

CURRICULUM VITAE

Last name: HOREANU

First name: Niculina Genoveva

Date and place of birth:

Address: Iași,

Telephone no:

Civil status: married

E-mail:

Studies, trainings:

June 2019 - "Healthy with Good Science" symposium, College of Pharmacists of Romania;

June 2019 - "Faith and Health in the Romanian Village" symposium, College of Pharmacists of Romania;

June 2019 - "You are well. You're doing well" symposium, College of Pharmacists of Romania;

November 2016 - GMP and FDA Compliance in Quality Assurance Units course, taught by lecturers from Concept Heidelberg, European Compliance Academy;

September 30, 2014 - "Quality by Design" course, supported by UMETRICS lecturers at the Antibiotice headquarters;

June - July 2014 - Summer School **a+**, the 5th edition, the "Organizational Development" module, supported by lecturers from the Faculty of Economics and Business Administration Iasi

January 25, 2013 - National Conference on Modern Interdisciplinary Medical Management, the first edition, organized by the College of Pharmacists of Romania;

October 18 - 19, 2012 - "Medicine and Faith. The elderly patient: an approach with science and soul" symposium, College of Pharmacists of Romania;

June - July 2012 - Summer School **a+**, the 3rd edition, "Creativity, Innovation and Improvement" module, with two components: "Ideas are free of charge" and "Process Management", and "Organizational Behavior" Module, supported by lecturers from the Faculty of Economics and Business Administration Iasi;

June - July 2011 - Summer School **a+**, the second edition, "Creativity and Innovation" module, supported by lecturers from the Alexandru Ioan Cuza University, Faculty of Economics and Business Administration Iasi;

June - July 2011 - Summer School **a+**, the second edition, Labor Legislation Module, supported by lecturers from ITM Iasi;

March 29, 2011 - „Stress - a daily problem" symposium organized by Antibiotice S.A. Iasi; certificate of participation issued by the College of Pharmacists of Romania,

September 13 - 17, 2010 - GMP Trainign for QA and QC (modules 1 - 4) supported by Novatek International:

1. Aseptic Media Fill / Media Fills

- ICH and FDA Regulations on the aseptic manufacture
- Recommendations on validation of aseptic processes
- Media fills for validation
- Routine media fills
- Staff training and qualification
- Documentation requirements

2. Environmental Monitoring

- Environmental considerations: Clean room standards, qualification and monitoring
- Air borne microbial and non-viable particle monitoring
- Non-viable particle monitoring
- Microbial monitoring
- Intervention monitoring

3. Risk Management System

- Quality risk management (QRM) in aseptic processes and for finished products as: tablets, capsules, ointments and suppositories, active substance obtained by biosynthesis.
- QRM process
- Risk assessment, control, communication, review
- Risk assessment tools
- 3-D risk assessment, FMEA, HACCP, FTA
- Implications of risk assessment on processing
- Implications of risk determination on validation

4. Root cause Investigation for CAPA

- Cause-effect investigations
- CAPA process development
- Issues related to the human factor and CAPA training
- CAPA: Too much or Not enough?
- A review of 483 observations and CAPA citations
- The use of a closed-loop CAPA system as a hub for quality management.

June 29 - July 09, 2010 - Summer School **a+**, “Management and development in the age of turbulence” module, supported by lecturers from the Faculty of Economics and Business Administration Iasi;

November 2007 - March 2008 - English language course, EuroEd Foundation, Iasi;

2006 - 2007, Master’s Degree in Management and Pharmaceutical Marketing, “Gr. T. Popa” University of Medicine and Pharmacy, Faculty of Pharmacy, Iasi;

December 2006 - “Labour Security and Health” skills upgrade course, Antibiotice S.A. Iasi;

November 2006 - elected as a member of the College of Pharmacists of Romania;

2004 - “Gr. T. Popa” University of Medicine and Pharmacy - Varian Training Certificate - In Vitro Dissolution of Ointments, Creams and Transdermals;

2004 - “Labour Security and Health” skills upgrade course;

2001 - Senior Pharmacist, specialist in General Pharmacy;

1998 - admission to the doctorate in Pharmaceutical Technology and Biopharmacy, “Gr. T. Popa” University of Medicine and Pharmacy, Faculty of Pharmacy, Iasi;

1987-1992 - “Gr. T. Popa” University of Medicine and Pharmacy, Faculty of Pharmacy, Iasi;

Professional activity:

November 2019 - present: Executive Director - Topical Product Division;

February 2005 - November 2019: Production Manager, Ointment & Suppository Plant, Antibiotice S.A. Iaşi;

August 2002 - February 2005: Technologist Pharmacist, Ointment & Suppository Plant, Antibiotice S.A. Iaşi;

Involvement for preparing the documentation for the medicinal products to be registered by the National Agency for Medicines and Medical Devices;

Cooperation with the Faculty of Pharmacy Iasi, Department of Pharmaceutical Technology and Biopharmacy;

Seminar and laboratory tutor for the 3rd and 4th year students of the Faculty of Pharmacy;

1996 - 2002 - Head of laboratory - production, research and development in the pharmaceutical field- S.C. Hyperion S.A. Iaşi

1995 - 1996 - Pharmacist within the Pharmacy of the „Sf. Spiridon” Hospital Iaşi;

1995 - Pharmacist, specialist in General Pharmacy;

1993-1996 - Resident pharmacist, specialist in General Pharmacy - “Gr. T. Popa” University of Medicine and Pharmacy, Faculty of Pharmacy, Iasi;

1992-1993 - trainee pharmacist - The County Hospital, Botosani

Skills:

- exigency, seriousness;
- team spirit, communication skills, flexibility;
- capacity of adapting to all the work conditions, stress resistance;
- quick understanding.

Scientific activity:

Co-author:

Invention Patent, 2000 - haemorrhoidal ointment

Other skills:

Foreign languages:

- English (written, reading);
- computer knowledge: Microsoft Word, Microsoft Excel, Internet explorer