



A Three-Day Remote Course

## **Introduction to Computer Systems Validation**

Course Code: R3502

UKHSA  
Porton Down, Country



**CONTRACT**

## INTRODUCTION

This course is the ideal training opportunity for people needing to gain a foundational understanding of computerised system validation. The knowledge gained will help attendees to validate systems within their own organisation for use in GxP (GLP, GCP, GMP, GDP and GPvP) environments, and to audit validated computerised systems to assure compliance with the applicable GxP regulations.

The course starts with an introduction to the regulatory requirements and the system lifecycle and then concentrates on the practicalities of validating computerised systems and auditing these systems.

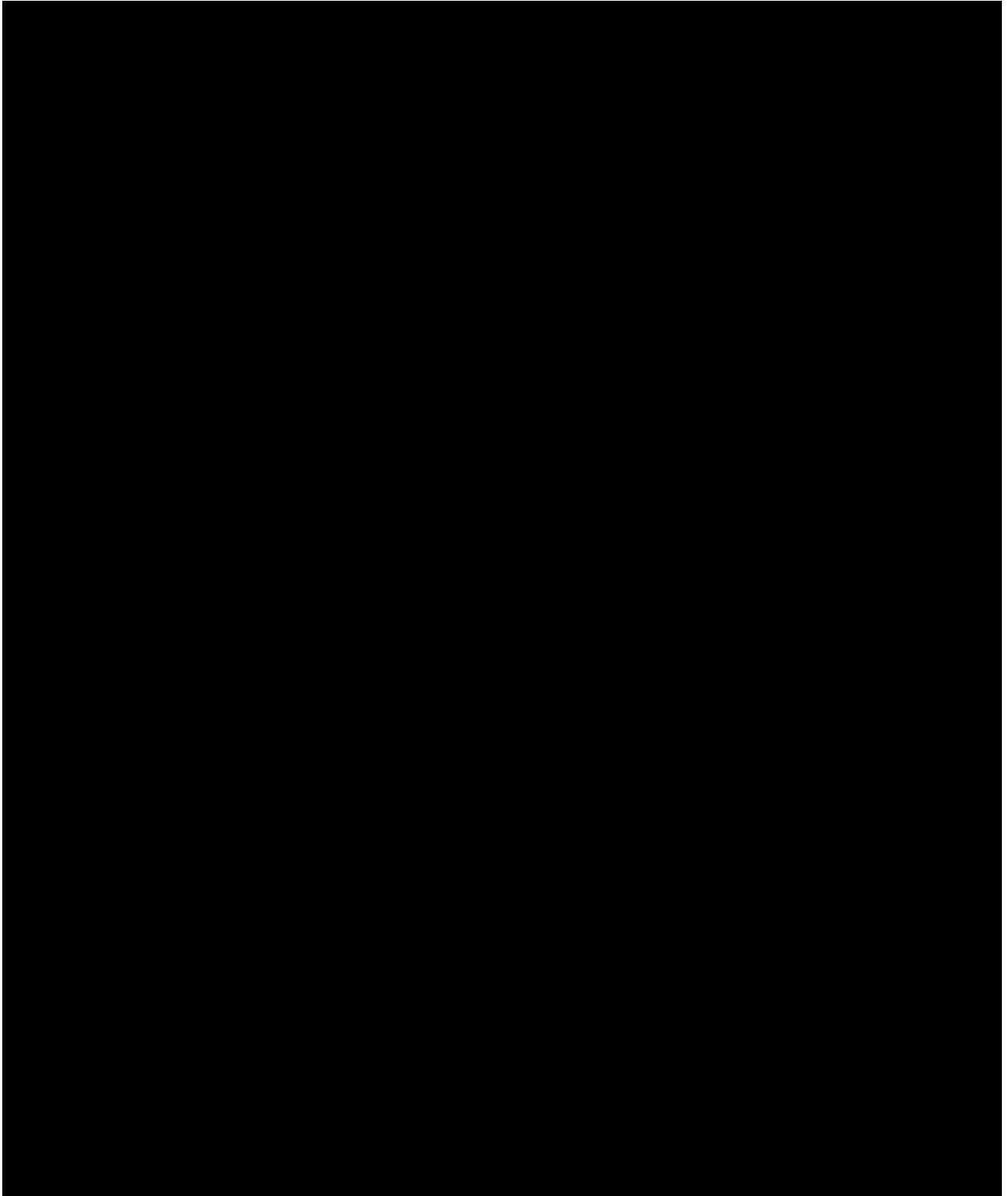
The course provides a mixture of presentations, discussions and practical workshops.

**This course will provide delegates with an understanding of the computerised system validation process, including:**

- Determining the need and scope of computerised system validation
- Definition of end user requirements
- Risk management, including supplier assessment and techniques for audit planning
- Validation planning and reporting
- Linking system development with good business practices
- Formal testing and qualification
- Overview of data integrity and security issues
- How to assess system validation documentation to verify compliance

The language of the course will be English.

## THE TUTORS



# THE COURSE PROGRAMME

## Day 1

- 09:00 **Welcome, Introduction and Course Objectives**
- 09:45 **Why Validate? Regulations and Guidance on Computerised System Validation**  
Overview of the regulations and guidance applicable to CSV and their key expectations.
- 10:30 Break
- 10:45 **The System Lifecycle**  
The concept of the SLC and the key outputs from it
- 12:00 Lunch
- 12:45 **The Validation Process**  
The approach to validation for different system types and a look at some of the key deliverables
- 14:00 **Project Introduction**
- 14:15 **Exercise 1 – User Requirements**  
Capturing, agreeing and documenting the user requirements for a system
- 15:15 Break
- 15:30 **Exercise 1 Feedback**
- 16:00 **Risk Management**  
Risk management and its impact on validation. Identifying the deliverables required. Then group discussion on risk assessment for 3 systems.
- 17:00 **Questions and Answers**  
Answers to any outstanding questions from Day 1.
- 17.15 Close of Day

## Day 2

09:00 **Supplier Assessment**

The different approaches to supplier assessment and the things to be considered when assessing a supplier

10:15 **Exercise 2 – Supplier Assessment**

Planning a vendor audit with a focus on the key validation deliverables.

11:00 Break

11:15 **Exercise 2 Feedback**

11:45 **Test Overview and Test Planning**

The different test phases, the purpose of each test phase and things to be considered when planning and reporting testing

12:45 Lunch

13:30 **Test Overview and Test Planning**

Continued

14:15 **Test Script Design, Execution and Review**

What a good test script looks like and the key things to consider when creating, executing and reviewing a test script

15.30 Break

15:45 **Workshop 3 – Creating a Test Script**

Create a test script based on the user requirements created on day 2.

17.15 Close of Day

## Day 3

09.00 **Exercise 3 Feedback**

09.30 **Infrastructure Configuration and Qualification**

10.30 Break

10.45 **Validation Reporting**

Overview of the Validation Report and what should be included in it

11.15 **Maintaining the Validated State**

The procedures and records needed to ensure the system remains fit for purpose

12.30 Lunch

13.15 **Change Control**

Key concepts related to making changes to validated systems

14.00 **Exercise 4 – Change Control**

14.45 **Exercise 4 feedback**

15.15 **Break**

15.30 **Data Integrity and Security**

How can we assure the integrity and security of our data

16.45 **Course Objectives Summary & Panel Discussion**

A round up of key learning from the course

17.00 Close of Course

TRAINING COSTS:

Item	Quantity	Fee	Total
STANDARD COURSE FEES			
The following are indicative costs and will be charged at cost after the event:			
EXTRA DELEGATE CHARGES			
		COURSE FEES SUBTOTAL	
DEVELOPMENT CHARGES			
INDICATIVE TOTAL CHARGE			£21,155.00

OTHER POTENTIAL ADDITIONS (As referenced above)

- Additional Delegates:		
		per person
- Course Development:		
		per hour

VAT

All charges are subject to VAT at the standard rate.

PAYMENT

UKHSA will be invoiced for 50% of the standard course fees upon acceptance of the final contract.

The remaining 50% of the course fees along with charges for any additional delegates and development time will be invoiced within fourteen days of the end of the course.

Payments will be due within 30 days of the invoice date or before the course, whichever is soonest.

## SUPPLEMENTARY NOTES:

### ADDITIONAL DELEGATE BENEFITS

- All employees of UKHSA attending the above training sessions will have the option of applying for free RQA membership for the calendar year in which the training takes place (this cannot be used as a renewal method for a recently lapsed membership). Please visit our [website](#) for further details on the many benefits to becoming a member of RQA.
- A copy of the RQA publication [Computerised System Validation](#) will be included in the electronic material for each delegate attending the training.
- If there are no changes to the content of the above programme all attendees will gain **19** CPD points when attending the training in full. CPD stands for Continuing Professional Development (CPD) and is the term used to describe the learning activities professionals engage in to develop and enhance their abilities. CPD accredited training courses, workshops and events allow professionals to use the learning time towards individual CPD requirements and the most effective way of demonstrating that training has been undertaken is through the collection of CPD points. This RQA course was submitted to the CPD Certification Service to establish that it has all the important elements of a good course - structure, objectives, feedback, etc. following which the above points were accordingly assigned.

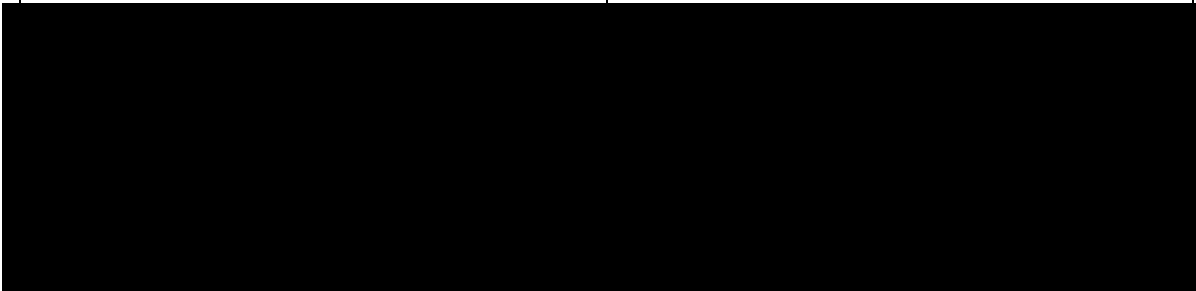


APPENDIX 1

STANDARD TERMS AND CONDITIONS

RQA’s standard Terms and Conditions (attached) apply with the following exceptions / additions:

- There are no exceptions or additions affecting this specification.

Signed on behalf of the RQA:	Signed on behalf of the UK Health
	
Date Signed: 27/01/2023	Date Signed: 30/01/2023

UKHSA will hereon be referred to as “the client”.

## APPENDIX 1

---

<sup>1</sup> For convenience, you can respond to this e-mail indicating that you accept the contract. A signed paper copy can also be provided on request.

## APPENDIX 1 (CONT) - STANDARD TERMS AND CONDITIONS

### Expenses

Expenses are passed on to the client at cost. [REDACTED]

[REDACTED] Air tickets will be purchased on the most economical fully-flexible fare consistent with the timing and duration of the flight. Where a flexible fare is not available or if the client requests that RQA uses restricted fares then the client is responsible for all additional costs caused by delays, cancellations or any other reason. Flights on “point-to-point” carriers may be subject to a supplement where this involves extended check-in or transfer time. Flexible rail tickets will be purchased in standard class.

### Invoices

Invoices will be issued in accordance with the timetable above. The invoices will detail the professional fees and expenses, in reimbursement groups for travel, accommodation and other expenses. Receipts for expenses are not provided with invoices but may be examined at RQA’s offices by arrangement and at the client’s expense.

### Credit Period and Late Payment

The credit period is 30 days from the date of the invoice. RQA understands and will exercise its right to claim interest and compensation for debt recovery costs if payment is not received within the credit period. Interest and compensation will be charged at the statutory level set out in the “Late Payment of Commercial Debts Regulations” (2002) and the “Late Payment of Commercial Debt (Interest) Act” (1998, as amended).

### Confirmation of Attendee Numbers

An estimate of delegate numbers is required at the time of booking.

Final numbers and delegate information should be provided two weeks prior to the course start date(s). These numbers will be used for compiling the final invoice, unless numbers increase in which case the greater number will be used for invoicing.

### Liability

RQA will maintain the insurance cover required by the “Employers Liability (Compulsory Insurance) Regulations of 1998 and as subsequently amended. Otherwise, RQA’s liability is limited to the cost of materials directly involved in the activities carried out by RQA as defined in the scope of this specification.

### Access and Availability

The client is responsible for ensuring that RQA has access to the facilities, personnel, materials, records and other items required for the timely conduct of the work. Any additional costs caused by non-availability of access or materials, except for materials provided by RQA, will be the client’s responsibility.

### Health & Safety

The client is responsible for the Health & Safety of any tutors supplied by RQA for the duration of the training course.

### **Postponement by the client**

Postponement at any time will result in all agreed expenses necessarily incurred at the time of postponement being charged. Postponement after acceptance of this specification and less than 3 months before commencement will result in an administration fee [REDACTED] being charged.

### **Cancellation by the client**

Cancellation at any time will result in any initial payment and all agreed expenses necessarily incurred at the time of cancellation being charged. Cancellation after acceptance of this specification but more than 14 days before commencement will result in 50% of the contract price being charged. Cancellation less than 14 days before commencement will result in the full contract price being charged. These charges may be reduced or waived if RQA is able to attract suitable replacement work.

### **Postponement or Cancellation by RQA**

Unfortunately, there are very rare occasions where the event may need to be cancelled by RQA or its tutors. If this happens RQA will carry out all reasonable actions to reschedule this as soon as possible or to organise alternative training arrangements. If this is not possible a partial or full refund may be given depending on circumstances.

### **Non-Disclosure of Confidential Information**

All information relating to, or derived from, this specification is treated as confidential unless otherwise agreed. The conditions of any specific confidentiality agreement covering this specification will also apply.

### **Delegates' Materials**

Each delegate will receive:

- A comprehensive set of course notes including the presentations given and other relevant background materials. Access to course material will be emailed to delegates in advance of the course.
- A certificate of attendance

### **Evaluation Reports**

Following the course delegates will be asked to give feedback on the training. RQA will pass on an evaluation report to the client after analysing the responses. RQA reserves the right to use quotes and statistics from this feedback anonymously for marketing purposes. Permission will be gained from the client prior to the use of any reference to the client and/or use of the client's logo.

### **Amendment**

In order to provide the best possible training course, RQA may make minor revisions to this specification (such as the order of delivery) without formal approval from the Client. Any major changes to the aims or content of the course and all changes that may result in a change to the contract price will require the documented agreement of the Client and RQA.

### **Ownership of Materials**

Unless otherwise specified, all materials (including materials customised for this training project) remain the property of RQA (or the original owners where used with their permission by RQA). Copying or other use of the material is not permitted without documented agreement from RQA.