CURRICULUM VITAE

First Name/ Last Name	**MIHAELA LĂCRĂMIOARA TURLEA**
Address	18, Balanței Street, 300737, Timisoara, Romania
Telephone	**0040-746-913-373**
E-mail	mihaela.turlea@yahoo.com
Nationality	Romanian
Date and place of birth	10 May 1984, Brad, Romania

Professional Experience:

- **Clinical Research Regulatory Specialist & Quality Assurance Specialist at „Opera CRO" – Timisoara, Romania**

March 2016-Present

Responsibilities:

Coordinating efforts associated with the preparation of regulatory documents or submissions.
Coordinating, preparing, or reviewing regulatory submissions for domestic or international projects.
Identifying relevant guidance documents, international standards, or consensus standards and provide interpretive assistance.
Interpreting regulatory rules or rule changes and ensuring that they are communicated through corporate policies and procedures.
Maintaining current knowledge base of existing and emerging regulations, standards, or guidance documents.
Recommending changes to company procedures in response to changes in regulations or standards.
Obtaining and distributing updated information regarding domestic or international laws, guidelines, or standards.
Preparing or maintaining technical files as necessary to obtain and sustain product approval.
Reviewing product promotional materials, labeling, batch records, specification sheets, or test methods for compliance with applicable regulations and policies.
Writing or updating standard operating procedures, work instructions, or policies.
Communicating with regulatory agencies regarding pre-submission strategies, potential regulatory pathways, compliance test requirements, or clarification and follow-up of submissions under review.
Advising project teams on subjects such as premarket regulatory requirements, export and labeling requirements, or clinical study compliance issues.
Compiling and maintaining regulatory documentation databases or systems.
Determining the types of regulatory submissions or internal documentation that are required in situations such as proposed device changes or labeling changes.
Participating in internal or external audits.
Preparing or directing the preparation of additional information or responses as requested by regulatory agencies.
Providing technical review of data or reports that will be incorporated into regulatory submissions to assure scientific rigor, accuracy, and clarity of presentation.
Developing or conducting employee regulatory training.
Reviewing clinical protocols to ensure collection of data needed for regulatory submissions.
Preparing responses to customer requests for information, such as product data, written regulatory affairs statements, surveys, or questionnaires.
Escorting government inspectors during inspections and providing post-inspection follow-up information as requested.
Analyzing product complaints and making recommendations regarding their reportability.
Developing or tracking quality metrics.
Coordinating recall or market withdrawal activities as necessary.
Directing the collection and preparation of laboratory samples as requested by regulatory agencies.
Reviewing adverse drug reactions and file all related reports in accordance with regulatory agency guidelines.

- **Regulatory Affairs Assistant & Quality Assurance Associate at „Opera CRO" – Timisoara, Romania**

May 2015-February 2016

Responsibilities:

Ensuring that all processes contributing to the performance of a clinical trial are conducted properly.
Troubleshooting clinical trials and activities.
Managing and maintaining databases for the quality system.
Preparing and assisting in preparation of annual reports and quality trending reports.
Reporting the status of the quality levels of staff, systems and production activities.

Presiding over improvement programs.
Evaluating quality events, incidents, queries, and complaints.
Keeping up to date with all related quality legislation and compliance issues
Compiling and preparing materials for submission to regulatory agencies.
Documenting internal regulatory processes.
Ensuring regulatory rules are communicated through corporate policies and procedures.
Utilizing guidance documents, international standards, or consensus standards and interpret for guidance.
Ensuring that investigator, vendor, facility and system audits are conducted.
Communicating any critical compliance risks noted from these activities to senior management.
Assuming a lead role for the preparation, conduct, and responses to regulatory agency.
Providing leadership and strategy in line with global strategic objectives.

- **Bank Officer at *„Romanian International Bank"* – Timisoara, Romania**

June 2013-April 2015

Responsibilities:
Serving as one point telephonic contact to customers on banking solutions.
Advising bank customers on financial investments.
Handling customers professionally.
Learning about banking products to respond to related customer queries.
Monitoring staff duties like ledger entries, payment and trade authentication.
Supervising bank processes.
Investigating discrepancies in bank operations.
Communicating to Front Office and update department management of branch operations and status.
Inspecting staff preparation of payments and reports.
Conducting performance appraisal of bank staff.
Preparing management reports.

- **Commisioner at „O.A.D.O.R - Organization For The Defense Of Human Rights In Romania - NGO" – Timisoara, Romania**

November 2011 - Present

Responsibilities:
Prevention of crimes and abuses of human rights in accordance with internal regulations.

- **Collaborator at „C.R.F.C.A.P.L.T - Ministry of Internal Affairs" – Timisoara, Romania**

July 2011 – December 2011

Responsibilities:
Developing European projects
Training for public administration improvement.

- **Quality Manager at „ S.C. Energoterom SRL" – Timisoara, Romania**

March 2009 – July 2011

Responsibilities:
Quality System Management for Health, Environment and Operational Safety
Preparing and organizing of Internal audit for all systems.
SOPs implementation, continuous monitoring in order to improve the Quality System Management in accordance with ISO 9001:2000, ISO 14001:2004 and SR OHSAS 18001:2008 requirements.

Qualifications:

Good Clinical Practice (GCP) Certificate - NIDA Trial Network, April 2016
Human resources manager - S.C. PSIHO PROFIL SRL Timisoara, July 2011
Project manager - S.C. A&C CONSULTING CENTRE SRL Timisoara, May 2010
Leadership, resources management, coaching and sustainable development for environment protection - S.C. A&C CONSULTING CENTRE SRL Timisoara, May 2010
Process approach of management systems - S.C. Q-INSPECT SRL Bucharest, February 2010
Quality Auditors Trainer for Health and Occupational Safety – SRAC Bucharest, August 2009
Occupational Safety Inspector - S.C. GILAL SRL Timisoara, May 2009

Education:

Chemical engineering degree - Organic Chemical Technology - Politehnica University of Timisoara - UPT - 2008

Languages:

English (Effective operational proficiency or advanced);
French (Vantage or upper intermediate)

Clinical Study Experience
Phase III study, indication Orthopedics - Clinical Research Regulatory Specialist & Quality Assurance Specialist
Phase III study, indication Acute Low Back Pain - Clinical Research Regulatory Specialist & Quality Assurance Specialist
Phase III interventional study, indication Cataract and Presbyopia - Clinical Research Regulatory Specialist & Quality Assurance Specialist
Phase III retrospective study, indication Cataract and Presbyopia - Clinical Research Regulatory Specialist & Quality Assurance Specialist
Phase III study, indication Recurrent Bacterial Vaginosis - Regulatory Affairs Assistant & Quality Assurance Associate
Phase IV study, indication Pediatric Functional Constipation - Regulatory Affairs Assistant & Quality Assurance Associate
Phase III study, indication Orthopedics - Regulatory Affairs Assistant & Quality Assurance Associate
Phase III study, indication Diabetes - Regulatory Affairs Assistant & Quality Assurance Associate

Driving licence: B category

Skills: The participation in the research projects have developed my teamwork spirit and communication skills. I am attentive to details, I have sense of responsibility**,** I am open to new challenges and I want to develop my level of experience.

PC skills: IT literate
Microsoft Internet Explorer
Microsoft Office Suite (Word, Excel, Outlook, Power Point, Access)