Extension Seminar in Clinical Trials

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	• 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	**Kerry Watts,** *Senior Project and Policy Officer, Advanced Therapeutics, Office for Health and Medical Research, NSW Ministry of Health, NSW* **Katrina Orr,** *Senior Teletrial Pharmacist, Australian Teletrial Program - Western Australia, WA Country Health Service, Department of Research and Innovation, WA*
National Clinical Trials Framework	• 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	**Liam King,** *National Research Lead and Cancer Care Coordinator – Pharmacy, Ramsay Health, Brisbane, Qld*
Human Research Ethics Committee (HREC) membership: how to review a submitted protocol and IB	• 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	**June Challen,** *Specialist Pharmacist Investigational Drugs, SA Health, Adelaide, SA*

Program

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

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