STERILITY TESTING OF PHARMACEUTICAL PRODUCTS

Tim Sandle

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## Introduction

- Regulatory Documents for Parametric Release
  - US documents
  - EU and global documents
  - ISO standards

## Sterile Product Suitability for Parametric Release

## Risk Assessing the Manufacturing Process

- Risk based application for parametric release
- Ongoing risk assessment of the process

## Requirements for Parametric Release

- Quality Management Systems
  - Other quality documents

## Validation

- Biological indicator validation
  - Purity
  - Population
  - D-value

## Process Definitions

## Product Definition and Design Control

## Equipment, Facility Design and Qualification

## Process Steps

- Cleaning and decontamination
- Inspection and assembly
- Packaging, including the materials and techniques
- Sterilizer loading
- Sterilization cycle
- Storage and distribution
- Record keeping

## Microbial Control

- Environmental control monitoring
- Bioburden and endotoxin control
- Pre-sterilization product bioburden

## Personnel Training

## Change Control

## Release Procedure

## Conclusion