

19UMBDC02	DSE-Core 1 Quality Assurance and Quality Control	4hrs/week	4Credits
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Objectives:

1. For better perception in pharmaceutical microbiology standards
2. To understand industrial requirement of microbial technology
3. To get better opportunities in pharmaceutical industry/laboratories/ Research institutes
4. To be equipped with standard operating procedures as per regulatory authorities

**Unit 1: Total Quality Management System
(12hrs)**

- Basic concept of Total quality management
- Importance of quality
- Components of TQM
- Advantages of quality
- Types of Quality measures

**Unit 2: Quality Assurance
(12hrs)**

- Hazard and risk analysis in pharmaceutical products
- Personnel's in Quality assurance
- Functions of quality assurance
- Organizational setup in QA
- Importance of QA


**Unit 3: Quality Control
(12hrs)**

- Definition : Quality Control and its types in various industries
- Principles of quality control
- Methods of quality control in food industry
- Methods of quality control in Pharma industry
- Corrective and Preventive actions

**Unit 4: Quality Audits and inspections
(12hrs)**

- Self inspections and internal assessments
- Purpose of audits
- Types of Audit
- Methods to carry out audits
- Regulatory Compliance

**Unit 5: Regulatory guidelines on Quality systems in industry
(12 hrs)**


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- Regulatory bodies in industries
- FDA, USFDA, FSSAI and ISO
- Quality Standards in India : ISI, AGMARKS
- Commodity based standards
- Some case study

Text Book

1. Quality Assurance in Microbiology by Rajesh Bhatia, Rattan Lal Ihhpunjani. CBS publishers & distributors, New Delhi.(UNIT-1-5)
2. Good manufacturing practices for Pharmaceuticals By Sydney H. Willing, Murray M. Tuckerman, Willam S. Hitchings IV. Second edition Mercel Dekker NC New York (UNIT-1-5)

Reference Book

1. Vyas S. P., Dixit V. (2007) Pharmaceutical Biotechnology, CBS Publishers & Distributors
2. Stephen P. D., Norman A. H., Sean P. G., Brendan F. G. (2011) Hugo & Russell Pharmaceutical Microbiology 8th Ed. Wiley-Blackwell Publishing house
3. John S. Wolfson and David C. Hooper, (1989) Quinolone antimicrobial agents. American Society for Microbiology, Washington.
4. Cooper M. S. (1972) Quality control in the Pharmaceutical Industry Vol.2 Academic Press Inc.
5. Sidney H.W. Murray M. Tuckerman, W., S. Hitchings IV. Mercel D.,(2007) Good Manufacturing Practices for Pharmaceuticals, Second Edition, NC New York

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