

CURRICULUM VITAE

Aysenur KOSE



PERSONAL INFORMATION:

Birth Date and Birth Place: 29.05.1995, Erzincan (Turkey)

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EDUCATION:

September 2014 – June 2019 Erciyes University Faculty of Pharmacy

September 2010 – June 2013 Hatay Osman Ötken Anatolian High School

September 2009 – June 2010 Batman Anatolian High School

EXPERIENCE:

Aug 2022 – Present DeltaPV Ilac Danismanlik Saglik Urun ve Hiz. Tic. A.S.
Pharmacovigilance Manager

- Assigning as Local Qualified Pharmacovigilance Responsible Person for the companies which sign a service agreement,
- Preparing/Quality Controlling/Approving/Tracking of PSMF, PBRER, RMP, ICSR, Literature Reports, Safety Alerts Screening Results/Dear Doctor Letters,
- Submitting PSMF, PBRER, RMP, ICSR, Dear Doctor Letters to Turkish Health Authority, when necessary,
- Performing weekly work schedule plans with PV Team Leader and PV Specialists,
- Controlling all of the pharmacovigilance, materiovigilance and cosmetovigilance related standard operating procedures,
- Dividing special tasks the team members according to their workloads,
- Being present at inspections and audits,
- Arranging appropriate corrective actions and closing findings based on the inspection/audit reports,
- Being available 7/24 as PV contact point,
- Informing the companies when there is a change in the local PV regulation/guidelines,
- Giving basic and refresher PV training to the companies' employees.

June 2021 – Aug 2022

DeltaPV Ilac Danismanlik Saglik Urun ve Hiz. Tic. A.S.

Pharmacovigilance Team Leader

- Assigning as deputy Local Qualified Pharmacovigilance Responsible Person for the companies which sign a service agreement,
- Preparing/Quality Controlling/Tracking of PSMF, PBRER, RMP, ICSR, Literature Reports, Safety Alerts Screening Results/Dear Doctor Letters,
- Submitting PSMF, PBRER, RMP, ICSR, Dear Doctor Letters to Turkish Health Authority, when necessary,
- Performing weekly work schedule plans with PV Specialists,
- Preparing all of the pharmacovigilance, materiovigilance and cosmetovigilance related standard operating procedures,
- Being present at inspections and audits,
- Being available 7/24 as PV contact point,
- Informing the companies when there is a change in the local PV regulation/guidelines,
- Giving basic and refresher PV training to the companies' employees.

Oct 2019 – June 2021

DeltaPV Ilac Danismanlik Saglik Urun ve Hiz. Tic. A.S.

Pharmacovigilance Specialist

- Assigning as deputy Local Qualified Pharmacovigilance Responsible Person for the companies which sign a service agreement,
- Preparing/Tracking of PSMF, PBRER, RMP, ICSR, Literature Reports, Safety Alerts Screening Results/Dear Doctor Letters,
- Submitting PSMF, PBRER, RMP, ICSR, Dear Doctor Letters to Turkish Health Authority, when necessary,
- Being present at inspections and audits,
- Being available 7/24 as PV contact point,
- Informing the companies when there is a change in the local PV regulation/guidelines,
- Giving basic and refresher PV training to the companies' employees.

February 2019-June 2019

Istanbul Pharmacy - *Intern Pharmacist*

June 2018 - January 2019

Ipek Birer Pharmacy - *Intern Pharmacist*

June 2017 - August 2017

Roland Apotheke - *Intern Pharmacist*

June 2016 - August 2016

Sakarya Yenikent State Hospital - *Intern Pharmacist*

LANGUAGE SKILLS:

Turkish: Mother language

English: Advanced

German: Intermediate

DATABASES HANDLED:

Argus

VeevaVault

Sympto

MedDRA

EDUCATION ON PHARMACOVIGILANCE:

DATE	TRAINING
29-Feb-2024	MedDRA: Safety Data Analysis and SMQs / <i>The Maintenance and Support Services Organization (MSSO) (Face-to-face training)</i>
28-Feb-2024	Coding with MedDRA / <i>The Maintenance and Support Services Organization (MSSO) (Face-to-face training)</i>
23-Jan-2024	Advanced MedDRA Coding- Webinar / <i>The Maintenance and Support Services Organization (MSSO)</i>
08-23 June 2023	Veeva - Salus Pharmacovigilance Database System Training
14-Jun-2023	Standardised MedDRA Queries (SMQs) - Webinar / <i>The Maintenance and Support Services Organization (MSSO)</i>
19-Jan-2023	Advanced MedDRA Coding Webinar / <i>The Maintenance and Support Services Organization (MSSO)</i>
12-Jan-2023	MedDRA Coding Basic- Webinar / <i>The Maintenance and Support Services Organization (MSSO)</i>
28-31-Mar-2022	Sympto® Pharmacovigilance Database System Training / E2B System
15-Mar-2022	Collecting high quality ADR reports / <i>WHO-Uppsala Monitoring Centre (Online learning)</i>
25-Feb-2022	Essentials of pharmacovigilance communications / <i>WHO-Uppsala Monitoring Centre (Online learning)</i>
2-3 Dec 2021	Qualified Person for Pharmacovigilance Training – Turkish Medicines and Medical Devices Agency
23-Nov-2021	Advanced MedDRA Coding Webinar / <i>The Maintenance and Support Services Organization (MSSO)</i>
20-Mar-2021	Introduction to pharmacovigilance / <i>WHO-Uppsala Monitoring Centre</i>

	<i>(Online learning)</i>
20-Mar-2021	Introduction to signal detection / <i>WHO-Uppsala Monitoring Centre (Online learning)</i>
20-Mar-2021	Causality assessment of single case safety reports / <i>WHO-Uppsala Monitoring Centre (Online learning)</i>
20-Mar-2021	Causality assessment of case series / <i>WHO-Uppsala Monitoring Centre (Online learning)</i>
20-Mar-2021	Signal assessment / <i>WHO-Uppsala Monitoring Centre (Online learning)</i>
20-Mar-2021	Statistical reasoning and algorithms in pharmacovigilance / <i>WHO-Uppsala Monitoring Centre (Online learning)</i>
20-Mar-2021	Signal detection and assessment- Learning path / <i>WHO-Uppsala Monitoring Centre (Online learning)</i>
20-Oct-2020	MedDRA Coding Basic- Webinar / <i>The Maintenance and Support Services Organization (MSSO)</i>