I.Batch Production Record

Note: Objectives:

1. To understand how to create and issue a Batch Production Record
2. To understand how to complete the manufacturing instructions
3. To understand deviations
4. To use the Inventory during the training project
5. To complete information needed for the training project

A. Overview of Batch Production Records

1. **SAY: In this section, you will learn about Batch Production Records. You will learn how to create and issue a BPR, how to fill out the manufacturing instructions and how to use inventory during manufacturing.**

2. **You will need both roles in creating and issuing BPRs. Only a Project Manager can create them and only a Quality Manager can issue. If you are the Quality Manager, please log out and Project Manager – please log in.**

3. **Click on the Batch Production Record menu. This is where you will create and use Batch Records. Click the Add New Record to start you first one.**

4. **Batch records can only be created from approved Master Production Records. Select the Project Title for the MPR you just made. Click the blue up arrow to select the Product Name. You will see all of the Products associated with this project in this list. There's only one now which in this case it is "Training oWIP-6 mg/mL – 1 oz. Amber Bottler". Click the Product Name. At this point the rest of the fields will auto-populate with the information from the corresponding MPR. A Batch # will automatically be assigned by InstantGMP. If you have your own numbering system for numbering batches, you can enter that in the Production # field. Click confirm to complete this form.**

5. **You are now at the Cover Page of the Batch Production Record. You will see the same information that you just created on the Master Production Record. Everything that was done in the MPR besides the signatures was just copied to this batch record and this record was automatically assigned a unique batch number.**

6. **Click the Update button. An Issue button now appears. A QA signature is required to issue each batch. InstantGMP will go through the Bill of Materials and make sure that there is sufficient material in an Approved state to produce this batch. If something is missing, you will get an error message. When QA signs and the batch record is issued, you can start using it for manufacturing and operators can enter data.**

7. **Note to Vape Customers – your instance does not require specifications so the check for materials in an approved status described above will not be done.**

8. **Quality Manager – please click the Issue button and sign it. Click confirm.**

9. **We are back at the Batch Production Record summary where we can see all of the batches that were created. You can see that the status is now "Issued" which indicates that your batch is now ready for production. Find the blue hyper linked Product Name and click on it.**

10. **SAY: You will see that many screens are read only copies of the MPR. Click the Materials tab, the Equipment and In-process tabs and note that these are the same as the MPR you created.**

B. BPR Manufacturing Instructions

11. **Select the Manufacturing Instructions tab. The Manufacturing Instructions Screen shows a list of the Actions that need to be taken. If the batch had not been issued, these instructions would be read only and there would be no update icons next to each Step.**

12. **What you see here is a summary of the instructions you wrote in the MPR. Steps with no status check mark have not yet started. A yellow check mark indicates an action is needed at that step. A red check mark indicates a deviation is open at that step. A green check mark indicates the step has been completed and the corresponding inventory has been used.**

13. **Click the Update icon next to Step 10 and we'll take a closer look at this screen. This is a detailed view of an individual step. The information at the top of the screen will show you the product you are making, the batch #, the production # and the action that need to be taken.**

14. **I'll tell you about the rest of the information on this screen. Then I'll tell what you need to do to complete this Manufacturing instruction.**

    - **Material: This shows the material that was selected from the Bill of Materials for this step.**
    - **Part #: This is the Part number for the material.**
    - **Step: This is the current manufacturing instruction step.**
    - **Action: This the action that needs to be performed at this step.**
    - **Target, Min, Max, Range, Unit: This is the target, min, max and range for the Action or Material to be measured out. If there is an inventory item to measure**

out, the actual result must be between the min and max otherwise an error will display.

- Inventory Button: This button appears when the Inventory checkbox was selected for this step on the MPR. When clicked, you will see the list of material receipts available for this material. You will then go into the Inventory Use screen where you can make adjustments to material inventory during manufacturing.
- Scan: This is used to scan the barcode on a material label. This will take you directly to the Inventory Use screen for the specific receipt of the material just scanned.
- Result: This is where you will record your results.
- Comments: This is where you can record comments that don't have an effect on the results or cause a deviation.
- Deviation Comment: This is where you record observations of anything that does meet requirements or expectations. Putting anything into this field will make it mandatory that a Quality Manager review the comment and sign this step.
- Attachment: If an attachment was added to the step at the MPR, it will appear here. You can also upload a document to this step.
- Performer Required: If the Performer Required checkbox was selected on the MPR, this Sign button appears. A Performer must sign otherwise this BPR cannot be completed.
- Verifier Required: If the Verifier Required checkbox was selected on the MPR, this Sign button appears. A Verifier must sign otherwise this BPR cannot be completed.

15. Click the Inventory button. This will allow you to select the Receipt # of the material you will measure out.

16. What you see now are all of the receipts of the Training Liquid. For now, there is only one, but in real life you could have many. Click the blue Receipt # hyperlink to get to the Inventory Use screen. Here you will typically see a history of how this material was used. Since we haven't used this material before, there are no entries. Note there are two buttons at the bottom of the screen. The Use Material button creates a history of use of a material. The Change Location button is available if you want to update the Bin Location for this material.

17. Click the Use Material button to get to the screen where you can record the quantity you are using for this batch. At the top of the screen, you will see the material name, the vendor lot # and the Production # of the batch you are making.

18. Enter the quantity used as 3, the unit as L and the purpose as "Production." When you sign with your digital signature, the vendor lot # and the production # will be connected for tracking and tracing of materials automatically. Sign and confirm.

19. **We are now back at the instructions screen. Now you will see a new table that shows the Receipt # and Vendor Lot # of the material you used. It also shows the quantity that was used. Enter the result "Staged." Since this is a step where tight controls are needed to ensure the quality of the final product, you Setup a requirement for two signatures when you created the MPR. The Project Manager can now sign where it says "Performer Required". The Quality Manager can sign where it says "Verifier Required". When you have both signed, click confirm.**

20. **Now we can go into step 20. Click the Inventory button and then the hyperlink for the Receipt number. Click the Use Material button to get to the Inventory Use screen for the 1 oz. Amber Bottle. Enter the quantity used as 100 ea. and the purpose as "Production." Sign and confirm.**

21. **We are now back at the instructions screen. Enter the result as "Staged". Click confirm.**

22. **Next go into step 30. Go in and record the result as "3 mL added to each bottle." Enter a comment in the deviation comment field. Type in "Spilled 10 mL". Click confirm.**

23. **Note that the summary step now has a red check mark. Select the Update icon to go back into the step. A new signature prompt for a mandatory QA signature appears. Normally, a Quality Manager would review the deviation and decide if an investigation is needed. If an investigation report is written, it can be uploaded to this step. Quality Manager - you sign for this now. Note that the summary step now has a green check mark.**

24. **One last step to go. Go into step 40. Enter the result as "99 bottles filled". Click Confirm**

C. BPR Review

25. **You are done with manufacturing, but not done with the process just yet. You still need the batch record reviewed. Go to the "Executed BPR Review" tab. Here you will see the list of reviewers that was created in the Project Personnel screen. InstantGMP will check that all steps were completed, all required signatures were obtained and all deviations were closed. If anything is left open, an error message will display the problems. Each of the approvers will need to click the Sign button and enter their digital signature. When the first person enters their signature and the signature is accepted the Status on the BPR summary screen will change to "Locked". This means that this BPR cannot be edited or changed. Project Manager – go ahead and sign.**

26. When all signatures are completed, the BPR Status will show as “Reviewed”. Quality Manager - enter your signature now.

27. There is just one final action which is to add this batch to Inventory. Click the Cover Page tab. Here you will see a new button labeled “Add Batch to Inventory.” When you click that button the batch can be added to inventory. Click it now.

D. Add Batch to Inventory

28. Here you can record the size of the batch you just made. When you enter the number and approve, this batch is automatically added to Inventory with a status of Quarantine. This allows users to keep track of amounts distributed or sold. Enter 99, click the Approve button, then enter your digital signature and Confirm.

29. For purposes of this training we will ship our pretend Training oWIP to clear the inventory of all Training oWIP and emulate a sale. We will go to the inventory use screen via the main menu and deduct inventory and sign off.

30. Project Manager - click on the Inventory Use menu and find your Training oWIP under Material Name. Click the blue hyperlink Receipt # and then the Use Material button. Enter the Quantity Used as 99, the unit as ea. and the purpose as “Sold to packager.” Sign and confirm.

31. Click the “Deleted Inventory” and you will see your Training oWIP on this list.

32. You have now come through a full cycle of production. You entered some raw materials in the program, Setup specifications for them, created a Project and authored a Master Production Record and got it approved. Next you ordered the raw materials and received them into inventory, then issued a Batch Production Record, completed the manufacturing and added your completed product into inventory.

33. So you now at the end of the software training. If you are looking for more information or GMP compliance or for some training on advanced topics, please visit InstantGMP.com