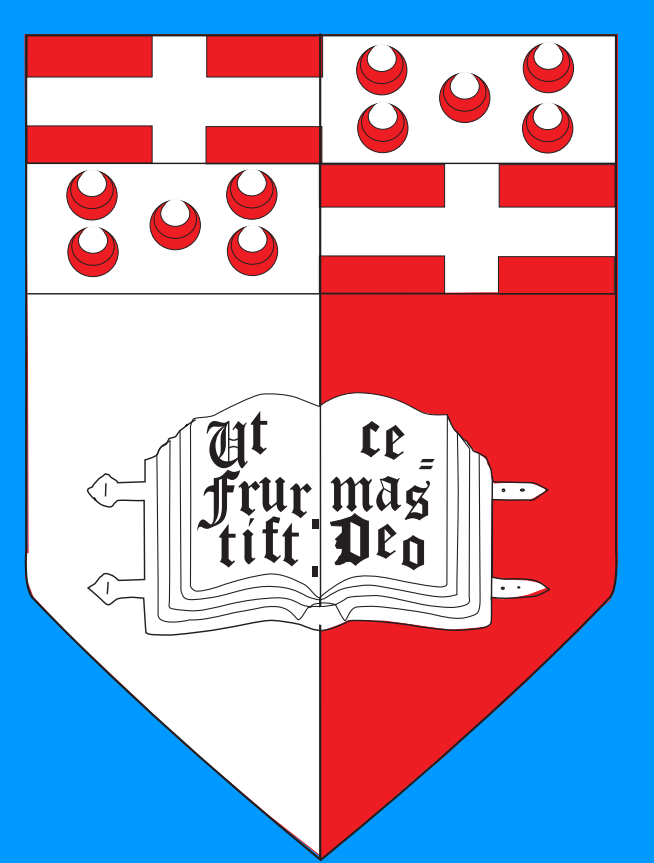


# Developing GMP systems for partial manufacturing of pharmaceuticals

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## Introduction

Partial manufacturing refers to the repackaging and re-labelling of medicinal products. This may be required when medicinal products are imported from outside the European Union<sup>1</sup> or brought into a country through parallel importation<sup>2</sup>, and must be carried out within the context of a quality system<sup>3, 4</sup>.

## Objective

To develop a template of the quality systems utilised in partial manufacturing plants in order to facilitate the application of Good Manufacturing Practice (GMP) in such facilities.

## Method

Data collection was carried out in two local facilities, through:

- semi-structured interviews
- participant observation
- non-participant observation

A list of Standard Operating Procedures (SOPs) was developed based on the sections of the 'EU Guide to Good Manufacturing Practice'<sup>5</sup> applicable to partial manufacturing.

Plan for Results: Identify the SOP aim and title

Collect Data: European guidelines and data collected during research

Define Purpose: The performance the procedure covers

Define Scope: The SOP applicability and limitations

Write SOP: Place the data in short, imperative steps

Review SOP: Ensure the SOP is complete and can be performed in the steps it is written

Define Responsibilities and Training: Define individuals responsible for proper implementation; personnel requiring training and individuals responsible for training them

Record Sheets: Add templates of the respective record sheets in the appendix

Definitions: Define terms, acronyms and abbreviations used frequently within the SOP

*The method followed in writing the procedures*

The resulting quality system template was validated through a gap analysis with the 'EU Guide to Good Manufacturing Practice'<sup>5</sup> and through expert review by five professionals.

## Results

The quality system template developed is made up of 27 Standard Operating Procedures.

SOP for SOPs  
Cleaning and Maintenance  
Personnel Hygiene  
Temperature Control  
Pest Control  
Goods Inwards  
Labels and PILs  
Assembly Procedure  
Process Flow  
Batch Documentation  
Quality Control  
Deviations  
Batch Release  
Training of Personnel  
Self Inspections and Suppliers' Audits  
Handling Complaints  
Product Recalls  
Returns  
Rework Procedure  
Corrective and Preventive Action  
Annual Product Review  
Change Control SOP  
Handling of Rejects and Expired Materials  
Handling Work in Progress  
Maintenance of Equipment and Utilities  
Quality Risk Management  
Process Validation and Re-validation

*Final list of standard operating procedures developed for the quality system template*

Each procedure contains the GMP principles associated with the respective topic and specific steps, including different recommendations, for applying each corresponding principle to partial manufacturing. In the validation phase of the study, the reviewers established that the template:

- > is a robust tool which provides a basis on which partial manufacturers can design a quality system specific to their needs.
- > is comprehensive with respect to the GMP components included, each topic being well described.

## Conclusion

The template facilitates the application of GMP principles in partial manufacturing plants by serving as a starting point and comprehensive guide for the quality systems in such facilities.

## References

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