

# Data Integrity Training Course

Thursday 23<sup>rd</sup> November 2017, 9.00am-4:30pm, Cardiff, United Kingdom

**Course Overview:** Delegates will learn about Data Integrity threats and issues posed within paper and electronic systems and how to comply with regulatory requirements. Delegates will leave the course with a clear understanding of the current expectations of EU Inspectors (such as the UK's MHRA) and the FDA.

**Who will the course benefit?** This course is aimed principally at Management and Supervisory roles who need a detailed understanding of the Data Integrity requirements and regulatory expectations. The course will provide the delegates with the understanding required to enable implementation of required Data Integrity governance systems, methodologies and programmes.

## Course Content:

- Background and introduction to Data Integrity
- Industry Regulations and Guidance
- Introduction to the Data Life cycle model
- Stage 1 – Data Collection
- Stage 2 – Data Processing
- Stage 3 – Data Review
- Stage 4 – Data Reporting
- Stage 5 – Data Archiving
- Risk identification, audit challenge and threat management
- The Governance System – what do you need?
- Outsourced GMP activities – expectations and implications
- Identification of audit challenges and additional governance
- Implications for New projects
- Review of example warning letters and citations

## Course Location:

The Holiday Inn – North M4, Junction 32, Merthyr Road, Tongwynlais, Cardiff, CF15 7LH, United Kingdom

Telephone: +44 (0)2920 522262 • email: [frontdesk.hicardiffnorthm4@kewgreen.co.uk](mailto:frontdesk.hicardiffnorthm4@kewgreen.co.uk)

Web: [www.ihg.com/holidayinn/hotels/gb/en/cardiff/cwlcw/hoteldetail](http://www.ihg.com/holidayinn/hotels/gb/en/cardiff/cwlcw/hoteldetail)

**Course Tutors:** £595.00 per delegate plus VAT\*. Course will be charged in GB pounds.

\* VAT will not be charged for courses held outside the UK. VAT will be charged for the courses held in the UK, however delegates from outside the UK but within the European Union (EU) will not be charged VAT if they supply their own company's national VAT number when booking. VAT will not be charged for any delegates coming from outside the EU.

## Course Tutors: David Thompson and Dominic Parry

**David** is a computer systems validation and compliance expert. He has worked in the IT/Computer Systems arena for almost 30 years, the last 16 years he has provided Consultancy, Auditing and Training to the pharmaceutical/biotech and healthcare industry across the UK, Europe, Asia and the U.S.A. He is a Chartered Engineer with both the MIET and the MInstMC and a member of the GAMP MES SIG. In his current role he is Owner and Principal Consultant of Clarity Compliance Solutions Limited.

**Dominic** has worked in the pharmaceutical industry since 1992, and is a leading pharmaceutical quality management specialist. He worked for 4 years at Evans Medical Limited (now Novartis Vaccines) as a Production Development Scientist. He then moved to Hoechst Marion Roussel (now Patheon, UK), where he worked for 4 years as a Quality Assurance Officer and then Validation Manager for the sterile manufacturing operations. Over the past 15 years he has worked as a leading pharmaceutical GMP trainer and Quality Management System specialist. He works closely with pharmaceutical companies and their suppliers on evaluating, developing and continually improving their quality systems. He is generally recognised as one of the leading GMP trainers in the UK and brings an enormous amount of interest, enthusiasm and fun into the training he presents. He is Managing Director of Inspired Pharma Training Limited.

**Accommodation:** The cost of accommodation is not included in the course cost, if required please book accommodation yourself directly with the hotel by calling +44 (0)2920 528132.

## The cost includes:

- Refreshments and lunch during the course times.
- Course folder containing copies of slides and supplementary notes and handouts.
- Course attendance certificate.
- Full tutor support and access during course times.

**Payment:** Payment can be made by bank transfer or cheque.

To book your place please [email](#) or complete our [booking form](#).

To discuss further please contact us:

Enquiries: +44 (0)1633 400939 or +44 (0)7735 204233 - [claire.thompson@clarity-compliance.com](mailto:claire.thompson@clarity-compliance.com)

Consulting: +44 (0)1633 400939 or +44 (0)7725 744636 - [david.thompson@clarity-compliance.com](mailto:david.thompson@clarity-compliance.com)