Pierre Rousseau
Biotechnology & Pharmaceutical Senior Consultant

Acta Biopharma, Lyon, France
Since 2019

Biotechnology & Pharmaceutical Senior Consultant

- Provide support for addressing US FDA Warning Letter
- Prepare Validation Master Plan
- Support for the start-up of new biotechnology facility in China

Sanofi Genzyme, Lyon, France
2016 - 2018

Head of Process Control and Quality for the Viral Vector Unit

- Develop Process Control Strategy (PCS) and Continued Process Verification (CPV)
- Ensure adequate quality system and practices for the new BSL2 Viral Vector Unit start-up
- Develop strict and efficient confinement of the new Viral Vector Unit
- Support site regulatory inspections
- Acted as Site Quality Head for 6 months

Sanofi Pasteur, Lyon, France
2014 - 2016

Director – Site Quality Support

- Prepare and accompany manufacturing sites for regulatory and corporate inspections
- Ensure site compliance with Sanofi corporate policies and guidelines
- Ensure coordination between Sanofi Pasteur Corporate Quality and Sanofi Pasteur sites
- Participate in the quality risk process with prevention and mitigation plans
- Lead Sanofi Pasteur procedures and processes harmonization between sites
- Provide quality and compliance support for projects
- Ensure qualification and validation practice harmonization and simplification

Genzyme Polyclonals, Lyon, France
2009 – 2013

Director - Quality Operations

- Head of the Quality Operations Department (Validation/Quality Control/Quality Assurance)
- Lead the start-up from a quality point of view of the new Genzyme Polyclonals facility
- Reporting to the VP Quality Europe, ensure compliance of activities to support regulatory authorities' inspections
- Ensure compliance with Genzyme corporate standards
- Lead corporate and regulatory authorities' inspections
- Manage implementation of an enterprise LIMS system

Genzyme Corporation, Madison, Wisconsin, USA / Montreal, QC, Canada
2005 – 2009

Quality Director

- Ensure proper quality/supply of an injectable product (aseptic fill) manufactured in Montreal by a CMO
- Ensure full FDA compliance of the product manufactured by the CMO
- Regular presence at the CMO site to coordinate activities and address quality issues
- Participate in the manufacturing transfer of the injectable product from the CMO site to a Genzyme manufacturing site

Genzyme Polyclonals, Marcy l'Etoile, France
2001 - 2005

Director - Quality Operations

- Lead Quality Control, Quality Assurance, Validation and Quality System Departments which represents over 40 persons
- Ensure compliance of manufacturing and testing operations for sterile biological products
- Ensure compliance towards applicable Genzyme Corporation and cGMP regulations (products sold in 50 different countries)
- Coordinate and manage inspections of all regulatory authorities including FDA
- Determine Quality Operation priorities and strategic plans along with other Senior Directors

Validapro, Laval, Québec, Canada
1995 - 2001

Director of Operations

- Start the company (Validation and Compliance) with two colleagues
- Participate in the strategic development plans of the company
- Manage Validation Department (approximately 20 professionals)
- Prepare tenders for validation projects

- Plan and manage training, validation and compliance projects
- Provide internally and externally training sessions on cGMPs
- Conduct Audits

Major projects:

- Biotechnology pilot plant validation for clinical studies
- Validation of several cleaning processes
- Validation of utilities, automated systems, and equipment
- Design and validation of controlled environment systems
- Validation of BSL-2 laboratories (bio-hazard level 2)
- Design and validation of laboratories testing blood products using PCR technology
- Validation of sterile production facilities and systems
- Validation of aseptic production of radio-labelled drugs

Most of these projects were conducted with these firms:

- Novartis (Canada)
- Steris (Canada)
- Sanofi (Canada, France and United-States)
- Abbott (Canada)
- MDS Nordion (Canada)
- Aeterna Laboratories (Canada)
- Schering Plough (Canada and Columbia)
- Becton Dickinson (France)
- OM Pharma (Switzerland and Portugal)
- Galderma (Canada and France)
- BMS (Canada and France)

***Wellcome**,* Kirkland, Québec, Canada
1990 - 1995

Validation Supervisor: 1990 –1995

- Supervise Validation Department (team of 7 professionals)
- Coordinate all validation activities for the Sterile Manufacturing, Tablet Manufacturing, Ointment Cream and Liquid Manufacturing, and Packaging Departments
- Ensure validation compliance according to requirements of Canadian Health Authority, FDA, and other regulatory authorities
- Defend company position during inspections
- Establish and maintain critical paths for validation projects
- Participate with other departments in the development of new processes, optimization of existing ones and problem solving
- Develop validation protocols including equipment (IQs and OQs) and process qualifications (PQs)
- Analyze test results and data, establish proper conclusions and obtain approval of the final documentation
- Participate in the development and validation of automated CIP, SIP, aseptic manufacturing line for sterile ophthalmic ointment systems
- Provide technical expertise to other departments

Allergan, Pointe-Claire, Québec, Canada
1987 - 1989

Quality Assurance and Laboratory Supervisor: 1988 - 1989

- Manage both the Chemistry Laboratories and Quality Assurance Services
- Review documentation and release production batches for sale
- Ensure compliance with Canadian GMPs for both, plant and manufacturing processes
- Maintain validation compliance

Validation Specialist: 1987 - 1988

- Plan all validation activities, perform all related testing and ensure approval of all completed documentation for manufacturing of sterile products filled aseptically
- Ensure company validation compliance with regulations according to Health Canada, FDA, and other regulatory authorities

Institute of Parasitology, ***McGill University***, Montreal, Québec, Canada
1985 - 1987

Research Assistant

Isolate and characterize tubulin, a cytoskeletal protein suspected to be the target of certain antiparasitic drugs. This work was achieved through various biochemical techniques such as HPLC, ELISA assays, monoclonal antibodies, etc.