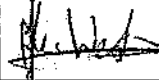

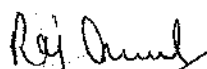


STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_016

SOP Title: Printing labels

Role	Name	Signature	Date
SOP Author	Alex Weston – Principal Pharmacist R&D		02-Mar-2018
SOP Reviewer	Victoria Croome – Clinical Trials Technician		06-Mar-2018
SOP Authoriser	Raj Parekh- Chief Pharmacist		05-APR-2018
SOP Review Date	June 2020	Procedure date stamp:	

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	01-Dec-2012	V.1- Initial Version	14-Nov-2012
2	August 2016	V.2 – Reviewed to ensure still current, make reference to Form 15 and SOP CP/R&D_026	
3	1-June-2018	Reviewed to ensure content still current. Removed requirement for PDF copies of labels to be produced as these do not align correctly in the printer.	05-Apr-2018

STANDARD OPERATING PROCEDURE (SOP)**SOP Number: CP/R&D_016****SOP Title: Printing labels****1. PURPOSE AND CONTEXT**

- 1.1. To ensure that any additional labels used in dispensing clinical trials have been approved for use.

2. DEFINITIONS

- 2.1. Printing labels – process of producing dispensing labels to which further information will be added at the time of dispensing, e.g. date of dispensing, patient's name

3. PROCEDURE and RESPONSIBILITIES

- 3.1. The clinical trials technician or pharmacist will produce the master copy of labels where it has been decided that these are required.
- 3.2. The electronic master copy will be saved on the pharmacy "clinical trials" drive only accessible to pharmacy staff. See SOP CP/R&D_026 for document control procedure.
- 3.3. Any staff involved in the dispensing process should notify pharmacy staff that more labels are needed before the last label has been used.
- 3.4. When labels are first produced, Form 15 (printing labels worksheet) will be completed which will show:
 - Study name
 - Study title
 - EudraCT number
 - Master copy of label
 - Name of person who created labels
 - Name of person checking printed labels
 - Confirmation that labels are suitable for use
 - Signature of person approving labels for use
 - Date labels approved for use
- 3.5. The copies of Form 15 will be stored in the relevant "Pharmacy Documents Control" file.
- 3.6. The printed labels will be stored in the relevant pharmacy working documents folder.
- 3.7. For updating labels, see "Pharmacy Documents Control SOP CP/R&D_026".

	Responsibility	Undertaken by	Activity
1	Chief pharmacist	Clinical Trials Pharmacist	Deciding on the need for additional labels.
2	Clinical trials pharmacist	Clinical trials pharmacist or clinical trials technician	Producing master copies, reviewing master copies and printing labels
3			

4. SUPPORTING MATERIAL and ATTACHMENTS

- Form 15 (Printing labels worksheet)
- SH CP 1 Medicines Control, Administration and Prescribing Policy
- SOP CP/R&D_026 Pharmacy Documents Control

5. TRAINING

- ICH-GCP guidelines

6. REFERENCES

