

Pharmaceutical
Research Centre

STANDARD OPERATING PROCEDURE

4 TRAINING AND COMPETENCE RECORDS

VERSION 1

Pharmaceutical Research Centre
Nottingham Science Park,
Nottingham,
NG1 2AA

WRITTEN BY: *F Spall*
F SPALL

DATE: *25.08.2005*

APPROVED BY: *D McIntyre*
D McINTYRE BSc (Hons) MRQA
HEAD OF QUALITY ASSURANCE

DATE: *02.08.2006*

1 INTRODUCTION

- 1.1 This document describes the format for recording staff training and the process for routine review of staff competence.
- 1.2 Training is the process by which members of staff are taught the house procedures and standards necessary for the conduct of their job. Similar teaching by consultants or agencies is "External Training" and will be documented in individual curricula vitae.
- 1.3 Competence is an individual's ability to perform specified tasks to an acceptable standard, usually following training or external training. Competence may erode with time, thus it is necessary to make regular assessments to assure that trained staff remain competent.

2 RESPONSIBILITIES

All line managers and members of staff must comply with the requirements of this procedure.

3 TRAINING

- 3.1 Each department will establish a standard set of training record forms as illustrated in Appendix 1. The number of forms will depend on the breakdown of trainable activities, but should be consistent for all staff.
- 3.2 Management will employ discretion, on a case-by-case basis, to identify the most appropriate trainer for specific tasks. As each area of training commences for an individual, the 'start date' should be completed and signed by the trainer; similarly, the 'end date' should be entered and signed when training is complete. The trainee will sign it at this stage to indicate that the training has been received.
- 3.3 Any blank start and completion dates represent activities for which the individual is not trained.
- 3.4 Any lines, which contain a start date, but a blank completion date, represent activities for which the individual is currently in training.

(Training may be intermittent, in which case the overall start and completion dates apply).

- 3.5 Note that training is given against the written categories of procedure in the left-hand column: not against specific SOPs. The referenced SOPs are listed simply as a definition of the scope of the addressed procedure.

4 COMPETENCE

- 4.1 The successful completion of a training period, which may be a subjective assessment by supervisory staff or demonstrated by satisfactory completion of a "test", confers initial competence, but this must be re-assessed annually. The reassessment may again be subjective or objective.
- 4.2 The reassessment for activities objective and subjective will be covered in a reassessment of general competence sheet bound into the front of the Training Record. It will show the occasion on which competence in all trained activities was re-assessed and the assessor (Appendix 2).
- 4.3 It is anticipated that competence re-assessment will take place in the presence of the individual, and may be linked to performance appraisal.

5 COMPILATION OF TRAINING RECORDS

- 5.1 Each individual's record will be compiled as follows:

Title page

Reassessment of general competence sheet

Principles of the required regulatory standards

General procedures

6 PRIOR TRAINING

It is also accepted that some aspects of received training will not have been recorded under previous systems, but that re-training is not appropriate simply to complete the record. This is particularly the case with long-established staff. In this situation, management may exercise discretion in the declaration of competence in the absence of a record of dates of training, but it is recommended that management support such declarations by a short explanatory statement in lieu of a specific record of training.

7 ARCHIVE

The training and competence records should be archived once the individual leaves the company, in line with the company's records retention schedule.

APPENDIX 1 TRAINING RECORD

NAME:						
POSITION:						
PROCEDURE	TRAINING START DATE	SUPERVISED BY	TRAINING COMPLETION DATE	SUPERVISED BY	TRAINEE ACCEPTANCE	REFERENCE SOP NUMBER

APPENDIX 2

REASSESSMENT OF GENERAL COMPETENCE

The training and competence records for the named person above have been reviewed on the dates given. Any areas in which competence has lapsed or retraining required has been indicated in the records, otherwise the named person is confirmed as competent in all areas in which they are currently recorded as trained.

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