#### CURRICULUM VITAE

#### PERSONAL INFORMATION

Name Address Phone E-mail

Daniela PASCARIU IASI, ROMANIA

E-mail
Nationality
Birth date

daniela.pascariu@antibiotice.ro Romanian

#### WORK EXPERIENCE

- Occupation held
- Date (from to)
- Name and address of the employer
- Type of business
- Main activities and responsibilities

## **Executive Director Quality Assurance**

10.2021 – present

Antibiotice S.A., 1 Valea Lupului, Iaşi, Romania

Pharmaceutical Industry

Implementation of the company business strategies by planning, organizing, coordinating and controlling the activities of the subordinate structures;

Annual establishment of the objectives of the subordinated structures according to the objectives of the direction

Establishing responsibilities for meeting the objectives of the department

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#### **Business Development Manager**

02.2020 to 10.2021

Antibiotice S.A., 1 Valea Lupului nr.1, Iași, Romania

Pharmaceutical Industry

Department activity coordination

Research and identify new business opportunities, including new markets, potential development business areas, trends, customers, partnerships, products and services, or new ways to reach existing markets

Staff training and help for team members to develop their skills.

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#### Manager Regulatory Affairs, Antibiotice S.A. Iași

07.2011 to 03.2020

Antibiotice S.A., 1 Valea Lupului nr.1, Iași, Romania

Pharmaceutical Industry

Coordination of the department activities

Develop and update global, regional or national regulatory strategies Strategic support for regulatory requirements for research,

development and clinical trials for all products, especially for complex

and / or critical products

Supervision of compliance with regulations applicable to documentation to support quality, safety and efficiency Negotiate with regulators on complex issues throughout the product life cycle

Establishes and maintains working relationships with multiple governmental and non-governmental organizations that have an impact on market access and distribution

- Occupation held
- Date (from to)
- Name and address of the employer
- Type of business
- Main activities and responsibilities

## **Head of Regulatory Affairs Department**

02.2007 to 07.2011

Antibiotice S.A., 1 Valea Lupului nr.1, Iași, Romania

Pharmaceutical Industry

Coordination of the department activities

Develop and update global, regional or national regulatory strategies Strategic support for regulatory requirements for research, development and clinical trials for all products, especially for complex

and / or critical products

Supervision of compliance with regulations applicable to documentation to support quality, safety and efficiency

Negotiate with regulators on complex issues throughout the product life cycle

Establishes and maintains working relationships with multiple governmental and non-governmental organizations that have an impact on market access and distribution

### · Occupation held

#### • Date (from - to)

- Name and address of the employer
- Type of business
- Main activities and responsibilities
- Occupation held
- Date (from to)
- Name and address of the employer
- Type of business
- Main activities and responsibilities

# Regulatory Affairs Responsible for the authorisation/renewal procedures for foreign countries

02.2005 to 01.2007

Antibiotice S.A., 1 Valea Lupului nr.1, Iași, Romania

Pharmaceutical Industry

Coordination of the authorisation/renewal procedures for foreign countries

## Pharmacist - Regulatory Affairs Department

10.2003 to 02.2005

Antibiotice S.A., 1 Valea Lupului nr.1, Iași, Romania

Pharmaceutical Industry

Elaboration of the authorisation/renewal dossier

## • Occupation held

- Date (from to)
- Name and address of the employer
- Type of business
- Main activities and responsibilities

#### **Head Pharmacist**

08.1997 to 07.2003 SC Montero Iasi

En-gross distribution and storage company Coordination of the activity

# **EDUCATION AND TRAINING**

<ul> <li>Date (from – to)</li> <li>Name and type of organization providing education and training</li> <li>Specialization</li> </ul>	1992 to 1997 "Gr. T. Popa" University, Iaşi, Romania, Faculty of Pharmacy Pharmacist		
<ul> <li>Date (from – to)</li> <li>Name and type of organization providing education and training</li> <li>Specialization</li> </ul>	2000 "Management and Marketing Techniques", course at Chamber of Commerce and Industry of Iasi Management and Marketing		
<ul> <li>Date (from – to)</li> <li>Name and type of organization providing education and training</li> <li>Specialization</li> </ul>	2005 to 2007 "Al. I. Cuza " University of Iasi, Postgraduate School of Economics – ELITEC Master - International Business		
<ul><li>Date (from – to)</li><li>Organization</li></ul>	22-23.02.2006 Certificate of Continuing Professional Development, Pharmaceutical Training International: "Preparing the Chemistry and Pharmacy section of the CTD"		
<ul> <li>Specialization</li> <li>Date (from – to)</li> <li>Organization</li> <li>Specialization</li> </ul>	EU's pharmaceutical legislation 24-25.07.2006 Certificate of Continuing Professional Development, "Regulatory Affairs Training: Generic Registration" by Cardinal Health, UK Regulatory Affairs		
<ul><li> Date (from – to)</li><li> Organization</li><li> Specialization</li></ul>	28 – 29.05.2007 Certificate of Continuing Professional Development "US-FDA Drug Submission Procedures", Pharmaceutical Training International, at Antibiotice Iaşi Regulatory Affairs		
<ul><li> Date (from – to)</li><li> Organization</li><li> Specialization</li></ul>	n Certificate of Continuing Professional Development "US-FDA Drug Submission Procedures", Pharmaceutical Training International, at Antibiotice Iași		
<ul><li>Date (from – go)</li><li>Organization</li><li>Specialization</li></ul>	29.06–09.07.2010 Summer school a+ Management and development module in era of turbulence, lecturers at the University "Al. I. Cuza" of Iaşi, Faculty of Economics and Business Administration		
<ul><li>Date (from – to)</li><li>Organization</li><li>Specialization</li></ul>	25.03.2011 Consultation with target patient groups for the Package Leaflet. Regulatory Affairs		

06 - 07.2011• Date (from - to)Summer school a +, 2<sup>nd</sup> Edition, module I Creativity and Organization Innovation, lecturers from the University "Al. I. Cuza" of Iași, Faculty of Economics and Business Administration, Module III Labour Legislation, lecturers from ITM Iasi Specialization Business 06 - 07.2012• Date (from - to)Summer School a +, 3<sup>rd</sup> Edition, Creativity modules, Organization Innovation and improvement, with the two components: Ideas do not cost and Process Management; Organizational behaviour, lecturers from the University "Al. I. Cuza" of Iaşi, Faculty of Economics and Business Administration **Business**  Specialization • Date (from - to)10 2012 Organization The symposium "Medicine and faith. The elderly patient: an approach with science and soul." The College of Pharmacists from Romania. Specialization Health • Date (from - to)01.2013 Organization National Conference of Interdisciplinary Modern Medical Management, 1st Edition, Iaşi, The College of Pharmacists from Romania, People and Companies. Management Specialization 06 - 07.2014 • Data (de la – până la) Summer school + 5<sup>th</sup> edition, module "Organizational Development", Organizație lecturers from the University" Al. I. Cuza" of Iasi, Faculty of Economics and Business Administration Specialization **Business** • Date (from – to) 09 2014 Training Quality by Design, lectors from Organization UMETRICS, Antibiotice Iasi Specialization Regulatory • Date (from – to) 02.2015 Organization Filling Variations, Informa Life Sciences, London, UK Regulatory Affairs Specialization • Date (from - to)25.07.2019 "Time management", International Job Finder Organization Specialization Management

# PERSONAL SKILLS AND COMPETENCES

Mother tongue	Romanian			
Other foreign languages		Reading skills	Writing skills	Speaking skills
	English	Proficient user	Proficient user	Proficient user
	French	Elementary	Elementary	Elementary
		User	User	User
Driving license	B from 1999			