

Standard Operating Procedure

Title: Production Logbooks

4.	Register Logbook	2
5.	Communication Logbook	3
6.	MI Sheet Logbook	3
7.	Summary of Changes	3

Procedure

1. Background

Production Logbooks are used for a variety of reasons throughout the production area to aid with the recording of information relevant to machine operation or batch records.

Logbooks required are determined by [GMP requirements](#) for the traceability of data, events, and communications.

a) Each area must have:

Register Logbook recording, in sequence, all production batches processed in the area. The logbook is to be ruled up according to the template set out in point 4.

b) Finishing Line logbook.

These logbooks are an important source of information and must be retained for future reference.

The Team is responsible for the generation and proper maintenance of the logbook.

2. Filing

When a logbook has been filled, the Team should ensure that the logbooks are sent to the Quality assurance Department for logging in the Documentation Database as a quality file (refer [SOP QMS-015](#)).

Production logbooks are retained for a minimum of 15 years in the Technical File system. (See [SOP QMS-010](#))

3. Issuing and Labelling New Logbooks

The Team should issue the next logbook for the particular area through as consumable inventory.

The logbook must be labelled on the front cover with the following information:

- Team
- Line name
- Title of the logbook (i.e. Register, Communications)
- Year
- Date issued

All pages in the logbook are numbered sequentially.

No pages are to be removed from logbooks.

Correction to a logbook should follow the requirements of GMP and [SOP QMS-020](#).

4. Register Logbook

The Register Logbook is always to be ruled up according to the following format: Other columns may be added e.g. [Line Clearance](#), Line Opening.