



Fundamentals of Quality - For Newcomers to the Medical Device Industry

Training Brochure



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INTRODUCTION

This program is designed for newcomers seeking a foundational understanding of quality management in the medical device industry. Led by industry experts and enriched with hands-on learning, participants will develop the skills needed to navigate regulatory requirements, implement quality practices, and contribute to the delivery of safe, high-quality medical devices. Step into the medical device manufacturing industry with confidence and make a meaningful impact.

COURSE OBJECTIVES

After participating in the training, you will acquire a strong foundation in the essential quality knowledge required in the medical device industry.

COURSE OUTLINE

1. Quality
2. Quality gurus
3. Quality management
4. Quality Assurance (QA) vs. Quality Control (QC)
5. Understanding roles and responsibilities: managers, executives, engineers, supervisors & operators
6. Quality plan vs. control plan
7. Essential standards & regulations
8. Prevention vs. detection
9. Concept- system, process, variation
10. Supplier / customer
11. Cost of Quality

DURATION

One (1) full day

MODE OF TRAINING

Remote Online Training or Classroom Training

COURSE AGENDA

Time	Details
9.00 am – 12.30 pm	Quality Quality gurus

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12.30 pm – 1.45 pm	Quality management Quality Assurance (QA) vs. Quality Control (QC) Understanding roles and responsibilities: managers, executives, engineers, supervisors & operators
1.45 pm – 5.15 pm	Lunch break Quality plan vs. control plan Essential standards & regulations Prevention vs. detection Concept- system, process, variation Supplier / customer Cost of Quality

CONTACT

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