



Extension Seminar in Clinical Trials

Preliminary program

Self-paced learning package: available from Friday 22 March 2024

Presentation	Learning objectives	Presenter
Clinical trials manufacturing: considerations for TGA GMP licenced vs. non-licenced facilities and international perspectives on clinical trials manufacturing	<ul style="list-style-type: none"> • Compare the standards for GMP licenced manufacturing vs non-GMP licenced manufacturing • Justify when you need a GMP licence to manufacture clinical trials • Discuss GMP training essentials • Identify the special considerations for advanced therapeutics • Explore and apply data from international databases • Explain the process and importance of being prepared for a GMP audit • Explain the variables in international regulations and what is and is not appropriate in Australia 	<p>Kerry Watts, Senior Project and Policy Officer, Advanced Therapeutics, Office for Health and Medical Research, NSW Ministry of Health, NSW</p> <p>Katrina Orr, Senior Teletrial Pharmacist, Australian Teletrial Program - Western Australia, WA Country Health Service, Department of Research and Innovation, WA</p>
National Clinical Trials Framework	<ul style="list-style-type: none"> • Explain what the National Clinical Trials Governance Framework is and how it applies to health service organisations • Discuss the history of the Clinical Trials Governance framework • Describe how the clinical trials governance framework applies to pharmacy • Identify the key areas of focus when coming up for accreditation 	<p>Liam King, National Research Lead and Cancer Care Coordinator – Pharmacy, Ramsay Health, Brisbane, Qld</p>
Human Research Ethics Committee (HREC) membership: how to review a submitted protocol and IB	<ul style="list-style-type: none"> • Overview information and essential documents provided in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (GCP) • Describe the purpose and expected content of an Investigator’s Brochure (IB) • Outline requirements for a clinical trial protocol • Explain key considerations, critical elements and best practices to facilitate a thorough and effective HREC review process for protocols and IBs 	<p>June Challen, Specialist Pharmacist Investigational Drugs, SA Health, Adelaide, SA</p>



Live seminar: Saturday 4 May 2024

All times listed are in AEST

Time (AEST)	Session
0945-1000	Online login and registration available
1000-1005	Welcome and introductions
1005-1015	Review and open Q&A Liam King , <i>National Research Lead and Cancer Care Coordinator – Pharmacy, Ramsay Health, Brisbane, Qld</i>
1015-1130	Growing your clinical trials unit Romana Cecchele , <i>Senior Pharmacist – Investigational Drug Unit, Royal Prince Alfred Hospital, Sydney, NSW</i>
1130-1150	Break
1150-1250	Budgeting and invoicing Eugenia Hong , <i>Clinical Trials Pharmacy Manager, Pharmacy Department, Royal Melbourne Hospital, Melbourne, Vic</i>
1250-1330	Electronic pharmacy files and online accountability Janet Gaon , <i>Senior Clinical Trials and Application Specialist Pharmacist, Chris O'Brien Lifehouse, Sydney, NSW</i>
1330-1345	Break
1345-1445	Clinical trials and Good Manufacturing Practice Kerry Watts , <i>Senior Project and Policy Officer, Advanced Therapeutics, Office for Health and Medical Research, NSW Ministry of Health, NSW</i> Katrina Orr , <i>Senior Teletrial Pharmacist, Australian Teletrial Program - Western Australia, WA Country Health Service, Department of Research and Innovation, WA</i>
1445-1500	Therapeutic Goods Administration (TGA) Good Clinical Practice (GCP) Inspection Program Anastasia Makshakova , <i>Senior Good Clinical Practice (GCP) Inspector – Risk Management Section, Therapeutic Goods Administration, Australian Government Department of Health and Aged Care, Canberra, ACT</i>
1500-1515	National Clinical Trial Reform Agenda Dr Bernadette Aliprandi-Costa , <i>Director Clinical Trials Policy Section, Health Economics and Research Division, Department of Health and Aged Care, Australian Government</i>
1515-1545	Questions and discussion
1545	Seminar close

Please note: presentation recordings from the live virtual seminar will not be available