Process validation for the medical device industry

Course Description

BSI's "Process validation for the medical device industry" one day course has been designed to help manufacturers gain awareness of quality requirements regarding validation and the nature of "special processes". Learn the generally accepted principles of validation, and introduce how-to-do methods of Installation, Operational, and Process Qualification.

Learning Objectives

On completion of this training, participants will be able to:

- Appreciate concepts and rationale of process validation
- Recognise the importance of process validation
- Gain awareness of FDA and ISO 13485 expectations and GHTF guidance
- Recognize situations where a process requires validation
- Create a Master validation plan and validation protocols
- Define objectives of equipment and process validations
- Recognize relevant and pertinent factors of PV studies
- Plan for worst case conditions and challenges
- Complete Installation, Operational and Performance qualification
- Maintain a state of validation.

Intended Audience

- Quality, Product Development and Manufacturing personnel involved in process validation
- Regulatory Affairs Managers
- Auditors of medical device manufacturing firms (internal and external).

Course Duration

One day.

Prerequisites

Attendees are expected to have formal education appropriate to the job functions listed above. Some familiarity with FDA/QSR or ISO13485 is helpful. Students must have mathematical skills and experience in a medical device manufacturing environment is recommended.

How will I learn?

We use accelerated learning techniques that encourage interaction and collaboration, keep the course varied and put your learning in context. Our tutors are the best in their field and will make sure your learning needs are met. Choose between public or in-company courses tailored to your business – whatever delivers the most positive and successful outcome for you.

Where will I learn?

We deliver five star learning at first class venues. Each venue has been selected to provide the best possible learning environment so you can maximize your learning experience.

Who are we?

As an EU Notified Body, our expertise is in auditing to the requirements of the Directives. Our tutors are skilled in transferring knowledge contained within each standard to help you embed excellence within your organization. With over 65,000 clients in 150 countries worldwide, you can trust BSI to help you perform better, reduce risk and grow sustainably.

Why train with us?

We've trained and audited thousands of businesses using the same standards so we can genuinely benchmark performance. And we can take you from beginner to certification quickly then support you with follow-up courses and webinars – and all this for the price of your course.

Did you know?

Our tutors are active practitioners in their subjects, ensuring the latest developments are fully understood. We are the leaders in medical devices regulatory expertise with over 200 BSI Medical Device product and regulation experts around the world.

Next step:

To book this course, call one of our dedicated training experts on 1 800 862 6752 or book online at bsigroup.ca/training

In-company Training

Discuss your product development in confidential surroundings by opting for bespoke in-company training.

Toronto Office
6205B Airport Road, Suite 414
Mississauga, ON L4V 1E3
T: 416 620 9991
TF: 1 800 862 6752
F: 416 620 9911

Ottawa Office
515 Legget Drive, Suite 110
Ottawa, ON K2K 3G4
T: 613 271 7007
TF: 1 800 862 6752
F: 613 271 9007

Montréal
1, Place Ville Marie, Suite 2901
Montréal, QC H3B 2C4
T: 514 940 1778
TF: 1 800 862 6752
F: 514 866 2115

Call +1 800 862 6752 visit: www.bsigroup.ca/training

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