台灣藥物臨床研究協會
Taiwan Clinical Research Association

2025 年九月份會議

日期：2025 年 9 月 22 日 (星期一)

地點：中國文化大學建國本部(大夏館) 國際會議廳 (台北市建國南路二段 231 號 B1)

議程：

時　間	主　　題	主講人
13:00 ~ 13:30	報到	
13:30 ~ 13:40	**會務報告**	**孫婷婷 理事長**
13:40 ~ 14:30	**Task Force 報告**	**Task Force Leads** & Co-Leads ♦ GA – **Muting**/Carol/Mandy/Nicole ♦ EC – **Sharon**/Anna/Curtis ♦ C&C – **Lillian**/Jessie/Leila/Nora/Tracy ♦ EDU – **Vivi**/Mandy/Patty/Stephen ♦ BTT – **Alice**/Nora
14:30 ~ 14:40	**臨時動議 & Wrap up**	**孫婷婷 理事長**
14:40 ~ 15:00	Break	
15:00 ~ 16:30	**專題演講 (目前暫定為線上演講)** ❖ ICH GCP – Changes in the Revision 3	**Rebecca Stanbrook** BPharm (hons)/ MRPharmS/ FFRPS/ DipRQA/FRQA

Speaker Introduction：

Rebecca Stanbrook

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This presentation will explore the recently adopted ICH E6(R3) Principles and Annex 1 with a reference to the eagerly awaited annex 2. Hear from one of the members of the Expert Working Group at ICH responsible for writing the guideline.

- Currently Rebecca works as GCP Strategic Lead in Process & Risk Surveillance, in the Strategy, Portfolio and Programme Operations Group of Development in Novartis Pharma AG. In this role she supports the implementation of the revision to ICH GCP and provides guidance and training on Good Clinical Practice.
- Rebecca is the EFPIA **Topic lead for ICH E6(R3) Expert Working Group**, the group is responsible to rewriting the Good Clinical Practice Guideline, the global standard for the conduct of clinical trials.
- Prior to joining Novartis, Rebecca was **Group Manager, Inspections (GLP/GCP/PV)** at the Medicines and Healthcare products Regulatory Agency (**MHRA**). Since she joined the Agency in 2003, Rebecca held a number of positions within the fields of GCP and Pharmacovigilance. She helped shape the GCP and Pharmacovigilance statutory programmers in their early stages and was a member of one of the teams conducting the first statutory GCP inspections in the UK. Rebecca's group at the Agency wrote the **Good Clinical Practice Guide** and the **Good Pharmacovigilance Guide**.

Prior to joining the Agency, Rebecca worked at a number of pharmaceutical companies in various roles across all aspects of the industry. To date she has over 30 years' experience in the industry or as a regulator. Rebecca has been based at the Basel Headquarters of Novartis since May 2014. In her spare time Rebecca enjoys skiing and is a member of the Novartis ladies football club.

Rebecca is delighted to be a member of the **Industrial Pharmacy Expert Advisory Group** of the Royal Pharmaceutical Society and an ACT-EU MSP Adhoc member representing the European Industrial Pharmacist Group.