GetReskilled

Computer Systems Validation (CSV)

Full Time | Part Time | Online

www.getreskilled.com

Contents

Welcome

Accelerate your career in the Pharmaceutical and Medical Device Manufacturing Industries, in the shortest time possible with our online delivered modules.

- Join the 3,150 people over the last 10 years who have used our courses to build their careers in these industries worldwide.
- Get an industry recognised qualification and confirm your knowledge to your employers.
- Delivered online worldwide on our learning management system with 24/7 access. No Travel Required. Easily juggle your work and home life.
- Ideal for people who want to make a career change into the Pharmaceutical or Medical Device Manufacturing Industries or those who are currently in this sector and want to upgrade their skills set.

"I found the course was run very professionally, The course notes and videos supplied were excellent, the notes tied in very efficiently and accurately with the videos. Dr Joe Brady's presentation on the videos and his expertise and help at the webinars was outstanding. I found it very easy to continue studying even though I found employment 2 months into the course."

Denis Hegarty

Program Overview

Who is this module for?

Computer Systems Validation (CSV) is suitable for anyone with a manufacturing, science, engineering, quality or logistical background and who would like to pursue or advance their career in the pharmaceutical or medical device manufacturing industry with a professional qualification.

What can you expect?

- This module is delivered on our Learning Management System with a mixture of short (10 minute) content rich videos, downloadable notes, case studies, and worked examples allowing you to complete the course at your own pace. You will have access to our online learning environment where you can communicate with us, your classmates and lecturers with discussion boards.
- This module culminates in the completion of a full assignment which offers you the opportunity to solidify your knowledge and apply the content in a real world situation. In addition, you will also be requested to regularly post on our discussion board forum and invited to join our LinkedIn Groups of Alumni.

What will you learn?

You will learn how to manage all of the electronic data for computer system validation from across a manufacturing facility, in line with the rules and guidelines for the specification, design and verification of computerized systems in a regulated environment.

Who are the Lecturers?

All our lecturers continue to work with industry and have years of frontline industry and regulatory experience. They will deliver the most up-to-date course content while blending their insights and experience into a program that gets you results.

"This course is excellent. It is very well delivered through weekly lectures and webinar tutorials which entail self-assessments at the end of each week and gave me invaluable experience required to advance in this new sector."

Louise Dineen

Program Content

Course Overview:

How do you replace paper records with electronic data and make sure the system is completely transparent, robust and tamperproof? And how do you store those electronic data records so that they stand the test of time? How do you upgrade the computer software in a manufacturing facility and make sure nothing crashes or no data is lost? In this course, you will learn how to manage all of the electronic data for computer system validation across a manufacturing facility.

Why Take This Course:

- Learn the fundamentals of computer system hardware and software
- Develop a system description and user requirement suitable for manufacturing safe medicines.
- Apply the principals and practices of computer system validation to various pharmaceutical computer system projects.
- Learn how to manage electronic data using GAMP®5 and 21 CFR Part 11 ERES.

Core Content:

Week 1 – Software Categories, Life Cycle Phases, and Operational Activities

- Drivers for GAMPS
- Life Cycle Phases of Computerized Systems
- Computerized Systems in Regulated GxP Environments
- GAMP 5 Software Categories
- Operational Activities
- Handover
- Product and Process Understanding
- End User Activities

Week 2 – Record Anatomy and Data Flow Analysis

- Electronic Record Content, Structure and Context, and Record Anatomy
- Records and Signatures required by 21 CFR Part 211
- PLC Controlled Packaging Equipment
- Supervisory Control and Data Acquisition (SCADA)
- Data Flow Analysis
- Example Records and Signatures Required by ICH Q7

Week 3 – Science Based Quality Risk Management, Validation Planning, and Categorization of Laboratory Computerized Systems

- Supplier Activities
- Validation Planning
- Science Based Quality Risk Management
- Risk Management Considerations Generic Hazards
- Requirements Traceability Matrix (RTM)
- Efficiency Improvements (Continuous Improvements)
- Categorization of Laboratory Computerized Systems

Week 4 – Identify Regulated Records and Signatures, and Impact Assessment of Electronic Records

- HPLC System
- Chromatography Data System (CDS)
- GxP Records and Signatures Required by 11 CFR Part 820
- Prerequisites for Good Electronic Records Management
- Laboratory Information Management System (LIMS)
- Identify Regulated Records and Signatures
- Electronic Production Records (EPR)
- Impact Assessment of Electronic Records
- Spreadsheets

Week 5 – Specification and Verification, Scalable Validation Deliverables and Configuration Management

- Organizational Change
- Outsourced IS/IT Environment
- IT Compliance
- Development versus Implementation Life Cycle
- ASTM E 2500 – 07

"I would rate the course 10 out 10 and would highly recommend to others, the tutor managed to get excellent group interaction right from the beginning, very interesting, informative and very well presented. Relevant totally to my needs and expectations. The most practical course I have ever attended"

Andy Wnuk, MSc Eng

- Testing Documentation Structure & Verification Terminology
- Scalable Validation Deliverables
- Patch and Update Management
- Operational Change and Configuration Management
- Repair Activity
- Periodic Review
- Backup and Restore

Week 6 – Good Electronic Records Management Transactions, and Audit Trails

- Good Electronic Records Management Transactions
- Audit Trails
- AutoCAD Used For Managing Pack Drawings
- Building Management Systems (BMS)
- FDA Predicate Rule 21 CFR Part 211 – Subparts D and J
- FDA 21 CFR Part 11 – 'Electronic Records; Electronic Signatures' (ERES)

Week 7 – Electronic Data Archiving, Business Continuity Management, and System backup, Archival, and Disaster Recovery

- Electronic Data Archiving Part
- Typical Tasks Supporting Validation (B)
- Security Management
- Business Continuity Management
- System Retirement Decommissioning and Disposal
- Copies of Records

Week 8 – Controls to Maintain Electronic Record Integrity, and Risk Controls for Electronic Signatures

- Complying with 21 CFR Part 11 ERES - Types of Controls Required
- Complying with 21 CFR Part 11 - Key Areas for Guidance
- Batch Record System
- Enterprise Resource Planning (ERP) Systems
- Controls to Maintain Electronic Record Integrity
- Risk Controls for Electronic Records
- Risk Controls for Electronic Signatures
- User ERES Responsibilities
- Supplier ERES Responsibilities

Complete the Following Activities & Workshops:

You will produce a number of deliverables during the course including:

- Determine the end user supplier activities during the lifecycle of a computerized system
- Identify where you would use risk based decision making throughout the lifecyle of a computerized system
- Prepare a Configuration Management Process Flow Diagram and identify where to use Change Control
- Define the content of typical logs and accompanying records for both incident Management and corrective and preventive action (CAPA)
- Determine suitable risk controls when assessing electronic records and electronic signatures

Delivered Online – No Travel Required

All modules are delivered online on a Learning Management System with 24/7 access using a mixture of short videos with downloadable notes, Q&A activities, worked examples, and online discussion boards.

6-Weeks to Complete (Full Time)

Complete this module with 4-weeks study and an extra 2- weeks to complete the end of module assignment.

10-Weeks to Complete (Part Time)

Complete this module with 8-weeks study and an extra 2- weeks to complete the end of module assignment.

15 Hours per Week (Part-Time)

You will need to study around 15-hours per week depending on your prior experience and familiarity with the materials with an additional 30 hours to complete the end of module assignment.

Easily Juggle Your Work and Home Life

Taking these courses online makes juggling your work and home life so much easier than a classroom delivered course. No long commutes, traffic jams or crowded trains to deal with on the way to class.

"I found this course very beneficial and I am delighted that, even at early stages in the course, it has already provided me with the opportunity to secure a position within the pharmaceutical industry."

David O'Shea

Extreme Flexibility on the Schedule

We offer extreme flexibility on the delivery of our courses and can easily accommodate breaks in your schedule.

92% Course Completion Rate

We are serious about helping you finish this program so your course administrator will personally check your progress every week and follow up by email or even a phone call to keep you on schedule.

Complete an End of Module Assignment

Prepare a report to identify different types of computerized systems and explain how from data-flow analysis potential source of undesired events or where record integrity could be compromised? Then specify an electronic record for one system and the main categories of controls to maintain its integrity and compliance to 21 CFR Part 11 and the signatures required by 21 CFR Part 211, 21 CFR Part 820 and ICH Q7.

Certification

You will receive an end of course certificate from GetReskilled which along with others modules can build into an academic accreditation from the Dublin Institute of Technology (Ireland) subject to the following criteria:

- Passing a written or oral Exam on the materials
- The submission of all assessments and the end of module assignment

Admission Criteria

This is a technical training programme for people coming from a technical, manufacturing, scientific or logistics background looking to work in production, engineering and quality roles within the pharmaceutical, biopharmaceutical or medical device manufacturing sector.

Recognized Prior Learning (RPL) will be taken into account in assessing applicants for this programme.

Available Worldwide

Available worldwide and in certain US States. Contact us for details.

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