AROOTIN GHARIBIAN

Ostrava-Poruba, Moravia-Silesia, Czechia

SKILLS

Industry Skills	**Regulatory Affairs, Scientific Marketing, In Vitro Diagnostics.**
Research Skills	**Clinical Research and Data Analysis, Systematic Reviews.**
Regulatory Knowledge	**EU-MDR & EU-IVDR, QMS, ISMS, Risk Management.**
Domain Knowledge	**Flow-Cytometry, Genomics and Molecular Biology.**
Tools & Frameworks	**LMS/DMS, Weka ML & Visualization Platform.**
Programming Languages	**R For Statistical Programming, Scripting.**

WORK HISTORY

Researcher, Computational Biology — **February 2022 - June 2023**
VSB - Technical University of Ostrava — ***Ostrava, Czechia***

Medical Writer, Pharmacovigilance — **August 2022 - December 2022**
Regulatory Affairs Team Lead, MDR — **May 2020 - August 2022**
ClinChoice LLC. — ***Yerevan, Armenia***

Application Sales and Scientific Marketing Specialist, IVD devices — **October 2017 - April 2020**
Electronic Pezeshki Pishrafteh Co. Ltd. — ***Tehran, Iran***

EXPERIENCE

Regulatory Affairs Team Lead, MDR — **ClinChoice LLC**

- **Coordinated MDR TD submission project in a cross-functional team.**
- **Supervised TD compilation for MDR re-certification submissions to a Notified Body: Submitted 50 Class II & III medical devices, and 2 combination products, in 18 months.**
- **Established control processes for continuous compliance of TDs with respect to EU-MDR.**
- **Defined standard procedure development strategies including: Training and Risk management plans complying with ISO-13485 & ISO-27701.**
- **Represented the Medical devices Regulatory Affairs team on RFP meetings.**
- **Prepared and conducted training for medical device regulations and QMS.**
- **Provided consultation for regulatory requirements of EU-MDR.**

Pharmacovigilance Medical Writer — **ClinChoice LLC**

- **Prepared Ad-hoc systematic reviews for submission to regulatory authorities.**
- **Developed high-level search strategy with surveillance physician and Medical librarians.**
- **Performed routine literature searches and identified/analyzed relevant publications.**
- **Performed Ad-hoc comprehensive Literature Review for designated safety signal.**
- **Developed key timelines for medical writing production and delivery.**

Application Sales and Scientific Marketing — **Electronic Pezeshki Pishrafteh Co. Ltd.**

- **Management of scientific marketing activities for haemostasis and haematology IVD Devices.**
- **Supported regulatory affairs and quality assurance for continuous availability of critical centers.**
- **Management of process adaptation and methodology transition for ISO 15189 compliance.**
- **Executed training activities for end-users and internal field service engineers.**
- **Executed sales trend and competition analysis for 200+ nation-wide devices.**
- **Implemented new testing protocols based on national requirements.**
- **Mediated post-market quality review and adverse event reporting.**

RESEARCH EXPERIENCE

Research Scientist — **VSB - TUO**

- **Implemented ML algorithm for movement detection of migratory cells *in-vitro*.**
- **Implemented Clinical Data Analysis pipeline for unsupervised data mining.**

Research Associate — **NIGEB**

- **Submitted and was awarded a grant from ICGEB.**
- **Published a Literature Review for non-invasive methods of early detection of breast cancer.**
- **Analysed data for early detection of breast cancer using plasma cell-free DNA methylation pattern.**

EDUCATION

Cellular and Molecular Biology *

Master of Science; — **2011 – 2014**
Thesis Title: A study on the role of LTBP-1 in human trabecular meshwork cells. — ***University of Tehran***

Bachelor of Science; — **2006 - 2010**
Thesis Title: Genetic delimitation of *Amaranthaceae* and *Plumbaginaceae* populations. — ***University of Tehran***

TRAINING

MDR regulatory affairs comprehensive training: — **May 2020**
Technical Documentation, NB submission, GDP, GMP, GDPR. — ***Ethicon, Inc.***

Pharmacovigilance medical writing: — **August 2022**
Regulatory Systematic Review Writing, AMA Manual of Style, GVP — ***Janssen Pharmaceuticals***

AWARDS

Google Android Security Award — **May 2022**
For characterization of a High Severity Security Vulnerability affecting Android 10, 11, 12, 12L.

* Official statement of comparability to EU equivalent degree available, issued by Palacký University, Olomouc, Czech Republic.