



Curriculum Vitae

Personal information **assia allalou**

Work experience

Ø April 2023 - Present : Technical Advisor – Health general Directorate – Medical Devices & In vitro Medical Devices – Ministry of health - Paris (75007)

Contributed to EU regulatory processes on medical devices (MD) and in vitro diagnostic medical devices (IVD), including analysis of legislative and technical texts, preparation of national instructions and briefing notes, and coordination with legal and technical stakeholders for implementation follow-up.

Monitored and analysed European Commission initiatives related to the implementation of MDR/IVDR, including secondary legislation, European database developments, notified bodies, common specifications and harmonised standards.

Supported the transposition and adaptation of EU regulatory frameworks into national law in close coordination with the national medicines agency (ANSM) and relevant ministerial services.

Contributed to health crisis preparedness and response activities, including medical device shortages, through analysis, coordination with national and European stakeholders, and participation in relevant governance fora.

Covered specialised regulatory portfolios including medical imaging (notably mammography), dental devices and medical food products, in liaison with competent national authorities (DGOS, DGS).

Participated in cross-cutting EU and national initiatives involving medical device and IVD components, contributing to inter-institutional coordination and policy development.

Ø November 2021 - April 2023 : Technical Project Manager – Health general Directorate – Political Board of Health Products, Medical Practice and Care Quality – Ministry of health - Paris (75007)

Taking part in the conception, implementation and assessment of public politics in terms of quality of medical practices : :

- Management of the project to set up the clinical audit for all medical imaging specialities as part of EURATOM Directive transposition
- Development of an action plan to secure acts of aesthetics purposes (tattoo and body piercing)
- Coordination of the update of hygiene and safety training relating to the hygiene rules applicable to tattooing and body piercing
- Participation in the continuous adaptation of the surveillance system for monitoring serious side effects associated with medical practices

Ø 2016 – octobre 2021 : **Market surveillance inspector – ANSM – Saint-Denis (93)**

- **Medical Devices market surveillance - mission of inspection :** Inspection on site (France and abroad) the applications of laws and regulations as well as compliance with the standards relating to medical devices
- **Mission of coordination, drafting and follow-up of the administrative follow up** (Health Policy decision, Injonction, reminder of the law etc) for medical devices, in vitro medical devices and cosmetic products
- **Mission of participation on European work relating to European collaboration in inspection :**
 - ANSM representation in medical devices inspection groupe within WP4 and the JIG « Joint Inspection Group » sub group
 - Participation in the training of European inspectors within the JAMS « joint action on market surveillance – medical devices » group and the JIM « Joint Inspections of Manufacturers ». November 2019 and May 2021
 - Inspection missions in Europe in collaboration with local inspectors (Belgium, Sweden)
- **ANSM internal auditor mission within the framework of ISO 9001 certification (since 2019)**

Ø2012 - 2016 : **Technical-Regulatory activity in Medical devices –ANSM**

- Compliance evaluation of devices regarding European directives and other regulatory references in the field.
- (Re)assessment of the benefit/risk ratio of medical devices.

Ø2006 - 2012 : **Medical devices vigilance assessor – ANSM**

- Evaluation of incident reports (implants and consumables) : expertise in Orthopedics, traumatology, blood transfusion, transplant, medically assisted procreation, infusion

In vitro medical devices vigilance assessor - ANSM

- Evaluation of incident reports involving an in vitro medical device.

Ø2002 – 2006 : **Laboratory Technician - Perpétuel Secours Hospital in Levallois-Perret (92) /CHI Poissy / Saint Germain en Laye (78)**

Night and weekend service, emergency analyses ; hematology, bacteriology, biochemistry, drug dosage and serology laboratories

Education and training

- **Sept - Jun 2006 :** Specialized Master in « Public Health Policy and Health Security » - Paris Descartes University - Paris 5
- **Feb- Jul 2006 :** **AFSSAPS – Saint-Denis (93)** - 2nd year Master internship : assessor in in vitro medical device unit : implementation of a protocol for monitoring incidents relating to blood glucose meters.
- **Sept - Jun 2005 :** Master's Degree in Biochemistry - Paris Diderot

University - Paris 7

- **Feb - Aug 2005** : **Stockholm University - SWEDEN** - 1st year Master internship : Study of the interaction between proteins involved in the regulation of nitrogenase in *Rhodospirillum rubrum*.
- **Sept - Jun 2003** : National Diploma in Specialized technology (DNTS) at l'ENCPB – Paris 13
- **Sept - Jun 2000 - 2002** : High technician Certificate in Biological Analysis at l'ENCPB – Paris 13
- **May - Jul 2003** : **Diagnostica Stago – Asnières sur seine (92)** - DNTS Internship : development and analysis of Customer satisfaction questionnaires.
- **Summers 2000 and 2001** : **Portes de l'Oise Hospital - Beaumont sur Oise (95) / Cochin Hospital - Paris (75)** - Internship in a biological analysis laboratory.

Additional information

Publications

Jan 2017 - Taking part in epidemiology work in the field of orthopedics – work published in a peer-reviewed journal: “Exchangeable Femoral Neck (Dual-Modular) THA Prostheses have poorer Survivorship Than Other Designs: A Nationwide Cohort of 324,108 Patients” in *Clinical Orthopedics and Related Research* -

Projects

Writing of a thematic file on hip prostheses with metal-metal friction couple : [https://archiveansm.integra.fr/Activites/Surveillance-des-dispositifs-medicaux-implantables/Surveillance-des-protheses-de-hanche/\(offset\)/1#paragraph_42262](https://archiveansm.integra.fr/Activites/Surveillance-des-dispositifs-medicaux-implantables/Surveillance-des-protheses-de-hanche/(offset)/1#paragraph_42262).

Memberships

Other Relevant Information