**Translator**

**Iryna Akhtyrska**

Contacts:

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**education**

Bachelors Degree in English and German languages, 2007

National University of Ostroh Academy, Ukraine

Specialist Degree in Business English, 2008

National University of Ostroh Academy, Ukraine

Bachelors Degree in Journalism, 2013

Lviv National University n.a. Ivan Franko, Ukraine

**Professional experience**

Parexel Ukraine, Kyiv, Ukraine CMA I November 2013 - July 2014

CMA: Clinical Monitoring Associate: Responsible for in-house clinical site monitoring, CRA and COL support

* Conduct remote visits (initiation, monitoring, termination)
* Collaborate with CRA on site issues/actions
* Perform regular reviews of site level data (e.g. EDC, ISIS) and ensure timely and high quality data entry compliance from sites
* Responsible for the follow up on CF QC findings raised by RMAs
* In case of necessity conduct brief translation of study related documentation
* Update all relevant tracking systems on an ongoing basis
* Collect updated/amended regulatory documents in collaboration with CRA and CTS as needed
* Provide collected documents to ROA for tracking, coding, scanning and uploading to WIP/sending to study mailbox, where possible
* Inform responsible COL of work status regularly
* Maintain a working knowledge and ensure compliance with applicable ICH-GCP Guidelines, local regulatory requirements and PAREXEL SOP and stud specific procedure (e.g. Monitoring Plan)

PPD, Kyiv, Ukraine  *SIA PA II April 2013 – November 2013*

PA: Project Assistant: Responsible for providing project administrative support to Clinical Team Managers, Project Managers and/or CRAs on designated project teams.

* Responsible for administration and preparation for trial set up
* Maintaining project files and documentation according to the relevant SOPs
* Assisting in preparation of Regulatory Authorities packages for submission.
* Preparation under supervision Ethics Committee packages for submission.
* Maintaining tracking databases
* Conduct of regulatory documents translation and documents related to local IEC approvals, submissions and notifications.
* Performing translation and QC of clinical trial document including but not limited to ICF and Patient Questionnaires.
* Providing support and help for new Pas who joined the company, performing “buddy” duties.
* Preparation of site specific essential documents necessary for site activation.
* Providing support to SIA CRAs and Country Approval Specialists

PPD, Kyiv, Ukraine *PA II January 2012 –April 2013*

PA: Project Assistant: Responsible for providing project administrative support to Clinical Team Managers, Project Managers and/or CRAs on designated project teams.

* Responsible for the background administration and preparation for trial set up
* Maintaining project files and documentation according to the relevant SOPs and WPDs
* Assisting in the organization of investigator, project team and client meetings
* Assisting in preparation of Regulatory and Ethics Committee packages
* Maintaining study status tracking forms, trial supplies dispatch and receipt records, investigator payment records, etc.
* Conduct of regulatory documents translation and QC.
* Maintaining tracking databases

LLC Staff Service Ukraina for Pfizer H.C.P. Corporation, Kyiv Ukraine

*Clinical Trial Assistant March 2011- January 2012*

* Support ing preparation of site initiation packages (e.g. SMF);
* Assistance CRAs for the responsibility of tracking, distribution and filing of clinical trial documents/information with quality review for accuracy and completeness;
* Support CRAs with handling all types of correspondence;
* Providing logistic and administrative support to project teams, including preparation for Investigator Meetings and other business events;
* Translation of documents related to clinical trials operations, including but not limited to RA approvals, notifications, submissions and reports.

Farmasoft CT LLC for Pfizer H.C.P. Corporation, Kyiv Ukraine

*Assistant to HCO December 2009- March 2011*

* Dealing with incoming emails, faxes and post, screen telephone calls, requests, correspond on behalf of
* the HCO if necessary;
* Producing documents, brief papers, reports and presentations;
* Translation of documents related to clinical trials operations, including but not limited to RA approvals, notifications, submissions and reports.
* Preparation of business trips orders/reports and financial monthly reports for HCO;
* Providing support during the meetings arranged by HCO's;
* Providing other administrative support within ClinOps, upon agreement with HCO.

Farmasoft CT LLC for Pfizer H.C.P. Corporation Kyiv Ukraine

*Clinical Trials Assistant November 2008-December 2009*

* Producing documents, brief papers, reports and presentations;
* Translation of documents related to clinical trials operations, including but not limited to RA approvals, notifications, submissions and reports.

Rivne OMNI-net Center

*Information Specialist August 2007- November2008*

* Translation of medical texts, including but not limited to newspaper articles, e-mails, reports and Power
* Point presentations;
* Interpreting during international conferences and workshops;
* Work with databases, including EUROCAT database and New-Borns Register;
* General office administration duties.

**LICENSES & CERTIFICATIONS**

* Students Literary Translation Contest, First Prize Diploma in English Language section, Donetsk National University, Donetsk, Ukraine, 2007
* GCP Training Certificate #2180, International Foundation for Clinical Research, Kyiv, Ukraine, 2009
* Certificate of EBA Personal Assistant School attendance, Kyiv, Ukraine, 2010

**Computer Experience**

MS Word, Excel, PowerPoint, Nitro Pro, Adobe Reader, Adobe Acrobat, Outlook, Internet Explorer - confident user

# TrANSLATION SKILLS

Translation pairs:

English – Ukrainian

Ukrainian – English

Russian – English

English - Russian