Investigation of Sterility Test Failure **Investigation #** _____

Part 1. Batch Information:

Product Name: _____ Product Code & Batch #: _____
Date of Manufacturing/Filling: _____ Filling Machine: _____
Container and Closure: _____ Filling Room: _____

Part 2. Description of Test Failure & Possible Root Cause:

_____

_____

Notification of QA: Who was notified/Date & Time _____

Part 3. QC Test Data

Date of Test: _____ Test Room: _____
Technician:_____ Test Method #: _____
Results Date & Time: _____
Negative Control: _____Manipulative Control: _____
Media Growth Promotion: _____
Media Type & Batch #:_____
Media Expiration Date: _____
Number of Positive Units: _____ Organism(s) identified: _____

Environmental Results During Test: Viables- Air- _____
Surface-_____
Personnel Monitoring- _____
Viable Organism Identification (Note which sample):

_____
Non-Viable Counts: _____
Is the first sterility test invalid? Yes/No, and if yes, explain

_____

Get QA Approval for Retest: _____
If it is invalid, get retain samples for a repeat sterility test: _____
Repeat Test Results:_____

Part 4. Review of QC Data & History:

Data/History	**Comments**	**Reviewed By/Date**
Sterility Isolate found elsewhere in lab?		
Technician comments?		
Test Deviations?		
Review of Cleaning/Disinfection of Sterility Test Suite & Exp. Date of Disinfectants		

Review of sample handling/Chain of Custody		
False Positives in testing or Controls?		
Other batches positive if tested the same day?		
Review of C of A's for materials, filters, solutions		
Certification of HEPAs, LF or Isolation Unit		
Review of Sterilization Cycles for equipment		
Technician Training & Qualification Record		

Written By (QC Staff)/Date: _____
Approved By (QC)/Date: _____

Part 5. Quality Assurance Review of Manufacturing/Filling:

Review interventions during filling of the batch:_____
Review of Media Fills (12 months): _____
Review Deviations/Investigations/Interventions for this batch:
_____
_____
Review History of Deviations and Investigations for product: _____
_____
Review of Sterility or Environmental Positives with Same Isolate: _____
_____
Filling Room Environmental Monitoring Results:

Sample	**Location**	**Results**
Viables- Air		
Viables- Surface		
Viables-Personnel*		
Non-Viables **		

*Note Activity of Person prior to taking sample exiting room. Review previous excursions for same person in last 6 months.
**If possible, isolate source by using portable particulate monitor.

Attach Review of Manufacturing (Compounding) and Filling Activities by Production Personnel Include:

Bioburden/ Filter Integrity for Aseptic Products

Sterilization Cycle for Terminally Sterilized Products
Disinfection of Areas
Raw Material/Component Tests and Handling
Utility Tests

List Batches to be placed on hold:

_____
_____
_____

Written By/Date: _____
Approved By/Date: _____

Part 6. Risk Based Assessment:

Explain if non-viable or viable count (EM results) could potentially impact the sterility of the product._____
_____

Dosage Form of the Product: Injectable_____Ophthalmic_____Topical_____

Sterility Test Organism _____

Possible sources of specific organism recovered_____

Other dates specific organism was recovered and location (e.g., EM monitoring in Sterility Testing Suite or Aseptic Filling Room _____

List specific deviations or interventions during batch filling: _____

_____

Is the product capable of sustaining growth of the organism?_____

Is there more sampling that needs to be done to find root causes?
Describe_____

List possible root causes._____

_____

What is the most probable root cause? _____

Are experiments needed to confirm?_____
_____

Written By/Date: _____ Approved By/Date: _____

Part 7. Final QA Assessment:

Corrective Action: What should be an immediate action? How should batch disposition be impacted? _____

_____

Preventive Action: What needs to be done to prevent a recurrence of the event?

_____

_____

Follow-up to ensure effectiveness of actions _____

_____

Written By/Date: _____ Approved By/Date:_____

QA notes/Batch Disposition Decision: _____

QA approval/Date:_____