

Jun-I Wu

REGULATORY AFFAIRS SPECIALIST

Zhubei City, Hsinchu County, Taiwan

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Regulatory affairs specialist for medical devices including IVD and IVD data analysis

Experience

AlfaBeta CRO Ltd.

Regulatory Affairs Specialist

Zhubei City, Taiwan

Jan. 2020 - Present

- Provide lectures of IVD pre-clinical tests (CLSI ep5, 6, 7, 9, 17, 25)
- IVD pre-clinical test planning, *data analysis using R*, and report (ELISA, strip, molecular test and analyzer)
- FDA Q-submission (Oral Cancer IVD and IVD for chronic kidney disease), Registration of Class I device (Spectrophotometer), EUA submission (Ventilator)
- TFDA QSD translation and submission (Electrosurgical cutting and coagulation device), device registration (Manual surgical instruments)
- EU Clinical evaluation report writing including LSR (Blood pressure measuring system, Extra-oral source X-ray System, Medical displays, thermometers, contact lenses, Intermittent pneumatic compression device and sequential compression device), self-declaration of conformity of general IVD (Spectrophotometer)
- Clinical trial planning, submission, and GCP activities and documentation (retrospective for oral cancer IVD, prospective for mobile X-ray system)

China Medical University Hospital

IVD Biomarker Project Research Associate

Zhunan County, Taiwan

Jan. 2017 - 2018

- Discovery and validation of blood biomarker for earlier stage lung cancer

Publications

- Lin, Yi-Pei, **Jun-I. Wu**, Chien-Wei Tseng, Huei-Jane Chen, and Lu-Hai Wang. 2019. "Gjb4 Serves as a Novel Biomarker for Lung Cancer and Promotes Metastasis and Chemoresistance via Src Activation." *Oncogene* 38 (6): 822–37.
- **Wu, Jun-I**, Yi-Pei Lin, Chien-Wei Tseng, Hui-Jane Chen, and Lu-Hai Wang. 2019. "Crabp2 Promotes Metastasis of Lung Cancer Cells via HuR and Integrin B1/FAK/ERK Signaling." *Scientific Reports* 9 (1): 845.

Education

National Central University

Ph.D. in Molecular Medicine

Chungli County, Taiwan

2019

National Cheng Kung University

MS. in Biochemistry and Molecular Biology

Tainan City, Taiwan

2008

Certificate and Skills

TOEIC (955), IVD preclinical data analysis (R), parametrized reproducible report making (RMarkdown & officeverse), bash. Adept user of Linux.