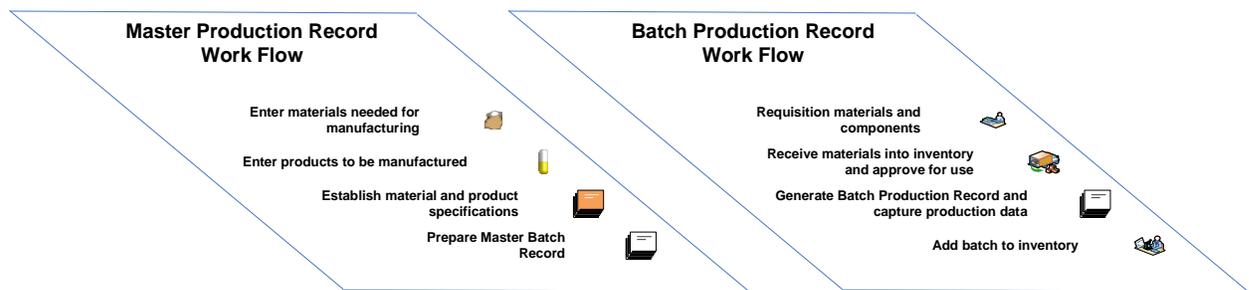


A. MPR/BPR Overview

1. All GMP manufacturers are required to keep Master Production Records (MPRs) and Batch Production Records (BPRs) in order to comply with FDA regulations. The InstantGMP software is designed to keep you in compliance with these regulations as you prepare and use its electronic batch records. I'll start your training with a quick review of Master Production Records and Batch Production Records.

Good Manufacturing Practices Work Flows Reinforced in InstantGMP



2. Master Production Records, also known as Master Manufacturing Formulas, are templates that include the manufacturing instructions that will be followed during Batch Production. Think of a Master Batch Record as a plan that has to have Quality approval that ensures each batch you make will be done properly. The Batch Record is a copy of the Master where you can document the when, how, by whom, with what tools and in what environment a product was produced. This ensures that multiple batches made from copies of the Master will be uniform and will meet its anticipated requirements. This is one of the fundamentals of quality in manufacturing.
3. During the training, you will be guided through the prerequisites that are necessary to create a Master Production Record. You will enter some personnel, several vendors and some materials and a product for training purposes. You will then create specifications for each material and your product. Then you can create your first Master Production Record.
4. When you finish writing the Master Production Record, you will be guided through the prerequisite steps needed to get ready to manufacture using a Batch Production Record. These steps include purchasing some materials, receiving them into inventory, updating their status to Approved and generating a Batch Production Record. At that point you will go through the process of actually manufacturing something with a Batch Production Record.

5. Think of the Master Production Record as a plan and the Batch Production Record is a copy of the Master. The batch record displays the when, the how, by whom, with what tools and in what environment a product is produced and allows the actual results to be captured. This ensures that multiple batches made from copies of the Master will be uniform and will meet its anticipated requirements. This is one of the fundamentals of quality in manufacturing.

6. You will begin your training by working in the Setup module. Here you can add personnel, vendors, material types and statuses, tests, methods, and countries.