CURRICULUM VITAE

PERSONAL INFORMATION

Name	**Gianina - Gabriela MACOVEI**
Nationality	Romanian
Age	44

WORK EXPERIENCE

• Occupation held	**Executive Director – Research & Development & Innovation**
• Date (from - to)	10.2024 – present
• Name and address of the employer	Antibiotice S.A., 1 Valea Lupului Str., Iaşi, Romania
• Type of business	Pharmaceutical Industry
• Main activities and responsibilities	Implementation of the companies' business strategies by planning, organizing, coordinating and controlling subordinate structural activities; Overseeing Research Development and Innovation strategies, team management and resource allocation. Identifying emerging technologies, stimulating innovation and increasing product competitiveness. Coordination of the activity of the Medical and Scientific Documentation Department

• Occupation held	**Executive Director – Portfolio Management**
• Date (from - to)	05.2023 – 10.2024
• Name and address of the employer	Antibiotice S.A., 1 Valea Lupului Str., Iaşi, Romania
• Type of business	Pharmaceutical Industry
• 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;

• Occupation held	**Executive Manager – Sterile Products and APIs Division, Antibiotice S.A., Iasi**
• Date (from - to)	11.2022 – 05.2023
• Name and address of the employer	Antibiotice S.A., 1 Valea Lupului Str., Iaşi, Romania
• Type of business	Pharmaceutical Industry
• 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

• Occupation held	**Manager – Sterile Products and APIs Division, Antibiotice S.A., Iasi**
• Date (from - to)	11.2021 – 11.2022
• Name and address of the employer	Antibiotice S.A., 1 Valea Lupului Str., Iaşi, Romania
• Type of business	Pharmaceutical Industry
• 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

• Occupation held	**Manager – Clinical Trials Center, Antibiotice S.A., Iasi**
• Date (from - to)	06.2021 – 11.2021
• Name and address of the employer	Antibiotice S.A., 1 Valea Lupului Str., Iaşi, Romania
• Type of business	Pharmaceutical Industry
• Main activities and responsibilities	Implementation of the company's business strategies by planning, organizing, coordinating and controlling the activity of subordinate structures; Supporting the inspections carried out by the competent authorities in accordance with EU's GLP/GCP/GMP legislation, ISO

• Occupation held	**Manager - Regulatory Affairs and Clinical Studies, Antibiotice S.A., Iasi**
• Date (from - to)	11.2020 – 06.2021
• Name and address of the employer	Antibiotice S.A., 1 Valea Lupului Str., Iaşi, Romania
• Type of business	Pharmaceutical Industry
• Main activities and responsibilities	Coordination of the Clinical Trials Center activities Coordination of the Regulatory Affairs Department activities Supporting the inspections carried out by the competent authorities in accordance with EU's GLP/GCP/GMP legislation, ISO

• Occupation held	**Manager – Clinical Trials Center, Antibiotice S.A., Iasi**
• Date (from - to)	11.2018 - 11.2020
• Name and address of the employer	Antibiotice S.A., 1 Valea Lupului Str., Iaşi, Romania
• Type of business	Pharmaceutical Industry
• Main activities and responsibilities	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

• Occupation held	**Manager – Quality Control Unit, Antibiotice S.A., Iasi**
• Date (from - to)	03.2018 – 11.2018
• Name and address of the employer	Antibiotice S.A., 1 Valea Lupului Str., Iaşi, Romania
• Type of business	Pharmaceutical Industry
• Main activities and responsibilities	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

• Occupation held	**Manager – Center for Drug Evaluation, Antibiotice S.A., Iasi**
• Date (from - to)	10.2017 – 03.2018
• Name and address of the employer	Antibiotice S.A., 1 Valea Lupului Str., Iaşi, Romania
• Type of business	Pharmaceutical Industry
• Main activities and responsibilities	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

• Occupation held	**Head of Instrumental Analyses Lab, Quality Control, Antibiotice S.A., Iasi**
• Date (from - to)	05.2008 – 10.2017
• Name and address of the employer	Antibiotice S.A., 1 Valea Lupului Str., Iaşi, Romania
• Type of business	Pharmaceutical Industry
• Main activities and responsibilities	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., Iaşi, 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	Bachelor's Degree, „Gh. Asachi" Technical University, Iasi , Faculty of Industrial Chemistry, Iasi
• Specialization	**Engineering economics**

• Date (from – to)	***March 14, 2025***
• Organization	Certificate of Completion - *ESRS (European Sustainability Reporting Standards)*, organized by ENVISIA – Boards of Elite,
• Specialization	Sustainability reporting, ESG compliance, corporate disclosure requirements
• Date (from – to)	***October 2024 – February 2025***
• Organization	Certificate of Completion, PwC's Mini MBA Programe, PwC's Academy
• Specialization	**MBA**
• Date (from – to)	***May 04, 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 - *How to Develop an Effective Contamination Control Strategy, NSF Health Sciences Ltd*
• Specialization	QA/QC
• Date (from – to)	***November 22, 2021***
• Organization	*Certificate of Training - Data Integrity, RSSL Training*
• Specialization	QA/QC
• Date (from – to)	***September 17, 2021***
• Organization	Certificate of Completion - *Key Quality Systems Training, NSF Health Sciences Ltd*
• Specialization	Pharmaceutical
• Date (from – to)	***November 25, 2020***
• Organization	Certificate of Completion, *COLORCON Coating School*
• Specialization	Pharmaceutical
• Date (from – go)	***November 20, 2020***
• Organization	Annual Clinical Trials Symposium, Avantyo Institute of Clinical Research
• Specialization	EU's pharmaceutical legislation
• Date (from – to)	***September 17-18, 2020***
• Organization	Clinical Research Associate (CRA) Training for Advanced Level, Avantyo Institute of Clinical Research.
• Specialization	EU's pharmaceutical legislation

• Date (from – to)	***February 27-28, 2020***
• Organization	Clinical Research Associate (CRA) Training for Entry Level, Avantyo Institute of Clinical Research
• Specialization	EU's pharmaceutical legislation
• Date (from – to)	***November 21-22, 2019***
• Organization	Root Cause Analysis, ECA Academy
• Specialization	QA/QC
• Date (from – to)	***October 18, 2019***
• Organization	*Topical Products Lifecycle with Regulatory Perspective, BII World*
• Specialization	EU's pharmaceutical legislation
• Date (from – to)	***October 11, 2019***
• Organization	Clinical Trials Symposium 2019, Avantyo Institute of Clinical Research
• Specialization	EU's pharmaceutical legislation
• Date (from – to)	***November 06, 2018***
• Organization	Complaints, CAPA, Recall, Concept Heidelberg, ECA Academy
• Specialization	QA/QC
• Date (from – to)	***November 02, 2018***
• Organization	GMP Preventative Maintenance Requirements, ECA Academy
• Specialization	EU's pharmaceutical legislation
• Date (from – to)	***October 1, 2018***
• Organization	Pharmacokinetics and Bio-pharmacy Applied in the Drug Industry, Laurian Vlase, Ph.D
• Specialization	R&D
• Date (from – to)	***September 23 – 28, 2018***
• Organization	PDA/FDA Joint Regulatory Conference (training in regulatory issues, quality assurance and quality control in pharmaceutical area), Parenteral Drug Association, SUA
• Specialization	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 in cooperation with "Carol Davila" University of Medicine and Pharmacy of Bucharest
• Specialization	QA/QC
• Date (from – to)	***June - July 2014***
• Organization	"Al.I.Cuza" University of Iaşi, Faculty of Economics and Business Administration, Summer School a+, 5th Edition, module "Organizational Development"
• Specialization	Business
• Date (from – to)	***June 14, 2013***
• Organization	*ANMDM (Engl. The National Agency for Medicines and Medical Devices from Romania), ARPIM (Engl. The Romanian*

	Association of International Medicine Manufacturers), APMGR (Engl. Association of Generic Medicine Producers from Romania) Bucharest, Workshop
• Specialization	EU's pharmaceutical legislation
• Date (from – to)	***June - July 2012***
• Organization	Summer School a+, 3rd 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 Iaşi, Faculty of Economics and Business Administration
• Specialization	Business
• Date (from – to)	***February 2012***
• Organization	United States Pharmacopeia, Pharmacopeial Education, Dissolution: Theory and Practice
• Specialization	QA/QC
• Date (from – to)	***June - July 2011***
• Organization	"Al.I.Cuza" University of Iaşi, Faculty of Economics and Business Administration, Summer School a+, 2nd Edition, module II "Leadership and Communication", module III "Labor Legislation", module VI "Statistic Analysis in Quality Assurance and Quality Control"
• Specialization	Business
• Date (from – to)	***September 13-17, 2010***
• Organization	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
• Specialization	EU's pharmaceutical legislation
• Date (from – to)	***March 20, 2009***
• Organization	Laboratory Classes, ABL&E Jasco Romania
• Specialization	QA/QC
• Date (from – to)	***November 9, 2007***
• Organization	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
• Specialization	QA/QC
• Date (from – to)	***June 5, 2007***
• Organization	"High-Performance Spectrometry in Research & Manufacturing" Symposium held by THERMO SCIENTIFIC at the University of Agronomic Sciences and Veterinary Medicine of Bucharest

• Specialization	QA/QC
• Date (from – to)	***11.09.2006 – 15.09.2006***
• Organization	Krug International Ltd., Hemtek D.o.o. & Waters Co.; field of study/occupational skills: HPLC and MS
• Specialization	QA/QC
• Date (from – to)	***2003***
• Organization	"Gh. Asachi" Technical University of Iaşi, Faculty of Industrial Chemistry; field of study/occupational skills: student scientific session "Cobalt - Extraction, Properties, Compounds*"*
• Specialization	Industry
• Date (from – to)	***2000***
• Organization	PC programming – Certificate of Proficiency
• Specialization	Programing

PERSONAL SKILLS AND COMPETENCES

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