

I. Master Production Record

A. MPR Record Definition

Note: Objectives:

1. To understand how to Setup a Master Production Record
2. To understand the details of setting up the manufacturing instruction in the MPR
3. To add information needed for the training project

1. **SAY: Project Manager - you can log in now to create the Master Production Record. Click Batch Record in the main menu and then click on the Master Production Record menu. Click the Add New Record. According to FDA requirements, you will need a Master Production Record (MPR), which is sometimes called a Master Manufacturing Record or Master Manufacturing Formula, for each unique combination of product, recipe and batch size.**

1) Cover Page

2. **On this screen, just like the menus, you will work from the top down. I'll describe each of the fields as you enter data. First select the Training Project from the drop down. This isolates the products and clients that were added to this Project.**

Note: If the trainee starts to ask questions about how this works for their company, or asking distracting questions, tell them that we will cover this in detail in the Dry Run. This session is just about showing how the software works.

3. **Next click the update icon for the Product Name. This brings up a list of the products that were created at the project level. Select the Part # hyper link for "Training Product-6 mg/mL-1 oz. Amber glass bottle".**
- **Client:** Select your company name from the drop down list. Only the clients added to this project will show up.
 - **Author:** Select your name from the drop down list.
 - **Formulation Id:** This is a required field that refers to a formulation or a recipe. Enter "Training Formulation" in this field.
 - **Product Strength:** This Read Only field shows the strength of the product you created as part of the Product Name.
 - **Theoretical Batch Yield:** Enter 100. This is the total amount that will be produced if you don't pull samples or if you won't lose any material during production. This number is going to be used when a subsequent Master

Production Record is created where you want scale up or scale down the size of your batch.

- **Batch Size:** Enter 90. This is the total amount to be produced minus the anticipated amounts for sampling, rejects and line loss.
 - **Unit:** This is a Read Only field that is a copy of the unit you selected when you created the material.
 - **Primary Container:** This is a Read Only field that displays the Primary Container you selected when you defined your Product Name.
 - **Amount/Primary Container:** This is optional, but is required if you are going to use InstantGMP to do cost estimations.
 - **Amount Unit:** This is only required if you are going to use InstantGMP to do cost estimations.
 - **# of Containers:** This is optional unless you are going to use InstantGMP to do cost estimations.
 - **Auto populate BOM Quantity on Mfg. Instructions:** Click this box. This allows the system to automatically add the Bill of Material quantity to a manufacturing instruction step. It also allows the system to automatically update the quantities in the Bill of Materials and on the manufacturing instructions when you scale up or scale down the batch size.
 - **Purpose:** This is not a required field, but could be used for keeping you organized. For example, you might use it to indicate the market or geographical region where the product is to be sold.
 - **Scope:** This is not a required field, but could be useful if you make the same product for different reasons. For example, the scope could be “immune support” or “heart health”.
 - **Attachment:** This is optional. You can select the “Upload” button and attach a file such as an Excel, word, PDF or jpeg. Whatever you attach here will be copied into the Batch Production Record that is created from this MPR.
4. Click the Confirm button to complete this form. Now you have started a Master Production Record.
- 2) Materials
5. Click on the Materials tab. This brings up the screen where you can enter your Bill of Materials. You will enter each material that will be in the product or will be used to manufacture the product.

6. Click the Add New Record to bring up an entry screen. Click the blue up arrow at the end of the Part # row to get a list of your available materials. Click the blue hyperlink part # for the Training Liquid. The Material Name will auto-populate when the Part # is selected.
7. For the Quantity/Batch, enter the amount of the material that will be needed to make the entire batch including any samples or allowances for line loss. In this case we will need 3 L of Training Liquid. Enter 3 for the quantity and L as the unit.
8. The composition is optional. Here you can enter the amount of the material that will be in one dosage unit, or in one primary container. For training purposes, enter 30 as the quantity and mL as the unit. This is how much liquid will be put in one bottle during manufacturing. Press Confirm.
9. Enter the second material. Click the Add New Record and then select the part # for the 1 oz. Amber Bottle. Enter 100 as the quantity and the unit as ea. Enter the Composition as 1 and corresponding unit as ea. Press Confirm.
10. I'll touch briefly on the next two screens, but you don't need them for this Training Project.

3) Equipment

11. Click the Equipment Tab. If you want to include equipment on your MPR, you can select them on this screen. The equipment list is created in Equipment sub-menu under the Setup menu item.

4) In-Process

12. Click the In-Process Tab. If you want to do in-process testing as part of your MPR, you can add tests and methods on this screen as a handy reference.

5) Manufacturing Instructions

13. Click the Manufacturing Instructions tab. This is the part of the MPR where you will define the steps and activities needed for making a batch of your product. Each manufacturing instruction step in the MPR will be used to create specific actions and rules that will then appear in the corresponding Batch Production Record manufacturing instruction.
14. When you write manufacturing instructions, you will enter each manufacturing instruction one at a time. When you're done, you see a list of your steps on this

screen. Click the Add New Record to start entering the first step. I'll talk about the parts of this form as you enter your data.

- **Step**: Enter 10 as the step number. You can choose your own numbering system. InstantGMP will automatically display the steps in numerical order on the Manufacturing Instructions summary screen.
 - **Part #**: You will select a part # any time you need to use an inventory item in a manufacturing step. For example, you will need to do this if you want to weigh or measure a material at this step. Click the update icon and select the Part # for the Training Liquid. The Version number will fill in automatically.
 - **Inventory**: You will check this box if Inventory will be updated at this step in the batch. This will allow you to decrement this material from inventory during manufacturing. Since you selected the auto populate BOM Quantity on the cover page, a default action will appear above the Action field. In this case the message shows the Quantity/Batch and unit for the material that needs to be measured out.
 - **Performer**: Click the Performer box to show a Performer signature is needed for this step in the batch. You typically do this for each step where you want a record of who performed the step and when.
 - **Verifier**: Click the Verifier box to show a Verifier signature is needed for this step. You should do this on every step that will have a significant impact on the quality of the final product. Measuring out an ingredient is an example.
 - **Action**: This is where you put the instructions for the operator to perform. Enter "Stage in production room" in this field.
 - **Target**: (Optional). You can enter a target measurement such as a weight or a mixing time.
 - **Range**: (Optional). This is the allowable range of the target measurement.
 - **Unit**: (Optional) This is the unit of the target measurement
 - **Attachment**: You can attach any file (for example, a word document or an Excel spreadsheet) to each manufacturing step. Whatever you attach here will show up in the batch record and can be modified if necessary at that point. Some examples are things like a worksheet or an SOP that the operator needs to complete at this step.
15. Press Confirm to complete this step and bring you back to the summary.
16. You will enter some more data for a four step manufacturing process. Click the Add New Record to star the next step, put in 20 where is says Step. You get to choose your own step # system. We like to use 10, 20, 30 etc. so we have some room between steps if we want to add some later on.

17. Click the update icon for a Part # and select the 1 oz. Amber glass bottle. Click the Inventory check box, the Performer check box and the Verifier check box. The Action is "Stage in production room". Click confirm to finish this step.
18. Click the Add New Record and enter information that I give for the next step. The Step # is 30. The Action is "Add 30 mL of Training Liquid to each bottle". Press Confirm.
19. Start the next step by clicking the Add New Record. The Step # is 40. The Action is "Record the number of bottles produced". Press Confirm to finish.
20. Now you have all of the manufacturing instructions entered. Your last task is to approve this MPR. Click the MPR Approvals tab.
21. The personnel that you see on this list were selected in the Project Personnel screen. In this case, the Project Manager and the Quality Manager appears. Project Manager - click the Sign button in the Approve column and enter you credentials. Your digital signature and the date/time stamp appears to the right of your name. Quality Manager - click the Sign button in the Approve column and enter your credentials. When the first signature is done, the MPR will be locked and no further edits can be made. When all signatures are completed, the MPR will be approved and can be used to generate Batch Production Records.
22. Click the Master Production Record menu. You will now see that your MPR is in this list with a Status of Approved and three icons to its right. The copy icon allows you to make a complete copy of this MPR that will can be changed any way you want. Next is the Version icon that allows you to make a copy of this MPR for minor changes and assigns the next sequential version number in the process. The Scale up/down icon makes a copy of the MRP and lets you change the Theoretical Batch Yield. InstantGMP will automatically calculate and update the quantities in the Bill of Materials and in the manufacturing steps based on the new Batch Yield.
23. You have now completed the Master Production Record process. The next tasks will get you ready to create a batch record and then to make a batch. Any questions before we move on?