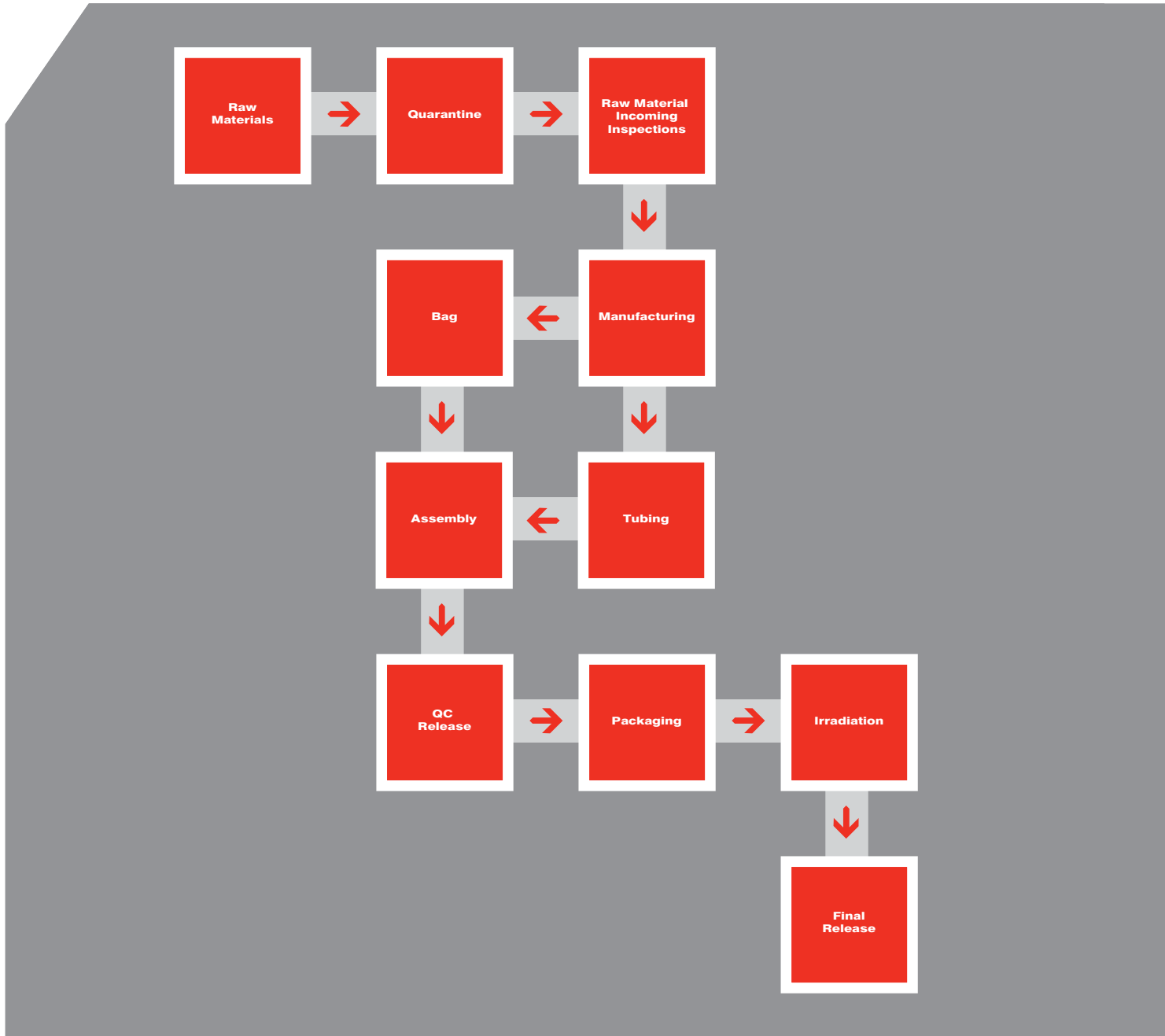


In-Process Testing

Single-Use Bioprocessing Systems Process Flow Chart



Single-Use Bioprocessing Systems In-Process Testing

Raw Material Incoming Inspections

Polyethylene (Inner, Outer Layer)

- Packaging and film is inspected to ensure there is no compromise to integrity.
 - Thickness is measured and verified against raw material specification.
 - Film is visually inspected for clarity, blemishes, or pits.
 - IR scan is performed on each film and compared against master IR scan.
 - Inner layer film received is sampled for endotoxin analysis.
- If there is evidence of trauma, the film is rejected and quarantined.

Ethyl Vinyl Acetate

- Packaging and film is inspected to ensure there is no compromise to integrity.
 - Thickness is measured and verified against specifications.
 - Film is visually inspected for clarity, blemishes or pits.
 - Film is sampled for endotoxin analysis.
 - IR scan is performed on each film and compared against master IR scan of film.
- If there is evidence of trauma, the film is rejected and quarantined.

Tubing Components

- Tubing spools are inspected to ensure there is no compromise to integrity.
 - Inner diameter and outer diameter are verified against specifications.
- If there is evidence of trauma, the tubing is rejected and quarantined.
- Visual inspection includes:
 - Flash (overage of plastic in mold, edges on the component).
 - Short shots (not enough plastic in mold, missing part of component).
 - Particulates (contamination).

Manufacturing: In-Process Testing

Visual inspection

- Prior to assembly, the bag is inspected for pits, particulates, material of animal origin (hair), bubbles, overlapped seams, seam wrinkles, and excess film outside of the seam, etc.
- Post assembly, the bag is inspected by measuring the port location tolerance and tube length tolerance.

Bag Measurement

- Bag is measured to guarantee dimensions are within specification.

Pressure Decay

- Test performed on polyethylene bags designed to check the integrity of the film and seam post manufacture.
- Bag is filled to a specific pressure and monitored to ensure there is no decrease in pressure over a specified period of time.

Burst Test

- Destructive test performed on ethyl vinyl acetate bags to ensure seam strength.
- Product is filled until a rupture occurs in the product.
 - To be within specification, rupture can not occur at the point of a seam.

Tubing Measurement

- Prior to assembly, tubing is measured to ensure it has been cut within allowed tolerance limits.

Sampling

- Sampling is performed according to ANSI guidelines and product specifications.
 - ANSI guidelines dictate the number of products sampled according to lot size produced.