Curriculum Vitae

Personal information

Nadire Lleshi

Work experience

08/2008 - I am working as a Head of Manufacturing Authorization Division and still I'm employer of Kosovo Medicines Agency.

Republic of Kosovo, Regulatory Medicines and Medical Device Authority.

07/1999-08/2008 - Head of Ecology Laboratory, Department of Human Ecology, Institute of Public Health, Prizren, Kosovo -

04/1988-03/1999 - CEO of j.s. Company EDICO as a chemical factory under a Holding Company "Emin Duraku" Gjakove, Kosovo.

Education and training

10/1982 - 12/1987

Diploma, branch Chemistry, University of Prishtina, Kosovo

10/2003 - 12/2006

Diploma, master degree, Chemistry, University of Prishtina, Kosovo

10/2006 - 12/2011

Master Degree Diploma, branch Pharmacy, University Tirana, Albania

09/2014-12/2014

Certificate/ Improving Global Health focusing in Quality and Safety/Harvard University, USA

09/2020 - 03/2022

Drug Development/Product management/ Specialization/UC San Diego, USA

Certificate of 120.0 0Hours CPD in Specialization recognized by TOPRA (The Organization for Professionals in Regulatory Affairs).

Additional information

Publications

1. Academy of Science of Kosovo: "Environment in Kosovo-Resources and Human factor"

I participated with scientific theme entitled "Determination of Heavy Metals in Vegetables" October, 2007

2. "Days of Preventive Medicine of Kosova" I participate with the theme: "Water pollution in the period 2000-2004 in Prizren region" June/2005

3. Second Pharmacy Conference with International Participation, I present the theme : Procedures of application for Marketing Authorization " June/ 2017

Projects

Bfarm / IPA Project

Clinical Trial Trainings (group of GCP inspectors, observers), EMA/IPA training.

Memberships

TOPRA - Member of the Organization for Professionals in Regulatory Affairs

Member of a Pharmaceutical Society, Kosovo

Other Relevant Information

- I was honored to be a part of EU Twinning Project founded by IPA in 2010-2012, between Kosovo Medicines Agency and Bfarm, Germany for two years, and i have been in Bfarm three times as a part of that project, were we got general knowledge of regulatory procedures in EU in order to bring our legislation closer to the EU. For each held training we was equipped with Bfarm Certificates.

- In Jun/2017 I was in Croatia in intensive course for two weeks in regulatory procedures in EU for Quality, Clinical and Non-Clinical documentation (Module 3, 4 and 5 of registration dossier).

- I also have completed some several courses on strategic and business management and the Environmental Management System ISO 140001-2015 for which I have been provided with relevant certificates.

- I participate in the development of scientific guidelines in our field and in the harmonization of regulations on medicinal products with the regulations and guidelines of the European Union/EMA and International institutions (I was a part of Drafting of the main Low for Medicinal Products and Medical Device and the main Administrative Instruction for regulatory procedures for obtaining Marketing Authorization Certificates).

- As a member of TOPRA, I have conducted several trainings, mainly online, were I have been provided with relevant certificates.

- I participate in many trainings in the framework of Regulation and Pharmacovigilance in Region, EU and outside of the EU, participation in FIP and visits and effective communications with regulatory Agencies, internal teams and stakeholders which is crucial for successful outcomes.