## OBJECTIVE

To document the system for conducting manufacturing experiments at the Waynesville site.

## ATTACHMENTS

Recommendation for Manufacturing Experiment
Revision Form
Training Form

## PROCEDURE

This procedure shall be used when intentionally manufacturing products by processes outside the documented quality system. It provides a structure that allows manufacturing personnel and facilities to be used safely and efficiently to improve products and processes.

Each manufacturing experiment includes the Recommendation for Manufacturing Experiment form and the appropriate attachments. The recommendation form serves two functions. It is first of all a guide to help identify what changes may be needed. Secondly, it is a communication tool between the experiment sponsor and those conducting the experiment. Careful planning and clear communications are keys to successful experiments.

### Conducting the Experiment

The Experiment's Sponsor is responsible for completing the Recommendation for Manufacturing Experiment form and appropriate check sheets, and for gathering or preparing documents with experimental instructions for each change from standard. This planning needs to be completed far enough in advance to allow systems to be setup. Except in emergencies.

The manufacturing experiment form provides guidance on documentation that may be needed for a particular experiment. The completed forms and other attached documents serve as a communication tool and as work instructions for the experiment. They should be completed in a thorough manner with instructions that are clear and easy to understand.

**Releasing Experimental Product for Sale**

Product produced under a Manufacturing Experiment may require special release authorization. This decision is made based on the type(s) of changes made in the experiment and the possibility these may impact the final product. It is the responsibility of Production Manager to approve the release method to be used on any experimental product. Experimental product with properties outside normal release limits always requires special release authorization.

**Safety precautions, including PPE** - List any new safety precautions, protective equipment, warnings or other information necessary for Operations to complete the experiment without injury or incident. Avoid non-specific statements like "Follow all area safety rules"that add clutter to the document and may make it less effective.

**Objective** - The objective of the experiment needs to be clearly defined. It may help to think of the objective as it relates to the most common categories of experiments:

1. Test a hypothesis to see if the desired results are achieved, or
2. To document a deviation from the standard quality system until that process can be validated and standardized.

**Parameters** - List the parameters which will be adjusted or varied during the experiment (line speeds, flow rates, dryer temperatures, etc.).

**Product Release** - List the complete product release criteria.

**Not for distribution/sale** - Check only if you plan not to release for distribution or sale.

**Product May Be Sold** – Check if you plan to release the product for sale. Also, check whether special product release is required or if it can be directly released if within standard release limits. The Production Manager will review and approve this release.

**Detailed instructions** - List detailed instructions for the experiment. Include information not included in the attachments or which bears repeating. Consider information about the sequence or order of the experiment, test methods, special samples, changes to standard procedures, material handling, potential problems or defects, how to contact the Sponsor, or any other helpful information

**Experiment Review and Approval**

Experiments are approved by:
Area Manager(s)

**Distribution of Experiment**

It is the sponsor's responsibility to insure that a copy of the approved ME is distributed. Other specific information follows.

**Running the Experiment**

Operating area affected by the experiment is responsible for scheduling and completing the experiment according to instructions. The sponsor and everyone involved should work together to ensure the instructions are understood.
Changes to an experiment after it is approved shall be noted on the appropriate experimental documents and approved by the experiment sponsor and a representative of the operating area.

**Document Control**

Approved experiments and attached documents become work instructions for the operating areas. Forms and attachments should copy clearly.
The sponsor is responsible for distribution of the approved ME

# TRAINING DOCUMENTATION

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| Revision Number | Revision Date | Revision Author | Revision Description |
|---|---|---|---|
| 00 | 09/09/2005 | CM | New Document |
| 01 | 06/08/2009 | PT | - Placed on new procedure format<br>- 3 Year Revision/ No Changes |
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