Computer System, Medical Device and Software Validation
GAMP®5 Training

Thursday 18th July (1 day)

9 a.m. to 5 p.m. (registration 8:45)

Winnington Hall
Northwich, Cheshire, CW8 4DU


This annex applies to all forms of computerised systems used as part of GMP regulated activity. A computerised system is a set of software and hardware components which together fulfil certain functionalities. The regulation states “The application should be validated; IT infrastructure should be qualified”

Where a computerised system replaces a manual operation, there should be no resultant decrease in product quality, process control or quality assurance. There should be no increase in the overall risk of the process.

Attending this course will help you understand the regulation and how using GAMP can help you to ensure your Computer Systems and underlying IT infrastructure are always inspection ready.

With over 25 years’ experience delivering corporate compliance, Compliance Control understands the need to enhance quality and increase efficiency and is able to offer affordable solutions, tailor made to your business requirements, fully compliant and validated.

The Presenters will be David Forrest Chief Executive and Bob Crawshaw, Principal Consultant.

The morning will cover Computer System Validation as detailed in the ISPE GAMP®5 guide. Validation Planning and Reporting, and the completed Computer Systems Validation life cycle will be discussed. The session will cover a wide range of Computer Systems ranging from equipment, to Laboratories, to ERP and IT Infrastructure Qualification. The use of Electronic Records and Electronic Signatures will also be discussed. ISO 9001, 13485 and Medical Device International Standard 62304 will also be discussed.

The afternoon will cover Implementation and Management of a Quality Management system. This will include Document Management, Change Management, Corrective Action and Preventative Action (CAPA), Deviations, Complaints, Audits, and Training Records. The session will end with a discussion of an electronic system, showing how Computer System Validation, and IT Systems and Equipment can be effectively managed through an electronic system.

We are offering this training for £200 (+VAT) this includes tuition, coffee breaks, lunch and training materials.

REGISTER TODAY! Limited spaces are available. To avoid disappointment please register by emailing: thomas.clare@compliance-control.com, or by calling Tel: 01606 871113.

Please provide the names and e-mail addresses of the delegates who are attending.

We will then issue an invoice direct to your company that must be paid BEFORE the training.