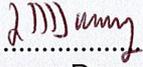


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DOCUMENT APPROVAL

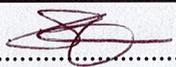
Author's Signature:

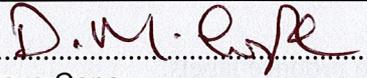
Your signature indicates that this document has been prepared in accordance with company standards or guidelines and adequately reflects the tasks and deliverables necessary.

Signature		Date	07-Dec-2016
Print Name	James Drury		
Title	Quality Assurance & Engineer		

Reviewer's Signature:

Your signature indicates that, you have reviewed this document and that it accurately and completely reflects the tasks and deliverables necessary.

Signature		Date	7 Dec 2016
Print Name	Steve Harris		
Title	Head of M&P manufacturing		

Signature		Date	7 th Dec 2016
Print Name	Dave Cope		
Title	Deputy Head of CoilThread		

Quality Assurance/Compliance Approver's Signature:

Your signature indicates that this document complies with company standards or guidelines; and that the documentation and information contained herein complies with applicable regulatory, corporate, divisional/departamental requirements, and current Good Manufacturing Practices.

Signature		Date	07 Dec 2016
Print Name	Gary Crawley		
Title	Quality Manager		

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1.0 PURPOSE

- 1.1. The purpose of the document is to define the SOP (Standard Operating Procedures) to be followed by ADVANEX EUROPE Ltd, in order to ensure that the Labels prepared for use with both pharmaceutical and none-pharmaceutical product is done in a controlled and consistent manner.

2.0 SCOPE

- 2.1. This document provides a generic procedure to be followed where no customer specific requirements have been provided. If customer specific requirements are provided they automatically supersede this document.
- 2.2. All equipment and processes on the pharmaceutical sections have been formally qualified and validated. All personnel working on the pharmaceutical sections are responsible for ensuring that no changes are made to the process without full change control as defined in SOP/PH001 (Document Number AEU00226).

3.0 TERMS, DEFINITIONS & ABBREVIATIONS

- 3.1. Label Gallery 3 – The computer program used to produce labels.

4.0 HEALTH, SAFETY & ENVIRONMENTAL

- 4.1. GMP (Good Manufacturing Practice) guidelines apply if used on pharmaceutical sections (Document Number AEU00389).
- 4.2. Within the factory area safety footwear is mandatory.
- 4.3. Within the factory area safety glasses must be worn at all times.

5.0 ASSOCIATED DOCUMENTS

- 5.1. Packaging discrepancy form (pharmaceutical use only).
- 5.2. Works Order Instructions: Allowing full traceability for the batch.

6.0 PROCEDURE

- 6.1. **Label Preparation.**

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Figure 1: Examples of label print work station.

6.1.1. **Setting Up Work Area.** Using a label print work station, as shown by the examples in Figure 1:



Figure 2: Identification of button location on the Thermal Printers.

6.1.2. **Installing the Required Label Blanks.** If there are no labels currently installed in the printer or the ones present are not the required type, unlock the print head and remove any labels present, using Figure 1: as a guide, replace with correct type, label side up, then lock the print head down, press the “Feed” then press the “Line” buttons, as shown in Figure 2: Using the printers instructions that are printed on the printers inside flip over lid as shown in Figure 1: as a guide.



Figure 3: Label Gallery 3 Desktop Icon.

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6.1.3. **Opening Computer Program.** Open the Label Gallery 3 program. From the desktop by double clicking the icon shown in Figure 3:



Figure 4: Label Gallery 3 login page.

6.1.4. **Login to Program.** On the login page that appears, as shown in Figure 4: enter the required Username and Password.



Figure 5: The Open Icon.

6.1.5. **Open Template.** Once the program has opened, click the “Open” icon. As shown in Figure 5:



Figure 6: Example of label template selection.

6.1.6. **Selecting Template.** On the Box that appears, click the “Labels Shortcut”, open the folder for the section that manufactured the type of component you are printing labels for, as shown in the example in Figure 6: chose the label type, then click “Open”.

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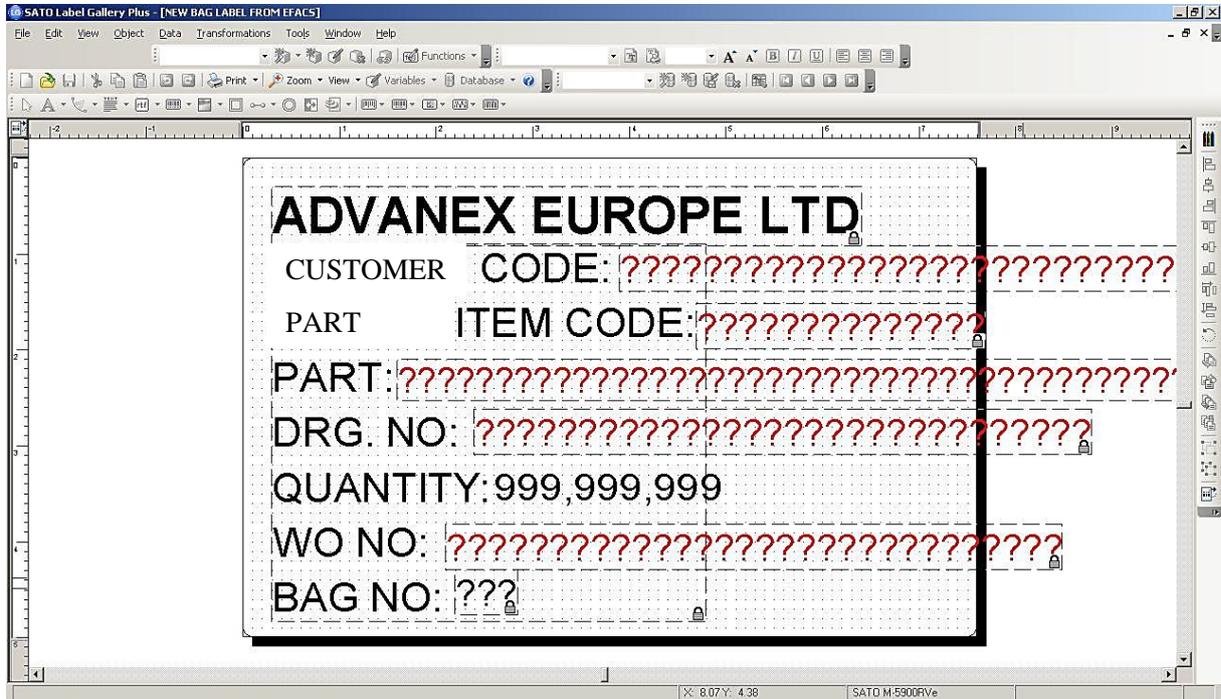
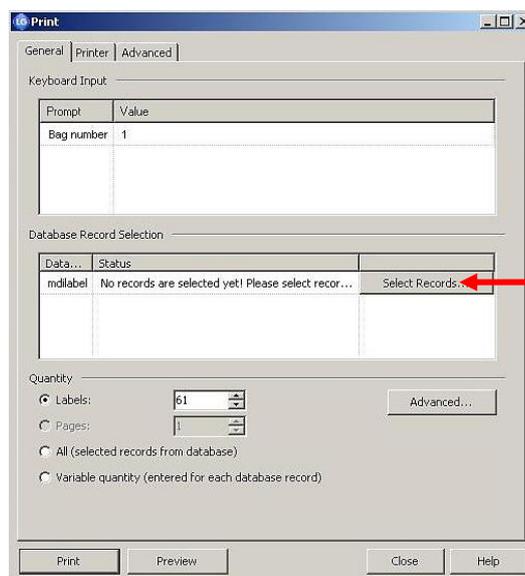


Figure 7: Example of label requiring Work Order Instruction information.

6.1.7. **Verifying Template.** When the label template has loaded, ensure it is correct for the product, if the label is not correct then reload the template as described from step 6.1.6.

6.1.8. **Open Data Entry Box.** If Correct, click the “Print” Icon

6.2. Labels for Bag and Boxes.



Click here to select the Work Order Instruction Number

Figure 8: Print box for the data entry for the labels as used for bag and box labels.

6.2.1. **Print Box.** For bag and box labels click the “Select Records” button on the “Print” box that appears.

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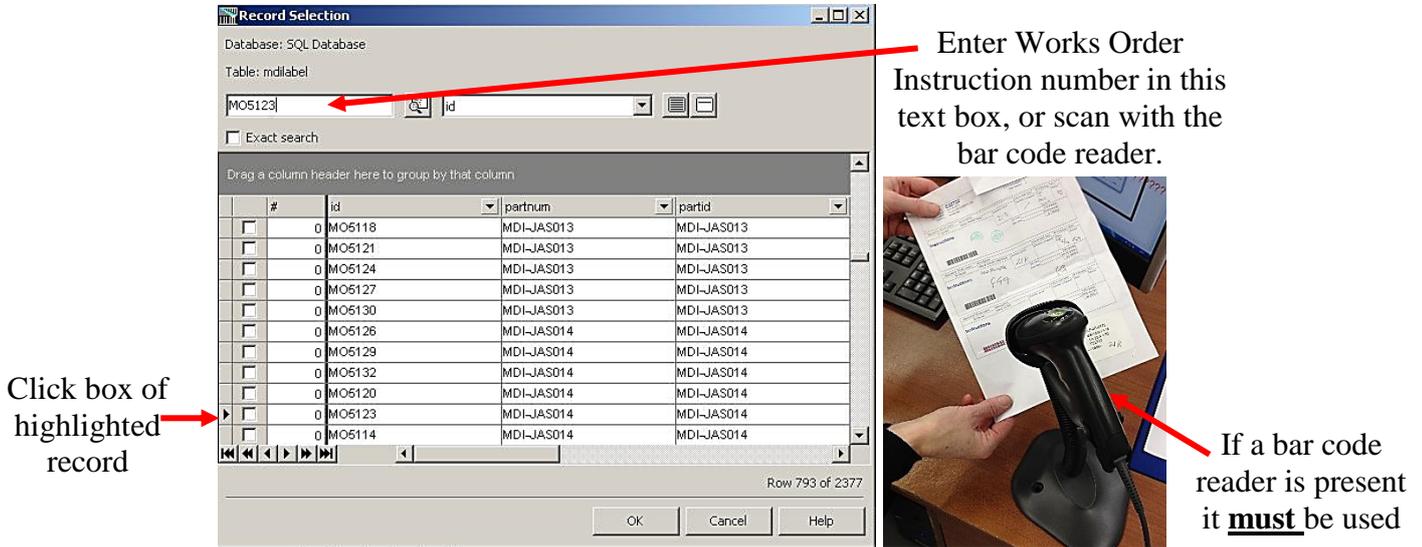


Figure 9: Record Selection box and bar code scanner.

6.2.2. **Selecting Works Order Instruction.** Enter the Works Order Instruction number in the “Record Selection” box that pops up, either by manually typing the number or by use of the bar code scanner, if present, ensuring that, where appropriate, a number ‘0’ (Zero) is not used instead of a letter ‘O’. When the required Work Order Instruction number is highlighted by the black arrow, click the check box then select “OK”, as shown in Figure 9:

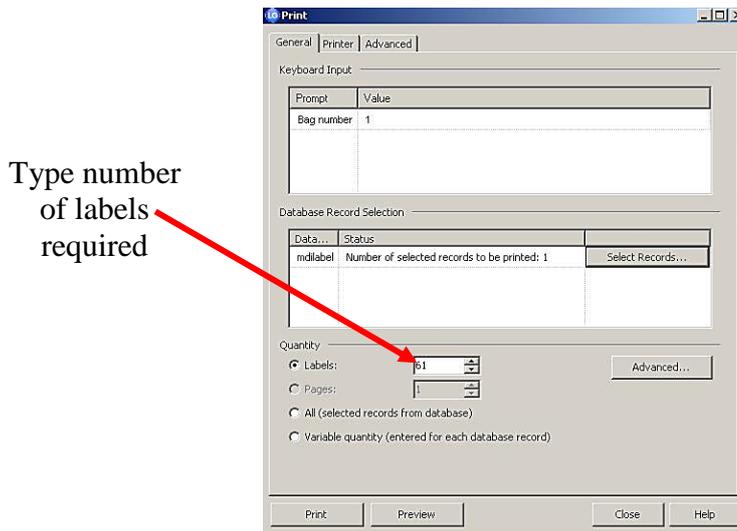


Figure 10: Print box for the data entry for the labels showing the template selected.

6.2.3. **Quantity of Labels.** When the Print Box returns, ensure that the Status box has changed from “No records selected yet! Please select recor...” to “Number of selected records to be printed: 1”, also check that the circle for “Labels:” has been selected and enter the required quantity as detailed on the Works Order Instruction and one additional for verification and reference, as shown in Figure 10: then click “Preview” and ensure that the information shown on the label is as required.

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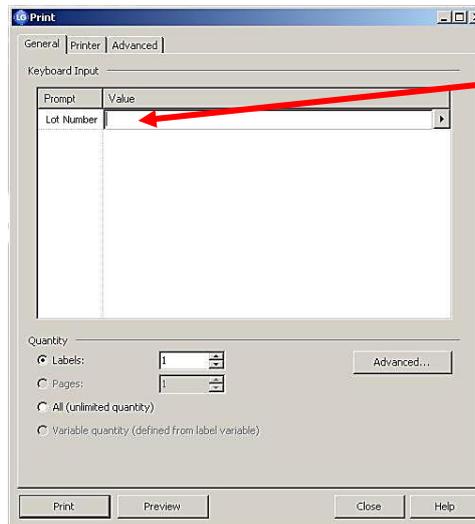


Ensure required number of labels plus one extra is displayed here

Figure 11: Print control.

6.2.4. Print labels. Ensure require number of labels plus one extra is displayed in the print control box, if correct click the “Print” button on the print control in the right hand side corner of the screen, as shown in Figure 11: If not correct, click the “Cancel” button and go back to step 6.2.4.

6.3. Labels for Sample Components.



Enter just the number part of the Works Order number here

Figure 12: Print box for labels for Samples.

6.3.1. Print Box. If sample labels are required follow steps as described up to 6.1.8, when the Print box appears enter the number part of the Works Order Instruction (without the two letter prefix) in the “Lot Number” box, click in the circle for “Labels” and enter the required number, then click “Preview” and ensure that the information shown on the label is as required.

6.3.2. Print labels. Ensure require number of labels plus one extra is displayed in the print control box, if correct click the “Print” button on the print control in the right hand side corner of the screen, as shown in Figure 11: If not correct, click the “Cancel” button and go back to step 6.3.1.

6.4. Labels for Picking Lists.

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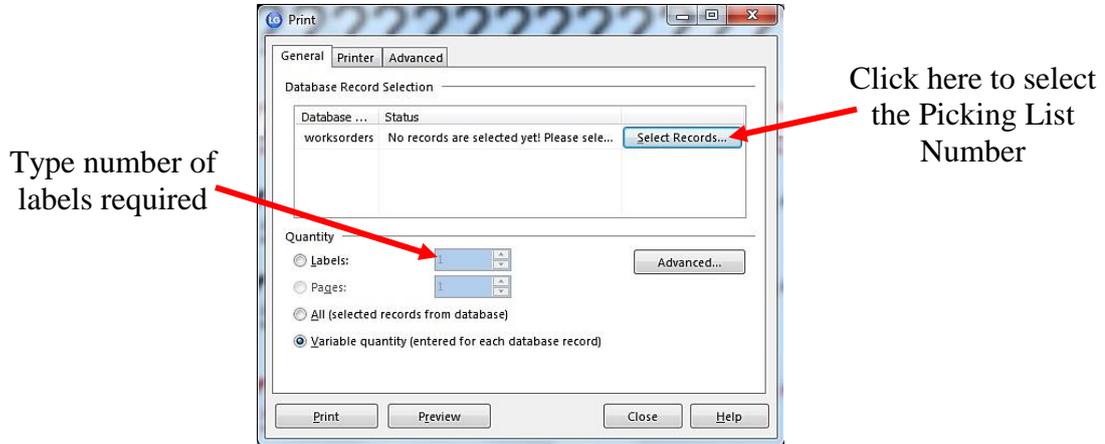


Figure 13: Print box for labels for Picking List Labels.

- 6.4.1. **Print Box.** If labels are required for a Picking List follow steps as described up to 6.1.8, when the Print box appears click the “[Select Records](#)” button.
- 6.4.2. **Selecting Picking Lists Number.** Enter the Picking List number (also called the “Serial number”) in the “Record Selection” box that pops up, ensuring that, were appropriate, a number ‘0’ (Zero) is not used instead of a letter ‘O’ also ensure that all characters of the number are entered including the first letter, and the hyphen (-) with the number that follows it. When the required Picking List number is highlighted by the black arrow, click the check box then select “[OK](#)”, as shown in Figure 9:
- 6.4.3. **Quantity of Labels.** When the Print Box returns, ensure that the Status box has changed from “No records selected yet! Please sele...” to “Number of selected records to be printed:1”, also check that the circle for “Labels:” has been selected and enter the required quantity so as each gusset bag and box have appropriate labels, the picking list to be sent with the components also requires a copy of the label, one further label is required for verification and reference to be kept with the retained copy of the Picking list, then click “[Preview](#)” and ensure that the information shown on the label is as required.
- 6.4.4. **Print labels.** Ensure required number of labels is displayed in the print control box, if correct click the “[Print](#)” button on the print control in the right hand side corner of the screen, as shown in Figure 11: If not correct, click the “[Cancel](#)” button and go back to step 6.4.1

6.5. Task Completion.

- 6.5.1. **Check Labels.** Once labels have been printed and checked, close the template and repeat procedure as required until all required labels have been printed.
- 6.5.2. **Close Print Program.** When all labels have been checked close the Label Gallery 3 program.