陳 映樺

台湾食品薬物管理署 衛生福利部（TFDA） 部長

Ms. Ellen, Ying-Hua Chen is the Director of Quality Compliance & Management Division (GXP Inspectorate) at the Taiwan FDA, overseeing GMP/GDP, medical device QMS, GTP, and GLP compliance. She is an Executive Bureau Member of PIC/S and currently chairs the PIC/S Sub-Committee on Budget, Risk and Audit, having previously chaired the PIC/S Sub-Committee on GMDP Harmonization. With over 20 years of experience in GXP inspections and regulatory policy, she actively leads the implementation of revised GMP standards, including PIC/S Annex 1, and advances international regulatory convergence. Ellen holds an M.Sc. in Technology & Innovation Management from National Chengchi University, Taiwan, and a B.Sc. in Pharmacy from Taipei Medical University.

10 月 22 日（木）14:20　講演

台湾における Annex 1 実施の展望：TFDA の規制的視点と PIC/S との協働

Navigating Annex 1 Implementation in Taiwan: TFDA’s Regulatory Perspectives and PIC/S Collaboration

This presentation provides an overview of Taiwan FDA's regulatory journey and supervisory framework in implementing the revised PIC/S GMP Annex 1, highlighting the practical implementation of core principles—such as the Contamination Control Strategy (CCS) —into routine inspections and industry compliance. It explores TFDA's regulatory perspectives on adopting innovative technologies, including barrier systems to enhance aseptic manufacturing robustness. Furthermore, drawing on TFDA's active collaboration within the PIC/S framework, the session will share insights on advancing international regulatory harmonization, inspection consistency, and mutual reliance, thereby strengthening global supply chain resilience and assuring sterile product quality and patient safety worldwide.