



## Curriculum Vitae

Personal information **Radu Sorin Timofei**

### Work experience

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#### **07/2016 – Present**

##### **Head of Information Technology and Communications Service (IT Manager)**

National Agency for Medicines and Medical Devices of Romania (ANMDMR)  
Bucharest, Romania

Responsible for the coordination and strategic development of the Agency's IT and communications infrastructure. Leading the planning and implementation of digital transformation initiatives aimed at improving regulatory processes, operational efficiency and data management within the Agency.

Main responsibilities include:

- Initiation, coordination and implementation of IT&C projects supporting the digitalisation of regulatory activities.
- Development and management of IT infrastructure, including servers, networks, data storage and cybersecurity measures.
- Technical analysis and support for public procurement procedures related to IT systems, infrastructure and software solutions.
- Oversight of enterprise systems supporting regulatory processes and information management.
- Participation in European Medicines Agency (EMA) governance structures, including the EMA IT Directors Group, contributing to discussions on interoperability, regulatory IT systems and digital collaboration within the European medicines regulatory network.
- Contribution to the development of national and European digital initiatives related to regulatory data, information systems and secure infrastructure.

#### **09/1998 – 07/2016**

##### **IT Specialist / Programmer and Internet Investigator (Counterfeit Medicines)**

National Agency for Medicines and Medical Devices of Romania (ANMDMR)  
Bucharest, Romania

Responsible for the administration and maintenance of the Agency's IT infrastructure and for supporting regulatory and investigative activities related to illegal online medicines distribution.

Main responsibilities included:

- Administration of the Agency's IT infrastructure, including servers, workstations and network equipment.
- Management of software licensing, IT asset inventory and implementation of internal IT security policies.
- Technical support and maintenance of internal systems and communications infrastructure.
- Internet-based investigations aimed at identifying illegal online sales of medicines and counterfeit pharmaceutical products.
- Preparation of investigation reports and technical documentation to support enforcement actions by competent authorities.
- Identification and reporting of websites involved in illegal pharmaceutical activities, leading to the suspension or closure of multiple platforms distributing counterfeit or unauthorized medicines.

#### **01/2005 – 09/2018**

##### **Business Coordinator**

PC Planet Network SRL  
Bucharest, Romania

- Design and deployment of communication network infrastructures based on fibre optic and structured cabling technologies.
- Planning and implementation of star-topology network architectures using fibre optic backbone connectivity.
- Provision of customised IT and connectivity solutions for both residential and corporate clients.
- Coordination of technical teams responsible for infrastructure deployment, maintenance and support services.
- Participation in specialised projects including the design and installation of CCTV systems for restricted-access environments in cooperation with public institutions.

### Education and training

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03/2024 – 06/2024

ITIL® 4 Foundation Certification

Institution: Accredited Training Provider (AXELOS framework)

Country: Romania

Subjects/skills covered: IT service management principles, service value system, service lifecycle, incident and problem management, IT governance and service delivery best practices.

05/2023 – 06/2023

CompTIA Security+ (SY0-601) Certification

Institution: Accredited Training Provider

Country: Romania

Subjects/skills covered: cybersecurity principles, network security, threat detection, risk management, incident response, identity and access management, security governance frameworks.

10/2021 – 11/2021

Cyber-Security and Classified Information Protection

Institution: INTENSEC Cyber Division

Country: Romania  
Subjects/skills covered: protection of classified information, cybersecurity policies and procedures, secure infrastructure management, risk mitigation and compliance with information security standards.

09/2021 – 10/2021  
Information Systems Security Procedures and Tools Specialist  
Institution: INTENSEC Cyber Division  
Country: Romania  
Subjects/skills covered: information systems security procedures, security tools, operational security practices and incident management.

05/2011 – 05/2011  
Certificate – Completion of the Internet Investigators' Course  
Institution: Irish Medicines Board, U.S. Food and Drug Administration (FDA) and INFARMED  
Country: Portugal  
Subjects/skills covered: investigation of illegal online sale of medicines, identification of counterfeit medicines websites, digital evidence collection and international regulatory cooperation.

01/2009 – 03/2009  
Quality Management Systems – ISO 9001:2008  
Institution: QUASARO  
Country: Romania  
Subjects/skills covered: quality management systems implementation, process management, internal auditing and compliance with ISO standards.

09/2013 – 07/2016  
Bachelor Degree in Economics and Management  
Institution: Hyperion University  
Country: Romania  
Subjects/skills covered: business management, organisational management, economics, strategic planning and administration.

01/2001 – 12/2001  
Oracle Computer Training Programme  
Institution: Oracle Computer Training Centre  
Country: Romania  
Subjects/skills covered: database fundamentals, SQL, database administration basics and enterprise database technologies.

## Additional information

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### Publications

### Projects

#### 06/2024 – Present

##### **Digitalisation of the National Agency for Medicines and Medical Devices of Romania (ANMDMR)**

Project funded through Romania's National Recovery and Resilience Plan (PNRR) – Pillar II: Digital Transformation, Component C7, Investment I3.2 – Digitalisation of healthcare institutions under the authority of the Ministry of Health.

Role: coordination and technical oversight of digital transformation initiatives within ANMDMR.

Main activities include the implementation of enterprise digital systems, optimisation of internal workflows, development of electronic document management capabilities and improvement of regulatory data management and operational efficiency.

#### 03/2024 – Present

##### **Modernization of the Electronic Reporting System for Medicine Stocks (SER) – Project Coordinator**

Project funded through Romania's National Recovery and Resilience Plan (PNRR) – Pillar II: Digital Transformation. The project aims to modernise the national electronic reporting system for medicine stocks in order to improve data accuracy, enhance reporting efficiency and support the monitoring and prevention of medicine shortages at national level.

#### 07/2023 – Present

##### **Coordination and Harmonisation of Systems for Monitoring Medicines Shortages – European Network**

Contribution to initiatives aimed at improving digital information exchange within the European medicines regulatory network for monitoring and reporting medicine shortages.

The project supports preventive and mitigation strategies to reduce the likelihood of shortages and strengthens cooperation between national competent authorities and European institutions.

#### 01/2023 – Present

##### **National Digital Platform for Submission of Publicity Materials for Medicinal Products**

Business and technical analysis for the development of a digital platform allowing pharmaceutical companies to submit promotional and publicity materials electronically for regulatory review.

The project contributes to the digitalisation of regulatory processes and improved transparency and efficiency within the national medicines authority.

#### 10/2022 – Present

##### **Digital Platform for Electronic Submission of Clinical Trial Documentation**

Business and project analysis for the implementation of a digital platform enabling electronic submission and management of clinical trial documentation submitted to the national competent authority.

The platform supports the digitalisation of regulatory workflows and facilitates communication between sponsors and the authority.

#### 07/2020 – Present

##### **National Platform for Reporting Suspected Adverse Reactions to COVID-19 Vaccines**

Business analysis and project implementation of a national digital platform dedicated to reporting suspected adverse reactions following COVID-19 vaccination.

The platform supports pharmacovigilance activities by enabling healthcare professionals and citizens to report adverse reactions, contributing to the rapid identification of new safety information.

#### 06/2021 – 06/2022

##### **Implementation of Virtualisation and High-Availability Storage Infrastructure at ANMDMR**

Coordination and implementation of an enterprise IT infrastructure solution based on server virtualisation technologies and RAID storage systems, including both hardware and software components.

The project improved resilience, data security and performance of the Agency's IT infrastructure and ensured higher availability of regulatory information systems.

### Memberships

**Participation in the EMA IT Directors and Experts Network**

Member of the IT Directors and Experts community within the European Medicines Agency (EMA) network. Participation in discussions and exchanges related to regulatory IT systems, digital transformation, interoperability and secure information management within the European medicines regulatory network.

**Participation in European Medicines Agency (EMA) Working Groups and Digital Initiatives**

Participation in collaborative activities and technical exchanges related to regulatory IT infrastructure, digital platforms and data management supporting cooperation between national competent authorities and the European Medicines Agency.

**Contribution to European Digital Initiatives in the Medicines Regulatory Network**

Involvement in initiatives related to regulatory data standardisation, digital systems interoperability and implementation of common European digital solutions supporting medicines regulation.

## Other Relevant Information

**Expertise in Digital Transformation and Regulatory Information Systems**

Extensive experience in the design, implementation and management of information systems supporting medicines regulation and public health administration. Responsible for coordinating digital transformation initiatives, IT infrastructure development and secure data management within the National Agency for Medicines and Medical Devices in Romania (ANMMDMR).

Professional activities include the planning and implementation of enterprise IT infrastructure, virtualisation environments, secure communication systems and regulatory digital platforms used for data exchange with national and European partners.

Active involvement in projects related to the digitalisation of regulatory processes, interoperability of health information systems and implementation of European digital initiatives within the medicines regulatory network.

Areas of expertise include digital governance, IT infrastructure and network architecture, regulatory data management, information security, and coordination of complex IT projects within public sector organisations.