

## about the presenters



**Chris Reid** Chris Reid has worked in Life science industries for circa 30 years. He founded Integrity Solutions Ltd in 1998. He has worked with leading

global organisations overseeing the delivery of quality and compliance solutions and has experience across a variety of organisations and disciplines. Chris has worked across pharmaceuticals, biotechnology, medical devices and cosmetic industries and all regulatory domains. Chris is a member of the ISPE GAMP Global Steering Committee. He is a former member of the ISPE Board of Directors and currently is a member of the ISPE Foundation Board, executive team.

**Thanabalan Subramanian** is Head of Quality at Integrity, responsible for the Quality Services organisation covering CSV compliance projects, Audit management, Data Integrity programmes, Training and Organisation design/change. He has a Masters Advanced Manufacturing Systems and has over 29 years of validation experience. Thanabalan is the Chair of the ISPE GAMP CoP Europe Steering Committee. Also, a member of the ISPE GAMP CoP UK and Global Steering Committee, R&D & Data. Integrity SIGs. Recently re-joined the IT committee for the Research Quality Association (RQA).



**Kevin Sweeney** Sweeney has over 25 years investigation experience with the Irish National police force An Garda Siochana.

He spent the majority of his career investigating terrorist offences and other serious crimes. He has also received training from the Criminal Assets Bureau in investigating the criminal assets of organised crime and from Interpol in investigating intellectual property fraud. He also holds a doctorate in criminology from the University of Limerick. His research examined the legality and effectiveness of police interrogation and questioning practices.

Since joining the Compliance Group in 2016 he has performed numerous DI / fraud investigations and delivered remediation programmes in the pharmaceutical industry.



[www.compliancegroup.eu](http://www.compliancegroup.eu)

[www.gxp.ie](http://www.gxp.ie)

[www.compliancemanagement.eu](http://www.compliancemanagement.eu)

## data integrity

Data Integrity is the holistic approach including policies, processes, culture and behaviours that ensure data produced to support the regulatory submission, product quality or product clinical and safety data is accurate, protected and retrievable.

### about the course

This course has developed over many years and is constantly being updated as technology and regulatory expectations progress. This course will form part of the broader SME Training Series being developed by GXP Training in conjunction with The Compliance Group and Integrity. The presentations will include real life examples and the learning experience will be enhanced by using carefully structured workshops. Attendees will receive PDF file versions of all the presentations

### course content

#### day one

- What is Data Integrity?
- Data and Decisions we make
- Regulatory Perspective
- Data Integrity Governance Triangle (Culture, Processes & Procedures, Technology)
- ALCOA+ and the Data Lifecycle
- Tools & Techniques for Assessing Data Integrity Risk (Maturity Assessment, Gemba, etc)

#### Why Major DI Issues Occur

- Organisation Culture
- Findings from Previous Investigations
- Red Flags

#### day two

##### Data Integrity Programme case study

- Approach
- Challenges
- Outcomes
- Remediation plans

Assessing the maturity of your Data Integrity controls

Quality Risk Management and Electronic Records

Data Integrity and End User Applications (word, excel etc)

### who should attend

This course will benefit all involved in a GxP regulated environment that require a working knowledge of Data Integrity and associated, validation and operational support of computerised systems. The course goes to SME level.

### about gxp training

GXP Training was set up to harness the expertise within The Compliance Group, Compliance Management and its wider network to develop and deliver a suite of Training Courses in the GxP environment. As well as providing professional and focus schedule courses that will provide cost effective ways to meet training needs within the industry, all courses will be available for in-house trainings, should this be the customers preferred route. We also do live-online training.

### what else should I know

Course fee: €1,500 for the two days. The course fee includes all course material, lunch and refreshments. Please note that certain aspects of this course can be organised on an in-house basis. Please contact us for further information.

### how to apply

Applications can be made online at [www.gxp.ie/training](http://www.gxp.ie/training)

### location and date

This course will be live and in-person. For full details of the next date and location, please see the course page on [www.gxp.ie/training](http://www.gxp.ie/training)