GOOD LABORATORY PRACTICE (GLP) ALIGNMENT BOOTCAMP

Day	Topics	Duration	Objectives	Case Studies & Workshops
1	**Introduction to the OECD Principles of GLP** Introduction Overview of a lab-focused QMS (ISO 17025) The Fundamental Points of GLP: (purpose, structure and requirements of GLP) OECD Principles vs FDA 21CFR Part 58 vs the OECD GLP Principles. What's the same – what's different NATA Accreditation – why would you do it (benefits of QS Certification)	2.5 hours	Describe the fundamentals of an GLP aligned quality management system Apply a process of implementing a quality management system that aligns with GLP Describe the difference, using examples, between a Rule-based and a principles-based QMS.	**Pre-reading and pre-assessment:** What is a QMS (review of QS Primer). **Case Study:** what can go wrong. **Workshop:** A QS Model for GLP. Participants will explore QMS models. This workshop integrates learnings from the QS Primer.
	Resources The role of Management Personnel – roles and responsibilities, and training Infrastructure : GLP requirements for Buildings and Equipment	2.5 hours	Document operations and activities: what SOPs and Records are needed to demonstrate compliance with GLP principles for: • Competency of personnel • Environmental control • Equipment suitability Apply a process of implementing a quality management system that aligns with GLP (or how to integrate science and organisational skills) How to Implement a QMS: how to use tools eg RACI Matrix, Training Needs Analysis	**Case Study:** Good Science & Good Organisation – Management's Responsibility **Workshop**: use calibration of a test system to explore how to implement a QMS that aligns with GLP. **Activity**: Participants to list the important variables which need to be controlled to prevent disturbance in studies or contamination between studies. General comparison.
	Characterization The Test Item The Test System	2.5 hours	Document operations and activities - what SOPs and Records are needed to demonstrate compliance with GLP principles for: • Receipt	**Case Study**: Is GMP required for production of batches used in GLP studies. **Activity**: Points to consider to assure the quality of the test item.

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			• Storage • Preparation • Administration • Observations and Test Results • Reporting Implement a QMS (Identification and traceability, – how to use tools such as process mapping and SIPOC)	**Case Study:** what are the challenges associated with the different types of test systems? e.g. animals vs Cell Culture.
2	**RULES** The Protocol and Study Plan • Why is it important to identify the start and end dates • How to handle amendments to the protocol • How to handle deviations from the protocol • Difference between a deviation and a planned change • Review and approval process (scientific and compliance) Standard Operating Procedures (SOPs) and Test Methods • Is it OK to cross reference procedures and methods from the Study Protocol? • What procedures must be listed in the protocol	3 hours	Document operations and activities (Study Plans, Protocols, SOPs, Proforma - templates) Implement a QMS (how to roll out study plans, protocols and SOPs, schedules & communication tool(s))	**Pre-Class Activity:** Read sections 8.1 and 8.2 of the OECD GLP Principles **Case Study:** Demonstration of how scientific aspects are addressed in protocols. **Activity:** Which scientific aspects are included in protocols for their own studies. **Case Study:** Managing deviations from, and changes to, study protocols and SOP. Designing and writing protocols for "right first time" compliance. Critical Success Factors.
	RESULTS Raw Data and Data Collection • Definitions, examples and how it often goes wrong Final Report – what required, what can be left out.	4 hours	Document operations and activities (how to design effective Data Collection Forms) Describe with examples, the ALCOA+ principles How to prepare a Study Report – (template)	**Case Study**: when data loses its integrity. The loss of IP. **Case Study:** use of computerised test systems **Case Study:** how to deal with spreadsheets

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	Archiving – which records must be archived in the Study File Indexing – how to ensure study files and supporting data can be easily retrieved through the specified retention time 21CFR Part 11 – requirements for Electronic Records and Electronic Signatures		Implement a QMS (understand what changes when computers are used)	
3	**QUALITY ASSURANCE** The role of the QA unit in: • Protocol (Or Study Plan) Review • SOP Review • Planning (Master Schedule, Inspection Plan) • Education and support Audits and Inspections • Systems Audits vs Compliance audits • How to set the inspection schedule • Quality Assurance Statement (Study specific) • QA Inspections of Suppliers and Contractors • Issuing and Archiving of QA Files and Reports How to incorporate Quality Risk Management Principles into research activities and GLP principles. Revisiting NATA Accreditation	7 hours	Apply a process of implementing a QMS that aligns with GLP (The QMS Scaffold) Document operations and activities (Study-specific QA Protocol) Implement a QMS (creating a culture of compliance) Plan and conduct audits (FDA observational database)	**Pre-class reading:** section 2 of the OECD GLP Principles. OECD Consensus Document "Quality Assurance and GLP" - "Qualifications of QA personnel" (page 7). **Activity:** Discussion of page 7 of Consensus Document **Case Study:** How to schedule QA inspections and audits. **Case Study:** Anatomy of FDA Warning Letter(s). How to audit like a FDA inspector. **Case Study:** How to avoid a FDA Warning Letter