# MICROBIOLOGICAL NEEDS AND EMERGING CHALLENGES OF MICROBIOLOGISTS IN THE PHARMACEUTICAL INDUSTRY

# MICROBIOLOGICAL NEEDS OF THE PHARMACEUTICAL INDUSTRY

## A Pharmaceutical QC Microbiologist

- Must have a working knowledge of microbiological methods and challenge studies (i.e. microbiological enumeration, biological indicators – resistance performance tests for sterilization) disinfectant efficacy testing, antimicrobial / preservative effectiveness), microbiological assays (Vitamins/Amino Acids ) sterility testing methods, microbial test / assay validation techniques and deviation assessment/management in compliance to the Quality Objectives of Good Manufacturing Practices for Medicinal Products

# QUALITY OBJECTIVES OF GMP

- ✓ SAFE
- ✓ PURE
- ✓ EFFECTIVE

## A Pharmaceutical QC Microbiologist

- Must be able to develop solutions to complement **Quality Control testing activities and issues; and Quality initiatives with inter-organizational impact Production ; R& D; Business Development; Distribution following GLP/ GMP / GDP and other government regulations (i.e. FDA, PIC/S – Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme) and Pharmacopeia (USP, EP, BP, JP) standards.**

## Job Duties/Responsibilities:

- Follow company policies and procedures.
- Set personal performance goals and provide input to departmental objectives.
- Establish work priorities to meet targets and timelines.
- Manage competing priorities and allocate, adjust, and optimize assigned department resources.
- **Serve as the Quality representative on cross-functional teams.**
- Identify, design, and implement process and system improvements.
- Manage department and cross-functional initiatives.

## Job Duties/Responsibilities:

- Apply advanced theory, technical principles, expert judgment, and cross-functional expertise to independently address a broad range of complex problems.
- Troubleshoot and direct the resolution of Quality issues by fostering effective interdepartmental and cross-functional partnerships.
- Serve as a technical subject matter expert (SME) in support of department functions.
- Develop and train personnel and internal customers on relevant business processes.

## Job Duties/Responsibilities:

- Mentor junior personnel serving as a subject matter expert (SME) on Quality systems, processes and issues.
- Collaborate and author department policies and procedures.
- Make decisions that impact the goals and objectives of the department.
- Notify Management of potential quality or regulatory issues that may affect product quality or regulatory compliance.
- Follow proper safety precautions and laboratory technique in the use of reagents and other chemical compounds, including but not limited to organic solvents, acids and bases, biological toxins, microorganisms and potent compounds.

## Job Duties/Responsibilities:

- Sign documents for activities as authorized and described by Company policies, procedures and job descriptions.
- Be accountable for behaviors as described in Company Core Values and Competencies.
- Meets required scheduled performance on time.
- Perform any other tasks as requested by Management to support Quality oversight activities.

## Technical Duties/Responsibilities:

- Provide technical expertise in the development of test method validation protocols and supporting procedures.
- Ensure validated methods and supporting procedures adhere to approved regulatory specifications.
- Prepare validation summary reports for test method validation activities.
- Provide input into regulatory filings.
- Perform Quality Control testing for product release and stability samples.
- Support quality investigations for testing and test method discrepancies.
- Perform equipment validation for laboratory instruments used in GMP testing activities (i.e. Sterilizer Validation; Temperature mapping , Calibration techniques)

## Technical Duties/Responsibilities:

- Provide input into the generation of stability study protocols.
- Collaborate with departments to ensure product release and stability testing requirements are completed.
- Communicate testing or scheduling issues that may impact the timely release of final product to Quality Assurance Management.
- Compile trending reports for method validation and testing activities (Environmental Microbiology – Water, Air, Personnel)
- Develop and deliver training materials for new and revised test methods and laboratory procedures.

## The Qualification

- B.S. degree in a life science (preferably a Microbiology major) and years experience in the pharmaceutical, biopharmaceutical or related industry, or an equivalent combination of education and experience
- Sound knowledge of GMPs or equivalent regulations, Pharmacopeia requirements
- Ability to interpret and relate Quality standards for implementation and review
- Ability to make sound decisions about scheduling, allocation of resources, and managing priorities
- Ability to communicate clearly and professionally both in writing and verbally
- Flexibility in problem solving, providing direction and work hours to meet business objectives
- Working knowledge in microbiological examination of non-sterile products, microbial method validation, sterility testing, microbial disinfectant efficacy testing, and antimicrobial effectiveness testing, Biological tests (i.e. Endotoxin test) and assays (Vitamins and amino acids)

# EMERGING CHALLENGES OF MICROBIOLOGISTS IN THE PHARMACEUTICAL INDUSTRY

## Satisfying global regulatory requirements – ACTD, AFTA, PIC/S, ICH, EMEA, HAS, TGA

- Meeting pharmacopeial expectations
- Quality risk assessment
- Microbiology Test and Assay validations
- Sterile filter validation
- Contamination control
- Disinfection validation
- Application of modern microbial methods in manufacturing setting

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## Environmental Monitoring

- Sampling, detection and data analysis methods
- Air, Water, Surface, Personnel (Gowning)
- Scientific principles on recovery efficiency
- Setting alert/action limits

## Advancements and New Technologies

- Bio-sensors, bio chips and micro arrays
- Alternative microbiological methods
- Rapid microbiological ( ATP Bioluminescence) methods
- Use of statistics in qualification of new methods
- Microbial identification in the pharmaceutical industry
- Parametric release

## Microbial Contamination Control

- Microbiological aspects of cleaning validation
- Sterilization, disinfection and preservation
- Sterilization, disinfection validation
- Biotech, fermentation, purification
- Real-time detection

## Control of Pharmaceutical Grade Waters

- Validation
- Testing methods
- Remediation
- Biofilms
- Detection and control of objectionable organisms

## Endotoxin and Pyrogens

- In raw materials, WFI (Water for Injection) and drug product
- Control and removal strategies (gram negative microorganisms)
- Challenges with current detection methods (Limulus Amoebacyte Lysate)
- Allowable levels
- Innovations in detection methods

## Biologic Products/Biotechnology

- Upstream (culture control issues)
- Downstream (purification processes)
- Regulatory expectations

## Control of Sterile Products

- Media fills
- Aseptic processing
- Environmental Controls
- Personnel Monitoring
- Bioburden Control limits
- Container closure challenges

## Control of Non-Sterile Products

- Environmental monitoring
- Risk assessment
- Microbial challenges
- Objectionable organisms
- Quality of product intermediate steps
- Microbial Limits and specifications
- Predictive stability (Preservative efficacy)

## Continuous Improvement

- Laboratory Methods Validation
- Manufacturing Lead times
- Quality assessment, quality control
- Lean labs/future labs
- **Process analytical technology** (**PAT**) has been defined by the United States Food and Drug Administration (FDA) as a mechanism to design, analyze, and control pharmaceutical manufacturing processes through the measurement of Critical Process Parameters (CPP) which affect Critical Quality Attributes (CQA).

## Emerging Markets

- Harmonization and its limitations
- Compendial strategies
- Regulations and submissions
- Parallel imports
- Auditing standards

## Other Challenges

- Product and/or Labeling Attributes Potentially Impacting Sterility Assurance
- Investigation of Microbial Data Deviations
  - OOS or Laboratory error
- Contract Laboratories and Contract Manufacturers Accreditation
  - Challenges and benefits
- Myths and Misconceptions Associated with Microbiology in the Pharmaceutical Arena

THANK YOU
AND
GOD BLESS
YOU