FREQUENTLY ASKED QUESTIONS

Q. Where will the course be held?

A. You control the environment with courses being held at a location of your choosing

Q. If needed, can I contact the course director?

A. Prior discussions with the course director help customize the course to focus on specific areas that may require attention

Q. Is pricing of each course based on the number of participants?

A. Pricing for each course is a flat rate, and it is based on the number of days

Other benefits for having an onsite course:

Q: What are the benefits of having an on-site course vs. sending my employees to a public course?

A: The average cost of a public course is about $2,000.00 per attendee plus air travel and lodging which can average another $1,000.00, as well travel time as time per employee.

An on-site course can cost less than the cost of sending one a single employee to attend a public course, and the company can have several employees attend for the one flat rate

FDA and International Professional Consultingand On-site Training Services

Other types of services include:

- On-site Mock FDA Inspections.
- ISO13485 Audits
- 1st and 2nd Party Audits (vendor audits).
- Implementation of Quality Systemsin compliance with 21 CFR Parts 820, 210, 211,
- MDD, and CE marking requirements. Implementation of Risk Management strategies based on the most current Quality System Regulations
- Design Control Dossier Reviews

For more information, please contact us at:

Monarch Quality Systems Solutions
32 Quaker StreetMarlton, NJ 08053
Phone: (856) 810-3780
Fax: (856)596-0155
info@monarchquality.com
www.monarchquality.com

MQSS Monarch Quality Systems Solutions

Monarch Quality System Solutions has a proven record of helping businesses cut back expenses with reliable raining, consulting and conferences.

MQSS is a professional firm specializing in consulting and education services for thebio-medical technology industry. MQSS helps companies improve operating performanceby implementing efficient and effectivequality system solutions and processes inorder to reduce non-value-added operations and re-solve FDA and EU Regulatory compliance issues.

The Flexibility of On-Site Training

Our ability to customize to your specific needs spans the entire range of possibilities, from adjusting course content to developing relevant case studies to incorporating a vari-ety of instructional techniques.

Maximizing Your Training Investment

MQSS is committed to ensuring that partici-pants have a consistent, high-quality on-site training experience, regardless of their loca-tion. Our Managers for On-Site Training are available to discuss your training needs.
For more information on how your organiza-tion can benefit from MQSS's on-site solu-tions, please call (856) 810 3780 or email info@monarchquality.com
or jackelynr@comcast.net

HOW CAN YOU MAKE SURE YOU HAVE THE BEST?

Any MQSS course can be presented by our course directors at a location conven-ient to you. On-Site training offers several benefits:

- Cost effectiveness. Have travel restrictions? Eliminate participant lodging and travel ex-penses, reduce time out of the office. Receive corporate volume discounts.
- Immediate impact. Increase productivity, improve compliance, raise morale, and accel-erate the rate of development.
- Convenience and control. Design a program that meets your organization's specific goals and objectives; schedule it when it best ac-commodates your workloads, and track the performance of your participants through completion of individual courses.
- An in-house course allows for smaller more intimate discussions specifically addressing the needs of your organization. In-depth, de-tailed discussions occur without risking confi-dentiality

List of some of the on-site Training Courses

1. Process Validation for Medical Devices
2. Root Cause Analysis for CAPA
3. Reporting Failure Investigations and Process Deviation
4. Effective Quality Assurance Auditing for FDA Regulated Industries
5. How to Implement Risk Management Principles and Activities Within all Quality Systems
6. FDA Inspections: What To Expect And How To Prepare
7. Comprehensive Overview of FDA Regu-latory Compliance for Drugs and Biotech Products
8. Overview of FDA Regulatory Compliance for Medical Devices
9. How to Develop an Effective Complaint Handling & Post Market Surveillance Pro-gram for Medical Devices
10. Auditing and Qualifying Suppliers and Vendors

Know all our courses