Syllabus

Pharmaceutical Microbiology

(Department Quality Control)

Introduction
Quality Control Microbiology

- Introduction to Procedures of testing in QC Microbiology
- Introduction to instruments used
- Awareness and understanding of Documentation

Responsibilities of QC Microbiologists in PHARMACEUTICAL INDUSTRY

People trained in pharmaceutical microbiology, often known as pharmaceutical microbiologists, mainly work in quality control and assurance department in pharmaceutical companies, and their primary role is to ensure the quality of raw materials before they are processed in the production area, monitor the microbiological quality of environment and water, and validate methods used in testing.

RESPONSIBILITIES OF A PHARMA MICROBIOLOGIST

- **Enviormental monitoring (active and passive)**
- **Water sampling and testing**
- **TOC analysis**
- **Bioburden testing (By pour plate and filteration)**
- **MLT (Microbial Limit Test)**
- **GPT (Growth Promotion Test)**
- **BET(Bacterial endotoxin test)**
- **Sterility testing**

- Disinfectant efficacy test
- Identification of Microorganisms by API or Gene sequencer
- Culture preparation and maintenance
- Validations
- Trend preparation
- Particle counting
- Calibration and validation of instruments
- Media preparation
- Autoclave and DHS operation
- Handling of OOS
- Gowning Procedure (To enter in classified Testing and manufacturing area)
- Sampling of APIs and finished products
- Preparation of STPs, SOPs and MTPs etc.

Instruments used in Phamraceutical Microbiology

- LAMINAR AIR FLOW
- Microscope
- INCUBATORS
- PETRIPLATES (90mm AND RODAC)
- AIR SAMPLER
- AUTOCLAVE and DHS
- Ph and Conductivity meter
- TOC analyzer
- Colony Counter
- Analytical Balance
- Bunsen burner and Inoculation Loop
- Centrifuge
- Deep Freezer
- Hot Plate
- Hot Air Oven
- Vortex Mixture
- Gene sequencer
- Accessories related to various Tests

Instrument Qualification

- User requirement specification (URS)
- Design qualification (DQ)
- Factory acceptance testing (FAT)
- Site acceptance test (SAT)
- Installation qualification (IQ)
- Operational qualification (OQ)
- Performance qualification (PQ)

Calibration and validation

- Calibration of instruments
- Analytical method validation
- Analytical method development
- Maintenance of Microbial culture
- Preventive maintenance of instruments

Quality Management Documents

- Deviation
- Incident
- Change control
- OOS
- OOT investigation
- CAPA
- Risk assessment

Documents related to Microbiology Dept.

- Protocol preparation
- Report writing
- Revision of SOPs & MTPs
- Revision of specifications
- Data review
- Trend preparation

AUDIT Related

- Data integrity
- 21 CFR
- ICH
- USP
- MHRA guidelines
- Regulatory audits
- Internal audits

Conclusion

- Cover all the topics of syllabus
- Provide deep knowledge and understanding of principles and techniques
- Questions and answers (appropriate to interview)

THANKS AND ALL THE BEST FOR YOUR FUTURE