A. Setup

1. **I will open the Material Types menu under Setup to show you a typical screen.**

Note: Select the Materials Types menu under Setup

2. **Notice that the program displays four panels; Top Panel, Menu Panel, Records Panel and Search Panel. I'll brief you on all four. The top panel displays which user is logged in on this computer, and the current user's role. There are selectable buttons which will let you; go to the Home page, Clear Control Preferences, Change Password, and Exit. The Exit button logs you out of the program, which returns you to your Login screen.**

3. **When you first start using the program you will navigate the Menu in a top down order. Select a plus button (+) adjacent to a folder to display Submenus. Select a Submenu to display a summary list of existing records in the Records Panel. Select the minus button (-) adjacent to a folder to collapse the Submenus and simplify navigation.**

4. **The Search Panel performs searches and filtering of your records.**

5. **We will prepare the system by filling the data in the Setup menus so this information appears in drop downs later in the system. All this information is preliminary to entering materials and managing your inventory.**

6. **Before we get into details, I'd like to show you several features that are used throughout the program.**

7. **I selected a Submenu to display a list of existing records. The grey and white stripes are just to make viewing easier. You may select a panel's double arrow button to collapse and expand a panel.**

Demonstrate: Collapse and expand each of the panels.

8. **Hover your mouse over any icon in the program to display a tool tip. Select the blue hyperlink to see the details of an existing record. Click the Update icon to edit a record. Click the hyperlink to see the Read Only display where an Update button will get you to the edit screen. The Add New Record button will open an edit screen where you can enter new data. The update icon will display the same edit screen where you can make changes to the existing record. The changes allowed are limited to the data fields displayed.**

Demonstrate: Open a record through the Update icon and the Update button on the Read Only page.

9. **Once you confirm an entry it becomes a permanent record that cannot be deleted. This is required by the FDA and Part 11 for electronic records. That's why we use the word "Training" in our practice so it is clear to anyone including an FDA inspector that this data is not meant to be used for real products. With that in mind, be sure to check your spelling! Fields marked with an asterisk are required.**

10. **Select the Confirm icon to capture and save any changes you have made and to return to the list of records. Alternatively, you can Close to return to the list of records without saving your changes.**

11. **You may scroll through a list. When the list gets long you can use the pagination buttons to navigate to first page, previous page, next page and last page. You may also enter a page number to jump to. You can designate the number of records that will appear on each page.**

12. **Let's begin some hands on training! I'll guide you as you perform data entry.**

NOTE: Open and close the Setup menu. (Demonstrate)

13. **SAY: To use menus and submenus, click a main menu item to open and click again to close. This shows or hides the submenus. Click the Setup menu item to display the sub-menu items.**

1) Personnel

14. **SAY: Click the Personnel menu.**

15. **The personnel screen is where users can add in new personnel up to the amount of users purchased with the subscription. To update a new personnel, click the update icon next to ADM. Here you will see the entry or update screen. To enable Administrator Rights Permission, click the administrator checkbox. This grants the user access to the screens under the Setup menu.**

16. **If anyone incorrectly types their credentials, that is their username and password, in the log in screen, a message appears that the username or password are incorrect. If they incorrectly type their credentials three times, after the last failed attempt at logging in, the user will be locked out and an e-mail will be sent to the ADM. The ADM will not have the password on file, any user with ADM rights can go to the ADM record to change the password.**

17. **Enter the e-mail address of the person you want to get these e-mails in the Email field.**

18. There are two buttons at the bottom of entry screens – the Confirm button and the Close button. The Confirm button saves your information. The Close button closes the screen without saving the information.

19. Press confirm now. This lets the system know that you have finished working on this screen and you want your changes committed to the database.

20. The person with the Project Manager role can click the "Insert" icon to add new personnel. Now enter your first and last name, e-mail and phone #. You will see that the username is automatically generated.

21. Notice that there is a Default Job Function. Select the Project Manager from the drop down list.

22. Enter a password. As you do that the program will show the strength. The password strength must be a minimum of medium. Click the Administrator checkbox. This will allow you access to the Setup screens. Don't click the Disable checkbox. If you do, the system will disable you and you will not be allowed to log in.

23. You can create a barcode badge that can be scanned as an alternative to typing in your credentials when your digital signature is needed. Click the blue calendar icon next to Start Date and select today's date.

24. Click the blue calendar icon for the End Date. Select the double right arrow to select an end date. Now click the Create Badge button to generate your personal ID code. Click Confirm to return to the summary page.

25. Click the print icon next to your name to display a print preview of your badge. You can print this to any printer. Just make sure the printer is Setup to match the label that you will print this badge onto. This badge can only be scanned and used when you are the person logged into the computer with the bar code reader. Now Close this screen.

26. The person with the Quality Manager role can click the Add New Record button and go through the same process. Enter your name and password, select your default job function as "Quality Manager" and click the Administrator checkbox. Press Confirm when you are finished.

27. You will find that once you have finished entering Setup data, it will show up in drop down boxes or selection lists later in the application.

28. To add more personnel, simply repeat the steps and omit clicking the administrator box. Only project managers should be given administrative rights and should not give rights to any other roles.

29. Only the first name and last name fields are mandatory, we recommend filling in an email address as well.

30. The user ID is automatically assigned by the program with the following formula: first letter of the first name, first seven letters of the last name and a sequential number starting with 01.

2) Vendor

31. SAY: Click the Vendor menu.

32. Here you will see a list of the companies that will supply anything needed for production. Your company should appear on this list since it is a vendor for the products made with InstantGMP.

33. Click the Add New Record. The Vendor Entry screen appears where you can enter Vendor data. Type in the Vendor name "Training Manufacturer" and press Confirm. Once you confirm an entry it becomes a permanent record that cannot be deleted.

34. Now insert "Training Supplier" and then click Confirm.

3) Client

1. SAY: Click the Client sub-menu item.

2. A <u>Client</u> is a company that will be selling the end product. This may be your company, or will be customers if you are a contract manufacturer. Your company should automatically appear on this list.

4) Material Types and Material Status

35. Let's discuss the variety of Materials that must be entered into the inventory system.

36. Material is a very broad term. Raw materials include things like ingredients. labels or packaging. You will also include the names of products, Finished Goods and any Works in Process that you will manufacture.

37. A Work in Process is defined as any material that has been processed in some manner and which requires further processing. For example; you process a raw material by drying it in an oven and then place it in bulk storage for a future packaging operation. In this example three materials should be listed in inventory to be tracked, each with a unique name and part number. They are the raw material, work in process material and Finished Goods.

38. **The program will also accommodate excipients, primary containers that come in contact with the product, caps, labels, instruction pamphlets, desiccant packs, tamper-proof shrink tubing, etc. You may include packaging and shipping items as well**

NOTE: Objective: To clarify the difference between raw materials, incoming WIPs, outgoing WIPs and finished goods.

39. **SAY: Click the Material Types menu.**

40. **The objective of this next part is to introduce you to the difference between raw materials, incoming Work in Process (WIP), outgoing Work in Process and finished goods.**

41. **Raw Materials are those materials used in or for a recipe. These can include excipients, ingredients or components. These are typically things you purchase so you can manufacture something.**

42. **An incoming WIP is a preprocessed material that is partially manufactured and you plan to use it to manufacture something with it. Typically, the word "incoming "indicates that this something you buy. An example is a liquid that is pre-blended and will be used in manufacturing your own product.**

43. **A Finished Good is a material that you manufacture for sale to customers.**

44. **An outgoing Work in Process, is a processed bulk good that will undergo further processing as an ingredient in another product. An example is a non-flavored liquid such as a cough syrup or a protein base that is made in bulk and then made into product by adding a flavor.**

45. **The material types have been filled in for you with commonly used information. You don't need to enter any new ones at this time.**

46. **SAY: Click the Material Status menu.**

47. **This list has the essential material statuses you will need; Approved, Quarantine and Rejected. You can add more at any time if you wish.**

5) Storage Condition

NOTE: Click the Storage Condition menu. (Demonstrate)

48. **SAY: GMPs require that each material has a documented Storage Condition that indicates how your materials are protected. Some example Storage Conditions are:**

Refrigerated or 20-25 degrees Centigrade. We have entered "Ambient" as a default. For this session we will only use Ambient.

6) Units

NOTE: Click the Units menu to discuss unit conversions. (Demonstrate)

49. **SAY: The most common units of measure are already entered for you. InstantGMP will automatically convert units. For example, if you order something in pounds and weigh it out in kilograms, the conversion will be done for you so that the amounts are always accurate.**

7) Facility

NOTE: Click the Facility menu.

50. **SAY: The facility is the name or location of the manufacturing site that will be used for making your products. Facility will be used when you Setup rooms and room logs. Click the Add New Record button and enter the Facility as "Training Facility".**

8) Room

NOTE: Click the Room menu.

51. **SAY: The Room is the name or location of a manufacturing area that will be used when making your products. Click the Add New Record button, select "Training Facility" from the drop down, enter the Room # "000" and the Room Name as "Training Room".**

52. **Rooms can be named any way you want as long as everyone can identify the room from the name or number. Room names/numbers will be used when you view room logs.**

9) Bin Location

NOTE: Click the Bin Location menu.

53. **SAY: The Bin Location is the name of the place where a material is stored. Click the Add New Record button, select "Training Facility" from the Facility drop down and select "Training Room" from the Room drop down. Enter Bin # as 001 and Bin Name as "Training Bin".**

10) Equipment

54. **SAY: Click the equipment sub-menu. This list should include any equipment that will be used for making your products. The Equipment name and number combinations are "Read-Only" and must be unique. Click the Add New Record and enter the Equipment # as "000" and the Equipment Name as "Training Equipment. Press Confirm.**

11) Tests

55. **SAY: Click the Tests sub-menu. A test describes the characteristics of a material or product that will ensure the quality of the final product. Examples are Identification, pH, or test for absence of microbial contamination. This list should include any test names that will be used in setting specifications for raw materials, WIPs, components, packaging and labels as well as the finished goods.**

NOTE: Show how to enter a new test and then ask trainee to enter "Identification".

56. **SAY: Click the Add New Record to open the entry screen. Enter "Identification" in the open field, then click Confirm.**

12) Methods

NOTE: Click the Methods menu. (Demonstrate)

57. **SAY: Click the Methods menu. Methods describe the actual procedures that are needed to conduct a test. Examples are FTIR or HPLC for Identity, pH meter, and USP.**
58. **This list should include any methods that will be used in setting specifications for raw materials including packaging and labels, WIPs and finished products.**

NOTE: Show how to enter a new method and then ask trainee to enter "Visual Verification".

59. **Click the Add New Record and enter a new method called "Visual Verification" then click Confirm.**

13) Countries

60. **SAY: Click the Countries sub-menu. This list should include countries of any Clients including your own facility. United States is provided as a default. You can enter additional countries at any time.**

Note: Quick Review of Setup Functions.

61. **SAY: So far we covered all of the Setup screens that will be needed in the workflows leading up to creating a Master Batch Record. The next major topic covers Materials and Specifications.**