



GÖKÇE SÖZER

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PERSONAL PROFILE

Date of Birth :22-04-1977
Nationality :Turkish
Marital Status :Single
Interests :Dancing (flamenco); Jogging; Biking; Swimming; Cooking; Reading; Cinema; Art& Museums; Traveling

OBJECTIVE

Targeting a managerial position within the Clinical Research Department in a leading pharmaceutical manufacturing company.

The position will involve operating the following tasks:

- ✓ Having a major role in defining the feasibility of the new molecule pipeline
- ✓ Setting short medium and long term budget plan for the clinical research department within the company's vision and strategies
- ✓ Communicating the new pipelines with CRO's and conducting the clinical studies in minimum time and highest quality and most economical way
- ✓ Submission to MOH with maximum follow up
- ✓ Strong network and relations with Turkish MOH and related professors in related universities

LANGUAGE

English (Fluently); French(Fluently)

EXPERIENCE

Clinical Research Executive

Sanovel İlaç San ve Tic A.Ş./ İstanbul - Turkey

July 2020- Present

Lecturer

Medipol University Faculty of Pharmacy

March 2020-present

Clinical Research Specialist

Sanovel İlaç San ve Tic A.Ş./ İstanbul - Turkey

Mar 2004- July 2020

- ✓ Clinical phase study of biosimilar drugs
- ✓ Clinical phase study of topical drugs
- ✓ Clinical phase study of new combination drug
- ✓ Operated the conduction of more than 200 clinical studies of which 85% passed, followed by MOH submission and registration
- ✓ Preparation and submit to MOH a justification report backed with scientific literature for the non bioequivalent studies ,around 20% of the submissions were accepted by MOH and the BE result was reversed
- ✓ Operated the audit for the conducted clinical studies
- ✓ Prepared scientific reports for certain molecules that could be adaptable to biowaiver conditions, these reports were submitted and approved by MOH followed by initiating a circular letter directed to all manufacturing companies
- ✓ Business development relating the clinical studies

Research Assistant

Marmara University /Faculty of Pharmacy

Pharmaceutical Technology Dept.

2000-2004

- ✓ Pharmaceutical Technology instructor

EDUCATION

- ✓ PhD Degree: Marmara University/Faculty of Pharmacy/ Pharmaceutical Technology Department; (2015– 2019)
- ✓ Masters Degree: Marmara University/Faculty of Pharmacy/ Pharmaceutical Technology Department; (2000 – 2003)
- ✓ Bachelor of Pharmacy: Marmara University; (1996-2000)
- ✓ Bilfen Science College; (1993-1996)
- ✓ Saint Benoit French School; (1988 – 1993)

COURSES

- ✓ GCP training course 2019 Antalya
- ✓ I. Hematoloji Eğitim ve Araştırma Kongresi 2019 Belek-Antalya
- ✓ 8th BBBB International Conference on Pharmaceutical Sciences 2019 Çeşme-İzmir
- ✓ Erken Faz Klinik Araştırmalar Sempozyumu 2019 İzmir
- ✓ 1501 TÜBİTAK Project (Development And Release Property Evaluation Of Oral Solid Dosage Forms Containing Active Substance (dabigatran etexilat) 2015-2019 İstanbul-Turkey
- ✓ Bioequivalence Studies Symposium 2013 Leuven- Belgium
- ✓ Klinik Araştırmalar Sempozyumu 2009 İstanbul-Turkey
- ✓ Formulation Development for Generics 2007 İstanbul-Turkey
- ✓ Statistics for non Statisticians in pharmaceutical business 2006 İstanbul - Turkey
- ✓ Regulatory Update and Overview of BA/BE testing with an industry perspective 2006 İstanbul-Turkey
- ✓ BSC and Enhancement of Bioavailability Through Smart Formulation 2005 İstanbul- Turkey
- ✓ Update on The Regulatory Environment in Moving Market Pharmaceuticals 2005 İstanbul- Turkey
- ✓ 2nd Int. Symposium on Scientific and regulatory Aspects of Dissolution & Bioequivalence 2005 İstanbul- Turkey
- ✓ International Regulatory Workshop on Bioequivalence and Dissolution 2004 İstanbul- Turkey
- ✓ European Regulatory Procedures & STDS 2004 London - England
- ✓ *Oral Presentation* : VII. National Pharmaceutical Congress “_Multiparticular systems prepared with scleroglucan 2003 İstanbul-Turkey
- ✓ Symposium “Development and Delivery Challenges of the Next Generation of Drugs 2000 İstanbul- Turkey
- ✓ Postgraduate Research Symposium on Pharmaceutics 2000 İstanbul- Turkey
- ✓ Short Course “Coating Technology” 2000 İstanbul- Turkey