



## Curriculum Vitae

Personal information **Agathe Sarazin**

Work experience

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### **10/2025 - present**

#### **Pharmacovigilance assessor**

*Agence Nationale de sécurité du médicament et des produits de santé (ANSM), Saint-Denis (93) - France*

• DMM2, Unit 2, Pain Management, Anaesthesia, Rheumatology, Addiction Medicines (DR2A)

- Evaluation of reports (drafting of PSUSA, case studies)
- Assessment of Summary of Product Characteristics (SmPC) and package leaflet modification requests
- Writing of safety signals
- Collaboration with various public health actors
- Monitoring of safety data and maintaining the benefit-risk balance

### **10/2023 to 09/2025**

#### **Pharmacovigilance officer**

*Serb Pharmaceuticals (Corporate), Paris (75) - France*

#### **Drug and Safety monitoring**

- Management of Individual Case Safety Reports (ICSRs)
- Writing of safety reports (PBRERs, SDRs) and risk management plans (RMPs)
- Participation in projects for the launch of new international marketing authorizations

#### **Quality management system**

- Supervision of non-conformities through deviation/CAPA management
- Creation and updating of instructions, SOPs, and quality documents
- Establishment of the reconciliation process
- Internal and external reconciliations
- Communication management with service providers, updates of SDEAs
- Participation in audits and inspections

### **09/2022 to 09/2023**

#### **Apprenticeship – Pharmacovigilance associate**

*Recordati Rare Diseases (Corporate), Puteaux (92) - France*

- Safety signal detection
- Management of Individual Case Safety Reports (ICSRs)
- Supervision and review of Periodic Safety Update Reports (PSURs)

**04/2022 to 09/2022**

**Internship – Pharmacovigilance assessor**

*Agence Nationale de sécurité du médicament et des produits de santé (ANSM), Saint-Denis (93) - France*

- DMM2. Unit 4. Infectious and emerging diseases (MIE)
  - Evaluation of reports (drafting of PSUSA, case studies)
  - Assessment of Summary of Product Characteristics (SPC) and package leaflet modification requests
  - Writing of safety signals
  - Collaboration with various public health actors
  - Monitoring of safety data and maintaining the benefit-risk balance

**09/2021 to 01/2022**

**Pharmacy externship**

*CHU Robert Debré, Reims (51) - France*

- Regional Pharmacovigilance Center (CRPV)
  - Management of pharmacovigilance cases (data collection, comments, causality assessment, correspondences)
  - Entry of cases into the national database
  - Work on a significant case
- Ambulatory Medicine Unit - Oncology/Hematology (UMA-CH)

**07/2020 to 08/2021**

**Community Pharmacy (+ 600 h)**

*Pharmacie du Verbeau, Châlons en Champagne (51) - France*

Education and training

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EDUCATION

2024 | Reims, France

**Doctoral Thesis Defense**

*Topic: Periodic Safety Reports in Pharmacovigilance, a Key Tool for Drug Safety Surveillance: Issues and Impacts of Their Evaluation by Health Authorities. Case Study Illustration.*

**Grade: With Honors**

2022 - 2023 | Paris, France

**Master's Degree (M2) in Public Health – Vigilance and Health Safety**

Université de Paris Cité – Faculty of Medicine Paris Descartes

**Grade: Good**

2017 - 2023 | Reims, France

**Pharmacy studies** including first year of medicine

**Université de Reims Champagne-Ardenne (URCA)**

- Completion of the C2i Health Informatics Certification Track
- Certification of Aptitude for Vaccination
- Training in Emergency and First Aid Procedures (AFGSU)

**TRAINING / CERTIFICATION**

2024

- MHRA et FDA Inspections

2023

- MedDRA - Coding basis

- MedDRA – Advanced coding

- MedDRA – Data analysis and query  
building

- ISO 13485

Additional information

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Publications N/A

Projects N/A

Memberships N/A

Other Relevant Information N/A