

CURRICULUM VITAE

PERSONAL INFORMATION

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Nationality	Romanian
Birth date	

WORK EXPERIENCE

- | | |
|---|---|
| <ul style="list-style-type: none">• Occupation held• Date (from - to)• Name and address of the employer• Type of business• Main activities and responsibilities | <p>Executive Director - Quality Assurance Unit
10.2021 – present
Antibiotice S.A., 1 Valea Lupului Str., Iași, Romania</p> <p>Pharmaceutical Industry</p> <p>Implementation of the company business strategies by planning, organizing, coordinating and controlling the activities of the subordinate structures;</p> <p>Annual establishing of the objectives of the subordinated structures according to the objectives of the Unit</p> <p>Establishing responsibilities for meeting the objectives of the Unit</p> <p>Implementation and maintaining of an Integrated Management System (Quality, Environment, Occupational Health and Safety) to ensure compliance of the facilities, equipment, personnel, processes, methods and procedures of the company with the GMP principles and the requirements of the ISO 9001:2015, ISO 14001:2015, and ISO 45001:2018 standards</p> <p>Support and development of the local and international business partnerships by managing the process of obtaining and maintaining the necessary authorizations for the pharmaceutical products and active ingredients</p> |
| <ul style="list-style-type: none">• Occupation held• Date (from - to)• Name and address of the employer• Type of business• Main activities and responsibilities | <p>Business Development Manager
02.2020 to 10.2021
Antibiotice S.A., 1 Valea Lupului Str., Iași, Romania</p> <p>Pharmaceutical Industry</p> <p>Coordination of the department activities</p> <p>Research and identification of new business opportunities, including new markets, potential development areas, trends, customers, partnerships, products and services, or new ways to reach the existing markets</p> <p>Encouraging training and supporting team members to develop their skills.</p> |
| <ul style="list-style-type: none">• Occupation held | <p>Regulatory Affairs Manager, Antibiotice S.A. Iași</p> |

<ul style="list-style-type: none"> • Date (from - to) • Name and address of the employer • Type of business • Main activities and responsibilities 	<p>07.2011 to 03.2020</p> <p>Antibiotice S.A., 1 Valea Lupului Str., Iași, Romania</p> <p>Pharmaceutical Industry</p> <p>Coordination of the department activities</p> <p>Developing and updating global, regional or national regulatory strategies</p> <p>Strategic regulatory support for the research, development and clinical trials of all products, especially the complex and /or critical ones</p> <p>Supervision for compliance with the regulations applicable to the documentation supporting product quality, safety and efficiency</p> <p>Negotiation with the regulatory authorities on complex issues throughout the entire product life cycle</p> <p>Establishing and maintaining relationships with multiple governmental and non-governmental organizations with an impact on market access and distribution</p>
<ul style="list-style-type: none"> • Occupation held • Date (from - to) • Name and address of the employer • Type of business • Main activities and responsibilities 	<p>Head of Regulatory Affairs Department</p> <p>02.2007 to 07.2011</p> <p>Antibiotice S.A., 1 Valea Lupului Str., Iași, Romania</p> <p>Pharmaceutical Industry</p> <p>Coordination of the department activities</p> <p>Developing and updating global, regional or national regulatory strategies</p> <p>Strategic regulatory support for the research, development and clinical trials of all products, especially the complex and /or critical ones</p> <p>Supervision for compliance with the regulations applicable to the documentation supporting product quality, safety and efficiency</p> <p>Negotiation with the regulatory authorities on complex issues throughout the entire product life cycle</p> <p>Establishing and maintaining relationships with multiple governmental and non-governmental organizations with an impact on market access and distribution</p>
<ul style="list-style-type: none"> • Occupation held • Date (from - to) • Name and address of the employer • Type of business • Main activities and responsibilities 	<p>Regulatory Affairs Officer - authorisation/renewal procedures for foreign countries</p> <p>02.2005 to 01.2007</p> <p>Antibiotice S.A., 1 Valea Lupului Str., Iași, Romania</p> <p>Pharmaceutical Industry</p> <p>Coordination of the authorisation/renewal procedures for foreign countries</p>
<ul style="list-style-type: none"> • Occupation held • Date (from - to) • Name and address of the employer • Type of business • Main activities and responsibilities 	<p>Pharmacist - Regulatory Affairs Department</p> <p>10.2003 to 02.2005</p> <p>Antibiotice S.A., 1 Valea Lupului Str., Iași, Romania</p> <p>Pharmaceutical Industry</p> <p>Elaboration of the authorisation/renewal dossier</p>
<ul style="list-style-type: none"> • Occupation held 	<p>Head Pharmacist</p>

• Date (from - to)	08.1997 to 07.2003
• Name and address of the employer	SC Montero Iași
• Type of business	Wholesale distribution and storage company
• Main activities and responsibilities	Coordination of the activity

EDUCATION AND TRAINING

• Date (from – to)	1992 to 1997
• Name and type of organization providing education and training	"Gr. T. Popa" University of Medicine and Pharmacy of Iași, Romania, Faculty of Pharmacy
• Specialization	Pharmacist
• Date (from – to)	2000
• Name and type of organization providing education and training	"Management and Marketing Techniques", course held by the Chamber of Commerce and Industry of Iasi
• Specialization	Management and Marketing
• Date (from – to)	2005 to 2007
• Name and type of organization providing education and training	"Al. I. Cuza " University of Iasi, Postgraduate School of Economics – ELITEC
• Specialization	Master's degree in International Affairs
• Date (from – to)	22-23.02.2006
• Organization	Certificate of Continuing Professional Development, Pharmaceutical Training International: „Preparing the Chemistry and Pharmacy section of the CTD”
• Specialization	EU's pharmaceutical legislation
• Date (from – to)	24-25.07.2006
• Organization	Certificate of Continuing Professional Development, “Regulatory Affairs Training: Generic Registration” by Cardinal Health, UK
• Specialization	Regulatory Affairs
• Date (from – to)	28 – 29.05.2007
• Organization	Certificate of Continuing Professional Development „US-FDA Drug Submission Procedures”, Pharmaceutical Training International, at Antibiotice Iași
• Specialization	Regulatory Affairs
• Date (from – to)	31.05 – 01.06.2007
• Organization	Certificate of Continuing Professional Development „US-FDA Drug Submission Procedures”, Pharmaceutical Training International, at Antibiotice Iași
• Specialization	Regulatory Affairs
• Date (from – go)	29.06–09.07.2010

<ul style="list-style-type: none"> • Organization • Specialization 	Summer School a+: “Management and Development in the Age of Turbulence” module, held by lecturers from the “Al. I. Cuza” University of Iași, Faculty of Economics and Business Administration
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	25.03.2011 Consultation with target patient groups for the Package Leaflet. Regulatory Affairs
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	06 – 07.2011 Summer School a +, 2 nd Edition: module I “Creativity and Innovation”, lecturers from the “Al. I. Cuza” University of Iași, Faculty of Economics and Business Administration, Module III “Labour Legislation”, lecturers from the Territorial Labour Inspectorate of Iasi Business
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	06 – 07.2012 Summer School a +, 3 rd Edition: “Creativity, Innovation and Improvement” module, with the two components, i.e. “Ideas Are Free of Charge” and “Process Management; Organizational Behaviour”, lecturers from the “Al. I. Cuza” University of Iași, Faculty of Economics and Business Administration Business
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	10.2012 “Medicine and Faith. The Elderly Patient: An Approach with Science and Soul” Symposium organized by the College of Pharmacists from Romania. Health
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	01.2013 The National Conference of Modern Medical Interdisciplinary Management, 1 st Edition, Iași organized by the The College of Pharmacists from Romania and Oameni si Companii Ltd.. Management
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	06 - 07.2014 Summer School a+, 5 th Edition: “Organizational Development” module, lecturers from the “Al. I. Cuza” University of Iasi, Faculty of Economics and Business Administration Business
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	09.2014 Training: “Quality by Design”, lecturers from UMETRICS, held at Antibiotice Iasi Regulatory
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	02.2015 “Filling Variations” held by <i>Informa Life Sciences</i> , London, UK Regulatory Affairs
<ul style="list-style-type: none"> • Date (from – to) 	25.07.2019

<ul style="list-style-type: none"> • Organization • Specialization 	“Time Management”, International Job Finder Management
<ul style="list-style-type: none"> • Date (from – to) • Organization 	13.10.2020 „Analytical Instrument Qualification – a Continuum of Requirements from USP 1058 to GAMP 5”, a webinar held by ISPE
<ul style="list-style-type: none"> • Date (from – to) 	QA/QC
<ul style="list-style-type: none"> • Organization 	25.11.2020 “Evaluation of N-nitrosamines – Examining the Tools and Systems to Assist in such Assessments”, a webinar held by Scientific Update
<ul style="list-style-type: none"> • Specialization 	QA/QC
<ul style="list-style-type: none"> • Date (from – to) • Organization 	24.03.2021 „Sterility Series – What Can We Expect from New Annex 1”, an RSSL webinar, presented by Tim Sandl
<ul style="list-style-type: none"> • Specialization 	QA/QC
<ul style="list-style-type: none"> • Date (from – to) • Organization 	5.12.2020 “How to Avoid the Next Nitrosamine Crisis: 5 Lessons Learned about Impurity Detection”, a webinar held by Waters & Select Science
<ul style="list-style-type: none"> • Specialization 	QC
<ul style="list-style-type: none"> • Date (from – to) • Organization 	9.12.2020 “How to Master Raw Material ID in 2021”, a webinar organized by the European Pharmaceutical Review & Thermo Fisher Scientific
<ul style="list-style-type: none"> • Specialization 	QA/QC
<ul style="list-style-type: none"> • Date (from – to) • Organization 	24.04.2021 “GMP Refresher Interactive Training & Tests in Following Topics: GMP Knowledge, Qualification/Validation, Change Control, Deviations, Cleaning, Documentation”, held by Concept Heidelberg, the European Compliance Academy
<ul style="list-style-type: none"> • Specialization 	QA
<ul style="list-style-type: none"> • Date (from – to) • Organization 	28.04.2021 „Quality Risk Management for Pharmaceuticals”, an RSSL webinar presented by Tim Sandl
<ul style="list-style-type: none"> • Specialization 	QA
<ul style="list-style-type: none"> • Date (from – to) • Organization 	11.05.2021 „How Data Integrity is your first step toward a Pharma 4.0 strategy”, a webinar held by the European Pharmaceutical Review & Thermo Fisher Scientific
<ul style="list-style-type: none"> • Specialization 	QA/QC
<ul style="list-style-type: none"> • Date (from – to) • Organization 	26.05.2021 „Advancing Pharmaceutical Quality, Corrective Action/Preventive Action”, a webinar organized by ISPE
<ul style="list-style-type: none"> • Specialization 	QA
<ul style="list-style-type: none"> • Date (from – to) • Organization 	01.06.2021 „Quality Risk Management Tools to Improve Data Integrity in Micro QC”, a webinar organized by the European Pharmaceutical Review
<ul style="list-style-type: none"> • Specialization 	QA/QC

• Date (from – to)	30.06.2021
• Organization	„Cleanroom Design and Certification”, a webinar organized by RSSL, presented by Tim Sandl
• Specialization	QA
• Date (from – to)	29.09.2021
• Organization	“Spores in My Cleanroom – Remediation and Disinfection Strategies”, a webinar organized by RSSL, presented by Tim Sandl
• Specialization	QA/QC
• Date (from – to)	10.02.2022
• Organization	“Overview of ICH Q7 Online Training Courses”, a webinar organized by PDA
• Specialization	QA/QC
• Date (from – to)	24.02.2022
• Organization	“BE Studies with PK Endpoints for Drugs Submitted Under an ANDA Webinar”, organized by CDER Small Business and Industry Assistance (CDER SBIA) FDA, presented by Brenda Stodart
• Specialization	RA
• Date (from – to)	26-27.04.2022
• Organization	“Generic Drugs Forum 2022”, held by CDER Small Business and Industry Assistance (CDER SBIA) FDA, presented by Brenda Stodart
• Specialization	RA
• Date (from – to)	01.06.2022
• Organization	“Microbial Investigations: A New Standard from PDA”, organized by the European Pharmaceutical Review
• Specialization	QC
• Date (from – to)	20.06.2022
• Organization	“eLearning Foundations of GMP: Medicinal Products”, organized by PQM
• Specialization	QA/QC
• Date (from – to)	04.07.2022
• Organization	“eLearning Foundations of GMP: Quality Risk Management”, organized by PQM
• Specialization	QA/QC
• Date (from – to)	04.07.2022
• Organization	“eLearning Foundations of GMP: Deviations, Root Cause Analysis (RCA) Tools and Corrective and Preventive Action (CAPA) – Sequence Flow for Handling of Any Non-conformance in the GMP Environment”, organized by PQM
• Specialization	QA/QC
• Date (from – to)	12.07.2022
• Organization	“eLearning Foundations of GMP: Validation”, organized by PQM
• Specialization	QA/QC
• Date (from – to)	12.07.2022
• Organization	“eLearning Foundations of GMP: Qualification”, organized by PQM
• Specialization	QA/QC
• Date (from – to)	14.07.2022

• Organization	“eLearning Foundations of GMP: Data Integrity and Computer System Validation”, organized by PQM
• Specialization	QA/QC
• Date (from – to)	18.07.2022
• Organization	“eLearning Foundations of GMP: Auditing”, organized by PQM
• Specialization	QA/QC
• Date (from – to)	09.08.2022
• Organization	“eLearning Foundations of GMP: Water Systems”, organized by PQM
• Specialization	QA/QC
• Date (from – to)	09.11.2022
• Organization	“EU GMP Annex 1 – the Focal Point”, organized by RSSL
• Specialization	QA/QC
• Date (from – to)	18.01.2023
• Organization	“The Contamination Control Strategy – Putting the Jigsaw Together”, organized by RSSL
• Specialization	QA/QC
• Date (from – to)	31.01.2023
• Organization	“How to Develop an Effective Contamination Control Strategy”, held by NSF Health Science Ltd
• Specialization	QA/QC
• Date (from – to)	08.03.2023
• Organization	“Annex 1 2022 is Really Annex 1 2008: Learn How They Align”, organized by the European Pharmaceutical Review
• Specialization	QA/QC
• Date (from – to)	19.04.2023
• Organization	“Designing a Cleaning Validation Strategy”, organized by RSSL
• Specialization	QA/QC

PERSONAL SKILLS AND COMPETENCES

Mother tongue	Romanian			
Other foreign languages	English	Reading skills Proficient user	Writing skills Proficient user	Speaking skills Proficient user
	French	Elementary User	Elementary User	Elementary User
Social skills and competences	Team work and intercultural skills			
Driving license	B from 1999			