Ms. Ayşe BÖRKLÜ

CONTACT

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PERSONAL INFORMATION

Born on: 13.10.1990/ İSTANBUL
Driving license: B
Marital status: Single

EDUCATION

2023-…. Anadolu University, **Sociology** (Open Education)
2018-2023 Anadolu University, **International Relations** (Open Education)
2009-2016 İstanbul Technical University, **Chemical Engineering**
2004-2008 Sefaköy Anatolian High School

WORK EXPERIENCES

Sep.20/2023-…. VEFA Pharmaceuticals-*Regulatory Affairs Senior Specialist (TR & International Markets)*

- **NDA activities:** *Submission & follow-up marketing authorization dossiers for new product (Domestic and External Markets – especially CIS countries)*
- **CMC:** *Technical variations & Renewals*
- **Labelling:** *SmPC-PIL, mock-ups controlling and preparation*
- **Regulatory follow up:** Contributing with medicinal associations and chambers regarding to regulations, variations and strategies
- **Lifecycle management:** *Coordination and close follow-up with local colleagues (Graphic, R&D, Quality, Purchasement etc. and global suppliers)*
- Archiving
- Training and experience sharing with junior RA specialists

Dec.14/2022-Feb.06/2023 ERTE Cosmetics-*Regulatory Affairs and Documentation Specialist*

• **PIF preparation:** *Ingredients calculating and preparation, SDS preparation, mock-up controls*
• Local & global sample shipment and clinical test processes
• Following related local and global cosmetics regulations
• Coordination and close follow-up with local and global suppliers

Mar.01/2022-Agu.26/2022 VIATRIS Pharmaceuticals-*Regulatory Affairs Senior Specialist*

- **NDA activities:** *Submission & follow-up marketing authorization dossiers for new product*
  GMP and Prioritization submission
- **CMC:** *Technical variations & Renewals*
- **Labelling:** *SmPC-PIL, mock-ups controlling and preparation related to dispatched CCDS*
- **Regulatory follow up:** Contributing with medicinal associations and chambers regarding to regulations, variations and strategies
- **Lifecycle management:** *Coordination and close follow-up with local colleagues (Graphic, R&D, Quality, Purchasement etc. and global suppliers)*
- Archiving

Agu.04/2020-Dec.31/2021 BAYER Pharmaceuticals-*Regulatory Affairs Specialist – Consumer Health*

- **CMC:** *Technical variations & Renewals*
- **Labelling:** *SmPC-PIL, mock-ups controlling and preparation related to dispatched CCDS*
- **Regulatory follow up:** Contributing with medicinal associations and chambers regarding to regulations, variations and strategies
- **Lifecycle management:** *Coordination and close follow-up with local colleagues (Graphic, R&D, Quality, Purchasement etc. and global suppliers)*
- Archiving
- Cosmetics & food supplements dossier preparation as well medicinal products
- Coordination and close follow-up with local and global suppliers
- MDR training had gained, medical device responsibilities had been assisted

Feb.10/2020-Jul.17/2020 ADEKA Pharmaceuticals-*Regulatory Affairs Specialist*

- **NDA activities:** *Submission & follow-up marketing authorization dossiers for new product*
- **CMC:** *Technical variations & Renewals*
- **Labelling:** *SmPC-PIL, mock-ups controlling and preparation*
- **Regulatory follow up:** Contributing with medicinal associations and chambers regarding to regulations, variations and strategies

- **Lifecycle management:** *Coordination and close follow-up with local colleagues (Graphic, R&D, Quality, Purchasement etc. and global suppliers)*
- Archiving
- Coordination and close follow-up with local and global suppliers
- Pricing and reimbursement activities

Mar.6/2017-Jan.31/2020 KOÇAK FARMA Pharmaceuticals-*Regulatory Affairs Specialist*

- **NDA activities:** *Submission & follow-up marketing authorization dossiers for new product*
- **CMC:** *Technical variations & Renewals*
- **Labelling:** *SmPC-PIL, mock-ups controlling and preparation*
  Writing Clinical and Non-Clinical Parts of Module 2
- **Regulatory follow up:** Contributing with medicinal associations and chambers regarding to regulations, variations and strategies
- **Lifecycle management:** *Coordination and close follow-up with local colleagues (Graphic, R&D, Quality, Purchasement etc. and global suppliers)*
- Assisting management and follow-up the department works when the manager is on holiday or out of office.
- Archiving
- Coordination and close follow-up with local and global suppliers

Aug.17/2015-15.11.2016 World Medicine Pharmaceuticals-*International Regulatory Affairs Assistant Specialist (Specialized in the CIS countries regulation)*

- Assisting the collegues who are responsible for related countries: Preparation and follow up registration dossiers in accordance with CTD format making the necessary translations & Preparation and update of Summary of Product Characteristics (SmPC) and Patient Information Leaflets (PIL)
- Controlling and translation of the factory SOP
- Preparing CPP & MA copies

Feb.28/2014, Nov.6/2014 Interlab A.Ş., Isolab GmbH, Sigma Aldrich

• Exportation Operation Internship from Feb 28 to March 13
• Production Internship from March 13 to June 6
• Quality Control Internship from June 6 to November 6

Dec.10/2012, Nov.10/2013 AR-DEZ Sniper-SNIPER® TURKEY-*Biocidal Product Responsible*

• Production of the disinfectant named “Sniper” which formulated in U.S.A diluted and prepared to use in Turkey
• Management of regulatory the “Sniper” with Ministry of Health

• Marketing researches and accesses, competitive formulation, price and quota research, customer visits, key account sales tracking and supply controls
• Presenting firm on business trips, presentations and training technical sales staff
• Literature researches about the other products of company
• Performing the official corresponds and mails with head company of “Sniper” in the U.S.A
• Technical sales team training

MEMBERSHIPS
• TMMOB Chamber of Chemical Engineers, İstanbul

SKILLS
Language: English (Reading: Advanced, Writing: Advanced, Speaking: Advanced)
French (Reading: Beginner, Writing: Beginner, Speaking: Beginner)
German (Reading: Beginner, Writing: Beginner, Speaking: Beginner)
Turkish (Native)

Computer Skills: MS Office All Applications /Advanced
SAP Archive and Other Operations
SharePoint

PROJECTS - HONORS & AWARDS
• Certificated about “*Internal Auditor”* ISO 9001, 14001 and OHSAS 18001 in 2013
• *“Phthalic Anhydride Production Plant Design”* Design Project in 2014
• *“Degradation of Polycaprolactone”* Graduation Project in 2015
• Certificated about GMP Education in 2022

References will be provided upon request.