participating in medical meetings and training of the company's SOPs

·3 Planning and initiating of other medical projects in the Nordic organization, often together with the marketing department

·4 Budget responsibilities for all projects

·5 Participation in scientific meetings and congresses

Responsibilities(Neurology):

·6 Responsible CTL in Sweden

·7 Lead CRA in a Nordic/French double blind phase II study

·8 Nordic responsible Project Leader in a double blind phase III investigator initiated study

·9 Responsible of several local phase IIIb/V studies

Responsibilities (Growth Hormones):

·10 Responsible CTL in Sweden, planning of and conducting several Nordic phase V studies in children and one phase III study in adults.

Date of Employment: 03/1997 - 03/2005
Name of Employer: Janssen-Cilag AB
Job Title: CRA, CTA, assist medic dep
Key Responsibilities: 1: Monitoring of several studies within neurology, psychiatry and gastroenterology.

2: Responsible for the administration of clinical trials and the Trial Master File, planning of investigator meetings and other activities, such as scientific meetings, international congresses.

3. Responsible for the handling of the investigational products.

4. Assistent to the Medical Director and aministrative support to the Medical Affairs Team.

Clinical Trial Experience

Quintiles Clinical Trial Experience

Study Phase: Phase 2
Indication: Migraine
Drug Class: Analgesics / Narcotics
# of Countries: 2
# of Sites: 4
# of Patients: 32
Role: Clinical Research Associate
Key Responsibilities: Site manager

Study Phase: Phase 2
Indication: Migraine
Drug Class: Analgesics / Narcotics
# of Countries: 1
# of Sites: 4
# of Patients: 32
Role: Clinical Research Associate
Key Responsibilities: Site manager

Study Phase: Phase 2
Indication: Migraine
Drug Class: Analgesics / Narcotics
# of Countries: 1
# of Sites: 4
# of Patients: 32
Role: Clinical Research Associate
Key Responsibilities: Site manager

Study Phase: Phase 3
Indication: Migraine
Drug Class: Analgesics / Narcotics
# of Countries: 1
# of Sites: 2
# of Patients: 20
Role: Clinical Research Associate
Key Responsibilities: Site manager

Study Phase: Phase 2
Indication: Hyperlipidemia
Drug Class: Hyperlipidemics
# of Countries: 1
# of Sites: 2
# of Patients: 20

Role: Clinical Research Associate
Key Responsibilities: Site manager

Study Phase: Phase 2
Indication: Hyperlipidemia
Drug Class: Hyperlipidemics
# of Countries: 1
# of Sites: 2
# of Patients: 25
Role: Clinical Research Associate
Key Responsibilities: Site manager

Study Phase: Phase 2
Indication: Malignant Tumor of Ovary
Drug Class: Antineoplastic Agents
# of Countries: 1
# of Sites: 2
# of Patients: 9
Role: Clinical Research Associate
Key Responsibilities: Site manager

Department Specific Experience

Department: Clinical

Category	Experience
Inform	1-2
Medidata Rave	3-5
OC-RDC	0
EDC-Other	>5
In-House Monitoring Experience: ≥5 Years	Yes
On-Site Monitoring Experience: ≥5 Years	Yes
Audits and/or Regulatory Inspection	Yes
Closure Visits	Yes
Collection and Review of Regulatory Packages	Yes
Conducting CRA Training	Yes
Conducting GCP Training	Yes
Drug Accountability	Yes
Feasibilities	Yes
ICF/Study Document Development	Yes
Initiation Visits	Yes
International Project Experience	Yes

Category	Experience
Investigator Meeting Attendance	Yes
Liaising with Customer and/or External Vendors	Yes
Line Management of Clinical Staff	Yes
Management of SAEs	Yes
Monitoring Visits & Source Data Verification	Yes
Query Resolution	Yes
Reg Body and/or Ethics Comm Submissions	Yes
Re-labeling and/or IP Recall Process	Yes
Site Contracting	Yes
Site Selection Visits	Yes
Study Files Maintenance	Yes

Language(s)

Language	Speaking	Reading	Writing
English	Fluent	Fluent	Fluent
Swedish	Fluent	Fluent	Fluent
French	Basic	Basic	Basic
Norwegian	Business Level	Business Level	Business Level