



# Curriculum Vitae

Personal information **Violaine FRANCOIS**

Work experience

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## 1. Current position: Non-Clinical Assessor

Employer: FAMHP (Federal Agency for Medicines and Health Products), Belgium

Start date: 03/2017 ; End date: Present

Role purpose: Responsible for the assessment of the safety and efficacy data collected before the start of clinical trials (pre-clinical aspects). This includes pharmacological, pharmacokinetics and toxicological studies (in silico, in vitro, in vivo). These assessments are carried out as part of applications for clinical studies (national), marketing authorisations (national and European) and scientific advices (national and European).

Evaluation of the non-clinical sections of the following National/European submissions:

- Clinical Trial Applications (National and European)
- Scientific Advice (National and European)
- Marketing Authorisation Applications (National and European)
- Type II variations (National and European)

Key responsibilities:

- Develop expertise in a given scientific field and provide it to administrative and political bodies in order to support them in their decision-making and policy implementation.
- Evaluating scientific data on the safety and/or efficacy of medicines throughout their life cycle in the light of decisions taken at national and European level in the context of the benefit/risk balance.
- Provide scientifically supported advice in the field of expertise to formulate and defend the positions of the FAMHP and Belgium, including at national and international meetings, and contribute to the recognition of the FAMHP.
- Manage own workload working in conjunction with service coordinators and other assessors to meet deadlines.
- Act as a recognised expert with internal clients (assessors, file managers, inspectors, legal department, communication, etc.) and external national stakeholders.
- Develop partnerships with internal clients based on identified needs and answer questions related to his/her area of expertise.
- Guide and support less experienced evaluators in their activities and development in order to ensure the quality and consistency of the work and to maintain and further develop the scientific expertise within the team.
- Contribute to the optimisation of operations, processes and procedures.
- Participate in other ad-hoc tasks/projects as requested at national or European level.

Non-clinical expertise:

- Pharmacology (mechanism of action, molecular pathways, off-target effects...)
- Pharmacokinetics (Absorption, distribution, metabolism, excretion, drug-drug interactions)
- Toxicology (in vitro and in animal species) - safety assessment
- Safety pharmacology (cardiovascular, respiratory and central nervous systems)
- General toxicology (safety assessment, patophysiology and pathological manifestations of toxic effects, exposure and safety margins, ...).
- Reproductive and developmental toxicity (animal species, NAMs)
- Genotoxicity (in vitro studies, in vivo studies)
- Carcinogenicity (in vivo studies, weight-of-evidence approach)
- Immunotoxicity
- Environmental risk assessment for pharmaceuticals
- Laboratory animal science
- Good Laboratory practice (GLP)

Scientific expertise:

- small chemicals
- oncology
- gastrointestinal
- osteoarticular
- immunology
- microbiome
- live biotherapeutic products

## 2. Clinical Project Manager

Employer: EORTC (European Organization for Research and Treatment of Cancer), Belgium

Start date: 09/2014 ; End date: 02/2017

Key activities and responsibilities:

- Take overall responsibility for project management according to EORTC policies and processes, including scheduling and prioritizing activities at project level.
- Lead, motivate, and coordinate the project team (internal transversal coordination).
- Manage project's external stakeholders (incl. communication, contracts, budgets).
- Monitor and control the project execution, including managing issues and conflicts at project level (analysis, decision making, priorities allocation, actions execution).
- Manage project's changes with internal and external stakeholders.
- Identify and manage project's risks.

- Manage communication with internal stakeholders, including reporting and escalation of issues/conflicts beyond project level.
- Assist the regulatory affair manager for the submission to Competent Authorities and Ethics Committee in Europe.
- Within Projects Direction, contribute to improving management of projects.

Scientific expertise:

- oncology
- gastrointestinal

### 3. Experienced Research Scientist (Post-doc)

Employer: Immunobiology Unit, Université Libre de Bruxelles, Belgium

Start date: 10/2010 ; End date: 08/2014

Subject: Intestinal immunopathology is associated with decreased CD73-generated adenosine during lethal infection.

Role purpose: Responsible to manage a research project from its inception through to publication of the results in the scientific literature.

Key activities and responsibilities:

- Analyze the role of adenosine in the gastrointestinal tract during lethal infection.
- Design and validate lab experiments in mouse models.
- Communicate results in international oral presentations.
- Collaborate with research teams and medical units.
- Write research projects, scientific articles and reports.
- Train and supervise students.

Scientific expertise:

- immunology
- gastrointestinal inflammation
- microbiome

### 4. Research scientist (PhD in Biomedical and Pharmaceutical Sciences)

Employer: Ludwig Institute for Cancer Research, Institut de Duve, Belgium

Start date: 12/2005 ; End date: 09/2010

Subject: The CD4(+) T-cell response of melanoma patients to a MAGE-A3 peptide vaccine involves potential regulatory T cells.

Role purpose: Responsible to manage a research project from its inception through to publication of the results in the scientific literature.

Key activities and responsibilities:

- design and validation of lab experiments on human samples (cellular biology and molecular biology)
- development and writing of protocols
- planning and monitoring of research experiments
- analysis and problem solving
- analysis and presentation of results
- conduct independent project research
- management of team work
- collaboration with research groups and medical units in hospitals
- writing articles and reports
- presentations of research results at international conferences.

Scientific expertise:

- immunology
- oncology

## Education and training

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**Pharmaceuticals in the Environment**, International Master in Sustainable Drug Discovery, Ghent University, Belgium

- Date: September-December 2024 (Credit Certificate)
- Organisation: Ghent University, Faculty of Pharmacy
- Subject: Environmental Risk Assessment of pharmaceuticals.

**Environmental Risk Assessment (ERA) assessors training**, Amsterdam, The Netherlands

- Date: 23-24 May 2024
- Organisation: European Medicines Agency
- Subject: Assessment of Environmental Risk Assessment of medicines.

**ERT course B12 Reproductive and Developmental toxicity**, Antwerp University, Belgium

- Date: 5-9 February 2024
- Organisation: European Teratology Society
- Subject: Intensive training on the aspects of reproductive and developmental toxicology of pharmaceuticals and chemicals (physiology and reproduction, organs development, regulatory reproductive testing, non-classical methods).

**Workshop on Qualification of MicroPhysiological Systems including Organ-on-Chip Models for Specific Contexts of Use to be Applied in the Pharmaceutical Area**, Brussels, Belgium

- Date: 30 January 2024
- Organisation: Federal Agency for Medicines and Health Products (FAMHP)
- Subject: Workshop to determine what information needs to be included in future European regulatory guidance on qualification of Liver-on-chip models for predicting drug-induced liver injury and Heart-on-chip models for safety pharmacology testing.

**Environmental Risk Assessment (ERA) Informal Assessor Meeting**, online

- Date: 16-17 November 2023

- Organisation: Agenzia Italiana Del Farmaco (AIFA)
- Subject: Knowledge on the most relevant news and updates surrounding the regulatory landscape of the environmental risk assessment of pharmaceuticals.

**Safety pharmacology Society Annual Meeting**, Brussels, Belgium

- Date: 19-20 September 2023
- Organisation: Safety Pharmacology Society
- Subject: Knowledge on the most relevant news and updates surrounding the regulatory and scientific landscape of the safety pharmacology of pharmaceuticals (Preclinical drug development for safety pharmacologists, Central nervous system safety assessment, Cardiovascular safety assessment, Respiratory safety assessment, PK/PD modeling).

**ECOTOX knowledgebase**, online

- Date: 14 February 2023
- Organisation: ECOTOX
- Subject: ecotoxicology database.

**9th Annual World Meeting on Targeting Microbiota**, online

- Date: 19-21 November 2022
- Organisation: International society of microbiota
- Subject: Knowledge on the most relevant news and updates surrounding the scientific landscape of microbiota.

**Preclinical Assessor's meeting and EPFIA workshop**, Zagreb, Croatia

- Date: 01-03 June 2022
- Organisation: Agency for Medicinal Products and Medical Devices of Croatia (HALMED)
- Subject: Knowledge on the most relevant news and updates surrounding the regulatory non-clinical assessment of medicinal products.

**EUROTOX Congress**, online

- Date: 26 September - 01 October 2021
- Organisation: EUROTOX
- Subject: Knowledge on the most relevant news and updates surrounding the regulatory and scientific landscape of the toxicology of pharmaceuticals.

**Immunopharmacology and immunotoxicology**, Munich, Germany

- Date: 03-05 April 2018
- Organisation: HESI
- Subject: Knowledge on the most relevant news and updates surrounding the regulatory and scientific landscape on immunotoxicology.

**Practical application of toxicology in drug development course**, Cambridge, United-Kingdom

- Date: 16-21 July 2017
- Organisation: American college of toxicology and British Toxicology Society
- Subjects: Knowledge on the non-clinical evaluation of pharmaceuticals (pharmacology, safety pharmacology, organ systems, pharmacokinetics/ADME, general toxicology, clinical pathology, reproduction/developmental toxicology, genotoxicity, carcinogenicity, risk assessment, immunotoxicology, biotechnology products).

**Beltex, 5th Workshop on Non - Clinical Safety Assessment of Biopharmaceuticals "The importance of species selection to predict the human safety of biopharmaceuticals "**, Beerse, Belgium

- Date: 11 May 2017
- Organisation: Beltex
- Subjects: Knowledge on the species selection for biopharmaceuticals.

**BRAS - Introduction to regulatory affairs**, Brussels, Belgium

- Date: 08-09 May 2017
- Organisation: BRAS (Healixia)

**Good Clinical Practice (GCP)**, Brussels, Belgium

- Date: 15 September 2015
- Organisation: EORTC

**Drug Safety, Pharmacovigilance and Regulatory Affairs**, Brussels, Belgium

- Date: Avril 2013 (3 days)
- Organisation: Université Libre de Bruxelles, Pharmed
- Subject: Knowledge on the Drug safety, pharmacovigilance and regulatory affairs of pharmaceuticals.

**Science and technical training of laboratory animals (FELASA C)**, Brussels, Belgium

- Date: September 2010 (5 days)
- Organisation: Université Libre de Bruxelles
- Subjects: Intensive training on housing of experimental animals, morphology of laboratory animals, experimental design, biostatistics, legal aspects of animal experimentation.

**Master in Biomedical Sciences**, Lille, France

- Date: 01 September 2004-30 June 2005
- Organisation: Université Lille 2 Droit et Santé
- Main topics: immunology (Innate immunity, adaptive immunity, anti-infectious immunity) ; cellular biology ; molecular biology ; microbiology ; biostatistics (experimental design, epidemiology) ; genetic and genomics.

## Additional information

### Publications

- [2014] Intestinal immunopathology is associated with decreased CD73-generated adenosine during lethal infection  
V Francois et al., Mucosal Immunol . 2015 Jul;8(4):773-84
- [2014] Epstein-Barr virus infection induces an increase of T regulatory type 1 cells in Hodgkin lymphoma patients  
Morales et al., Br J Haematol . 2014 Sep;166(6):875-90

[2009] The CD4(+) T-cell response of melanoma patients to a MAGE-A3 peptide vaccine involves potential regulatory T cells  
V Francois et al., *Cancer Res* . 2009 May 15;69(10):4335-45  
[2009] Single-step antigen loading and activation of dendritic cells by mRNA electroporation for the purpose of therapeutic vaccination in melanoma patients  
Bonehill et al., *Clin Cancer Res* . 2009 May 15;15(10):3366-75  
[2009] Comparison of stable human Treg and Th clones by transcriptional profiling  
Stockis et al., *Eur J Immunol* . 2009 Mar;39(3):869-82  
[2007] Determination of a HLA II promiscuous peptide cocktail as potential vaccine against EBV latency II malignancies  
Depil et al., *J Immunother* . 2007 Feb-Mar;30(2):215-26  
[2006] Peptide-binding assays and HLA II transgenic Abeta degrees mice are consistent and complementary tools for identifying HLA II-restricted peptides  
Depil et al, *Vaccine* . 2006 Mar 20;24(13):2225-91.

## Projects

### Memberships

#### 1. Member of the Operational Expert Group for SEND project (Toxicology data)

Purpose: working group consisting of non-clinical assessors from several National Competent Authorities formed with the goal of evaluating the potential benefits and limitations of implementing SEND visualisation (toxicology data) in the regulatory review process resulting into recommendations.

#### 2. Member of the Environmental Risk Assessment European Specialised Expert Community (ERA ESEC)

Purpose: provide a platform of information sharing and communication on the topics that are of relevance to the community, in order for its members to gain and further optimise their knowledge relevant to the evaluation of product-related procedures within the regulatory framework.

### Other Relevant Information

#### 1. Non-clinical scientific expert at European Medicines Agency

Ad hoc participation as non-clinical scientific expert in the following European committees:

- Committee for Medicinal Products for Human Use (CHMP)
- Paediatric Committee (PDCO)
- Non-clinical Working Party (NcWP)
- Scientific Advice Working Party (SAWP)
- Innovation Task Force (ITF)

#### 2. Oral presentation (conferences and seminars)

**Live Biotherapeutic Products from a non-clinical perspective** - Oral presentation at the 16th Preclinical Assessors Meeting (PAM); [ 03/06/2022 – 03/06/2022 ] Zagreb, Croatia

**Role of adenosine in intestinal homeostasis** - Oral presentation at "3rd European Congress of Immunology"; [ 08/09/2012 – 08/09/2012 ] Glasgow, United-Kingdom

**Des lymphocytes T régulateurs spécifiques de MAGE-A3 sont détectés après vaccination chez des patients atteints de mélanome** - Oral presentation ; [ 26/03/2010 – 26/03/2010 ] Brussels, Belgium

**The CD4+ T-Cell response of melanoma patients to a MAGE-A3 peptide vaccine involves regulatory T cells** - Oral presentation [ 19/02/2010 – 19/02/2010 ] London School of Hygiene and Tropical Medicine, United-Kingdom

**Vaccination of melanoma patients with a MAGE-A3 peptide induced anti-MAGE- A3 helper and regulatory CD4+ T cells** - Oral presentation at "World Immune Regulation Meeting" ; [ 11/04/2007 – 11/04/2007 ] Davos, Switzerland