

Auditing Packaging Material Vendors

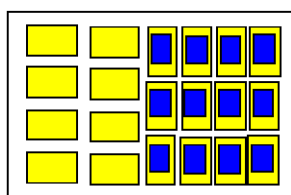
Goals

When you have completed this unit, you should be able to:

- Perform a packaging component supplier audit.
- Understand which worldwide requirements apply to packaging component suppliers.
- Use a range of information tools, including the contents of this module, in support of a packaging component supplier audit.
- Recognize compliance or non-compliance with regulations pertaining to packaging component supplier's requirements.

Definitions

Gang-printed labeling: Labeling derived from a sheet of material on which more than one item of labeling is printed. (see example below). Gang printing is considered to be an unacceptable practice for some industry since it increases the potential for label mix-up.



Packaging materials: Any material employed in the packaging of a medicinal product, excluding any other packaging used for transportation or shipment.

Packaging Component – Critical (PCC): Is any printed packaging component, primary (product contact) component or device. Furthermore any secondary packaging component critical to the microbiological integrity, stability and/or administration of the product (e.g. Aluminium pillow packs around semi permeables).

Packaging Component – Non-Critical (PCNC): Is any non-printed or secondary (non contact) packaging component or device that does not fall within the definition of a PCC.

Printed packaging components: Packaging materials that are printed and/or otherwise decorated. Examples would include cartons, labels, leaflets.

Reconciliation: A documented comparison between the amount of input materials and the output product, taking into account waste, samples and other losses inherent in the process.

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Line clearance

Line clearance is an essential element in product mix up prevention and needs to focus on:

- Input materials on the line from the previous batch
- Samples and waste from the previous batch
- Documents on the line from the previous batch
- Verification that any electronic data is wiped from consoles etc.
- Clearance after maintenance activity or major interruptions as appropriate.

Line clearance activities need to be documented and cover all areas, not just the machine or line:

- The whole machine, including hoppers, conveyers, reject stations, etc
- The floor around the line
- Benches, cupboards, shelves around the line
- Pallets.

The line clearance should be documented, signed and an independent check completed and signed before the area is released for use.

Contamination control

The facilities should be designed and laid out to appropriately reduce the risk of contamination from the environment and permit effective cleaning. Personnel gowning and hygiene practices are part of contamination control efforts that may be applicable.

The supplier should define the appropriate environmental conditions for handling and storage of the component(s) being manufactured. Guidance for minimum conditions can be found in PS 9000 Pharmaceutical Packaging Materials, as well as programs such as ISO 9001:2000 and ISO 9004:2000 for pharmaceutical packaging materials.

Validation and Qualification

Ensure the processes are adequately validated, qualified and/or demonstrated according to the quality critical parameters of the component being manufactured. This may be demonstrated in the form of capability studies.

Sampling

There should be an SOP that defines package component sampling. The components sampled should be representative of the batch and sampling should be conducted to prevent contamination from the sampling method.

Any packaging materials that meet appropriate written specifications should be formally approved and released for use. Any components that fail to meet such specifications must be rejected to prevent distribution.

Samples taken away from the line should not be returned to the line. They should be reconciled and placed in dedicated containers for destruction.

Documentation

The appropriate SOPs and batch records must be followed when documenting any information or data associated with a component manufacture. Other pertinent types of

documentation include:

- Records of how and who set up a particular machine

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Examples of common manufacturing and printing methods for package components

Molding

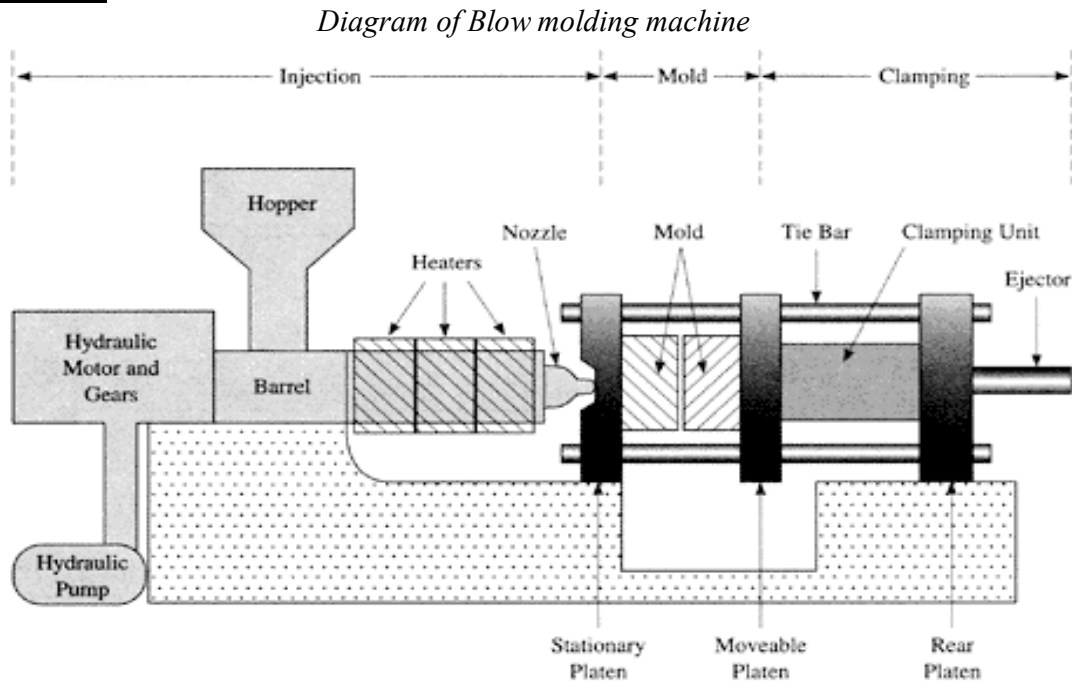


Figure 1 Injection molding machine showing three major functional units (injection, mold, and clamping) along with major components of each unit.

Broken down to its fundamental components, an injection machine is comprised of 3 functional units:

1. Injection – which melts and transmits the plastic granules.
2. Mold – the design portion which produces a specialized product
3. Clamping – which provides the controlled pressure to open and close the mold.

Injection blow molding is normally used for high quality bottles. Compared to extrusion blow molding, injection molding gives better definition of details and better control of thickness of the material. Important quality considerations are:

- Traceability of the polymer is maintained, that only virgin polymer is used (not regrind polymer).
- Key manufacturing parameters such as Temperature and Pressure
- Testing of polymer, for example, Melt Flow Index
- Maintenance and cleaning of the molds, cavities and barrel.
- Controls and confirmation of the critical specifications during manufacturing. For example, thickness of walls confirmed through QC inspection as a part of in-process testing.

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There are many manufacturers of syringes, and while each one uses a slightly different process, the basic steps remain the same:

1. Needle formation
2. Plastic component molding
3. Piece assembly,
4. Packaging,
5. Labeling and
6. Shipment.

The needle is normally produced from steel, which is heated and drawn through a die design to meet the size requirements. Most needles are purchased from specialist manufacturers.

The syringe tube can be manufactured by injection molding or glass manufacture as required. When all of the component pieces are available, final assembly can occur. As the tubes travel down the conveyer, the ends that cap the tube are affixed. Graduation marks are applied as appropriate, and the needle and safety cap can be attached at this time.

Manufacture should be in a clean environment and final component free from contamination.

The quality components used to manufacture syringes should be checked during each phase of the manufacture. Components should be checked to ensure size; shape and consistency are within specifications. Measuring equipment with the defined accuracy and precision should be used for measurement of the components.

Forces to activate the plunger, dismantle the syringe, removal of cap and removal of needle should be tested, reported and controlled. The reporting of quality attributes during manufacture is often completed on Statistical Control Charts where the manufacturing process can easily be monitored.

Key Parameters of a Packaging Component Audit

Prior to the audit

- Develop an understanding of the vendor manufacturing process specific to company requirements
- Obtain a list of company components that are manufactured at the site.
- Review recent rejections, complaints and issues, of the receiving site(s) and the respective statuses.
- Review any Quality Agreements and relevant registration requirements.
- Review compliance status of the site by checking for service history, recalls associated with the site, recent regulatory inspections (if applicable) and outcomes.
- Review previous audit reports and actions

During the audit

- Perform a walk through of the manufacturing area.
 - Ensure the production areas are clean and tidy.
 - Ensure the fabric is in good condition and appropriate design for control of the process.