Bio Pharmaceutical Solutions
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Good Manufacturing Process (GMP) / Good Clinical Practice (GCP)

Course overview

- Familiarisation with clinical trials, why they are required and the obligations of both the sponsor and the manufacturer when entering into a Commercial and Technical Contract to manufacture an investigational medicine.
- Elaborate on the different phases of a clinical trials and the cGMP requirements
- Define the terms blinding, placebo and randomisation as they affect a clinical trial
- Outline the requirements for FDA and TGA cGMP compliance
- Outline the GMP requirements for the manufacture of materials for clinical trials and list risk management strategies to correctly introduce a clinical trial into a business
- Outline the key GMP requirements for the packaging and labelling of materials for clinical trials
- Identify sources of errors and mix ups in the distribution of material for clinical trials
- Labelling requirements for IMP in the US, EU and Australia
- Outlining the links between GMP and GCP and how this interaction can influence the trial
- Action based learning scenarios developed from company experiences to reinforce the above

Course Duration

Initially Bio Pharmaceutical Solutions would undertake training needs analysis over 4 - 8 hours which will ensure that any information presented is contextualised to company in-house terminology and is consistent with company Standard Operating Procedures. This would also be used to identify and develop scenarios for action based learning during the program.

The training program would be delivered over a total of 1.5 days, with the first day spent covering the regulations and theory component with several small scenario based exercises to reinforce the learning's. A further 0.5 day follow would be scheduled for several weeks after this session and involves a more complex scenario and presentation by participants.

What will the participants learn?

Upon completion of this course, participants will be able to:

- Demonstrate a greater understanding of the phases of clinical trials, the design and their role in the clinical development and regulatory registration of products
- Understand the regulatory requirements for the production, handling, labelling and storage of IMP
- Identify issues, risk and strategies for mitigation of issues
- Gain firsthand experience on what resources, trials, tribulations and skills that are required to take a non-cGMP compliant laboratory process and apply cGMP/ Annexe 13 requirements to the manufacture of the IMP to satisfy local and international regulatory requirements.
- Familiarise themselves with clinical trials, why they are required and the obligations of both the sponsor and the manufacturer when entering into a Commercial and Technical Contract to manufacture an investigational medicine.