What is Good Clinical Practice (GCP)?

GCP is an international ethical and scientific quality standard for the design, conduct, recording and reporting of clinical trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and wellbeing of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data and reported results of clinical investigations are credible and accurate.

Comprising of 14 core principles, GCP applies to all clinical investigations that could affect the safety and wellbeing of human participants (in particular, clinical trials of medicinal products).

GCP was developed by the regulatory authorities of the EU, Japan and US in a steering group termed the Tripartite International Conference on Harmonisation (ICH) and came into effect as ‘guidance’ in 1997. The objective was to provide a unified standard to facilitate the mutual acceptance of clinical data by the regulatory authorities.

This introduction of GCP provided international assurance that:

- data and reported results of clinical investigations are credible and accurate
- the rights, safety and confidentiality of participants in clinical research are respected and protected

However, the introduction of the Medicines for Human Use Regulations (2004) and the Clinical Trials Directive (2001) compliance with GCP is now the law and is not simply guidance.

Staff involved in any aspect of clinical trial work need to be suitably qualified to ensure that they comply with GCP. This includes support departments.

There is no formal qualification and so it is essential to keep up to date records of education and training activity.

There are 14 Principles of GCP:

1. The rights, safety and well-being of the trial subjects shall prevail over the interests of science and society.
2. Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks.
3. Clinical trials shall be scientifically sound and guided by ethical principles in all their aspects.
4. The necessary procedures to secure the quality of every aspect of the trial shall be complied with.
5. The available non-clinical and clinical information on an investigational medicinal product shall be adequate to support the proposed clinical trial.

6. Clinical trials shall be conducted in accordance with the principles of the Declaration of Helsinki.

7. The protocol shall provide for the definition of inclusion and exclusion of subjects participating in a clinical trial, monitoring and publication policy.

8. The investigator and sponsor shall consider all relevant guidance with respect to commencing and conducting a clinical trial.

9. All clinical information shall be recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remains protected.

10. Before the trial is initiated, foreseeable risks and inconveniences have been weighed against the anticipated benefit for the individual trial subject and other present and future patients. A trial should be initiated and continued only if the anticipated benefits justify the risks.

11. The medical care given to, and medical decisions made on behalf of, subjects shall always be the responsibility of an appropriately qualified doctor or, when appropriate, of a qualified dentist.

12. A trial shall be initiated only if an ethics committee and the licensing authority comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks and may be continued only if compliance with this requirement is permanently monitored.

13. The rights of each subject to physical and mental integrity, to privacy and to the protection of the data concerning him in accordance with the Data Protection Act 1998 are safeguarded.

14. Provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor which may arise in relation to the clinical trial.