Curriculum Vitae

Name: Iulia Ioana Olaru

Work experience

February 2025-Present
RA Specialist – VITEMA SA

- Preparing and compiling, reviewing and submission of regulatory applications in accordance with EU and national requirements;
- Preparing and compiling documentation for food supplement registration;
- Tracking and monitoring queries/DLs/commitments from/to HA to ensure the implementation and compliance.
- Develop, maintain a thorough and up-to-date understanding of the regulatory environment and supporting data requirements; Align resources and discuss regulatory issues in cross-functional teams to ensure completion of project tasks.
- Communicate with peers and supervisors and ensure alignment on issues, questions, and goals.

August 2023-February 2025
RA Associate-AbbVie SRL

- Advanced support for products (development stage and commercialized products).
- Preparing and submission of the specific regulatory documents for products authorized and/or marketed or are to be marketed in RO.
- Reviewing and sign-off RA documents, including promo materials, label changes to ensure compliance with local and company requirements.
- Managing requests received from the HA, ensuring a precise translation of the requirements. Ensure the submission of any response/update of the product documentation to the HA.
- Reviewing PI in accordance with legal and regulatory requirements; ensure the information correctness; managing translation reviews and/or perform spot translations as requested.
- Collaborates with the quality and logistics department to organize timely sample deliveries.
- Collaborates with the MA department to ensure the necessary RA information for price approval for all new/strategic products.
- Ensures compliance with company policies, procedures, guidelines, local and EU regulations to fulfill statutory, quality and activity requirements within the global strategy and objectives.
- Support function within the affiliate for training, including onboarding.

August 2022- July 2023
RA Manager - Polisano Pharmaceuticals S.A.

- Coordinating and planning the regulatory affairs activities of the MAH (medicinal products and food supplements).
- Identifying the necessity for new regulatory procedures and SOPs to ensure regulatory compliance and operational efficiency.
- Working in cross-functional teams to ensure alignment on regulatory issues, questions, goals and ensure project completion.
- Providing regulatory support for new initiatives to project teams, stakeholders and customers with both EU and non-EU entities for project success.
- Evaluate the regulatory environment and contribute to providing internal advice and regulatory information throughout the product lifecycle to ensure product

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compliance.

- Communicating critical regulatory information throughout project lifecycles.
- Preparing, compiling, reviewing and submission of regulatory applications according with EU& national requirements and legislation; preparing and submission of new MA, renewals, variations, notifications.
- Employ effective technical and regulatory writing skills to author standard regulatory documents and reports.
- Tracking and monitoring queries/DLs/commitments from/to HA to ensure these are implemented and conformed to in a timely manner.
- Developing and maintaining up-to-date knowledge of regulatory requirements and supporting data requirements.
- Managing price application submissions and follow-up with the MoH.

August 2020- August 2022
RA Specialist - Polisano Pharmaceuticals S.A.

- Preparing and compiling, reviewing and submission of regulatory applications in accordance with EU and national requirements and legislation;
- Tracking, monitoring queries/DLs/commitments from/to HA to ensure these are implemented and conformed to in a timely manner.
- Develop and maintain a thorough and up-to-date understanding of the regulatory environment and supporting data requirements; Align resources and discuss regulatory issues in cross-functional teams to ensure completion of project tasks.
- Provide regulatory support to project teams, stakeholders, and customers.
- Evaluate the regulatory environment and contribute to providing internal advice and regulatory information throughout the product lifecycle to ensure compliance.
- Identify the need for new regulatory procedures and SOPs and participate in development and implementation.

May 2019 – August 2020
RA Specialist – Life Cycle Management-Zentiva S.A.

- Preparation, compilation, review, and submission of regulatory applications in accordance with EU and national requirements and legislation.
- Track and monitor queries/DLs/commitments from/to HA to ensure the implementation and compliance.
- Align resources and discuss regulatory issues in cross-functional teams to ensure completion of project tasks.
- Communicate with peers and supervisors and ensure alignment on issues, questions, and goals.
- Provide regulatory support to project teams, stakeholders, and customers, as required.
- Evaluate the regulatory environment and contribute to providing internal advice and regulatory information throughout the product lifecycle to ensure compliance.
- Identify the need for new regulatory procedures and SOPs and participate in development and implementation.

March 2018- May.2019
RA Officer- Laropharm SRL

- Medicinal product life cycle maintenance (variations, renewals, new MA).
- Ensure regulatory compliance and documentation for non-EU partners.
- Preparation, compilation, review, and submission of regulatory applications in accordance with EU and national requirements and legislation.

October 2008 – March 2018
Pharmacist Manager– Dexter Invest

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- Implementing, organizing, and supervising the reception, storage, and dispensing procedures according with GPP and national requirements
- Organizing the pharmaceutical laboratory according to the national regulations
- Management activities – planning, organizing, leadership, coordinating and controlling.
- Guiding students in pharmaceutical practice.
- Monthly reporting of prescriptions to the Health Insurance Authority.
- Ensuring the necessary daily stocks, controlling the flow of medicines.
- Elaborating the primary accounting documents.
- Organizing and supervising stock inventories.

October 2006 – September 2008
Pharmacist – Dexter Invest

- Reception, storage, dispensing the pharmaceutical products (RX/ORT/MDs/Food supplements). Counselling and providing patients. Drug release and prescription checking of free and compensated prescriptions, participation in health programs.
- Preparation of the magistral and officinal prescriptions. Participation in inventories.
- Mentoring students in pharmaceutical practice.

EDUCATIONAL BACKGROUND

MSc degree

- Interdisciplinary Master, University of Bucharest - Faculty of Informatics, UMF Carol Davila- Faculty of Pharmacy, Bucharest (Romania) - 2013 - 2015

BSc degree, License to practice pharmacy.

- UMF Carol Davila, Bucharest (Romania) – 2001- 2006

ADDITIONAL COURSES

- Legislația aplicabilă domeniului dispozitivelor medicale și importatorilor/distribuitorilor de MDs, prestatorilor de servicii in domeniul MDs.- MediaKompass, Oct 2023
- Variations to Marketing Authorizations - post – university course (RO) –Nov 2018
- Pharmacovigilance, UMF Carol Davila, Bucharest (Romania) - May 2014
- Regulatory Affairs, UMF Carol Davila, Bucharest (Romania) – March 2013

LANGUAGES

English

COMMUNICATION SKILLS

- Good communication skills gained through my experience.

ORGANISATIONAL / MANAGERIAL SKILLS

- Management experience, Analytical spirit, assessment, and improvement capacity.
- Organizational spirit gained from teamwork at the workplace, providing and transmitting information, Teamwork and Proactivity, Time management, Adaptability, Ability to work autonomously without direct supervision, Good attention to detail.

COMPUTER SKILLS

- Good command of Microsoft Office™ tools (Word, Excel, Power Point), Internet browsing, TrackWise, InSight, PegmaPharm, Share, eDMS, COSMOS, Veeva, TVT, AMS.

Driving License - B

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