

The Faculty of Pharmaceutical Medicine has accredited this course for 6 Continuing Professional Development credits.

GCP web-based training course designed and developed by **INFONETICA**



Certificate Of Achievement

ICH GCP Adapted for Germany in German

This is to certify that
Helmut Schweiger
of

has successfully passed a web-based examination covering all aspects of Good Clinical Practice as laid down in the International Committee on Harmonisation guidelines. The course is adapted according to the German regulations in regards the AMG (Arzneimittelgesetz) and German GCP guidelines by Dr Reiner Lehmann.

12 February 2014

Certificate No: 32087-42-36281

Nick Deaney, C.Sci,
International Course Director

It takes about 6 hours to complete the training depending on the level of experience.

- Teil 1: Einführung in GCP
- Teil 2: Zuständige Behörden (BOB) und Ethikkommission (EK)
- Teil 3: Prüfer
- Teil 4: Zuständigkeiten des Auftraggebers
- Teil 5: Zuständigkeiten des Monitors
- Teil 6: Bericht über die Sicherheit und über unerwünschte Ereignisse
- Teil 7: Prüfplan und Prüfplanänderungen
- Teil 8: Prüferinformation
- Teil 9: Essentielle Dokumente
- Teil 10: Spezialitäten des deutschen Arzneimittelgesetzes

Dr Reiner Lehmann,
German Course Director