WHITE TILLET

REGULATORY EXPERTISE MADE FOR YOU

Since it was founded in 1994, WHITE-TILLET has set itself apart by combining genuine expertise in the evaluation and regulation of both Medicinal Products and Medical Devices.

OUR EXPERTISE

QUALITY
- Implementation of ISO 13485 MD Quality Management System
- ISO 13485 or ISO 9001 quality audits
- ISO 14155 clinical audits
- Preparation for and assistance during Notified Body audits

DESIGN/DEVELOPMENT
- Advice and execution of development/design plans: quality, non-clinical and clinical (including clinical trial design)
- Development plan : budgets and road map

MARKETING
- Medicinal Products MA dossiers (including clinical modules)
- MD/IVD technical documentation in accordance with MDR/IVDR and MDD-IVDD/MDR-IVDR gap analysis
- Dossiers for MD intended to administer a medicinal product
- MD: expertise of biosafety (BRA) and clinical data evaluation (CER) reports
- IVD: expertise of performance evaluation reports
- Assistance with MA or CE marking procedures

MARKET ACCESS
- Dossier and reimbursement procedure (medicinal Products or MD - FR and EU)
- Advice on and assistance with price negotiations

POST-MARKET (MD)
- PMS/PMCF and Risk Management Plans (including IAU) for MD or IVD
- Assistance with MD vigilance and IVD vigilance
- Advice on advertising (including the use of clinical data)
- Regulatory assistance in the event of a serious incident or dispute with the authorities
- Regulatory watch

INTERNATIONAL
- Regulatory assistance in the UK, EU, USA and China
- Product regulatory positioning and associated regulatory roadmaps
- Agency meetings and notified bodies interactions

IFEP (INSTITUTE OF TRAINING IN HEALTH PRODUCT EXPERTISE) INTER- AND INTRA-COMPANY TRAINING DIVISION
- MD/IVD, Combination Products
- Medicinal Products, MD intended to administer a medicinal product
- Advanced therapies

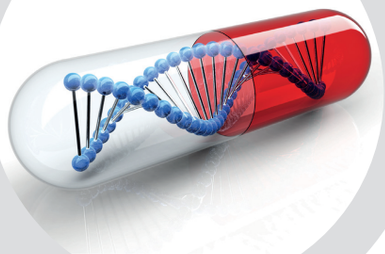
White - Tillet is a company of neovix GROUPE BIOSCIENCES

OUR AREAS OF ACTIVITY

Medical Devices, Medicinal Products (including Biologics), Combination Products (MD/ Medicines), IVD, Advanced therapies

OUR STRENGTHS

- Over 25 years of dual expertise in Medicinal Products and Medical Devices
- Strong in-house expertise combined with a wide network of collaborating Experts
- Portfolio of over 200 pharmaceutical and Medtech clients
- Research Tax Credit (RTC) approval
- Qualiopi registered training organisation



MORE INFORMATION

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Qualiopi processus certifié
RÉPUBLIQUE FRANÇAISE

La certification qualité a été délivrée au titre de la catégori d'action suivante :
L.6313-1 – 1° Actions de formation

CRÉDIT D'IMPÔT AGRÉMENT CIR RECHERCHE

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