

## A. Specifications

Note: this section is optional for Vape trainees. Do not go over this section unless specifically requested by the Vape trainee.

1. **SAY:** Once materials are entered into the system, you can set specifications for each one. Click on Specifications in the main menu. Materials need approved specs to be used in production. Specifications are characteristics a material must conform to through tests, methods, and acceptance limits. Each company must establish their own specifications. If you need guidance in what tests to use or how to create specifications for your organization, you can cover that during your process consulting.
2. You are now going to enter the specifications needed for this training practice. First select "All" from the Search Status drop-down menu to show all existing specifications both Approved Specs and those Specs Pending Approval. The default view for this screen is "Pending Approval" which why you have select "All" first. The materials you just entered will not show on this list until you create the first specification for each of them.
  - 1) Specification - Training Liquid
3. The person with the Project Manager role should be logged in at this time. If not, please log out and let the Project Manager log in.
4. Click the Add New Record button. This shows the "Select Part # to Version up" screen which is a list of materials with either no specifications or with previous locked down versions of specifications. Materials which have open (not signed) specification versions will not appear on this screen, but are on the previous screen. Choose the Training Liquid by clicking the Part # with the blue hyperlink.
5. InstantGMP started a new version of the specification for this material. For clarification here, a specification defines the tests, methods and limits for acceptance for a material. For example, a flavor could have attributes like color and scent. The specification also includes safety and handling data and sampling procedures.
6. Enter the effective date as today's date for training purposes. You would normally choose the date the specification is approved as the effective date. The Reason field is for a note to describe why another version of a specification is needed; for example, if new tests are required. This field does not need to be filled in for the first version of a spec.
7. The Safety and Handling Instructions are typically what an operator needs to know when handling this material. For example, gloves, mask and booties may be needed. Enter PPE which is short of Personal Protection Equipment.

8. Sampling Instructions are what the quality group will follow when sampling for testing. For example, you can enter "Collect 10 mL with a pipette".
  9. Click the Add Test button.
  10. For each attribute of your material, there needs to be a test such as identity or ph. For each test there must be a method or procedure by which the quality or attribute is measured. Each test and method combination needs an acceptance limit which defines the acceptable range for the attribute.
  11. First select the "Identification" test from the Test column drop down menu. Then pick the "Visual Verification" method that goes with this test from the Method column drop down. Next, enter "Conforms" an Acceptance Limit. The Sampling field is option in case there are special instructions needed for this particular test. The Release check box is only used if this test is going to be used to do release testing. This is the initial testing required before a material can be released for sale. You can add as many tests as needed.
  12. When all of the Test information is entered, we are ready for approval signatures. The Project Manager can click the first Approve button and put in their digital signature. The person with the Project Manager role should do this now. Note that their Badge Code can be scanned with a bar code scanner or they can enter their Username and Password.
  13. The Quality Manager needs to approve and will do so later. Quality Manager - if you try to scan your Badge Code, the system will show an error if you are not the person logged into the computer that is being used currently. This is because part 11 electronic documentation rules require at least two unique forms of identification. For the person who logged into the computer, their login credentials and their badge scan meet this requirement. Quality Manager - you'll enter your signatures when you are logged in later.
  14. Project Manager - click Confirm to complete the process for this specification.
- 2) Specification - 1 oz. Amber Bottle
15. There are two more materials that need specifications. Project Manager – please go to the Specifications menu and click the Add New Record button. Click the blue hyper link for the 1 oz. Amber Bottle. This brings you to the Create/Update Specification Version screen. InstantGMP automatically added a sequential version # of a specification for this material.

16. Enter the effective date as today's date for training purposes. Enter PPE in the Safety and Handling Instructions. Enter "Select 3 bottles" in the Sampling Instructions.

17. Click the Add Test button. Select the "Identification" test from the Test column drop down menu. Then pick the "Visual Verification" method that goes with this test from the Method column drop down. Next, enter "Conforms" an Acceptance Limit.

18. The person with the Project Manager role should approve now. Click Confirm to complete this specification.

3) Specification - Training oWIP

19. You are now ready to complete the last specification. Project Manager – please go to the Specifications menu and click the Add New Record button. Click the blue hyper link for the Training oWIP. This brings you to the Create/Update Specification Version screen. InstantGMP automatically added a sequential version # of a specification for this material.

20. Enter the effective date as today's date for training purposes. Enter PPE in the Safety and Handling Instructions. Enter "Select 10 bottles" in the Sampling Instructions.

21. Click the Add Test button. Select the "Identification" test from the Test column drop down menu. Then pick the "Visual Verification" method that goes with this test from the Method column drop down. Next, enter "Conforms" an Acceptance Limit.

22. The person with the Project Manager role should approve now. Click Confirm to complete this specification. Please log out.

23. Quality Manager - you can log in now. You can now sign where it says "QA Signature Required" on each of the three material specifications and click Confirm after each one to complete the process.

24. So now you are done with Specifications. Are there any GMP concepts or questions that you want a GMP expert to address for you? If so, we can give our GMP expert a heads up. Next we'll talk about setting up Projects.