



Sultane Havolli

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ABOUT ME

Passionate and accountable for what I do.

WORK EXPERIENCE-01/07/2017 – CURRENT – Prishtina, Kosovo

Senior assessor

Kosovo Medicines Agency (Ministry of Health)

- Scientific evaluation of dossiers of medications applying for granting Marketing Authorization Certificate in Republic of Kosovo.
- Professional assessment of applications for Generic, WEMU, Essentially Similar, Unilateral, Stand-alone applications, etc.
- Professional evaluation of CTD format with knowledge and full compliance of EU directives in this specific field.
- Member of scientific commission for preparing guidelines for Galen Formulation /preparations.(<https://akppm.rks-gov.net/DocumentsAndPublications/SinglePublication/6688>) -Member of commission for Renewals.
- Responsible person for regulatory Audit performed at "Denk Pharma" Munich Germany.
- Member of the professional commission on working and editing Essential Medicines list of Ministry of Health.
- Member of commission for editing Administrative Instruction of current law on Medicines and Medical Devices.
- Leading member of scientific committee for implementing special measures according to law for emergency situations (Pandemic Covid -19)
- Professional knowledge of Variations and part time variations evaluator.

REGCONSULTANCY -10/05/2022 – CURRENT-Founder and Managing director

Activities oriented in Health and Pharmaceutical industry consultancy. Focus of the company's work is on regulatory and legislative activities, business consulting activities and other management advice, combined service activities of office administration, other financial service activities, except for the insurance and pension fund.

01/08/2021 – 01/12/2021 – Prishtina, Kosovo

Editor-in-chief and author

Kosovo Chamber of Pharmacist and Kosovo Medicines Agency - Ministry of Health

Work on "Medicines Register 6" - a register consisting of products that have been granted a Marketing Authorization. Presented in their INN names and with their respective pharmaceutical forms and with the description of their indications, dosage, contraindications and pregnancy category

01/04/2012 – 01/07/2017 Obiliq, Kosovo Pharmacist "Reis Pharma"

-Dispensing and preparing prescriptions, patients advice and care, Particular test in pharmacy, preparing formulation.

02/03/2010 – 04/02/2011 – Prishtina Main responsible Pharmacist "Care Pharmacy"

Dispensing prescriptions, patients care and advising, particular tests in pharmacy, preparing formulation, management of medicines, stock, expiry, presenting new products Prishtina, Kosovo.

02/03/2010 – 04/02/2011 – Prishtina Main responsible pharmacist

Care Pharmacy, dispensing prescriptions, patients care and advising, particular test in pharmacy-Preparing formulation, management of medicines, stock, expiry, presenting new products Prishtina, Kosovo.

18/01/2008 – 05/01/2009 – Ferizaj, Kosovo High school professor "Universum" College

Teaching Pharmaceutical subjects according to Ministry of Education Science and Technology curricula.

-Additional teaching hours depending on directors request.

-Other learning activities with high school students.

EDUCATION

01/09/2017 – 2022 – Prishtina, Kosovo

Medicines Research and Control, Specialist University of Prishtina

01/09/2012 – 01/03/2016 – Stoke-on-Trent, United Kingdom

MBA, General Staffordshire University

01/09/2001 – 01/10/2007 – Tirana, Albania Pharmacist University of Tirana

01/09/1998 – 01/06/2001 – Prishtina, Kosovo Pharmaceutical technician Sh.m.m "Ali Sokoli"

08/10/2021 – 11/10/2021 – Prishtine , Prishtine, Kosovo

Training "Management of public contracts" AMRA-A consulting

02/06/2022 – 03/06/2022 – Prishtine, Prishtine, Kosovo

Strategic Management and Planning

Kosovo Institute for Public Administration

<https://ikap.rks-gov.net/>

LANGUAGE SKILLS

MOTHER TONGUE(S): Albanian

OTHER LANGUAGE(S):

English

	Listening	Reading	Spoken production	Spoken interaction	Writing
English	C2	C2	C2	C2	C2
Serbian/Croatian/ Bosnian	C2	C2	C2	C2	C2
German	A2	B2	A1	A1	A1
Spanish	B2	C2	B1	B1	C

CONFERENCES AND SEMINARS

26/09/2017 – 28/09/2017 > – London, UK

European Medicines Agency, representing Kosovo Medicines Agency

IPA advanced training European Medicines Agency, IPN - Joint CHMP/CVMP Quality Working Group **29/10/2020 – 30/10/2020 >**

– Virtual

DIA Workshop on Optimizing Variations Regulatory Framework-Speaker representing Kosovo Medicines Agency

Drug Information Association- attending as representative Kosovo Medicines Agency as a speaker, discussions and presentations about post approval changes of medicines.

<https://www.diaglobal.org/en/conference-listing/meetings/2020/04/dia-workshop-on-optimising-postapproval-change-regulatory-framework/speakers>

03/09/2020 – ongoing

CEFTA Secretariat- KMA representative for project implementation -

CEFTA Secretariat and AMD planned activities on requirements collection for SEED+ with a final goal to improve the electronic exchange of trade documents in the Western Balkans in line with the provisions and actions agreed in CEFTA Additional Protocol 5 (AP5).

The project is an ongoing work to discuss national documents and data requirements to identify how the implementation of AP5 technical annex would be possible. Representing documents and requirements from Kosovo Medicines Agency to assist the program.

06/09/2021 – 17/09/2021 > – Amsterdam - Virtual

–7th virtual meeting of contact points of the EMA sponsored IPA project <https://www.ema.europa.eu/en>

COMMUNICATION AND INTERPERSONAL SKILLS

● **Organizational, communicational and interpersonal skills**

- High knowledge of the range of pharmaceutical products generics and trade names and their indications.
- Knowledge of pharmaceutical market, and all regulatory activities.
- Very collaborative always giving maximum for the team and its function. -Communicative in written and verbal communication -Confident articulate and professional during communication.
- Able to prioritize duties and keep track.
- Critical, strategic thinking and evaluation, thorough analyzer.
- Decisive Intuition and focus on thinking outside the box.
- Always searching for new challenges ideas and businesses.
- Business background giving me the advantage and knowledge in business related decisions.