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[1] or brought into a country through parallel importation[2], and must be carried out within the context of a quality system[3, 4].

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'[5] applicable to partial manufacturing.

Plan for Results: Identify the SOP aim and title

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Collect Data: European guidelines and data collected during research

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Define Purpose: The performance the procedure covers

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Define Scope: The SOP applicability and limitations

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Write SOP: Place the data in short, imperative steps

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

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

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

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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'[5] 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 priciple 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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