Yves Th. TILLET

Full Curriculum Vitae (8p), September 2022

Yves Th. Tillet is PharmD, graduate of physiology and biochemistry (MSc), of the Business Administration Institute (MBA), and of Marketing and Strategy from the Centre for Higher Education (Paris).

Yves Th. Tillet began his professional career in the field of hospital biology (clinical biochemistry) during several years. Then, he was shareholder and general manager of a consulting firm specialising in "in and out" **Registration and Licensing of drugs** in Europe (IDD). He created and was President of a CRO specialised in **Clinical Trials and Biostatistics** (Clinica & Statistica). During this period, he organised a number of international seminars on the development of drugs and clinical methodology in collaboration with recognised experts.

In the 90s, **Yves Th. Tillet** and **Marie D. White** created the **Cabinet WHITE-TILLET** providing expertise and experience in the field of Consulting and Assistance in Quality, Development, Evaluation and Regulation of health products: Drugs, Herbals, Biologics, Advanced Therapies, Medical Devices, including IVD, Drug/Device Combinations, medical-related Cosmetics and Food Supplements.

Yves Th. Tillet was Director of IFEP (Institute for Training in Health Products Expertise) and also provided training and expertise to several official and professional organisations in France, among which is LNE/G-MED (the French Notified Body). During 10y, he taught quality, development and regulation, CTD, market access of drugs, medical devices and product combinations, at University of Cergy Pontoise and Faculty of Pharmacy of Paris & Lille.

Yves Th TILLET is member of the Galenic Academy Michel Lanquetin (Monaco), FTOPRA (UK) and Team-PRRC (EU)

In December 2020, WHITE-TILLET was sold to the NEOVIX BIOSCIOENCES Group and Yves Th Tillet accompanied this sale as Senior Advisor until December 31, 2022.

Today, Yves Th Tillet
manages the consulting company
TILLET EXPERTISE & BUSINESS (T.E.B.)
which operates in the field of
the Regulatory Expertise of Health Products
at the service of the economic development
of companies (Laboratory, Start-up, …)

Training organized by IFEP

Under the direction of Y. Th. TILLET

Institute for Training in Health Products Expertise

of

Cabinet WHITE-TILLET

(certified QUALIOPI for professional training)

- **DRUGS**
  - Genic Therapies
  - Cell Therapy
  - Biologics and biosimilars
  - Paediatric drugs
  - Orphan drugs
  - In silico Clinical Trials

- Impurities in drugs
- EU GMP
- US FDA: how does it work ?

- **MEDICAL DEVICES & IN VITRO DIAGNOSTIC**
  - Rule EU 2017/745
  - Post-Market Follow-up
  - Evaluation of clinical data of MD (MEDDEV 2.7/1.rev4)
  - Biological assessment of MD
  - Risk Management of MD
  - Post-Market Clinical Follow-up
  - E-Apps and IA as MD
  - ISO 13485:2016 et MDSAP
  - Combination product
  - Companion diagnostic
  - Reimbursement of MD/IVD in France
  - IVD: Rule EU 2017/746
  - IVD: assessment of performances
  - IVD: Post-market surveillance
  - IVD: responsibilities of economic operators
  - MDSAP
  - ISO 14155
  - ISO 13485:2016
  - PRRC: obligations and responsibilities

Publications

Leverge R, Bergmann JF, Simoneau G, Tillet Y and Bonnemain B. Bioavailability of Oral versus Intramuscular Iodinated Oil (Lipiodol ® UF) in Healthy Subjects. IDD Newsletter, August 2000.

Knellwolf AL, Simoneau G, Bergmann JF, Blain P, Sanson Le Pors MJ, Balland MA, de Wailly J, Tillet Y, Mongold JJ. Ophthalmic Insert Mydriasert ® a New Galenic Form to Deliver Neosynephrine and Tropicamid on a Continuous Basis for Per Surgery Mydriasis. Poster for a clinical pharmacology conference in Florence, Italy (2001).

Tillet Y. From state of the Art to clinical assessment. Preface document APPAMED (Union of medical care devices) compiled by Pr. PH. Thoumy, entitled: "Clinical evaluation of the orthosis of the ankle". Internal APPAMED document (2002).

Tillet Y. CE Marking: the point of regulation of medical devices administering drugs. Doses, February 2003.

Tillet Y. Why is quality useful? Doses, May 2003.

Rouard Ph et Tillet Y. The reimbursement of medical devices. Doses, February 2004.

Baufumé M and Tillet Y. Towards an engineering of innovation. Le Scialytique. The letter of the BIOCRITT. March 2004.

Tillet Y. Managing innovation. Doses, May 2004.

Tillet Y. The therapeutic properties of sea water. Pharmacie & Dispositifs Médicaux 2004;19:31-34.

Tillet Y. Quality is the mother of Safety and Efficacy. Doses, September 2004.

Tillet Y. Clinical trials: ten keys for better understanding. Doses, November 2004.

Tillet Y. Evaluation of drugs: saga and realities. Doses, January 2005.

Mahe I, Mouly S, Jarrin S, Otero J, Tavera C, Simoneau G, Tillet Y, Conti R, El Meski S, Gaudric A, Bergmann JF. Efficacy and safety of three ophthalmic inserts for topical anaesthesia of the cornea. An exploratory comparative dose-ranging, double-blind, randomised trial in healthy volunteers. Br J Clin Pharmacol. 59 :2, 220-226 (2004).

Tillet Y. Food complements: dangerous claims. Doses, April 2005.

Tillet Y. Drug/Device Combinations: a Promising Future. AMIPS Info 4ème Trim 2005 et 1er Trim 2006;72:74-77.

Mouly S, Mahe I, Haouchine B, Sanson-le-Pors MJ, Blain P, Tillet Y, Dewailly J, Mongold JJ, Bergmann JF. Pharmacodynamics of a new ophtalmic mydriatic insert in healthy volonteers : potential alternative as drug delivery system prior to cataract surgery. Basic Clin Pharmacol Toxicol. 2006;98(6):547:54.

Tillet Y. The re-examination process for reimbursement of generic medical devices in France. AMIPS Info 3ème et 4ème Trim 2006;74:90-94.

Tillet Y and Lebrun A. The new Regulations for biomedical research. Regulatory Rapporteur 2006;3(12):34.

Tillet Y and Lebrun A. What you Need to Know about the New Regulations for Biomedical Research in France. Thérapie Nov-Dec 2006;61(6):463-466.

WHITE-TILLET. The Biomedical Research in France: New Regulatory Basis and Practice. Writen by Aurélie Lebrun and supervised by Yves Tillet, 9th Ed May 2008 reviewed by Yves Tillet. In French, 103p. For any information, please contact white-tillet@white-tillet.com.

Mouly S, Orler JB, Tillet Y, Coudert AC, Oberli F, Preshaw P et Bergmann JF. Efficacy of a new oral lubricant solution in the management of psychotropic drug-induced xerostomia – A multicenter randomized controlled trial. J Clin Psychopharmacol 2007;27(5):437-43

Mouly S, Salom M, Tillet Y et al. Management of Xerostomia in Older Patients: A Randomized Controlled Trial Evaluating the Efficacy of a New Oral Lubricant Solution. Drugs Aging 2007;24(11):957-965.

Tillet Y. Clinical assessment of dressings: is the truth somewhere else? Profession Pharmacien; Hors-Série 2ème Trimestre 2008.

Trial C, Darbas H, Lavigne JP, Sotto A, Simoneau G, Tillet Y, Téot L. Assessment of the antimicrobial effectiveness of a new silver alginate wound dressing: a RCT. JWC 2010;19(1):20-26.

Tillet Y. Drugs and Medical Devices: the enemy brothers? Gazette de l'AFAR. July 2011.

Khemis A, Duteil L, Coudert AC, Tillet Y, Dereure O, Ortonne JP. Evaluation of efficacy and safety of an OGT-containing CS20 protective barrier gel compared with topical aciclovir and placebo on functional and objective symptoms of labial herpes recurrences: a randomized clinical trial. JEADV 2011; DOI: 10.1111/j.1468-3083.2011.04269.x

Maillols-Perroy AC et Tillet Y. *The French Act N°2011-2012*: Boosting Safety or Creating a Storm? Regulatoryfocus.org. Feb. 2012.

Maillols-Perroy AC et Tillet Y. Reform Act on Safety of Drug and Health Products in France: Announcement Effect, Strengthening or Upheaval? Thérapie 2012 Janvier-Février; 67 (1): 1–10 (in French).

Maillols-Perroy A.C., Tillet Y., Lewellen O. The new Medicinal Products and Health Products Safety Reform Act in France: Reform or storm? Regulatory Rapporteur - Vol 9, No 5, May 2012.

Tillet Y. Medical Assessment of drugs and medical devices to be reimbursed: rules in vigor, impact of the new Bertrand law, new announced reforms. Gazette de l'AFAR 2012;75:28-34 (in French).

Maillols-Perroy A.C. et Tillet Y. La loi de réforme de la sécurité sanitaire du médicament et des produits de santé en France : effet d'annonce, renforcement ou bouleversement ? Thérapie 2012 ;6(11) :1-10.

Maillols-Perroy A.C. et Tillet Y. L'adoption de la loi Jardé modifie l'encadrement juridique de la recherche clinique en France. Thérapie 2012 ;67(2) :77-87.

Tillet Y., Lewellen O, Maillols-Perroy A.C.. When does healthcare stand-alone software become a medical device? Topra Regulatory Rapporteur. January 2013.

Maillols-Perroy A.C. et Tillet Y. Legal issues in pharmaceutical digital communication in the EU. Regulatory Focus. RAPS Part 1, 2,3 ;April, May, June 2013.

Tillet Y and Dereure O. Plaies chroniques et pansements : que faut-il évaluer ? Pourquoi innover ? Les Points Clés en Plaies et Cicatrisation. Sous la direction d'Olivier Dereure. L'Européenne d'Edition. Novembre 2012.

Khemis A, Duteil L, Tillet Y, Dereure O, Ortonne JP. Evaluation of the activity and safety of CS® 21 genital protective barrier gel compared to topical aciclovir and placebo in symptoms of genital herpes recurrences: a randomized clinical trial. JEADV 2013.

Tillet Y et Elia-Foeillet S. Voyage dans le monde des dispositifs médicaux. La Gazette Juillet 2013 ;80 :4-10.

Tillet Y., Lewellen O., Perroy AC. When does healthcare stand-alone software become a medical device ? TOPRA Regulatory Rapporteur; 10 (1) January 2013:21-25.

Tillet Y et Maillols-Perroy A.C. Orphan Drugs in Europe: an opportunity for developers. Thérapie 2015 Juillet-Août; 70 (4): 351–357

Dubos C., Rath-Lavialle A., Tillet Y. How to set up and manage a 510(k) process? RIS.World; White-Paper October 2015.

Rath-Lavialle A., Tillet Y. La place des données cliniques dans l'évaluation de la conformité ou de la prise en charge des dispositifs médicaux. La Gazette de l'AFAR; 89 (Octobre 2015): 16-22.

Tillet Y, Rath-Lavialle A, Dubos C, Breysse A. L'évaluation Clinique de l'innovation de rupture. DeviceMed 2016, *In press*.

Tillet Y, Breysse A, Dreyfuss T, Dubos C, Lewellen O, Rath-Lavialle A, Tillet A, Yang M, Zerial A. Precision medicines and pharmacogenomic testing: from scientific basis to assessment, regulatory framework, labelling, and practical information. Gazette de l'AFAR, Numéro Spécial Mars 2016.

Tillet Y, Rath-Lavialle A, Dubos C, Breysse A. Medical devices and wound healing: why innovate and how to evaluate innovations. Wounds and Healing, Under the direction of Prof. Olivier Dereure; June 2016.

Tillet Y. Industriels du médicament : pourquoi tant de suspicion ? www.RIS.World 8 Décembre 2016.

Tillet Y. Affaire ESSURE : du médical au sociétal**.** www.RIS.World 12 Décembre 2016.

Tillet Yves. Faut-il élargir la notion de conflit d'intérêts. www.RIS.World May 2017.

Benoliel C, Dugue R, Ferreira-Theret P, Guitton B, Haddad L, Rath-Lavialle A, Tillet Y. Etude de l'activité antimicrobienne d'un gel buccal : le Klirich.

Tillet Y. Quand la CNEDiMTS retarde l'accès à l'innovation. WWW.RIS.World. Juin 2017. http://www.ris.world/news/quand-la-cnedimts-retarde-l%E2%80%99acc%C3%A8s-%C3%A0-l%E2%80%99innovation

Tillet Y, Rath-Lavialle A. The Reimbursement of Medical Devices in France. DeviceMed. November 2017

Tillet Y, Rath-Lavialle A. Les points clés du dossier médico-technique d'un dispositif médical en vue de son remboursement sous nom de marque en France. DeviceMed. A paraître en 2018

Tillet Y, Rath-Lavialle A. Les points clés du dossier médico-économique d'un dispositif médical en vue de son remboursement sous nom de marque en France. DeviceMed. A paraître en 2018

Tillet Y. How to assess medical devices combined with medicinal products that they administer ? STP Pharma Pratiques. 2018

Tillet Y, Rath-Lavialle A, Mezhoud W, Luyssaert C. Remboursement des médicaments en France : règles du jeu et importance des données cliniques. RIS.World. Mars 2018.

Tillet Y. Le Règlement UE 2017/745 : vers un désastre industriel ? www.RIS.World Juillet 2018. http://www.ris.world/news/le-règlement-ue-2017745%C2%A0-vers-un-désastre-industriel%C2%A0

Tillet Y, Rath-Lavialle A, Mezhoud W, Luyssaert C. Les dix points noirs du Règlement UE 2017/745. DeviceMed. Juillet 2018.

Tillet Y. Produits de santé : pourquoi tant d'incompréhension du public. www.RIS.World Janvier 2019. http://www.ris.world/?s=incompr%C3%A9hension

Tillet Y, Luyssaert C, Touila K. Le MDSAP est-il un programme d'audit comme les autres ? DeviceMed. 2019.

Tillet Y, Rath-Lavialle A, Luyssaert C, Touila K. MDR : l'enfer est pavé de bonnes intentions. Décembre 2019.
http://www.ris.world/europe-rdm-lenfer-est-pave-de-bonnes-intentions/

Tillet Y, Rath-Lavialle A, Luyssaert C, Touila K. L'importance du niveau de preuve des données cliniques pour évaluer les DM. DeviceMed 2020.

Tillet Y, Rath-Lavialle A, Luyssaert C, Touila K. E-Apps in health : when are they MD ? DeviceMed 2021 (to be published).

Tillet Y, Rath-Lavialle A, Luyssaert C, Touila K. Difference in quality management between medicines and medical devices: a historical and cultural approach. SFSTPP 2021 (to be published).

Jury de Thèses / Jury Thesis

FOURNIER Marielle. Thèse de Doctorat d'Etat en Pharmacie. Comparaison entre la réglementation des medicaments et celle des dispositifs médicaux en Europe. Université de Clermont-Ferrand, 1999.

GAIONI Samantha. Thèse de Doctorat d'Etat en Pharmacie. Produits combinés medicaments/dispositifs médicaux: réglementation en vigueur dans la Communauté Européenne en 2010 en vue de leur mise sur le marché. Paris XI 2010

HÖSCH CONGIA Sandrine. Thèse de Doctorat d'Etat en Pharmacie. La nouvelle réglementation de la recherché biomédicale en France: une necessaire evolution des dispositions antérieures définies par la loi Huriet-Sérisclat. Paris XI 2012

YANG Mi. Thèse de Doctorat d'Etat en Pharmacie. Médecine de précision, en cancérologie: défis et réussites. Paris XI Janvier 2015.

RATH-LAVIALLE Audeline. Thèse de Doctorat d'Etat en Pharmacie. La place des données cliniques dans l'évaluation de la conformité des dispositifs médicaux pour le marquage CE et pour la prise en charge en France. Paris V Mars 2015.

DREYFUSS Thomas. Thèse de Doctorat d'Etat en Pharmacie. Emerging Market Access Strategy in the Pharmaceutical Industry: the Exemple of Thaïland. Université de Strasbourg. 12 Juillet 2018.

LUYSSAERT Clémence. Thèse de Doctorat d'Etat en Pharmacie. Les frontières entre les statuts réglementaires des produits de santé. De leurs définitions à la position des autorités compétentes et les conséquences pour les industriels de la santé. Faculté de Pharmacie de Lille. Novembre 2019.

…….