



## Pharm. (MSc) Ahmet Ozan ÖZGEN

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### ABOUT

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I am experienced in clinical research and business development. Skilled in overseeing BE/BA studies and clinical trials, managing regulatory compliance, negotiation and contracts. Proven track record in stakeholder engagement, lead generation, and portfolio management. Passionate about leveraging data science and programming languages to deliver impactful solutions.

### LANGUAGES

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**Turkish:** Native language

**English:** Full professional proficiency (IELTS: 7.5 | eYDS: 92.5)

### EDUCATION

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**Akdeniz University, Gene and Cell Therapy (PhD)** | Antalya, Turkiye | 2024 ~ completed course period

**Akdeniz University, Medical Biotechnology (MSc)** | Antalya, Turkiye | 2021 ~2023

**Istanbul Medipol University, Pharmacy (BSc)** | Istanbul, Turkiye | 2014 ~ 2019

### WORK EXPERIENCE

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**Clinical Research Specialist at Nobel İlaç | İstanbul / Turkiye** [Apr. 2023–Current]

Nobel, as a pharmaceutical company, operates with five manufacturing facilities, three in Turkiye and one in Kazakhstan and Uzbekistan, while carrying out promotion and sales activities with its organizations in 20 countries, and through distributors in 30 countries. In my role, I contribute to preclinical and clinical activities, ensuring strict compliance with R&D timelines and product launches. Additionally, I manage responses to regulatory queries and deficiencies for regulatory submissions in over 50 countries. Key achievements include:

- Negotiated contracts with over 10 CROs across Europe, the USA, and India while establishing partnerships with various service vendors.
- Prepared clinical and non-clinical modules (CTD) for more than 30 medicinal products including biosimilars. Conducted preliminary research for more than 25 projects (generics & biosimilars).
- Integrated IMP procurement and regulatory affairs requests into an online platform. Also, Developed RPA software with a vendor to track study timelines, and EC/MoH applications.
- Monitoring visits to two clinical trials and fifteen BE studies in Turkiye. Also, site qualification audits to four sites in Turkiye and six in India.
- Accountable person for organizing pharmacovigilance activities within clinical trials.
- Successfully processed over 30 inquiries and deficiencies from regulatory authorities. Also, assisted in preparing CAPA for a BfArM site audit for a BE project.
- Organized and facilitated four investigator meetings.

## **Business Development Executive at Biocalis | İstanbul / Türkiye [June 2020–Apr. 2023]**

Biocalis is a healthcare company specializing in in-vitro diagnostics, medical devices and pharmaceuticals and leverages a wide distribution network spanning over 25 countries. In my role, I collaborated with an international team and managed accounts in EMEA and Central Asia, coordinating the efforts of our offices in Albania, Azerbaijan, Uzbekistan, and Russia while reporting directly to the managing director. I utilized HubSpot CRM and Excel to analyze performance metrics and track account activities. Key contributions include:

- Conducted market research for a partner (in-vitro diagnostics) to identify potential biomarkers of interest to CDMOs, CROs, and other research organizations, followed by lead generation through Springer's AdisInsight subscription.
- Initiated outbound lead generation for PCR Kits during the COVID-19 pandemic, successfully adding new accounts in Croatia, Romania, the UAE, and Pakistan. These accounts also began distributing our other in-vitro diagnostics.
- Identified a critical gap in the Albanian market and proposed adding cefuroxime to our Albanian portfolio to address the demand for secondary bacterial infection prevention in COVID-19 patients. Coordinated its registration process and significantly increased our revenue during the pandemic.
- Found and integrated an AI-powered 3D/4D aesthetic simulation software into our plastic surgery portfolio and supported over 20 plastic surgeons with product training and sales strategies.
- Created and delivered many materials (educational & promotional) to HCPs and patients in Türkiye, enhancing the reach of our Allurion intragastric balloon to over 3000 patients.

## **Retail Pharmacist at Avaroglu Pharmacy | İstanbul / Türkiye [Aug. 2019–June 2020]**

As a summary, I was responsible for coordinating safe and effective medication therapy for patients. Also, I had to adapt the everyday routine of the personnel to conditions caused by the COVID-19 pandemic.

## **Student Internship | Antalya & İstanbul / Türkiye**

I have worked for 3 months in a university hospital as a clinical pharmacist, 5 months in retail pharmacies and a month in the marketing department of a pharmaceutical company.

## **EXPERTISE SKILLS**

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- **Regulatory & Compliance:** ICH-GCP, ICH / EMA / FDA Guidelines, Data Integrity.
- **Technical:** CTD Module (clinical & non-clinical) Preparation and Assessment, Python/R (ML), SQL.
- **Soft Skills:** Cross-functional Collaboration, Stakeholder Management.

## **NETWORKS AND MEMBERSHIPS**

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### **Commission Member at Istanbul Chamber of Pharmacists [Oct. 2019–Aug. 2023]**

I worked in "Youth Assembly" and "Assistant Pharmacists" commissions. Our projects focused on the sustainable development goals of the UN and their adaptation to pharmacists in general. I have also volunteered for a week in one of the field pharmacies (Antakya, Türkiye) after the 6 February 2023 earthquakes.

### **Seeds for the Future (ICT Talent) - Huawei (Istanbul & Athens) [July 2022–Jan. 2023]**

As part of Huawei's global Corporate Social Responsibility flagship program; I have been selected for the program in 2022 after several interviews. I have led a team of 10, and we have developed and presented an AI-driven solution to prevent violence toward healthcare workers. We have won the Turkish part in the global competition and participated in the talent summit held in Athens.

## Youth Delegate at Istanbul Chamber of Pharmacists [Oct. 2017–Oct. 2019]

Youth Delegate IEO Youth Assembly is an autonomous structure where pharmacy students and pharmacists take place and produce together. I had been selected as a delegate in an election that took place in my faculty. I represented my faculty for 2 years and served in many projects. We have organized the first (2018) and the second (2019) pharmacist youth meetings.

## PUBLICATIONS

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- **In Silico Investigation of Anticancer Properties of Antimicrobial Peptides** - CoHE (Dissertation, 2024)
- **Enzymatic Targets for Drug Discovery Against Alzheimer's Disease** - Bentham Science (Book Chapter, 2023)
- **Pharmacokinetic Profile and a Bioequivalence Study of Apixaban in Healthy Volunteers** - Nobel Medicus (Research Article, 2023)
- **Models of Spike, Envelope and Membrane Proteins of SARS-CoV-2 Variants for Possible Therapeutics** - JOMTU (Research Article, 2022)
- **Antibiotic Susceptibility of Klebsiella pneumoniae Strains Isolated from Clinical Samples** - JOTCSA (Research Article, 2020)

## CONFERENCES AND SEMINARS

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- **PV Trainer** in Nobel İlac's end-of-the-year Meeting for 600+ employees | Antalya [Dec. 2023]
- **Exhibitor** (Medical Implants - SEBBIN) in ISAPS 2022 | Istanbul [Sept. 2022]
- **Guest Speaker** (Artificial Intelligence in Pharmacy) at the 8th National Congress of Hospital and Institutional Pharmacists [Mar. 2022]
- **Poster Presentation** – *6<sup>th</sup> CRC Book, 28-30. Document Classification with Optical Character Recognition and Support Vector Machines in Clinical Research* [Nov. 2024]
- **Oral Presentation** - *IPC Abstract Book, 276-277. Pharmacoeconomic Evaluation of Ulcerative Colitis and Crohn's Disease Treatments in Türkiye in Terms of Biosimilars* [Nov. 2023]
- **Oral Presentation** - *BIO Türkiye Abstract Book, 56-57. Pharmacoeconomic Evaluation of Nusinersen for Spinal Muscular Atrophy in Türkiye* [Sept. 2023]
- **Oral Presentation** - *IPTS 2022 Abstract Book, 175-177. In Silico Stability of Matrixyl Peptide Solution in Thermal Stress* [Feb. 2022]
- **Oral Presentation** - *IPC Abstract Book, 240-243. Pharmacoeconomic Evaluation of Biosimilars in Developing Countries* [Nov. 2021]
- **Poster Presentation** - *NCC Abstract Book, 372. Antibiotic Susceptibility of Klebsiella pneumoniae Strains Isolated from Clinical Samples* [Sept. 2019]

## CERTIFICATES & OTHER INFORMATION

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- GCP Training (Turkish Clinical Research Association, 2023)
- QPPV (TITCK, 2024)
- Internal Auditor (ISO 9001:2015)
- McKinsey Forward Program
- MUEF & TISD (8-week Pharmaceutical Industry Education Program)
- Driver's License (B)