

PERSONAL INFORMATION

Gela Camelia Lazar

WORK EXPERIENCE

February 2020–Present

Resident physician

University of Medicine and Pharmacy "Carol Davila" Bucharest (Romania)

February 2013–Present

**QPPV of National Agency for Medicines and Medical Devices of Romania
Pharmacovigilance assessor in the Pharmacovigilance and Risk Management
Unit, MD**

National Agency for Medicines and Medical Devices of Romania (Romania)

- Responsible Person for EudraVigilance of the Romanian National Agency for Medicines and Medical Devices

- Evaluation of pharmacovigilance elements within the Risk Management Plan for centralized and decentralized procedure authorized medicines (Educational materials, Direct Healthcare Professionals Communications)

- Evaluation of the documentation submitted for the renewal of medicinal products authorization

- Management of adverse reaction reports related to medicinal products in the EudraVigilance system (transmission, validation, completion, acknowledgement, management of all sources reports)

- Management of the e-mail account adr@anm.ro and contact@anm.ro

- ad-hoc trainings for other personnel

- Participant in SCOPE Joint Action

Business or sector European Procedures Department, Pharmacovigilance and Risk Management Service

December 2006–February 2013

Medical Doctor within Products Information Bureau, assessor

National Agency for Medicines and Medical Devices of Romania (Romania)

- Assessment of the product information within the Marketing Authorization dossier and annexes for national and centralized/decentralized/mutual recognition authorised medicinal products.

- Editing MA and annexes for Romanian and foreign medicinal products (including through "mutual recognition" procedure, centralised and decentralised procedure).

- Language evaluation of the product information within the post-opinion stage for centralized authorised medicinal products and related variations.

Business or sector European Procedures Department and National Procedures Department, Products Information Bureau

October 2006–November 2006

Medical doctor

Ambulance BGS Medical Unit (Romania)

Medical activities-medical consultations

June 2006–October 2006

Medical Director

Hipocrat Hyperclinic (Romania)

- Coordinating the medical team and the sales team

- Negotiation and conclusion of contracts, managing all type of issues related to it

- Medical services-medical examinations

- Completion and coordination of a national network of occupational medicine for Hipocrat Hyperclinic company

May 2005–May 2006 **Administrator**
 S.C. Sensiblu Optical S.R.L. (Romania)
 Administrator-legal representation

July 2004–May 2006 **Administrator, Medical Director, Key Account Manager and Medical doctor**
 S.C. Cristal Diagnostics S.R.L. (Romania)
 Administrator -legal representation, development and investment decision, purchases, participation in auctions, contracting medical services (laboratory and other specialties), staff recruitment and training
 Key Account Manager -preparation of marketing materials for medical services, maintaining relationships with family physicians and medical specialists, completion and coordination of a national network of occupational medicine for Cristal Diagnostics, negotiation and conclusion of occupational medicine contracts, management of all related issues and database.
 Medical Doctor - medical examinations, preparation of medical records, performing audiometry and spirometry, assessment of work risk factors related to occupational medicine, participation in Committee of Health and Safety at Work sessions, conducting supervision of medical leave, maternal risk assessment and managing patient tracking system.
 Medical Director - coordinating medical team (family physicians and doctors of other medical specialties, laboratory for the national occupational medicine network)

May 2004–June 2004 **Medical doctor**
 Ambulance BGS Medical Unit (Romania)
 - specific medical examinations, preparation of medical records
 - marketing activities, promoting and contracting healthcare services
 -establishing and coordinating a national network of occupational medicine for Ambulance BGS Medical Unit

January 2003–April 2004 **Occupational medicine**
 Simona Medical Center (Romania)
 Promotion of healthcare services, negotiation and conclusion of occupational medicine contracts, management of all related issues

January 2001–December 2001 **Medical doctor**
 Braila County Hospital (Romania)
 Medical consultations, preparation of medical records

EDUCATION AND TRAINING

September 2020–September 2020 **Attendance Certificate**
 EMA (Romania)
 7th Romanian Pharmacovigilance Workshop-EudraVigilance news, Signal detection, Covid-19 pharmacovigilance, MedDRA 23.1, inspections and audits, risk management plans -21-23 September 2020

October 2019–November 2019 **Attendance Certificate**
 WHO and Invima (Colombia)
 42nd Annual Meeting of Representatives of National Pharmacovigilance Centers

October 2018–October 2018 **Attendance Certificate**

- (Romania)
5th Romania Pharmacovigilance Workshop
- September 2017– **Attendance Certificate**
(Romania)
Sub-regional advanced training workshop on AEFI causality assessment for middle income countries organized by WHO
- September 2017– **Certificate**
(United Kingdom)
New EudraVigilance - Electronic Reporting of Individual Case Safety Reports (ICSRs) in the EEA
- February 2017– **Attendance Certificate**
(Romania)
“Signal Management in Pharmacovigilance” organized by Information Association (DIA)
- November 2016– **Attendance Certificate**
(United Kingdom)
Pharmacovigilance Assessors Training (London)
Pharmacovigilance assessments – challenges and solutions for pharmacovigilance assessors
- May 2015– **Attendance Certificate**
(Romania)
Pharmacovigilance Conference on risk management, electronic reporting, XEVMPD updates, audits, inspections and periodic reporting
- September 2014– **Attendance Certificate**
(Romania)
Pharmacovigilance Conference on risk management, electronic reporting, XEVMPD updates, audits, inspections and periodic reporting
- October 2013–October 2013 **Certificate**
(Romania)
EMA-DIA - EudraVigilance User Training Course, EudraVigilance User Responsible Person for EudraVigilance in NAMMD
- 2006–2007 **Completion of first year**
(Romania)
Faculty of Psychology and Sociology “Spiru Haret”
- 2003–2004 **Compentence diploma**
(Romania)

National Center for Education in Health, Bucharest (Romania)
Occupational Medicine Competency Course
Medical doctor with responsibilities for occupational health

1994–2000 **Medical doctor diploma**
(Romania)
The University of Medicine and Pharmacy

ADDITIONAL INFORMATION

Expertise

Publications

Projects

Memberships

Other Relevant Information