CURRICULUM VITAE

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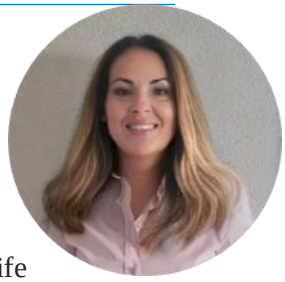

INTRODUCTION

Highly motivated Engineer with a BSc in Production Management and a keen interest in Life Sciences and Medical Technology. I recently pursued an advanced degree in Clinical, Regulatory Affairs, and Quality Assurance in Medical Devices and In-Vitro Diagnostics at FHNW School of Life Sciences. With over 15 years of experience supporting executive roles, I have a robust background in technical and administrative support across steel manufacturing, medical, biotechnology, and food industries. I excel in communication, teamwork, and conflict resolution, with strengths in problem-solving, analytical thinking, and decision-making. My exceptional organizational skills, adaptability, technical proficiency, and dedication to customer service ensure I consistently meet and exceed professional standards and client expectations.

PROFESSIONAL EXPERIENCE

05/2024 - **RAPS Switzerland Chapter – Chapter volunteer (remote)**

Regulatory Affairs Professionals Society (RAPS), Zürich, Bern, Basel, Vaud

05/ 2023-10/2023 **Intern, MedTech, Clinical, Regulatory Affairs and QA**

HL Technologies SA, La Chaux-de-Fonds, CH – Medical Device Manufacturer

- Device Qualification and classification
- QMS 13485
- Setting-up list of applicable standards for dental prosthetics device
- General Safety and Performance Requirements incl. identification of applicable requirements.
- Justification on non-applicable requirements and mapping of requirement to the applicable standard/method
- Verification and validation plan: Target relevant verification and validation activities (tests) to show compliance to the applicable GSPRs.
- Clinical Evaluation: assess biological equivalence due to material changes, evaluating clinical equivalence regarding performance and safety and ensuring technical equivalence in functionality and specifications.

01/2022-04/2023 **Assistant to Project/Archive Coordinator, Biotechnology, R&D Sample Archive**

LabCorp Drug Development, LabCorp Central Laboratory Services Sàrl, Füllinsdorf, Switzerland

- Assisted to the Sample Management Unit and R&D Archive of Central Nonclinical Laboratory Services in Project of Site Closure
- Perform variety of responsibility in compliance with GLP and GDP to ensure that services to clients, Pharma and MedTech companies, are provided in timely manner or as agreed in Service level Agreement.
- Accurate protocol and relevant documentation interpretation (i.e Sample Analysis Outline, Material Safety Data Sheet, Databases, client paperwork - more than 1000 clients).
- Sample and Raw data accession core tasks, including labelling, archival, disposal and trucking by using tracking system as appropriate to maintain sample, study, and data integrity.
- Document and record files, update database, and assist with problem solving, training and development to ensure adherence to company Global/Regional/Local SOPs as appropriate.
- Complies with relevant Environmental, Health and Safety Regulations and Company Policies.

2017-2021 **Business Owner, Facility Management, Client Services**
House Cleaning Juric, Dornach, Switzerland

- Managed company through business plan and develop, organize, and directed day-to-day operations.

2010-2015 **Senior Project Associate/Project Associate, Production &Trade, Health Care Line**

Neva Product Lupo Group, Health Care Line, Serbia

- Developed mid- and long-term contract plans by preparing strategies for protection, growth, and diversification of relationships with target customers and Health Care product portfolio management.
- Negotiated contracts with third-party companies for procurement of products, ensuring favorable terms and pricing.
- Organization and presentation of the products portfolio to potential clients.
- Collaborated with repair centers as part of the quality control process to guarantee that customer complaints were effectively resolved, and products were restored to optimal functionality.
- Logistic support

2008- **Assistant to Vice President of Operations for Europa/Eastern Europa, Mechanical Manufacturing, Replace, Repair and Rebuild**

Bearing Service Company of Pennsylvania, Serbia and Slovakia (US Steel Corporation plants)

- Assisted to the Vise President of Operations in Project Plant Preventive and Corrective Maintenance Operations (OEM industrial parts, MRO replacement parts, industrial equipment repair and rebuild) in US Steel Corporation plants in Serbia and Slovakia.
- Collaborate closely with cross-functional engineering teams (Design and Technology, Manufacturing Engineering for technique approvals, Repair Service Engineering for repair methods scheme approvals, R&D and Maintenace) from BSC, US Steel and SKF Sweden companies.
- Assisted in target critical points. root cause analysis and ensured high-quality industrial parts, the authenticity and reliability of components used in preventive and corrective maintenance operations and quality assurance and control procedure.
- Purchasing, logistic, appropriate documentations, and optimizing consignment stock min-max level for preventive measures and implement response for corrective measures.
- Responsible for general communication and collaboration with US Steel Corporation Executive Management and stakeholders.

2008- **Diploma Thesis**

Bearing Service Company of Pennsylvania, Serbia and Slovakia (US Steel Corporation plants)

- Research Project elements of mechanical engineering: Sliding and Rolling bearings and their characteristics in US Steel Corporation Plants in Serbia.

Testing and analyzing the starting friction coefficient and rotational torque, fatigue strength; the static load-carrying capacity; thermal conductivity and thermal expansion, preloading, etc.

2004- **Associate Managing Director**

DOO Production and Trade Nevena-Komerc, Serbia

- Managed the business's process and delivered day-to-day operation by implementing strategic initiatives and achieving organizational goals across 2 departments - leading team of 15 individuals.

1999- **Technical Secretary to the Director of Centre**
Centre for Social Work - Public Institution of Ministry of Labour, Employment, and

Social Affairs

- General Administration

EDUCATION

2023-2025 **MSc in Medical Technology in Regulatory Affairs – ongoing process, Atlantic Technological University of Ireland (rebranding University of Galaway).**

- Introduction to EU Medical Technology Regulatory Affairs
- Introduction to US Medical Technology Regulatory Affairs
- Technical Report Writing
- Global Medical Technology Regulatory Affairs Part 1
- Clinical Evaluation Reporting
- Quality Management System
- EU Medical Technology Regulatory Affairs- Advanced
- US Medical Technology Regulatory Affairs Advanced
- Risk Management, Labelling and Promotion
- Global Medical Technology Regulatory Affairs Part 2
- Design Assurance, Sterilization and Biocompatibility
- Post Market Surveillance

2022-2023 **CAS CA/RA/QA in Medical Devices and In Vitro Diagnostic, Life Sciences FHNW, Switzerland**

- Clinical Affairs, Regulatory Affairs and Quality Assurance in Medical Devices and In Vitro Diagnostic.
- Optimal preparation for regulation according to MDR 2017/745 and IVDR 2017/746
- Strategic planning and management of clinical evaluations, investigations in accordance with ISO 14155 and performance studies of IVDs
- Strategic and tactical communications for interactions with Notified Bodies and National Competent Authorities, as well as crisis management
- Management and technical support for new product development projects Leadership in implementing and maintaining ISO 13485 and US QSR quality management systems.
- Structuring of supply chain, production and marketing
- Technical expertise in key subjects such as Risk Management, Biocompatibility, Usability and software validation, according to current standards,

2006-2010 **BSc Engineering in Production Management, Technical Sciences, Technical University Novi Sad, Serbia.**

- Mathematics, Physics
- Materials and Technologies, Mechanical Engineering, Maintenance Technology
- Engineering, Innovation, and Industrial Design, Electrical Engineering and Electronics
- Quality Management System
- Principles of Projecting Machines, Projecting of Production Systems
- Probability, Statistics and Operational Research
- Environmental Engineering, Energetics and industrial Hydraulic and Pneumatics
- Information Systems and Graphic Communication Systems
- Strategic and Operation Management

Secondary Technical School "Milentije Popovic", Serbia

- Electrotechnics

FUTHER EDUCATION

Project Management course module of CAS, EPFL École polytechnique Lausanne, Switzerland.

- Development of a wearable device for subcutaneous drug injection / Group Project u Directeur du module dans le cadre de l'EPFL.
- Comprehensive analysis of the key factors you would consider when constructing a investment portfolio, in the pharmaceutical industry / Individual Project under Pharmaceuticals".

CERTIFICATES AND TRANINGS

- Good Manufacturing Practice and Good Distribution Practice - Concept Heidelberg.
- Good Laboratory Practice, Good Documentations Practice, Good Clinical Practice - LabCorp Drug Development.
- ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories Awareness, - BSI Training Academy

LANGUAGES

- Serbian/Croatian (mother tongue)
- English (fluent)
- German (A2)

REFERENCES

- Adrian Banderet, CEO at Hader Solutions & Distribution Ltd., QARA Director, HL Technology SA, La Chaux-de-Fonds, Neuchâtel, Switzerland,
- Marcel Lüscher, Archive Manager of Labcorp Drug Development, Füllinsdorf Switzerland.
- Health Care Line Neva Product Lupo Group, Serbia, Bozidar Stoiljkovic, Line Manager,
- Derek Cline, Vice President of BSC of Pennsylvania, United States.