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HM Government



European Union
European Regional
Development Fund



DATA INTEGRITY, COMPUTER
SYSTEMS VALIDATION,
AND IT COMPLIANCE FOR
BIOMAUNUFACTURING



DELIVERED IN CONJUNCTION WITH
CLARITY COMPLIANCE SOLUTIONS



A UK CENTRE OF EXCELLENCE
FOR THE BIOSCIENCE INDUSTRY

TRAINING

WELCOME

Dr Jen Vanderhoven

DIRECTOR

Welcome to the National Horizons Centre (NHC). We are Teesside University's centre of excellence for the biosciences and healthcare sector. With research, partnerships and training at our core, we bring together industry, academia, talent and world-class facilities to create real-world impact.

As a National Training Centre for Advanced Therapies, funded from the Department for Business, Energy & Industrial Strategy (BEIS) and Innovate UK (IUK) delivered through the Cell and Gene Therapy Catapult, our courses are industry approved and we have worked closely with key bioindustry leaders across the sector to ensure our courses have been designed to deliver vital skills needed for advanced therapies, vaccines manufacturing and bioprocessing.

This two-day course provides participants with an introduction to the regulatory requirements and IT/Data Integrity and Computer Systems Validation compliance requirements and considerations for the development of biotechnology and pharmaceuticals.

I look forward to welcoming you to the NHC.

The NHC is one of the National Training Centres part of the ATSTN programme funded from the Department for Business, Energy & Industrial Strategy (BEIS) and Innovate UK (IUK) delivered through the Cell and Gene Therapy Catapult.



COURSE OVERVIEW

Day one

- > **Session one:** Industry Regulations – introduction to GxP
- > **Session two:** Industry Guidance – how to deliver it?
- > **Session three:** Exercise - IT type challenges and risk areas faced within the biotech and pharmaceuticals industry
- > **Session four:** Introduction to Computer Systems Validation
- > **Session five:** Exercise - Data challenges and risk areas faced within the biotech and pharmaceuticals industry
- > **Session six:** Background and introduction to Data Integrity
- > **Session seven:** Introduction to the data lifecycle model
- > **Session eight:** Data Integrity applied to GxP regulations
- > **Session nine:** Data Integrity governance
- > **Session ten:** Warning letters – the potential Impact

Day two

- > **Session one:** Applying Computer Systems Validation to a project
- > **Session two:** Exercise - Computer Systems Validation risk analysis in the laboratory environment
- > **Session three:** Feedback presentation and group discussion
- > **Session four:** Data retention and archiving
- > **Session five:** Exercise - Data Integrity risk analysis in the laboratory environment
- > **Session six:** Developing a quality culture
- > **Session seven:** Hearts and minds of compliance – It's all about the patient!
- > **Session eight:** Assessment

