

CURRICULUM VITAE

PERSONAL INFORMATION

Name	Gianina - Gabriela MACOVEI
Nationality	Romanian
Age	42

WORK EXPERIENCE

<ul style="list-style-type: none">• Occupation held	Executive Director – Portfolio Management
<ul style="list-style-type: none">• Date (from - to)	05.2023 – present
<ul style="list-style-type: none">• Name and address of the employer	Antibiotice S.A., 1 Valea Lupului Str., Iași, Romania
<ul style="list-style-type: none">• Type of business	Pharmaceutical Industry
<ul style="list-style-type: none">• Main activities and responsibilities	Implementation of the companies' business strategies by planning, organizing, coordinating and controlling subordinate structural activities, according to the "from molecule to market" concept; Coordination of the Research Center's activity (pharmaceutical development, analytical research, clinical studies) Coordination of the activity of the Medical Department (portfolio management, scientific documentation and medical advisory, pharmacovigilance, scientific promotion, media promotion) Development of national and international business partnerships, by managing the companies' product portfolio;
<ul style="list-style-type: none">• Occupation held	Executive Manager – Sterile Products and APIs Division, Antibiotice S.A., Iasi
<ul style="list-style-type: none">• Date (from - to)	11.2022 – 05.2023
<ul style="list-style-type: none">• Name and address of the employer	Antibiotice S.A., 1 Valea Lupului Str., Iași, Romania
<ul style="list-style-type: none">• Type of business	Pharmaceutical Industry
<ul style="list-style-type: none">• Main activities and responsibilities	Implementation of the company business strategies by planning, organizing, coordinating, and controlling the activities of the subordinate structures; Coordination of the activity of sterile injectable powder production site; Coordination of the activity of the production site active substances obtained through the biosynthesis process; Supporting the inspections and audits carried out by the competent

	authorities as well as business partners, in accordance with EU's GMP, US FDA, ISO legislation
<ul style="list-style-type: none"> • Occupation held 	Manager – Sterile Products and APIs Division, Antibiotice S.A., Iasi
<ul style="list-style-type: none"> • Date (from - to) 	11.2021 – 11.2022
<ul style="list-style-type: none"> • Name and address of the employer 	Antibiotice S.A., 1 Valea Lupului Str., Iași, Romania
<ul style="list-style-type: none"> • Type of business 	Pharmaceutical Industry
<ul style="list-style-type: none"> • Main activities and responsibilities 	<p>Implementation of the company business strategies by planning, organizing, coordinating, and controlling the activities of the subordinate structures;</p> <p>Coordination of the activity of sterile injectable powder production site;</p> <p>Coordination of the activity of the production site active substances obtained through the biosynthesis process;</p> <p>Supporting the inspections and audits carried out by the competent authorities as well as business partners, in accordance with EU's GMP, US FDA, ISO legislation</p>
<ul style="list-style-type: none"> • Occupation held 	Manager – Clinical Trials Center, Antibiotice S.A., Iasi
<ul style="list-style-type: none"> • Date (from - to) 	06.2021 – 11.2021
<ul style="list-style-type: none"> • Name and address of the employer 	Antibiotice S.A., 1 Valea Lupului Str., Iași, Romania
<ul style="list-style-type: none"> • Type of business 	Pharmaceutical Industry
<ul style="list-style-type: none"> • Main activities and responsibilities 	<p>Implementation of the company's business strategies by planning, organizing, coordinating and controlling the activity of subordinate structures;</p> <p>Supporting the inspections carried out by the competent authorities in accordance with EU's GLP/GCP/GMP legislation, ISO</p>
<ul style="list-style-type: none"> • Occupation held 	Manager - Regulatory Affairs and Clinical Studies, Antibiotice S.A., Iasi
<ul style="list-style-type: none"> • Date (from - to) 	11.2020 – 06.2021
<ul style="list-style-type: none"> • Name and address of the employer 	Antibiotice S.A., 1 Valea Lupului Str., Iași, Romania
<ul style="list-style-type: none"> • Type of business 	Pharmaceutical Industry
<ul style="list-style-type: none"> • Main activities and responsibilities 	<p>Coordination of the Clinical Trials Center activities</p> <p>Coordination of the Regulatory Affairs Department activities</p> <p>Supporting the inspections carried out by the competent authorities in accordance with EU's GLP/GCP/GMP legislation, ISO</p>
<ul style="list-style-type: none"> • Occupation held 	Manager – Clinical Trials Center, Antibiotice S.A., Iasi
<ul style="list-style-type: none"> • Date (from - to) 	11.2018 - 11.2020
<ul style="list-style-type: none"> • Name and address of the 	Antibiotice S.A., 1 Valea Lupului Str., Iași, Romania

employer <ul style="list-style-type: none"> • Type of business • Main activities and responsibilities 	Pharmaceutical Industry Coordination of the Clinical Trials Center activities Supporting the inspections carried out by the competent authorities in accordance with EU's GLP/GCP/GMP legislation, ISO
<ul style="list-style-type: none"> • Occupation held • Date (from - to) • Name and address of the employer • Type of business • Main activities and responsibilities 	Manager – Quality Control Unit, Antibiotice S.A., Iasi 03.2018 – 11.2018 Antibiotice S.A., 1 Valea Lupului Str., Iași, Romania Pharmaceutical Industry Coordination and planification of the Unit activity Approving the training plan Release the Certificate of Analysis of all product baches Aproving OOS/OOT investigation Approving validations/qualification protocols Supporting the inspections and audits carried out by the competent authorities as well as business partners, in accordance with EU's GMP, US FDA, ISO legislation
<ul style="list-style-type: none"> • Occupation held • Date (from - to) • Name and address of the employer • Type of business • Main activities and responsibilities 	Manager – Center for Drug Evaluation, Antibiotice S.A., Iasi 10.2017 – 03.2018 Antibiotice S.A., 1 Valea Lupului Str., Iași, Romania Pharmaceutical Industry Coordination of the Center activities Supporting the inspections and audits carried out by the competent authorities as well as business partners, in accordance with EU's GLP/GCP/GMP legislation, ISO
<ul style="list-style-type: none"> • Occupation held • Date (from - to) • Name and address of the employer • Type of business • Main activities and responsibilities 	Head of Instrumental Analyses Lab, Quality Control, Antibiotice S.A., Iasi 05.2008 – 10.2017 Antibiotice S.A., 1 Valea Lupului Str., Iași, Romania Pharmaceutical Industry Coordination and planification of the laboratory activity Establishing the training topic Reviewing and release of the laboratory analyses Running OOS/OOT investigation Approving validations/qualification protocols Supporting the inspections and audits carried out by the competent authorities as well as business partners, in accordance with EU's GLP/GCP/GMP legislation, ISO for the QC activity

• Occupation held	Quality control analyst, Quality Control, Antibiotice S.A., Iasi
• Date (from - to)	09.2004 – 05.2008
• Name and address of the employer	Antibiotice S.A., 1 Valea Lupului Str., Iași, Romania
• Type of business	Pharmaceutical Industry
• Main activities and responsibilities	Performing QC analyses, QC registration, standard operating procedure (SOP's), method validation, personnel training

EDUCATION AND TRAINING

• Date (from – to)	2007 to 2008
• Name and type of organization providing education and training	Master's Degree in Management & Comercial Engineering, „Gh. Asachi” Technical University, Iasi
• Specialization	Management
• Date (from – to)	1999 to 2004
• Name and type of organization providing education and training	„Gh. Asachi” Technical University, Iasi, Faculty of Industrial Chemistry, Iasi
• Specialization	Engineering economics
• Date (from – to)	04.05.2023
• Organization	“Sustainability - Premises, Benefits and Legal Requirements”, organized by SC Denkstatt Romania SRL
• Specialization	Sustainability
• Date (from – to)	February 20, 2023
• Organization	Certificate of Completion - <i>How to Develop an Effective Contamination Control Strategy</i>
• Specialization	QA/QC
• Date (from – to)	November 22, 2021
• Organization	<i>Certificate of Training - Data Integrity, RSSL Training</i>
• Specialization	QA/QC
• Date (from – to)	September 17, 2021
• Organization	Certificate of Completion - <i>Key Quality Systems Training, NSF Health Sciences Ltd</i>
• Specialization	Pharmaceutical
• Date (from – to)	November 25, 2020
• Organization	Certificate of Completion, <i>COLORCON Coating School</i>
• Specialization	Pharmaceutical

<ul style="list-style-type: none"> • Date (from – go) • Organization • Specialization 	<p><i>November 20, 2020</i> Annual Clinical Trials Symposium, Avantyo Institute of Clinical Research EU's pharmaceutical legislation</p>
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	<p><i>September 17-18, 2020</i> Clinical Research Associate (CRA) Training for Advanced Level, Avantyo Institute of Clinical Research. EU's pharmaceutical legislation</p>
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	<p><i>February 27-28, 2020</i> Clinical Research Associate (CRA) Training for Entry Level, Avantyo Institute of Clinical Research EU's pharmaceutical legislation</p>
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	<p><i>November 21-22, 2019</i> Root Cause Analysis, ECA Academy QA/QC</p>
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	<p><i>October 18, 2019</i> <i>Topical Products Lifecycle with Regulatory Perspective, BII World</i> EU's pharmaceutical legislation</p>
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	<p><i>October 11, 2019</i> Clinical Trials Symposium 2019, Avantyo Institute of Clinical Research EU's pharmaceutical legislation</p>
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	<p><i>November 06, 2018</i> Complaints, CAPA, Recall, Concept Heidelberg, ECA Academy QA/QC</p>
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	<p><i>November 02, 2018</i> GMP Preventative Maintenance Requirements, ECA Academy EU's pharmaceutical legislation</p>
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	<p><i>October 1, 2018</i> Pharmacokinetics and Bio-pharmacy Applied in the Drug Industry, Laurian Vlase, Ph.D R&D</p>
<ul style="list-style-type: none"> • Date (from – to) • Organization 	<p><i>September 23 – 28, 2018</i> PDA/FDA Joint Regulatory Conference (training in regulatory issues,</p>

• Specialization	quality assurance and quality control in pharmaceutical area), Parenteral Drug Association, SUA QA/QC
• Date (from – to)	June 21, 2018
• Organization	Occupational Health and Safety Legislation, Occupational Education and Training Centre
• Specialization	Health & Safety legislation
• Date (from – to)	January 8 – 10, 2018
• Organization	Pharmacokinetics and Bio-pharmacy Applied in the Drug Industry, lecturer Laurian Vlase, Ph.D
• Specialization	EU's pharmaceutical legislation
• Date (from – to)	November 20, 2017
• Organization	Bioequivalence, Dissolution and Correlations in Vivo & in Vitro, lecturer Laurian Vlase
• Specialization	EU's pharmaceutical legislation
• Date (from – to)	December 6, 2016
• Organization	Pharmaceutical Laboratory Data Integrity, Concept Heidelberg, European Compliance Academy
• Specialization	QA/QC
• Date (from – to)	November 28 – 29, 2016
• Organization	GMP and FDA Compliance in Quality Assurance Units, Concept Heidelberg, European Compliance Academy
• Specialization	QA/QC
• Date (from – to)	October 27, 2016
• Organization	GLP training, TMQA
• Specialization	EU's pharmaceutical legislation
• Date (from – to)	June 28, 2016
• Organization	HPLC Troubleshooting, Phenomenex, Inc. (SUA) and MUSO SRL
• Specialization	QA/QC
• Date (from – to)	October 27, 2015
• Organization	OpenLAB ECM for Chemstation User Training, Agilent Technologies
• Specialization	QA/QC
• Date (from – to)	March 27, 2015
• Organization	Ion Chromatography: Theory vs. Practice tutorial, Metrom Romania
• Specialization	QA/QC
• Date (from – to)	October 14-15, 2014
• Organization	From Science to Guidance and Practice. Industrial Manufacturing and Control of Pharmaceutical Products Scientific workshop, O.F. System

<ul style="list-style-type: none"> • Specialization 	in cooperation with “Carol Davila” University of Medicine and Pharmacy of Bucharest QA/QC
<ul style="list-style-type: none"> • Date (from – to) • Organization 	June - July 2014 “Al.I.Cuza” University of Iași, Faculty of Economics and Business Administration, Summer School a+, 5 th Edition, module “Organizational Development”
<ul style="list-style-type: none"> • Specialization 	Business
<ul style="list-style-type: none"> • Date (from – to) • Organization 	June 14, 2013 ANMDM (<i>Engl. The National Agency for Medicines and Medical Devices</i>), ARPIM (<i>Engl. The Romanian Association of International Medicine Manufacturers</i>), APMGR (<i>Engl. Association of Generic Medicine Producers from Romania</i>) Bucharest, Workshop
<ul style="list-style-type: none"> • Specialization 	EU's pharmaceutical legislation
<ul style="list-style-type: none"> • Date (from – to) • Organization 	June - July 2012 Summer School a+, 3 rd Edition, module I “Creativity and Improvement”, with two parts, i.e. Ideas are Free of Charge and Process Management, and module II “Organizational Behavior”, lecturers from “Al.I.Cuza” University of Iași, Faculty of Economics and Business Administration
<ul style="list-style-type: none"> • Specialization 	Business
<ul style="list-style-type: none"> • Date (from – to) • Organization 	February 2012 United States Pharmacopeia, Pharmacopeial Education, Dissolution: Theory and Practice
<ul style="list-style-type: none"> • Specialization 	QA/QC
<ul style="list-style-type: none"> • Date (from – to) • Organization 	June - July 2011 “Al.I.Cuza” University of Iași, Faculty of Economics and Business Administration, Summer School a+, 2 nd Edition, module II “Leadership and Communication”, module III “Labor Legislation”, module VI “Statistic Analysis in Quality Assurance and Quality Control”
<ul style="list-style-type: none"> • Specialization 	Business
<ul style="list-style-type: none"> • Date (from – to) • Organization 	September 13-17, 2010 GMP Training for Quality Assurance and Quality Control, Novatek International, modules 5 to 8: Residual Solvent Testing, Near IR Spectroscopy in Pharmaceutical Industry - Theory and Practice, Development of HPLC Method and Validation Procedures, Pharmaceutical Impurities
<ul style="list-style-type: none"> • Specialization 	EU's pharmaceutical legislation
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	March 20, 2009 Laboratory Classes, ABL&E Jasco Romania QA/QC

<ul style="list-style-type: none"> • Date (from – to) • Organization 	<p>November 9, 2007</p> <p>Training for operating, data processing and preventive maintenance of the gas chromatograph Finnigan Focus GC equipped with a HeadSpace TriPlus HS autosampler and the corresponding software, and ChromCard data acquisition and processing, held by Pro Analysis Systems, authorized distributor of THERMO SCIENTIFIC</p>
<ul style="list-style-type: none"> • Specialization 	QA/QC
<ul style="list-style-type: none"> • Date (from – to) • Organization 	<p>June 5, 2007</p> <p>“High-Performance Spectrometry in Research & Manufacturing” Symposium held by THERMO SCIENTIFIC at the University of Agronomic Sciences and Veterinary Medicine of Bucharest</p>
<ul style="list-style-type: none"> • Specialization 	QA/QC
<ul style="list-style-type: none"> • Date (from – to) • Organization 	<p>11.09.2006 – 15.09.2006</p> <p>Krug International Ltd., Hemtek D.o.o. & Waters Co.; field of study/occupational skills: HPLC and MS</p>
<ul style="list-style-type: none"> • Specialization 	QA/QC
<ul style="list-style-type: none"> • Date (from – to) • Organization 	<p>2003</p> <p>“Gh. Asachi” Technical University of Iași, Faculty of Industrial Chemistry; field of study/occupational skills: student scientific session “Cobalt - Extraction, Properties, Compounds”</p>
<ul style="list-style-type: none"> • Specialization 	Industry
<ul style="list-style-type: none"> • Date (from – to) • Organization • Specialization 	<p>2000</p> <p>PC programming – Certificate of Proficiency</p> <p>Programing</p>

PERSONAL SKILLS AND COMPETENCES

Foreign languages	English	Reading skills Proficient user	Writing skills Proficient user	Speaking skills Proficient user
Social skills and competences	Team work, open communication, proactive, negotiation, leadership and participative management approach. Time management Organizational skills			
Driving license	B			