3.2.5 In Process Quality Control

Responsibility of Quality Control:

> The Quality control team shall have the responsibility and authority to approve or reject all components, product, closures, in-process materials, packaging material, labeling, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control team shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

In-Process QC Checks: In-Line and End of Line Inspections:

The purpose of in-process QC Checks is to establish and reinforce a "Right First Time" culture and develop effective and efficient Brand/Vendor relationships across the supply base.

This on-site inspection system is to determine the quality of order by checking the semi-finished and finished products' quality level in the production lines and ultimately to ensure that supply base performance will meet brand expectations.

There is no substitute for In-Process/ In-line inspection. It should take place as early as possible.

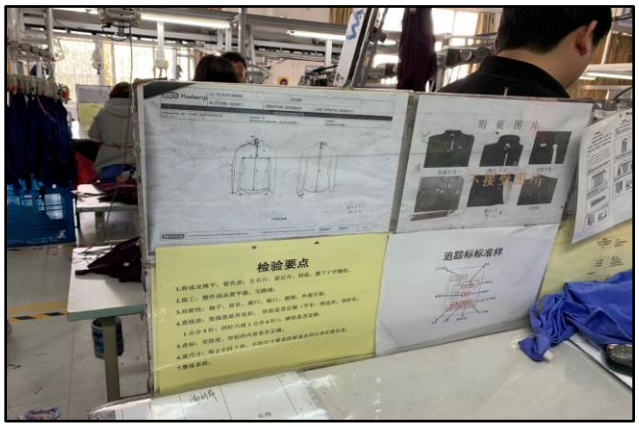
In-process auditing will provide the factory the ability to identify problems at an early stage, the opportunity to rectify quality issues before packing, a preliminary checking of the production status to prevent any unnecessary delivery slides and short shipments in the final stage.

In-Process/In-line Inspection Preparation:

- Have on hand the approved manufacturing standard, the style product file, the preproduction (PP) sample evaluation document, and all the standards including the approved tech pack.
- Review the style product file, the PP sample, and the approved standards, and any approval comments.
- Follow up on all lab-test reports for fabric and garments and make sure they are complete, passed/approved.
- Review the list of critical operations that were marked on the preproduction meeting minutes.
- The auditor must walk through the production lines, check each operation in sequence, and not be solely stationed at an inspection point or QC room.
- Review Pilot Run and preproduction meeting comments.

- If Inspection is on Bulk Launch, review Preproduction comments and Pilot Run reports including all
- comments on specification, quality, and garment presentation.
- Have a copy of the operational breakdown from the factory technical department.
- Review with factory management if necessary.
- The semi-finished goods should receive in-process QC checks to ensure any non-conforming goods are identified and the production line issue corrected.
    - All workers performing inspections should receive training and have written inspection procedure and criteria available for reference.
    - Inspection records and results and should be kept 18 months.

Good instructions for in-process QC check example

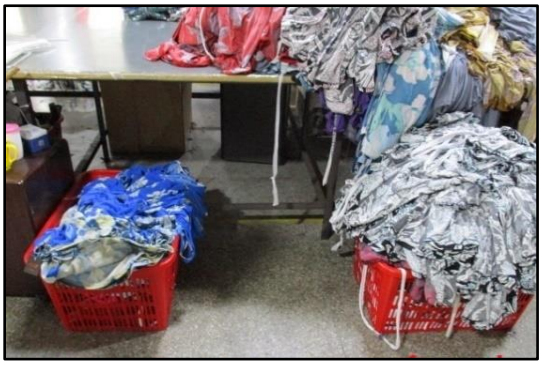


3.2.5 Defective and Non-Conforming Products

Defective or non-conforming materials found in IPQC inspection need to be clearly identified to prevent mixing with conforming materials.

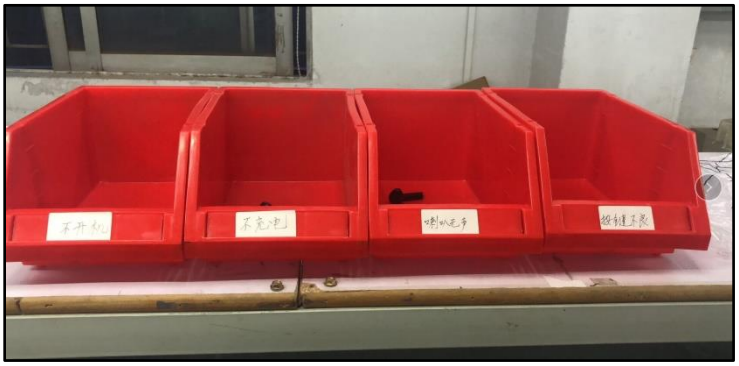
- A designated area with clear signage should be set up the IPQC area.
- Rework goods are to be clearly labeled, defects identified, and sent to separate rework area

Poor non-conforming identification examples:

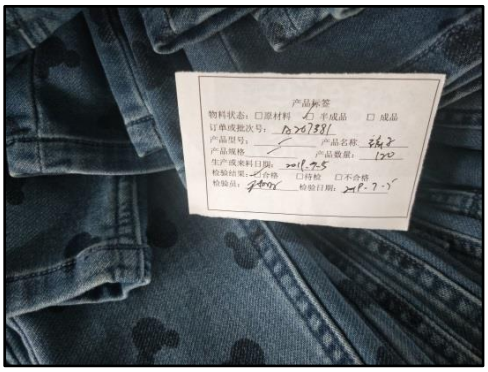


Conforming and non-conforming products not clearly

Good non-conforming identification examples:



Bins for defective products clearly labeled



Inspection status label on conforming products