**Tel: +38-067 909 84 58, +38-095-076 97 00**

**E-mail:** **krasser@mail.ru**

**Skype:** **krasser1978**

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# EDUCATION

# National Technical University of Ukraine “Kyiv Polytechnic Institute” (NTUU “KPI”) *1995-2001*

# Master’s degree in Biotechnology \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# PROFESSIONAL EXPERIENCE

**bioRASI LLC,** Kyiv, Ukraine, [www.biorasi.com](http://www.biorasi.com) *May 2013 – May 2014*

Associate, Clinical

# CURRENT RESPONSIBILITIES:

* To be fully aware of the Sponsor’s Study requirements.
* To ensure selected study sites are having adequate qualification, resources and facilities/equipment and can provide adequate eligible subjects, the investigators are of adequate qualifications.
* Business Development Associate: looking for potential sites for Sponsors’ CT projects Phase I-IV, BE studies in Ukraine. Price and enrollment rate assessment according to study Synopsis, negotiations with potential PI’s.
* Collected and prepared documents for RA initial submission according to MoH local regulations.
* Perform all types of site visits including Site Selection, Initiation, Monitoring, and Close-out. Perform drug accountability and other monitor activities at clinical study sites to assure adherence to Good Clinical Practices (GCPs), SOPs, and study protocols.
* To ensure that IRB/Ethics Committees submissions have been timely conducted and approvals received.
* Liaison with Local Depot to ensure labkits and drug storage and shipment.
* Selection of vendors for CT purposes (translations, local depot, all-Ukrainian taxi service for CRAs, Investigators and patients).
* To be a first-line contact with Clinical Sites and report to the trial Manager all major site related issues in an expedited manner.
* AE/SAE/AESI expertise; to undertaking all efforts the safety and well-being of trial subject are fully protected.
* To ensure that Investigators are fully briefed on the study.
* Discuss the study requirements with the Investigators at the Investigators’ meeting, reinforcing information provided in format presentation.
* Ensure that Investigator receive all study documents and any updates of them.
* Motivate investigator and site staff, providing ongoing study training.
* Perform source documents verification, retrieve Case Report Forms (CRFs) and performed query resolution in a timely manner.
* To follow with appropriate filing of documents in Investigator Site File and In-house Investigator Site File.
* Function as mentor and role model for other CRA team members to ensure study specific training for CRAs; Perform co-monitoring visits with less experienced CRAs and at problem sites as required.
* Performed site facilities inspection
* Medical writing (IB) according to ICH GCP regulations.

**FIRST MEDICAL Co.,** Kyiv, Ukraine, Apr 2011 – May 2013

Director, Chief Editor

Clinical Research Associate (all activities).

Responsibilities:

* General Financial and Administrative Management of the First Medical company LLC.
* Monitored clinical studies according to Sponsor’s requirements and ICH Guidelines.
* Preparing documentation for necessary approvals, observing feasibility, recruitment, performing monitoring at sites, reporting visits and contacts with site, assuring the presence of all relevant documents on site, collaborating with other departments for reporting safety information, collecting Case Report Forms, following up and solving data queries, reporting the progress of the study on a regular basis.
* Responsible for obtaining of appropriate documentation from sites.
* Conducted monitor training for new Clinical Research Associates.
* Performed electronic database quality control maintenance.
* Conducted protocol training at Investigator sites.
* Performed close-out visits.
* Supported Clinical Operations and Medical Affairs teams.
* Provided documentation to Clinical Research Associates.
* Served on New Product Development Teams.
* Provided clinical study tracking and performance metrics.
* Provided in-house support for the CRAs during their site visits.
* Proofreading and interpretation of the texts of various areas of knowledge (predominantly medicine, chemistry, biotechnology, Life Sciences, laboratory and medical devices)
* Feasibility management of the sites for potential clinical trials in Ukraine and Russia.
* Regulatory activities (as a team member) for the MoH and LECs submission of new MS study in Ukraine.
* Managing the translators’ team. QA management.

**Freelance translator -** *2008 – 2011*

* Medical, pharmaceutical and technical En-Ru, Ukr translations including patents.

**Privately held company *“Comby Factory”***

Kiev, Ukraine, *2006 – 2008*

Production engineer (full time)

Responsibilities:

* Organization and planning the production on the basis of the claims of the division of the sale
* Organization of work and the control of the effectiveness of the work of the production personnel
* Phase-by-phase technological control of production according to the requirements of the system of management by quality ISO 9001.
* Chemical laboratory analyses of half-finished products and finished production to the correspondence of Technical Regulations.
* Correction of formulas and sequence of conducting of the technological process with the mastery of the new forms of production.
* Work with the English-language technical documents and chemical product catalogues and technical translation (En-Ru) for cosmetics industry as well.

**Assembleon LLC,** Kiev, Ukraine *2005- 2006*

Chemical engineer, technologist. The chief of QA Department (full time)

*Contract production of electronics, the SMD- installation of electronic printed-circuit boards.*

Responsibilities:

* Correction of formulas and sequence of conducting of the technological process with the mastery of the new forms of production.
* Current quality control (stage-by-stage the control of technological process and finished production)
* Organization and quality control of the work of production personnel, the guarantee of working discipline in the shop.
* Provided of an industrial laboratory with the necessary equipment, chemicals and laboratory furniture
* Search for vendors of ingredients, chem. raw materials for conducting the R&D.
* Collection and analysis of materials from the exhibitions and the seminars: International industrial forum -2005, 2006. Public Health - 2005, 2006 and earlier, INTERСHARM-2005, 2006, CleanExpo-2005, 2006).
* Survey of literature and patents on the appropriate area.
* Work with the English-language technical documents and technical translation.
* Developed the new formula of special technical washing detergent with the assigned properties

**JSC “DIAPROFMED”, KIEV (Pharmaceutical, biotechnological enterprise.)**, *2003 –2005*

Technology engineer (full time)

Responsibilities:

* Development and the production of immunoassay test- systems for diagnostics of a number of the diseases

The function responsibilities and the achievement:

* Took part in the development of the technology of the production of immunoassay diagnostic test- systems to AIDS, syphilis and so forth.
* Designed of technological regulations, PFD and PID according to the standards of ISO 9001 quality system requirements
* Calculation of the material balances
* Participation in the design of “cleanroom” projects according to GMP.

**State Scientific and Technological Center of Conservation and Restoration of Monuments (SSTC "CONREST")** *2001-2003*

Responsibilities:

* Individual selecting and development of conservation and restoration technologies. Diagnostics of biodeterioration types
* Searching for new analytical and microbiological test procedures and improvement and adaptation of existing ones, involving up-to-date devices and diagnostic systems.
* Investigation of compatibility of different construction materials.
* Technical consulting and technology project designation involving modern systems of construction materials.
* Technical translations (En-Ru) of DIN standards (Waterproofing of Buildings and Structures, etc).
* Taking part in exhibitions (Building & Architecture 2002,2003).
* Searching and testing of different antiseptics for elimination of microorganisms and preservation of materials and constructions.
* Current coverage of antiseptics and disinfectants market in Ukraine.
* Successful cooperation with "Ukrprojectrestoration, Kievstatexpertise” and others.

**NATIONAL TECHNICAL UNIVERSITY OF UKRAINE, BIOTECHNOLOGY DEPARTMENT, Kiev** *1998 – 2001*

**Engineer- laboratory assistant** (partial employment)

Responsibilities:

* Engineering enzymology (search and study of promising enzymes is certain, other additives for the food and pharma industry)
* Study of compositions for bacterial probiotics.
* Conducting chemical, biochemical and microbiological analyses and finalizing new test procedures as well.

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# COMPUTER EXPERIENCE

MS Windows, MS Office, Translation Workspace, Fortis Revolution, SDL Trados 2009,2011, Fine Reader 10.0, Acrobat, mail clients, EDC, IWRS

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# AREAS OF THERAPEUTIC MONITORING EXPERIENCE

Central nervous system, immunology, oncology, infectious diseases.

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**SELECTED CLINICAL TRIAL EXPERIENCE**

* 2012 – 2014 - Treatment of Spasticity in Patients with Multiple Sclerosis. Phase III study.
* 2010 - 2012 - Acute Bacterial Skin Infections Caused by Staphylococcus aureus. Phase II study.
* 2010-2012 - Open-label, relapsing-remitting multiple sclerosis (RRMS), Phase IV study.
* Dec 2011 – June 2012- Prevalence of Viral Condyloma’s, observational study.
* 2013 - HER2 Positive Early Breast Cancer. Phase III study