Jeffrey Chern 陳錦豐

Founder & CEO of SEQPRO, Inc.

Master of Science in Molecular Medicine, National Taiwan University

Bachelor of Science in Medical Technology, National Taiwan University

Background

Before founding SEQPRO, Inc., Jeffrey Chern was a medical device evaluation engineer at ITRI, Taiwan (2005-2013). Being a US FDA 510(k) AP reviewer, TFDA designated GMP lead auditor and premarket reviewer, Jeffrey developed expertise on TPLC medical device regulations. As the project leader of Taiwan IDB Special Consulting Program for Electronic Medical Devices Industry (2008-2013), he assisted numerous ICT manufacturers to overcome regulatory hurdles throughout preclinical to clinical stages. Besides, Jeffrey has been playing an active role in regulatory harmonization activities. He used to be the cofounder and cochair of AHWP WG1a IVDD WG (2009-2013) and the member of GHTF SG1 IVD Subgroup (2010-2013).

Currently, SEQPRO, Inc. provides Total-Product-Life-Cycle consultation services for medical devices (including IVD medical devices) companies. The company assists their clients to deal with regulatory affairs analysis, quality management system, license holding, preclinical (e.g., software/AI/ML, usability, cyber security, etc.), and clinical safety and performance evaluation, including premarket registration of various countries, e.g, US, EU, China, Taiwan, ASEAN Countries, etc.

Most of projects consigned to SEQPRO, Inc. are related to total solution package on QMS and premarket registration consultation for medical devices with novel design or higher risk indications. The company also delivers customized regulatory training for government departments, manufacturers or research institutes. Besides, SEQPRO, inc. has established strong liaison network for GMP ODM/OEM production, medical device safety & performance testing, clinical trial implementation.

- Medical Device GMP & Risk Management
- Design Control and Safety & Performance Evaluation
- Clinical Evaluation
- Medical Device Human Factors &Usability Study