EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

Personal information

Caroline RICHARD

Work experience

Pharmaceutical Quality Assessor for Biological Products
12/2025 - Current position
French National Agency for Medicines and Health Products Safety (ANSM), France
Ensure the evaluation of the CMC (manufacturing process and controls) section of dossiers for medicinal products/biological products or products containing a biological substance in the context of centralised marketing authorisation applications, European scientific opinions and other European procedures (quality defects) and help defend the position taken during national or European collegiality meetings; Assess any referral concerning an issue relating to the manufacture and control of biological health products.

VP Quality Assurance and Regulatory Affairs
06/2021 – 09/2025
Astraveus, France
Led global regulatory strategy for cell and gene therapy (CGT) bioprocessing equipment, including scientific and regulatory interactions with ANSM and FDA (CBER). Defined regulatory roadmaps and implemented a partial QMS aligned with GMP and ISO 13485. Oversaw design control, technical documentation, and CMC activities, including GMP requirements for ATMPs, consumables, cleanrooms, and the qualification/validation of equipment and processes. Built and managed the Regulatory & Quality function and contributed to innovation ecosystems and public policy discussions. Supported corporate strategy through partnerships, competitive intelligence, investor due diligence, and the successful securing of major non-dilutive funding (EIC, Bpifrance).

Regulatory Scientist, CMC – Biologics and Advanced Therapies
03/2019 – 05/2021
Voisin Consulting Life Sciences, France
Led the development and execution of CMC strategies for biologics, including recombinant proteins, cell and gene therapies, blood-derived products, and combination products. Responsible for writing and reviewing regulatory submissions (Scientific Advice, IND/IMPD, BLA/MAA), particularly the Quality sections, ensuring alignment with global regulatory requirements. Developed CMC strategies tailored to the product type and development stage, including borderline product positioning. Acted as the interface between scientific and regulatory teams, bridging the gap between technical development and regulatory compliance.

Global Regulatory Affairs Intern, CMC-Devices
04/2018 – 08/2018
Sanofi, France
Global technical and regulatory development of a monoclonal antibody combined with a drug delivery device: Regulatory / Technical CMC, review of Quality Sections (Module 3) for regulatory submissions, preparation and review of Device-related sections, new Medical Device Regulation (EU) 2017/745, Human Factors Studies

Education and training

MSc. Pharmaceutical Biotechnology and Advanced Therapies
09/2018 – 09/2019
Paris Saclay University, France
Pharmaceutical biotechnology, biologics and ATMPs development, manufacturing and controls, including regulatory pathways: Regulatory affairs, Chemistry, Manufacturing and Controls (CMC), Quality-by-Design, Quality Management System, biopharmaceutical process development including upstream and downstream processes and scale-up, analytics including statistics, comparability assessment, method development and validation

Bachelor of Pharmacy - Pharm.D
09/2012 – 06/2018
Paris Cité (Descartes) University, France
Innovative product developments
Thesis about Manufacturing, Controls and Regulatory Pathways for Therapies Encapsulated within Red Blood Cells

Master's degree in Cellular Biology, Physiology and Pharmacology
2016 – 2017
Paris Cité (Descartes) University, France
Cellular Biology: Regulation and deregulation of the cell cycle, microtubular dynamics, cohesins and condensins, telomeres, aging and cancer, C. elegans as a model for the study of neurodegenerative diseases, Human IPS, use of pluripotent stem cells for the modeling of normal and pathological aging, use in cell therapy of pluripotent stem cells

Additional information

Publications

Projects

Memberships

Other Relevant Information