Advanced Good Manufacturing Practice Training Course

A 3 day intensive course for people wanting an in-depth appreciation of GMP

This 3-day intensive course is aimed at people who need a in-depth appreciation of the requirements of Good Manufacturing Practice (GMP). The course covers the need and history of GMP as well as the key GMP requirements at the various parts of a pharmaceutical manufacturing site, from goods-in to despatch of the finished product. The course is based on the requirements of **European Union (EU) GMP**, with comparison of this to other GMPs also provided. Delegates will leave the course with a very clear and well-rounded application of the requirements of GMP and how to apply these in the workplace.

Who will the course benefit?

This course is aimed at people who work **in Quality Assurance**, **Quality Control** and **Production** personnel who need a greater appreciation of GMP than is often offered via traditional *in-house* GMP awareness training courses. The course is aimed at **team leader** and **junior management** level as is used as a development course for people who are to be **managers of the future**. The course is ideal for people who are **new to the pharmaceutical industry** and are in a role where a very good working knowledge of GMP is essential.

Course overview:

This course is presented over 3 days and provides a real depth of information on the main aspects of pharmaceutical GMP. During the course the **main GMP requirements for purchasing, goods-in, the warehouse, production, packaging, Quality Control and batch release** are covered. In addition, the course also covers the main elements of the **Quality Management System** needed to provided medicines of the highest quality, including the requirements for **documentation, training and system monitoring and review**. The course is full of **interactive exercises** and workshops throughout the programme.

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Course contents:

DAY 1: The reasons for GMP and GMP in facility design

Why do we have GMP?

- The history of GMP
- Why do we have GMP?
- Approval of medicines and manufacturers

GMP – rules and guidelines

- European Union (EU) GMP and the EU Guide to GMP
- GMP in the United States
- Other GMPs from around the world

Premises and facility design

- Suitable premises and facility design
- Heating, Ventilation and Air-Conditioning systems
- Access, security and pest control

Equipment, maintenance and calibration

- Selection of equipment and installation
- Planned Preventive Maintenance (PPM)
- Calibration of measuring equipment.

Validation, qualification and change control

- The differences between validation and qualification
- The different stages of validation
- The importance of controlling changes

Water systems

- The different types of water
- Water system design, construction and monitoring

DAY 2: GMP in practice – incoming materials to product release

Purchasing, incoming materials, suppliers and outsourced activities

- GMP requirements for incoming materials
- Supplier selection and control
- Control of outsourced activities

The warehouse

- *Control of incoming materials*
- *Storage of materials*
- *Issue of materials to production*
- *Control of rejected and returned materials*

Manufacturing

- *Different types of dosage forms*
- *Initial checks of the area, equipment and materials*
- *Documentation and records*
- *Reporting of problems*
- *Cleaning of the equipment and area*

(continued)

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DAY 2: GMP in practice – incoming materials to product release

Packaging *(continued)*

- Packaging equipment design and facility layout
- Control of materials and product
- Overprinting of artwork

Quality Control

- Good Control Laboratory Practice
- Test specifications and pharmacopoeias
- Analytical method validation and method transfer
- Recording of results and release of materials
- Ongoing stability storage and testing

DAY 3: GMP and the Quality Management System

People and training

- Organisation charts, job descriptions and training records
- GMP, hygiene and job specific training
- Training design and evaluation

Key personnel in GMP

- The Heads of Production, QC and the Qualified Person
- The role of Quality and Quality Assurance
- The importance of Senior Management

Documentation, records and data integrity

- Control and approval of documents and records
- Data Integrity and regulatory concerns
- The use of computer systems

Quality Risk Management

- The need to make decisions based on risk
- ICH Q9 and its requirements
- Reactive and proactive risk assessments

Deviations, incidents and complaints

- CAPA systems – good and bad points
- Problem-solving and root-cause analysis
- Dealing with complaints effectively

Specific GMP requirements for certain types of products

- Sterile products manufacturing
- Biological products
- Advanced Therapy Medicinal Products

The Quality Management System

- Batch review and release
- Product Quality Review
- Internal auditing
- Management review
- Continual improvement
- The requirements of ICH Q10

www.inspiredpharma.com **info@inspiredpharma.com**

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Tutors:

Dominic Parry

Dominic has worked in the pharmaceutical industry since 1992, and is a leading pharmaceutical quality management specialist. He is generally recognised as one of the leading GMP trainers in the UK and brings an enormous amount of interest, enthusiasm and fun into the training he presents.

Andy Martin

Andy started working in the Pharmaceutical industry in 1985 as a lab technician for Smith & Nephew. During that time he had a number of roles in the Microbiology team. In 2007 he took up the position of Microbiology Manager for Catalent Pharma Solutions. Finally, in 2012, he began the current venture as a freelance pharmaceutical consultant.

Matt Morris

Matt is a dynamic, energetic and authentic trainer. He began his Pharma career at Napp Laboratories. He then spent 15 years with GlaxoSmithKline gaining extensive knowledge of GMP from roles in Packaging, Logistics and QC. More recently he has worked as GMP Learning and Development Manager for Lonza Biologics.

Course dates, venues and times:

Please **visit our website** for full details of the course venues. If required you should book accommodation yourself directly with the hotel. It is recommended that delegates stay at or close to the course venue. Please note that the cost of accommodation is not included in the course cost.

Tuesday 22nd – Thursday 24th October 2019
Reading, Berkshire UK
Tuesday 24th – Thursday 26th March 2020
Reading, Berkshire UK
Tuesday 22nd – Thursday 24th September 2019
Reading, Berkshire UK

Please book via our website www.inspiredpharma.com

The timings are as follows:

Day 1: **09.00 – 17.00**
Day 2: **09.00 – 17.00**
Day 3: **09.00 – 16.30**

Costs:

The cost of attending is **£1950** per delegate for the 3-day course. **For group booking discounts of up to 50% for more than one delegate please visit our website for further information**. Please visit our website for further details of what is included in the course costs.

The course will be charged in GB pounds. VAT (tax) will not be charged for courses held outside the UK. VAT will be charged for the courses held in the UK, however delegates from outside the UK but within the European Union (EU) will not be charged VAT if they supply their own company's national VAT number when booking. VAT will not be charged for any delegates coming from outside the EU.

Payment and cancellations:

Full payment must be made before the course start date in order to secure a place. Payments will only be refunded in full if cancelled in writing 4 weeks before the start of the course. Delegate substitution is acceptable but please inform us.

Contact us:

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