

# **Packaging Requirements of Pharma Industry & Expectations**

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# Introduction

**World-class manufacturers of food, pharmaceuticals and other critical products place heavy demands on their suppliers. In today's increasingly competitive environment, manufacturers expect vendors to meet often extraordinary quality, production, customization and timing requirements. Suppliers who cannot meet those exacting demands struggle, fail and often disappear.**

**Those who can meet these requirements emerge as profitable market leaders.**

# Why vendor assessment is required?

- To achieve 'built in' quality concept.
- Need for new product development.
- An alternate vendor development for existing products / Item.
- An existing vendor is coming up with an additional Item.
- Any other commercial reason.

# **Vendor Development for Primary and Printed Packaging Materials**

- **Packaging Development (PDD) will send the material specification to the prospective vendor and organise the samples.**
- **PDD will analyze the samples and COA**
- **If the samples are OK, PDD will advice SCM to procure the trial material. Trial batch may be taken for machine suitability where ever required.**

# **Vendor Development for Primary and Printed Packaging Materials**

**QA shall evaluate the vendor based on any of the following:**

- Samples from the vendor satisfactorily tested and approved as per specification**
- Trial batch qualifies the machine suitability test (if required)**

**Packaging Development along with SCM and QA will audit the factory once the samples are Approved.**

# **General expectations of the customer from the packaging industry**

- **Company Profile should be in place.**
- **What percentage of the produced materials are being supplied to pharma industries.**
- **Is there any FDA Drug Master File and is it periodically updated?**
- **Is this materials manufactured at other site?**
- **If multiple sites manufacture this material, what provisions are in place to provide on going assurance that the same process are used and the materials have the same quality.**

# **General expectations of the customer from the packaging industry**

- **Organisation Chart , specifically show the reporting relationship of QA and production personnel.**
- **Is there any SOP for training?**
- **Is there any training schedule in place and is that sufficient in number?**
- **Is there any training programme on cGMP and job specific training for operator.**
- **Are personnel hygiene and safety aspects given due attention?**

# **Expectations of the customer about Facility**

- **The premises should be designed and constructed in such a fashion so as to avoid entry of birds and insects. It should be well protected from weather.**
- **There should be adequate space to facilitate proper storage, logical flow of men and material and cleaning and should have sufficient light available.**

# **Expectations of the customer about Facility**

- **The facility should be neat and clean (within and surrounding)**
- **Adequate fire extinguishers should be in place and employees should be trained to use them.**

# Warehouse

- **The warehouse should be spacious and should be able to accommodate all the materials.**
- **There should be a SOP for all warehouse activities (material receipt to dispatch)**
- **The materials should be stored and labeled in a proper fashion so as identify the material easily and materials should be kept on pallets.**

# Warehouse

- **The materials like Adhesives, Adhesive labels, Foil rolls, PVC etc. should be kept in controlled environment.**
- **The quarantine, approved and rejected materials storage space should be clearly segregated.**
- **FIFO system should be followed for both issuance and dispatch.**

# Production

## Dispensing:

- **There should be a SOP for dispensing**
- **Suitable dispensing scale which is regularly calibrated should be available**
- **The dispensed materials should be labeled.**

## Processing:

- **An operating and cleaning SOP should be available for all equipments**
- **Line clearance should be taken prior to commencement of the activity and recorded.**

# Production

## Processing:

- All the starting materials and finished products should be analysed by QC.
- In process checks should be carried out and should be recorded
- There should be a SOP for house keeping and should be followed strictly.
- There should be a SOP for handling of scrap and plant waste.
- If there is any activity done by the sub-contractor, how to ensure the quality.
- Authorisation process should be followed strictly.

# Production

## Processing:

- Different packing line should be well segregated from each other
- Finished products should be properly labeled with all required detail, e.g., Customer name, material name, qty. packed etc.

# Expectations of the customer – Printed Packaging Materials

## Artwork Management

- **The Artworks should be kept safely under lock and key.**
- **The artworks of different customers / products should be segregated in a proper fashion and kept safely to avoid any mix-up**
- **Proof reading should be done against the original artwork and should be recorded**
- **All colours should be approved against pantone shade card.**

# **Expectations of the customer – Printed Packaging Materials**

## **Artwork Management**

- **The procedure of preparation of shade cards should be followed strictly**

## **Handling of cylinders, plates, approved designs**

- **The controlling of cylinders, plates etc. should be followed as per SOP**
- **All the cylinders, plate, artworks (soft and hard copies both) of the obsolete design should be destroyed / returned to the customer.**

# Expectations of the customer – Printed Packaging Materials

## Handling of cylinders, plates, approved designs

- The new design, cylinders, plate etc should be developed only after returning the old cylinders, plate etc to the customer.
- A log book should be maintained to record the movement of the design, cylinders, plate etc.
- Block proof should be handed over and approved by the customer before going for the commercial run.

# Special requirements – Printed packaging materials

## Reel fed Materials

- There should be a system for detecting the presence of joints in the reels.
- On line scanning of the bar code should be done and recorded
- There should be a procedure to detect the pin hole and should be properly recorded.

# Special requirements – Printed packaging materials

## Self adhesive label

- There should be a proper system to detect the joints if it is supplied in roll form
- There should be a system for counting the labels.

**IF THERE IS ANY DEVIATION FROM THE SYSTEM / SPECIFICATION THAT SHOULD BE IMMEDIATELY INFORMED TO THE CUSTOMER.**

# Unprinted packaging materials

## PVC, PVC/PVDC

If there is any change in grade of granule / change in source, that should immediately informed to the customer so that customer can analyze the change and take the necessary action.

## Alu. Foil

If it comes in direct contact with the product, any change in source, coating, etc. should be informed to the customer immediately.

# Quality control

- **There should be a well equipped QC lab. to carry out the testing the incoming as well as finished products.**
- **The QC personnel should be properly trained to carry out designated work.**
- **There should be a training calendar for training of QC professional and should be followed strictly.**
- **COA should be prepared and maintained.**

# Quality Assurance

- **There should be authorised procedures for all activities of the facility (General procedures, procedures to be followed during production activity, plant maintenance, equipment operation, cleaning, entry procedures, quality control and quality assurance procedures)**
- **There should be a procedure to handle complaints**
- **All technical changes should be done through change control.**

# Quality Assurance

- **Customer approval should be taken for any change related to his product.**
- **There should be a procedure related to product release.**
- **There should be a system of reviewing and updating the documents periodically.**

# Maintenance

- **A calendar should be prepared for preventive maintenance of the machines / equipments and strictly followed.**
- **Maintenance personnel should be trained to carry out their job. A training calendar should be prepared and maintained strictly. Every activity should be recorded.**
- **All the equipments should be calibrated as per schedule and recorded.**

# Transportation

- **The vendor should ensure the vehicle which is being used for transportation of goods should be clean and dry prior to loading.**

**THANK YOU**