

Curriculum Vitae

Personal information **Diby Olivier DIBY**

Work experience

1. Employer: ANSM
 - Start date: 112021
 - End date:
 - Position: Inspector
 - Activities: Inspections in Pharmacovigilance
 - Country: France
2. Employer: ANSM
 - Start date: 112015
 - End date: 112021
 - Position: Inspector
 - Activities: Inspections in both Materiovigilance and Pharmacovigilance
 - Country: France
3. Employer: BBAC sas
 - Start date: 112009
 - End date: 112015
 - Position: MD, Drug Safety Officer
 - Activities: Pharmacovigilance, Materiovigilance, Nutrivigilance and Medical information Physician.
 - _ Management of a team of 4 drug safety officers,
 - _ Managing medical information inquiries, Pharmacovigilance, nutrivigilance and materiovigilance case reports in accordance with regulations and laws in force
 - _ Writing case narratives and company comments in both French and English, writing Periodic Safety Update Reports, writing Field Safety Corrective Action reports, writing Variations reports about human medicinal product, writing Addendum, Summary and Signal reports,
 - _ Making assessment of ADRs based on WHO causality assessment, Naranjo and the French causality assessment,
 - _ Editing CIOMS I, line listing (CIOMS II), Summary Tabulation and xml files,
 - _ Weekly literature monitoring in French and international medical database (Medline, Embase and Reactions weekly),
 - _ Coding medical clinical data (from spontaneous reports and clinical trials) by MedDRA dictionary,
 - _ Quality control of clinical data and case narratives entered in the safety database « Safety_Easy »,
 - _ Submitting cases to the competent authorities, including reporting of the cases by EudraVigilance web site,
 - _ Making Medical review,
 - _ Participating to internal and external audits,
 - _ Participating to the French Regulatory Agency inspections.
 - Country: France
4. Employer: ANTICIPSANTE
 - Start date: 022008
 - End date: 112009
 - Position: MD, Drug Safety Officer
 - Activities:
 - Pharmacovigilance, Materiovigilance, Nutrivigilance and Medical information Physician.
 - Country: France
5. Employer: PHARMAPPEL
 - Start date: 012007
 - End date: 112007
 - Position: MD, Medical data coder
 - Activities: _ Coding of medical clinical data received from clinical trials, from various therapeutic areas (by MedDRA dictionary, MedDRA Points to Consider, Who Drug Dictionary Enhanced),
 - _ Writing coding convention
 - _ Editing coded data homogeneity listing,
 - _ Making quality control and medical validation and writing coding reports.
 - _ Trainer to medical clinical data coding received from clinical trials by using MedDRA and Who Drug dictionaries.
 - Country: France
6. Employer: UMANIS
 - Start date: 012005
 - End date: 012007
 - Position: MD, Data Manager
 - Activities: _ Coding of medical clinical data received from clinical trials, from various therapeutic areas (by MedDRA dictionary, MedDRA Points to Consider, Who Drug Dictionary Enhanced),
 - _ Writing coding convention
 - _ Editing coded data homogeneity listing,
 - _ Making quality control and medical validation and writing coding reports.
 - _ Paper CRF and eCRF annotation,
 - _ Database creation (Clintrial 4.3 client interface and Cleanweb server interface),
 - _ Data entry tests and guide,

- Database export from CT4.3 to SAS, from SAS/MACRO EXPORT to EXCEL,
 - Programming SAS Base1, SQL request (SQL PLUS), Database quality control,
 - Participating to the development of Cleanweb (a clinical research e_CRF database).
 - My suggestions were taken into account by Uppsala Monitoring Centre in 2005, to correct ATC code coding error that I found in the Who Drug dictionary.
 - Country: France
7. Employer: Hopital Maison Blanche and Centre Hospitalier de Lagny
- Start date: 012002
 - End date: 012005
 - Position: Internal medicine, nursing care
 - Activities:
- Care monitoring in geriatry and psychiatry Hospital.
- Country: France
8. Employer: AGENA
- Start date: 012000
 - End date: 012002
 - Position: Internal Medicine
 - Activities:
- Care monitoring in geriatry.
- Country: France
9. Employer: Hopital Maison Blanche and Centre Hospitalier de Lagny
- Start date: 011999
 - End date: 012000
 - Position: Internal Medicine, nursing care
 - Activities:
- Care monitoring in geriatry and psychiatry Hospital.
- Country: France

Education and training

26. Subject: Maintenance of a computerized system in its validated status
- Start date: 052022
 - End date: 052022
 - Qualification: Maintenance of a computerized system in its validated status skills
 - Organisation: IB Cegos formation
 - Country: France
25. Subject: Audit and control of IT security
- Start date: 032020
 - End date: 032020
 - Qualification: Audit and control of IT security skills
 - Organisation: IB Cegos formation
 - Country: France
24. Subject: Awareness of international security rules
- Start date: 072019
 - End date: 072019
 - Qualification: Awareness of international security rules skills
 - Organisation: AMARATE / ANSM
 - Country: France
23. Subject: Computerized system validation
- Start date: 012019
 - End date: 022019
 - Qualification: Computerized system validation, certificate
 - Organisation: QUALILAB / ANSM
 - Country: France
22. Subject: Inspection of quality risk management skills
- Start date: 012017
 - End date: 022017
 - Qualification: Inspection of quality risk management: level 2
 - Organisation: AFNOR / ANSM
 - Country: France
21. Subject: Analysis of causality skills
- Start date: 122016
 - End date: 122016
 - Qualification: Analysis of causality in the context of inspection and risk analysis in the context of evaluation
 - Organisation: NEERIA / ANSM
 - Country: France
20. Subject: PhV Inspectors Working Group Training course
- Start date: 102016
 - End date: 102016
 - Qualification: PhV Inspectors Working Group Training course / European Regulation on amendments to marketing authorization
 - Organisation: EMA / ANSM
 - Country: France
19. Subject: Relational dimensions of the inspection
- Start date: 092016
 - End date: 092016
 - Qualification: Relational dimensions of the inspection / Administrative follow_up of inspections

- Organisation: Ecole des Hautes Etudes de Santé Publique (EHESP) / ANSM
 - Country: France
18. Subject: Data integrity
- Start date: 062016
 - End date: 062016
 - Qualification: Data integrity in pharmaceutical industry skills
 - Organisation: ANSM
 - Country: France
17. Subject: Penal law in Pharmacovigilance
- Start date: 052016
 - End date: 052016
 - Qualification: Penal law skills / Pharmacovigilance
 - Organisation: ANSM
 - Country: France
16. Subject: MedDRA Coding
- Start date: 032016
 - End date: 032016
 - Qualification: MedDRA Coding skills
 - Organisation: MSSO / ANSM
 - Country: France
15. Subject: eVeReport database
- Start date: 062015
 - End date: 062015
 - Qualification: My eReport and eVeReport database administration
 - Organisation: eVeDrug
 - Country: France
14. Subject: SafetyEasy database
- Start date: 032014
 - End date: 032014
 - Qualification: SafetyEasy Advanced Application administration
 - Organisation: ABCUBE
 - Country: France
13. Subject: Quality audit
- Start date: 102013
 - End date: 062014
 - Qualification: University Diploma of Quality Auditor in Pharmaceutical industry
 - Organisation: Paris V, Faculty of pharmacy
 - Country: France
12. Subject: Materiovigilance workshop
- Start date: 112012
 - End date: 112012
 - Qualification: Materiovigilance skills
 - Organisation: Paris V, Faculty of pharmacy
 - Country: France
11. Subject: Auditing and inspecting workshop
- Start date: 102012
 - End date: 102012
 - Qualification: Auditing and inspecting skills
 - Organisation: Paris V, Faculty of pharmacy
 - Country: France
10. Subject: EudraVigilance Medicinal Product data entry
- Start date: 052011
 - End date: 052011
 - Qualification: EudraVigilance Medicinal Product data entry skills
 - Organisation: DIA
 - Country: France
9. Subject: Monitoring pharmacovigilance adverse effects
- Start date: 032009
 - End date: 032009
 - Qualification: Monitoring pharmacovigilance adverse effects skills
 - Organisation: IFIS
 - Country: France
8. Subject: Pharmacovigilance
- Start date: 112007
 - End date: 122007
 - Qualification: Pharmacovigilance Officer
 - Organisation: For Drug Consulting
 - Country: France
7. Subject: Coding with WhoART, MedDRA & WhoDRUG
- Start date: 022005
 - End date: 022005
 - Qualification: Medical coder
 - Organisation: UMANIS
 - Country: France
6. Subject: eCRF database development & management
- Start date: 092004
 - End date: 122004

- Qualification: Data manager certificate
 - Organisation: SUPSANTE Paris
 - Country: France
- 5. Subject: Health and safety in transport, air transport option
 - Start date: 092002
 - End date: 062003
 - Qualification: European master II
 - Organisation: Paris V Faculty of Biomedical
 - Country: France
- 4. Subject: Urgent medical assistance
 - Start date: 092001
 - End date: 062002
 - Qualification: University Diploma in Emergency Medical Assistance
 - Organisation: Paris V Faculty of Medicine & Emergency Medical Unit of Paris
 - Country: France
- 3. Subject: Gerontology
 - Start date: 092000
 - End date: 062001
 - Qualification: Gerontology skills
 - Organisation: CNED
 - Country: France
- 2. Subject: Biostatistics
 - Start date: 091999
 - End date: 062000
 - Qualification: Biostatistics skills
 - Organisation: Paris XI University
 - Country: France
- 1. Subject: Peripheral facial palsy: Etio_epidemiological clinical and therapeutic aspects (retrospective and prospective study)
 - Start date: 091989
 - End date: 061998
 - Qualification: Medicine Doctor & Certificate of post-doctoral education, issued by the Academy of Creteil (France), Certificate of scientific equivalence to the French Doctorate in Medicine, issued by the French Minister of National Education.
 - Organisation: Faculty of Medicine of Abidjan & Faculty of Health Sciences of Cotonou
 - Country: Côte d'Ivoire & Benin

Additional information

[Publications](#)

[Projects](#)

[Memberships](#)

[Other Relevant Information](#)