個人簡歷

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學歷

1999-2003 中國醫藥大學藥學系學士
2003-2005 國防醫學院藥學研究所藥劑組碩士
2011-2014 成功大學藥物科技與臨床藥學所博士

工作經歷

2007-2012 財團法人醫藥品查驗中心藥動審查員
2014-2015 財團法人醫藥品查驗中心資深藥動審查員
2015-2016 財團法人醫藥品查驗中心小組長
2017-至今 財團法人醫藥品查驗中心資深藥動審查員

專長

藥物動力學、藥物動力學/藥物藥效學的模型建構與模擬、法規科學。熟悉 NONMEM、Phoenix Winnonlin 等軟體

學術期刊論文 (第一作者或通訊作者以底線標示)

- Hsiao CL, Lin YL, **Hsu LF**, Hsu KY. Ten-year experience of the evaluation of ethnic sensitivity data. *Ther Innov Regul Sci.* 2011 Dec;45(6):717-724.
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- Chou CH, **Hsu LF**. Model-based simulation to support the extended dosing regimens of atezolizumab. *Eur J Clin Pharmacol.* 2020 (in press)

研討會論文

- **Hsu LF** A review and assessment of bridging study evaluation of monoclonal antibodies in Taiwan. AAPS National Biotechnology Conference, 2011, San Francisco, USA.
- **Hsu LF** Applications of population pharmacokinetics in drug labeling in Taiwan-a four-year (2008-2011) survey of 79 new drug applications. World Conference on Pharmacometrics, 2012, Seoul, Korea.

受邀演講

- **Hsu LF (2012),** "Application of Population PK/PD in Drug Review-From Regulatory Perspective" , presented at population pharmacokinetics/pharmacodynamics workshop, Taipei, Taiwan, March, 2012.
- **Hsu LF (2014),** "生體可用率/生體相等性試驗/溶離率曲線比對試驗之扮演的角色與法規考量", presented at Taipei Medical University, Taipei, Taiwan, December, 2014.
- **Hsu LF (2015),** "以 Bear (BA/BE for R)進行生體相等性試驗與樣本數計算", presented at Taiwan Research-based Biopharmaceutical Manufacturers Association (TRPMA), Taipei, Taiwan, May, 2015.

- **Hsu LF (2015),** "生體可用率/生體相等性試驗設計與統計分析之重點考量", presented at Chinese Pharmaceutical Manufacture and Development Association (CPMDA), Taipei, Taiwan, June, 2015.
- **Hsu LF (2015),** "藥品生體可用率及生體相等性試驗準則審查重點", presented at 藥品安定性試驗基準修訂(草案)暨 BA/BE 部分條文修正研討會, Taipei, Taiwan, September, 2015.
- **Hsu LF (2016),** "生體相等性試驗之法規考量: EMA 與 TFDA、USFDA 之比較", presented at 2016 國際藥品法規研討會, Taipei, Taiwan, July, 2016.
- **Hsu LF (2017),** "BE 試驗研究的科學審評", presented at 2017 深圳國際 BT 領袖峰會, Shenzhen, China, September, 2017.
- **Hsu LF (2017),** "抗癌用學名藥生體可用率及生體相等性試驗之設計與查驗登記", presented at 北榮人體試驗委員會, Taipei, Taiwan, August, 2017.
- **Hsu LF (2017),** "學名藥審查效率制度說明-藥物動力學 (PK) 部分", presented at TPMMA「藥品審查效率相關制度」說明會, Taipei, Taiwan, October, 2017.
- **Hsu LF (2018),** "Pharmacokinetic Considerations in the Development of Nanomedicines: Regulatory Perspective" , presented at 2018 International Advanced Drug Delivery Symposium (IADDS), Hsinchu, Taiwan, April, 2018.
- **Hsu LF (2018),** "新藥查驗登記的藥動學試驗", presented at 陽明藥學系『學產研鏈結人才培育計畫-藥品產業創新』系列課程, Taipei, Taiwan, July, 2018.
- **Hsu LF (2018),** "學名藥與生體相等性試驗", presented at 陽明藥學系『學產研鏈結人才培育計畫-藥品產業創新』系列課程, Taipei, Taiwan, July, 2018.
- **Hsu LF (2018),** "Role of Modeling and Simulation in Regulatory Review", presented at 2018 International Symposium on Quantitative Systems Pharmacology (QSP): Integration of Drug Discovery and Development, Taipei, Taiwan, April, 2018.
- **Hsu LF (2018),** "MIDD (Model-Informed Drug Development)-台灣 CDE 觀點", presented at 台灣醫藥品法規學會會員大會, Taipei, Taiwan, November, 2018.
- **Hsu LF (2019)**,"奈米劑型研發-法規觀點與藥物動力學考量" , presented at 陽明藥學系, Taipei, Taiwan, August, 2019.
- **Hsu LF (2019),** "新藥查驗登記的藥動學試驗", presented at 台大藥學系『守護健康-談藥品法規科學』系列課程, Taipei, Taiwan, October, 2019.
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- **Hsu LF (2019),** "Scientific Review of Bioequivalence Studies-Experience Sharing from Taiwan", 臺灣-東協藥政管理研討會 (閉門會議), Taipei, Taiwan, November, 2019.