

AROOTIN GHARIBIAN


Ostrava-Poruba, Moravia-Silesia, Czechia

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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 VSB - Technical University of Ostrava 	February 2022 - June 2023 Ostrava, Czechia
Medical Writer , Pharmacovigilance Regulatory Affairs Team Lead , MDR ClinChoice LLC	August 2022 - December 2022 May 2020 - August 2022 Yerevan, Armenia
Application Sales and Scientific Marketing Specialist , IVD devices Electronic Pezeshki Pishrafteh Co. Ltd.	October 2017 - April 2020 Tehran, Iran

EXPERIENCE

Regulatory Affairs Team Lead , MDR	ClinChoice LLC
<ul style="list-style-type: none">Coordinated MDR TD submission project in a cross-functional team. Supervised TD compilation for MDR recertification submissions to a Notified Body: 50 Class II & III medical devices, and 2 combination products submitted in 18 months.Established the control process for continuous compliance of TDs with respect to EU-MDR.Defined correct procedure development strategies for ISO-13485 & ISO-27701, including: Training plan, RARTPs, Standard Operating Procedures.Represented the Medical devices Regulatory Affairs team on RFP meetings.Prepared and conducted training related to medical device regulations.Provided consultation for regulatory requirements of EU-MDR.	
Pharmacovigilance Medical Writer	ClinChoice LLC
<ul style="list-style-type: none">Developed high-level search strategy with Surveillance Physician and Medical Librarians. Prepared Ad-hoc systematic reviews for submission to regulatory authorities.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.

- Executed scientific marketing activities, including:
Sales trend and competition data analysis,
- application haemostasis and haematology IVD Devices.
- Post-market quality review and adverse event reporting.
- Management of process adaption and methodology transition,
- Making available new testing protocols based on national requirements,
- Supporting regulatory affairs and quality assurance roles.

RESEARCH EXPERIENCE

Research Scientist

VSB - Technical University of Ostrava

- Implementation of ML algorithm for movement detection of *in-Vitro* migratory cells
- Clinical Data Analysis, Data Mining with supervised learning and association networks.

Research Associate

NIGEB

- Project: Early Detection of Breast Cancer using plasma cfDNA methylation pattern.
- Data Analysis, [Literature Review](#).

EDUCATION

[University of Tehran](#)

Master of Science; *Cellular and Molecular Biology**

Sep. 2011 – Sep. 2014

Thesis Title: A study on the role of LTBP-1 in human trabecular meshwork cells.

Bachelor of Science; *Cellular and Molecular Biology*

Sep. 2006 - Sep. 2010

Thesis Title: Genetic delimitation of [Amaranthaceae](#) and [Chenopodiaceae](#) populations.

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.

RELEVANT EXTRA-CURRICULAR ACTIVITIES

Birthright Armenia Volunteer program,
Institute of Molecular Biology, Bio-Informatics Group.

Dec. 2019
Yerevan, Armenia.

* Official statement of comparability to EU equivalent degree available, issued by [Palacký University, Olomouc, Czech Republic](#).