

Curriculum Vitae

Personal information **Simona Raluca Manole**

Work experience

1. Employer: National Agency for Medicines and Medical Devices of Romania
 - Start date: 062022
 - End date:
 - Position: Director of the Directorate for Good Distribution Practice Inspection
 - Activities: coordinating the activity of wholesale distribution of medicines for human use at the national level
 - Country: Romania
2. Employer: National Agency for Medicines and Medical Devices of Romania
 - Start date: 072021
 - End date: 052022
 - Position: GDP Inspector
 - Activities: conducting authorization inspections, respectively BPD certification of wholesale drug distribution units, conducting inspections to verify the activity of registered drug brokers, conducting inspections to verify the activity of wholesale distributors of raw materials used in the manufacture of medicines for human use; (as appropriate, unannounced inspections); prepares inspection reports; verifying the existence of the complete documentation necessary for carrying out the inspections of good distribution practice (BPD), and following the payment of the tariffs for them; participates in the preparation of service-specific documents; participates in the meetings of the Commission for inspections of GMP, GMP, GLP, GLP, BPSC, Pharmacovigilance; participates in the training of DGIF staff;
 - Country: Romania
3. Employer: FARMEXIM SA
 - Start date: 022021
 - End date: 072021
 - Position: Quality Management Specialist
 - Activities: coordinate, assist, train, and evaluate quality management processes according to GDP requirements, ISO standard and applicable legislation in the field of medicine, medical devices, food supplements; train staff on Quality Management process; gather, compile and evaluate different program data documents like incident reports, satisfaction surveys and recommendations;
 - Country: Romania
4. Employer: UCB PHARMA ROMANIA SRL
 - Start date: 122019
 - End date: 022021
 - Position: Responsible Person
 - Activities: Ensure that all aspects of the handling and distribution of pharmaceutical products comply with the requirements of the EU Good Manufacturing Practices/Good Distribution Practices and relevant local regulatory and legislative requirements; Ensure, in collaboration with Quality Lead, the implementation, maintenance and upgrading of the local Quality System in order to drive compliance with local/international GDP regulatory requirements and UCB global standard operating procedures; Provide quality oversight to local GDP vendors particularly such as warehouse/distribution service providers in compliance with UCB Quality Standards (qualification, quality/agreements, vendor management).
 - Country: Romania
5. Employer: GREEN NET SA (FARMEXIM GROUP)
 - Start date: 122015
 - End date: 122019
 - Position: Quality Manager /Responsible Person
 - Activities: Ensuring the compliance with the legislation in force and the rules of good distribution practice; preparing the specific documentation according to the guide of good distribution practice, ensuring its implementation ensuring the relationship with the authorities in order to maintain in force the operating permits / authorizations, necessary for all categories of products sold _ authorities in the field of medicines and medical devices (ANMDM) and food supplements (IBA); providing technical management for Aboca S.p.A Societa Agricola Italy (represented in Romania by Green Net SA);
 - Country: Romania
6. Employer: FARMACEUTICA REMEDIA SA
 - Start date: 122009
 - End date: 122015
 - Position: Quality Manager /Responsible Person
 - Activities: Ensuring the implementation of quality management according to ISO accreditation standards; Taking responsibility for Quality Department management, making sure that the necessary processes QMS are assessed, communicated, implemented and maintained; Assuring support and consultancy to operational departments in achieving the goals; Defining the processes that contribute to the qualitative development of operational departments' activities; Continuously monitoring and participating in improving key performance indicators; Elaborating work instructions regarding quality; Checking the preparation of process descriptions and work instructions elaborated by the process owners; Proposing performance criteria and participating in quality management assessment; Following the authorization / license renewal of the warehouse, collaborating with the other departments in order to obtain the mandatory permits for the warehouse's activity; Ensuring the compliance with the legislation in force and the rules of good distribution practice; _ Organizing all deposit activity under current legislation and the RBPD; • Pharmacist Warehouse Supervisor – Bucharest Warehouse • Back_up –Qualified

- Person Responsible for Pharmacovigilance
- Country: Romania
7. Employer: SC RALF FARMACIE SRL
- Start date: 022008
 - End date: 122011
 - Position: Administrator
 - Activities: Chief Pharmacist, Administrator
 - Country: Romania
8. Employer: PHARMAFARM SA_ GEDEON RICHTER GROUP
- Start date: 032000
 - End date: 012008
 - Position: Action Department Manager
 - Activities: Coordination of the Pharmaceutical Products Registration and Development Department Qualified Person Responsible for Pharmacovigilance
 - Country: Romania

Education and training

1. Subject: Faculty of Pharmacy, Carol Davila University of Medicine and Pharmacy, Bucharest
- Start date: 091995
 - End date: 092000
 - Qualification: Pharmacist
 - Organisation:
 - Country: Romania
2. Subject: Faculty of Pharmacy, Carol Davila University of Medicine and Pharmacy, Bucharest
- Start date: 012002
 - End date: 122004
 - Qualification: Specialist Pharmacist
 - Organisation: Residency Program in Pharmaceutical Laboratory – Carol Davila University of Medicine and Pharmacy, Bucharest
 - Country: Romania
3. Subject: DIMITRIE CANTEMIR Christian University, Bucharest
- Start date: 112006
 - End date: 052008
 - Qualification: specialization program in business administration
 - Organisation: Master Program in Marketing and Business Negotiations
 - Country: Romania

Additional information

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