Nadine AUTRAN

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EXPERIENCE PROFESSIONNELLE

CONSULTANT REGLEMENTAIRE — Depuis le 03/09/2024
IVD REG, Tours, France
Secteur DMDIV

CONSULTANT REGLEMENTAIRE — 25/10/2021 – 02/09/2024
CENCORA Pharmalex, NSW, Australia (remote from France)
Secteurs DMDIV et DM

CONSULTANT REGLEMENTAIRE — 03/07/2020 – 24/10/2021
iV PASS, Anglet, France
Secteur DMDIV

RESPONSABLE D'EQUIPE PRODUCTION — 24/02/2020 – 23/06/2020
CERBA XPERT, Saint-Ouen-l'Aumône, France
Secteur DMDIV

RESPONSABLE QUALITE ET AFFAIRES REGLEMENTAIRES — 04/02/2019 – 21/02/2020
GENFIT, Lille, France
Secteur DMDIV

RESPONSABLE QUALITE ET AFFAIRES REGLEMENTAIRES — 30/01/2017 – 05/11/2018
NEEDLE CONCEPT, Biarritz, France
Secteur DM

CONSULTANT REGLEMENTAIRE — 16/09/2015 – 27/01/2017
GEMACBIO, Saint Jean d'Illac, France
Secteurs DMDIV

RESPONSABLE DE PROJET — 01/09/2012 – 12/06/2015
VIRBAC, Penrith, NSW, Australie
R&D Vaccins

RESPONSABLE D'ETUDES — 01/06/2010 – 31/08/2012
VIRBAC, Carros, France
R&D Vaccins

CONSULTANT SCIENTIFIQUE 13/07/2007 – 31/12/2010

NH CONSULTANT, Dumbea, Nouvelle-Calédonie
Secteur DMDIV

ENSEIGNANTE 05/01/1998 – 06/07/2007

MINISTERE DE L'EDUCATION NATIONALE, Aquitaine, France

RESPONSABLE DE LABORATOIRE DE TOXICOLOGIE CELLULAIRE 01/05/1995 – 31/12/1997

MINISTERE DE LA DEFENSE, DGA, Vert-le-Petit, France

FORMATIONS DISPENSEES

- ✓ 2023
  - PharmaLex - Companion Diagnostics (CDxs)
  - PharmaLex - Regulation (EU) 2017/746 on in vitro diagnostic medical devices
  - PharmaLex - General technical aspects for Design and Development of IVD devices

WEBINARS ANIMES

- ✓ 2023
  - PharmaLex - Application du Règlement (UE) 2017/746 sur les dispositifs médicaux de diagnostic in vitro : Sommes-nous en conformité ?
  - PharmaLex - Countdown for EU health institutions using in-house devices
- ✓ 2020
  - Experts Medtech Webinars and Trainings - Le rapport d'évaluation des performances selon l'IVDR (UE) 2017/746
  - Experts Medtech Webinars and Trainings - Impact de la mise en application du règlement (UE) 2017/746 relatif aux Dispositifs Médicaux de Diagnostic In Vitro sur les dispositifs «maison» utilisés dans les établissements de santé

FORMATIONS SUIVIES

- ✓ PharmaLex - TGA Regulations and Applications – 2023
- ✓ PharmaLex - Data Protection According to General Data Protection Regulation (GDPR) - 2022
- ✓ GS1 - Unique Device Identification - 2021
- ✓ BSI - Performance Evaluation and Clinical Evidence for IVDs - 2020
- ✓ BSI - EN 62304/A1:2018 Medical device software - Software life-cycle processes - 2019
- ✓ BSI - Medical Device Single Audit Program - 2019
- ✓ DIDAXIS - Regulation (EU) 2017/746 on in vitro diagnostic medical devices - 2019
- ✓ CADUCEUM Academy - The clinical evaluation report in accordance with MEDDEV 2.7/1 - 2017
- ✓ CADUCEUM Academy - 21 CFR part 820 quality system regulation - 2017
- ✓ CADUCEUM Academy - Procedures for placing Medical Devices on the US market - 2017
- ✓ CADUCEUM Academy - EN 62366:2008 Medical device usability - 2017
- ✓ CADUCEUM Academy - Medical Device Post Market Surveillance - 2017
- ✓ CADUCEUM Academy - ISO 14971:2013 Medical Device Risk analysis - 2017
- ✓ CADUCEUM Academy - Awareness to biological evaluation of medical devices – NF EN ISO 10939-1:2010 - 2017
- ✓ CADUCEUM Academy - ISO 19011:2011 internal and supplier audits for medical device companies - 2017
- ✓ CADUCEUM Academy - Awareness to electrical security of medical devices - 2017
- ✓ CADUCEUM Academy - To control sterilization of medical devices in accordance with ISO 11135:2014 - 2017
- ✓ Avenir Conseil - Medical Device vigilance - 2017
- ✓ Avenir Conseil - Medical Devices CE-marking in accordance with DIR 93/42/EEC - 2017
- ✓ Avenir Conseil - Medical Device Regulation SOR/98-282 - 2017
- ✓ Avenir Conseil - Validation of medical device manufacturing processes - 2017
- ✓ PQB - ISO 13485:2016 preparation - 2017
- ✓ VIRBAC AUSTRALIA - Good Manufacturing Practice - 2013
- ✓ VIRBAC - In vitro relative potency tests for veterinary vaccines - 2012
- ✓ VIRBAC - Good Laboratory Practice - 2010
- ✓ UNIVERSITE PARIS VI - Doctorat de Biologie - 1994

LANGUES

- ✓ **Français** : langue maternelle
- ✓ **Anglais** : maîtrise professionnelle complète (C1)