Demet Akalgan Aklar

+90 (531) 387 8026 • demet.akalgan@gmail.com

Talented and accomplished pharmaceutical professional with background in regulatory affairs and official compliance.

SUMMARY OF QUALIFICATIONS

- 20 years of business experience on medicinal products, medical devices, clinical trials, cosmetics and food supplements.
- Double PhD on Pharmacognosy and Pharmacy Management, Master of Science on Phytotherapy. Various certifications and training on EuropeanUnion structure and ICH Guidelines (GMP, GDP, GCP)
- Adept at directing process improvements, technology implementations, strategic planning, and marketing.
- Excellent leadership and problem-solving skills. Multi-lingual.

EDUCATION

PhD. in Pharmacy Management, Ankara University Faculty of Pharmacy, Ankara, Turkey (*2012- 2023)*
PhD. in Pharmacognosy, Gazi University Faculty of Pharmacy, Ankara, Turkey (*2012-17)*
Master of Science in Phytotherapy, Gazi University Faculty of Pharmacy, Ankara, Turkey *(2010-12) 3.87/4.0*
B.S. in Pharmacy, Istanbul University Faculty of Pharmacy, Istanbul, Turkey (*1998-2002)*

PROFESSIONAL EXPERIENCE

ISTINYE UNIVERSITY PHARMACY FACULTY, Istanbul, Turkey — October 2019 – Present
Vice Dean — **(From 25.06.2021- still)**
Head of Pharmacognosy Department — **(From 25.10.2019- still)**
Head of Aromatherapy Center — **(From 01.10.2021- still)**

- Working as an Assist. Professor and Lecturing Herbal Medicine courses and giving laboratory lessons to international students.
- Directed graduation projects.
- Member and Head of various Commissions.

GİRNE AMERICAN UNIVERSITY Girne, North Cyprus — September 2018 – June 2023
Head of Pharmacognosy Department

- Lecturing Pharmacognosy I-II-III and Botany courses to international students.
- Providing consultation and support to university projects. Consulted for completed 16 graduation projects.
- Member of Internship Commission and did 500 students oral internship exam.

ARIN DERİN SAĞLIK HİZMETLERİ LTD. /
ART DE HUILE AROMATERAPİ HİZMETLERİ A.Ş, Istanbul, Turkey — January 2019 – October 2019
Responsible Technical Manager

- Successfully managed and administered the process of "Ecocert" organic certificate of the company.
- Managed all phases from procurement of raw materials to finished retail product.
- Managed manufacturing, labeling/packaging and distribution to end user in compliance with regulatory requirements.
- Managed import process of volatile oils and carrier oils from France in compliance with regulations.
- Oversaw all export activities of Art De Huile to North Cyprus.
- Acquired food supplement approvals from Ministry of Agriculture.
- Managed all official and regulatory requirements including notification system Ministry of Health.
- Prepared leaflets to doctors and pharmacists concerning volatile oils and carrier oils.

ALVIMEDICA Saluggia, Italy and Istanbul, Turkey January 2018 – July 2018
Global Regulatory Affairs Manager
As team leader, oversaw regulatory affairs, official requirements, certification, and audit processes of 96 countries that Alvimedica products are being distributed.

- Oversaw all official and regulatory requirements from R&D, manufacturing, pre-marketing, post-marketing, and sales to end user. Worked in coordination with various departments in preparing technicalfile to meet specific regulatory requirements of each individual market.
- Set up compliance with Social Security Agency, Reimbursement Positive List (SGK-SUT). Successfully matched right class and pricing with Class III balloon, catheter, and DES (Drug Eluting System) by SUT codes
- Established strong network and working relationships with market access stakeholders including decision-makers, key influencers, KOLs, other relevant bodies and associations on Cardiology.
- Attended and followed up association meetings.
- Successfully managed certification and audit process as well as legalization processes of Alvimedica products.
- Legalized FSC (Free Sales of Certificate), DoC (Declaration of Conformity), LoA (Letter of Authorization) including apostille concern of La Haye Agreement.
- Managed registration of Alvimedica products in 96 countries.
- Authorized international and local distributor agreements.
- Successfully managed preparation of seven STED Files (Summary of Technical Dossier) of Class III products.

TURKISH MINISTRY of HEALTH Ankara, Turkey June 2009 - December 2017
Member of Marketing Authorization Unit and Rational Usage of Drugs Unit (July 2015-December 2017)
Worked and managed on all aspects Health Ministry regulatory approval process involving below.

- CTD documentation of new access medicinal products, provided feedback about the process timeline, reviewed the documentation, and provide authorization if compliance regulations are satisfied,
- *Main Commission* which managed the initial application process and assessment of clinical data,
- *Pharmacology Commission* approval process (preparation of SPC: Summary of Product Characteristics)/PIL (Patient Information Letter),
- *Technology Commission* for expiration dates and storage conditions, *Biotechnology Commission* approval process.
- All administrative and technical requirements of MoH for regulatory approval process.
  Scientific assessment of pharmacological data of new products and worked in approval process of marketing material and its compliance with local regulations and law.
- Approval and publishing of SPC/PIL documents on TMMDA official web site.
- Organization of scientific consultation commissions.
- Obtaining pharmacokinetic data to get *in-vitro & in-vivo* compliances from bio-equivalent and bio-similar commissions and managing the approval process.
- Market Authorization Approval Unit on medicinal products.
- Collaborated with KOLs before providing approval for market authorization.
- Assessment of the clinical data which are being submitted to Scientific Commission of Ministry of Health Medicinal Products and Medical Devices Agency.

Chief of Hospital Pharmacist **July 2012-July2015**

- Worked for Rational Use of Medicinal Products Unit and coordinated all public hospital's compliance with National Action Plan for Awareness of Rational Use of Antibiotics.
- Audited Quality Standard of public hospitals in all Turkey. Provided trainings to health care teams on Total Quality Standard, audit criteria's involving accreditation standard of JCI (Joint Commission International).
- Worked as team leader to gather 8 billion USD (17 billion TL as of 2016) from World Bank to develop training centers for hospital pharmacists to provide training for medicinal products such as oncology, TPN (Total Parenteral Nutrition) and use of medical devices. Oversaw preparation of TORs (Terms of References) which was required from World Bank.
- Worked as teal leader on periodically analyzing data by collecting medicine and medicinal products data from all hospitals in Turkey and developed efficiency reports.
- As a social responsibility project, organized World Hygiene Day in coordination with WHO (World Health Organization) and Hacettepe University Faculty of Medicine, Infection Unit.

Chief of Cosmetics Department **July 2009- July 2012**

- Oversaw adaptation of EU directives, regulations, and standards of cosmetics products into Turkish legislation. Collaborated with various Ministries such as Ministry of Health, Ministry of Economy and Customs & Trade Ministry, submit the draft journal to Turkish Grand National Assembly and as per approval, published in Official Journal.
- Audited cosmetics producers in accordance with ICH-GMP and Cosmetics Regulations. Provided training for relevant Ministry of Health officials on audit process.
- Personally wrote guideline and standard for cosmetics producers in compliance with EU legislation on sunscreen products as well as organic & natural products (setting their differences).
- Represented Turkish Ministry of Health in European Commission DG SANCO in Brussels. Participated as guest speaker for various organizations such as Chemists Association, Toxicology Congress and IMMIB.
- As per Legislation 4073, started administrative transact for penalty for unsuitable medical devices and cosmetic products.

WORLD MEDICAL ASSOCIATION, Ferney Voltaire, France December 2008– June 2009

Pharmacist (MoH Representative)

Won a scholarship and granted to visit abroad and took acceptance from World Medical Association in France. Worked on clinical trials and ethics, adopted the guidelines to Turkish regulations. Attended committee meetings at United Nations and World Health Organization on clinical trials on pediatric patients and developed guidelines and regulation.

TURKISH MINISTRY of HEALTH Kirklareli, Turkey April 2004 - June 2009

Chief of Medicinal Products, Medical Devices, Cosmetics and Pharmacy Affairs Unit

- Audited pharmacies, pharmaceutical warehouses, and manufacturing facilities. Enforced official compliance regulations and worked as official authority (expert witness) in litigations.
- Provided patient services, responded to patient questions and complaints.
- Oversaw receipt control and authorized pharmacy payments.
- Completed over 600 compliance audits of pharmaceutical companies, pharmacies and hospitals.
- Audited narcotics and psychotropic medicines in the region.
- Audited pharmaceutical warehouses and distribution network as per article 984.

GLAXOSMITHKLINE PHARMACEUTICALS IND. & TRADE INC, Istanbul, Turkey 2002-2003
Intern & Temp. at Medical Services & Clinical Research Department

- Worked and operationally involved in CNS (Central Nervous System) project on epilepsy and migraine. Organized initial activity of clinical trial (startup meeting), preparation of ethic committee files, conducting clinical trials. Controlled CRF's. Got training in London office on ICH-GCP and GSK SOP's on clinical trials.
- Worked at clinical operations and GCP/GLP environment for a clinical operations support role. Assisted the Clinical Research Manager and Associate Director in interacting with the Clinical Operations group in the planning, execution and management of clinical samples.
- Supported the transfer of clinical samples from collaborators and CROs to GSK and third party storage facilities.
- Actively participated in tracking the training documentation across studies/research protocols.
- Exercised discretion and judgment in handling confidential information and followed regulations, ICH guidelines and GCP in all tasks.
- Monitored the progress of clinical studies at investigative sites or remotely, and ensure clinical trials are conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), ICH-GCP, and all applicable regulatory requirements.

PFIZER PHARMACEUTICALS Istanbul, Turkey 2001
Intern at Regulatory Affairs
Worked as intern on the regulatory affairs department. Observed all manufacturing processes of medicinal products from raw materials to finished products.

CERTIFICATIONS & TRAINING & MEMBERSHIPS

- 2nd Rational Antibiotic Use, Trainer Coordination Meeting, 20.09.2016-21.09.2016 (16 hours)
- Exhibited the scientific poster about "Evidence Based Pharmacy" and "Drug Management and Patient Safety" in ISOPS in 9-12 June 2015.
- Completed the master's thesis titled "Determination of Partenolide in Tanacetum argenteum (Lam.)Willd. Subsp. Argenteum" A poster of the thesis was presented in the Meeting of Herbal Medicine's Raw Materials 2012 (BIHAT). The study contributed to the treatment of migraine.
- Ankara University European Research Center (ATAUM), Advanced EU Course, 2011
- Baskent Communication Science Academy, Drama lessons, 2010.
- Participated in a play "Fazilet Eczanesi" by Haldun Taner and performed in Erciyes University Pharmacy Faculty, 2010.
- Ankara University European Research Center, 2010
- Ankara University European Research Center, 2009
- Granted a scholarship about Ethics in Clinical Trials, 2008
- Good Clinical Practice, GSK, London, 2003

PUBLICATIONS

Tosun, F., Akalgan, D., and Miski, M. (2019). Cytotoxic coumarins from the Apiaceae plants. 6th World Congress on Medicinal and Aromatic Plants,(WOCMAP),2019,Gazi Magosa- K.K.TC

Tosun, F., Akalgan, D., and Miski, M. (2017). Cytotoxic coumarins from the roots of Petroedmondia *syriaca (Boiss.) Tamamsch. 2nd International Gazi Pharma Symposium Series* (GPSS-2017), 11-13th October, Ankara.

Tosun, F., Akalgan, D., and Miski, M. (2017). Effects of the root extracts of *Petroedmondia syriaca* (Boiss.) Tamamsch. on the colon cancer cells, IX. Apiales Symposium, 31st July-2nd August 2017, Guangzhou-China.

Tosun, F., Akalgan, D., and Miski, M. (2016). Cytotoxic activity of the root extracts of *Petroedmondia syriaca* (Boiss.) Tamamsch., The 29th International Symposium on the Chemistry of Natural Products (ISCNP-29) and the 9th International Conference on Biodiversity (ICOB-9), Sept. 24th-27th, İzmir-Turkey.

Orhan, I.E., Tosun,F., Gülpınar,A.R., Kartal,M., Duran, A., Mihoglugil,F., and Akalgan,D. (2015). LC-MS quantification of parthenolide and cholinesterase inhibitory potential of selected Tanacetum L. (Emend. Briq.) taxa. Phytochemistry Letters, 11, 347-352.

Akalgan, D. (2012). Evaluation of Tanacetum argenteum (Lam.) Willd. Subsp. argenteum plant in terms of parthenolide. Master of Science Graduation Thesis-Yüksek Lisans Tezi, Gazi Üniversitesi Sağlık Bilimleri Enstitüsü, Ankara.

DELIVERED SEMINERS (AS SPEAKER)

- Explained European Union legislation to the Union of Exporters, March 2013
- 3rd Cosmetic Congress, Chemists Association, February 2013
- Cosmetics Working group meeting in Brussels of EU Studies, European Commission OTC Workshop, Ministry of Health
- OTC Workshop, Ministry of Health, December 2012. My speech was on the derma-cosmetic products.
- Clinical Research and Ethics, Ärztekammer Nordrhein-North Rhine Chamber of Physicians, Düsseldorf and Cologne by WMA to conduct interviews in the field of Ethics, February 2009
- TEDDY Clinical Research in Pediatric Patients Meeting, WMA – France, January 2009, the subject on the pediatric patients for clinical research ethics database.
- Cosmetic Regulations, Ministry of Health, June 2007. I delivered training on the new Legislative Framework.
- 3nd Rational Antibiotic Use, Trainer Coordination Meeting

ADDITIONAL INFORMATION

Languages	**:**	Conversational in French and Spanish, fluent in English and Turkish
Citizenship	**:**	Citizen of Turkey (Green Passport)
Memberships	**:**	Istanbul Chamber of Pharmacists, Rotary (Prince Islands), Circle d'orient (Buyuk Klup)
References	**:**	Professional and academic references available upon request.
Hobbies	**:**	Yoga (has 200 hours yoga alliance certificate).