Introduction to Pharmaceutical Good Manufacturing Practice (GMP)

Training course

Essential information about the course

Given the necessity of scaling manufacturing of existing products and developing more specialised, patient-centric drugs, the pharmaceutical industry is expanding into new markets. This market shift highlights the requirement to set up new, owned manufacturing sites or set up new contract manufacturing relationships. Therefore, the industry must ensure in parallel that individuals are upskilled to the GMP principles – it is paramount now more than ever.

The course is designed to provide you with an introduction to the fundamental principles of pharmaceutical GMP (PIC/S), the regulatory environment and product realization through market authorization, manufacturing, and lifecycle requirements.

Practical activities throughout the day will give you opportunity to illustrate your acquired knowledge of pharmaceutical GMP, so that the understandings can be utilized in the workplace on completion of the course.

Our course agenda

Day 1

- Benefits to you, welcome and introductions
- Course structure, aim and objectives
- Module 1: Impact of Good Manufacturing Practice (GMP) – Before and after
- Module 2: Pharmaceutical medicine and the life-cycle
- Module 3: GMP's and regulatory environment
- Module 4: GMP's and GxP
- Module 5: The pharmaceutical quality system (PQS)
- Module 6: Personnel Infrastructure and documentation/records
- Module 7: GMP manufacture
- Module 8: Other GMP systems
- Module 9: Review and summary

Book today at
bsigroup.com/training

Upon successful completion of your course, you'll receive an internationally recognized BSI certificate.

Make sure the course is right for you

Who is this course for?

The course is ideal for anyone involved in a pharmaceutical organization, including research and development (R&D), onsite dispensary/warehousing, production, packaging and labelling, quality control/quality assurance; or if you're in a role within an organization that supplies such organizations with services or materials (raw materials, Active Pharmaceutical Ingredient (API), filters, packaging materials or consumables).

What will I learn?	What are the benefits?
Upon completion of this course, you'll be able to: • Describe what a medicine is • Describe what pharmaceutical GMP is • Identify types of GxP's and the relationship to medicine life-cycle • Define key requirements of pharmaceutical GMP • Appreciate fundamental GMP principles • Recognize the role of the GMP regulator in a global market • Identify the quality management systems within GMP	This course will help you: • Gain fundamental knowledge of pharmaceutical GMP and how it links regulation to the regulator(s) and related Good Practices (GxP) • Identify the key requirements of pharmaceutical GMP • Gain a fundamental understanding of GMP compliance on product quality

Prerequisites - you are expected to have the following prior knowledge:

There are no formal prerequisites for this course.

Why invest in training from BSI?

We want to make sure you have the best learning experience possible. That's why we offer a range of training courses from beginner to expert. We create a positive learning environment, so you retain the knowledge and acquire the skills that will continue to be of use beyond the course.

When you attend a BSI training course, our tutors are the best in the business. They're truly passionate about sharing their knowledge and ensuring you learn. Trusted experts with years of hands-on and business experience, they bring the subject matter to life with relevant and contemporary examples to enhance your learning.

Training delivered at your site could be a convenient and cost-effective option, especially if you have multiple delegates. Talk to one of our experts to find out more.

bsi.

BSI Group
Kitemark Court
Davy Avenue, Knowlhill
Milton Keynes, MK5 8PP