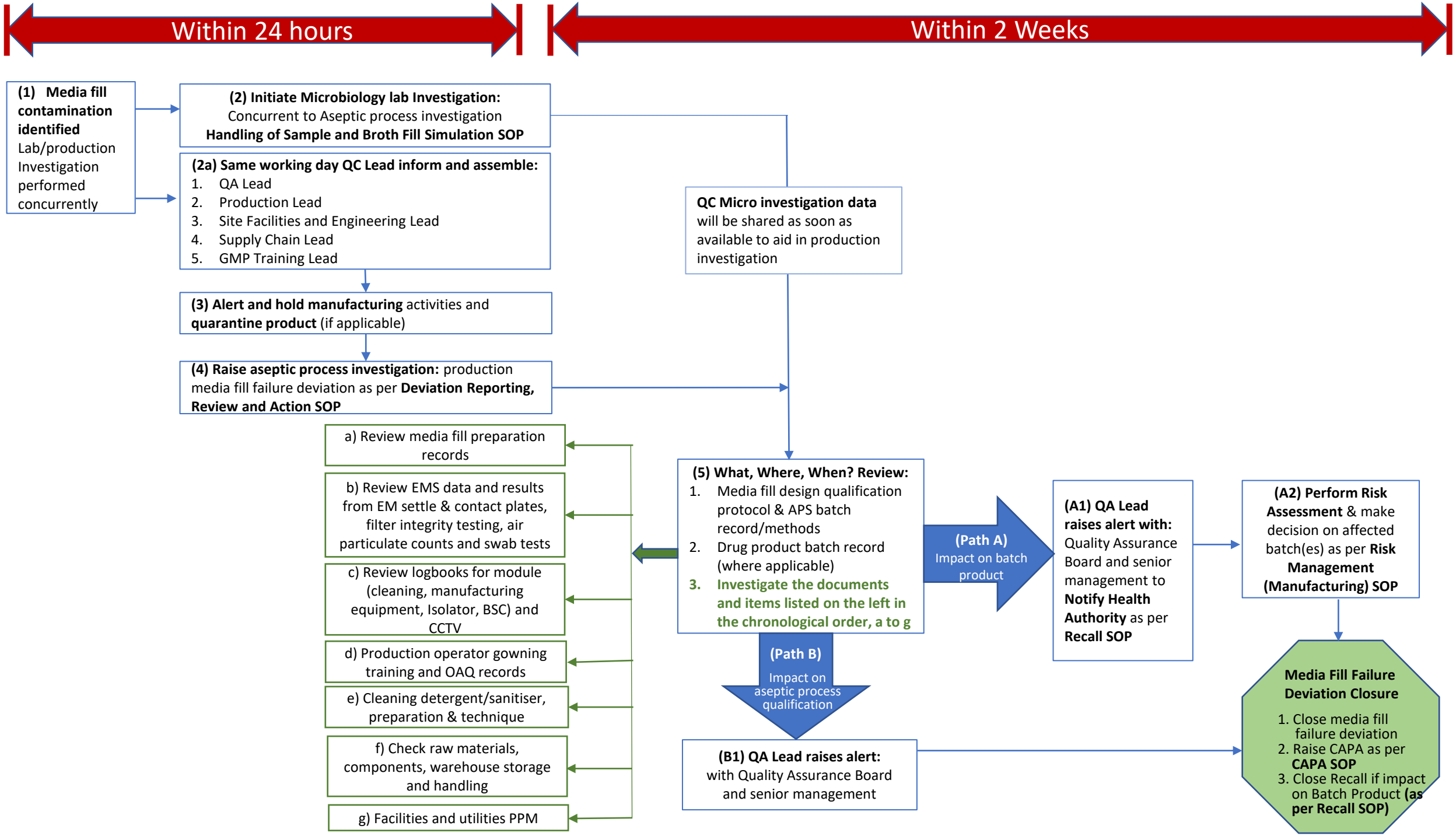
Within 24 hours
Within 2 Weeks
(1) Media fill contamination identified
Lab/production Investigation performed concurrently
(2) Initiate Microbiology lab Investigation:
Concurrent to Aseptic process investigation
Handling of Sample and Broth Fill Simulation SOP
(2a) Same working day QC Lead inform and assemble:
1. QA Lead
2. Production Lead
3. Site Facilities and Engineering Lead
4. Supply Chain Lead
5. GMP Training Lead
(3) Alert and hold manufacturing activities and quarantine product (if applicable)
(4) Raise aseptic process investigation: production media fill failure deviation as per Deviation Reporting, Review and Action SOP
QC Micro investigation data will be shared as soon as available to aid in production investigation
a) Review media fill preparation records
b) Review EMS data and results from EM settle & contact plates, filter integrity testing, air particulate counts and swab tests
c) Review logbooks for module (cleaning, manufacturing equipment, Isolator, BSC) and CCTV
d) Production operator gowning training and OAQ records
e) Cleaning detergent/sanitiser, preparation & technique
f) Check raw materials, components, warehouse storage and handling
g) Facilities and utilities PPM
(5) What, Where, When? Review:
1. Media fill design qualification protocol & APS batch record/methods
2. Drug product batch record (where applicable)
3. Investigate the documents and items listed on the left in the chronological order, a to g
(Path A)
Impact on batch product
(Path B)
Impact on aseptic process qualification
(A1) QA Lead raises alert with: Quality Assurance Board and senior management to Notify Health Authority as per Recall SOP
(A2) Perform Risk Assessment & make decision on affected batch(es) as per Risk Management (Manufacturing) SOP
(B1) QA Lead raises alert: with Quality Assurance Board and senior management
Media Fill Failure Deviation Closure
1. Close media fill failure deviation
2. Raise CAPA as per CAPA SOP
3. Close Recall if impact on Batch Product (as per Recall SOP)