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Compliance in Quality Control Reviewing Processes of Finished Products

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INTRODUCTION

- Quality Control (QC) documentation must be reliable and accurate to make sound batch release decisions.[1]
- It must be independently reviewed in a standardised manner to ensure reliable, quality-based decisions.[2]

AIM

- To develop a tool as a checklist to assist in mitigating and reducing errors that may occur during the QC documentation reviewing process of chemical analysis of finished drug products which may impact quality, patient safety or regulatory compliance.

METHOD

Phase I – Critical Evaluation of Literature

- Literature and legislation from Good Documentation Practices, data integrity and dossier perspectives

Phase II – Risk Assessments

- Ishikawa Diagrams and Failure Mode and Effects Analysis
- Reviewing processes for assay, content uniformity, related substances, dissolution by UV or HPLC, and residual solvents and mass spectroscopy by GC

Phase III – Development of Quality Control Reviewing Tool

- Development and validation of a compliance tool in the form of a checklist
- Quality Control Reviewing Tool was validated by a focus group discussion consisting of a group of five experts using convenience sampling

RESULTS

- A gap related to documentation reviewing and compliance checks of QC documentation of finished products was observed in literature.
- A general process flow for reviewing documentation of the analysis of finished product testing was outlined (Figure 1).
- The highest risks identified were related to human omission and commission failures such as regulatory compliance issues and transcription errors.
- The developed tool consists of four sections including process steps involved, documentation of checks, required actions and verification of actions taken.
- The tool assists QC reviewers in preventing identified failures such as omitting compliance and data integrity checks during the QC documentation reviewing process.

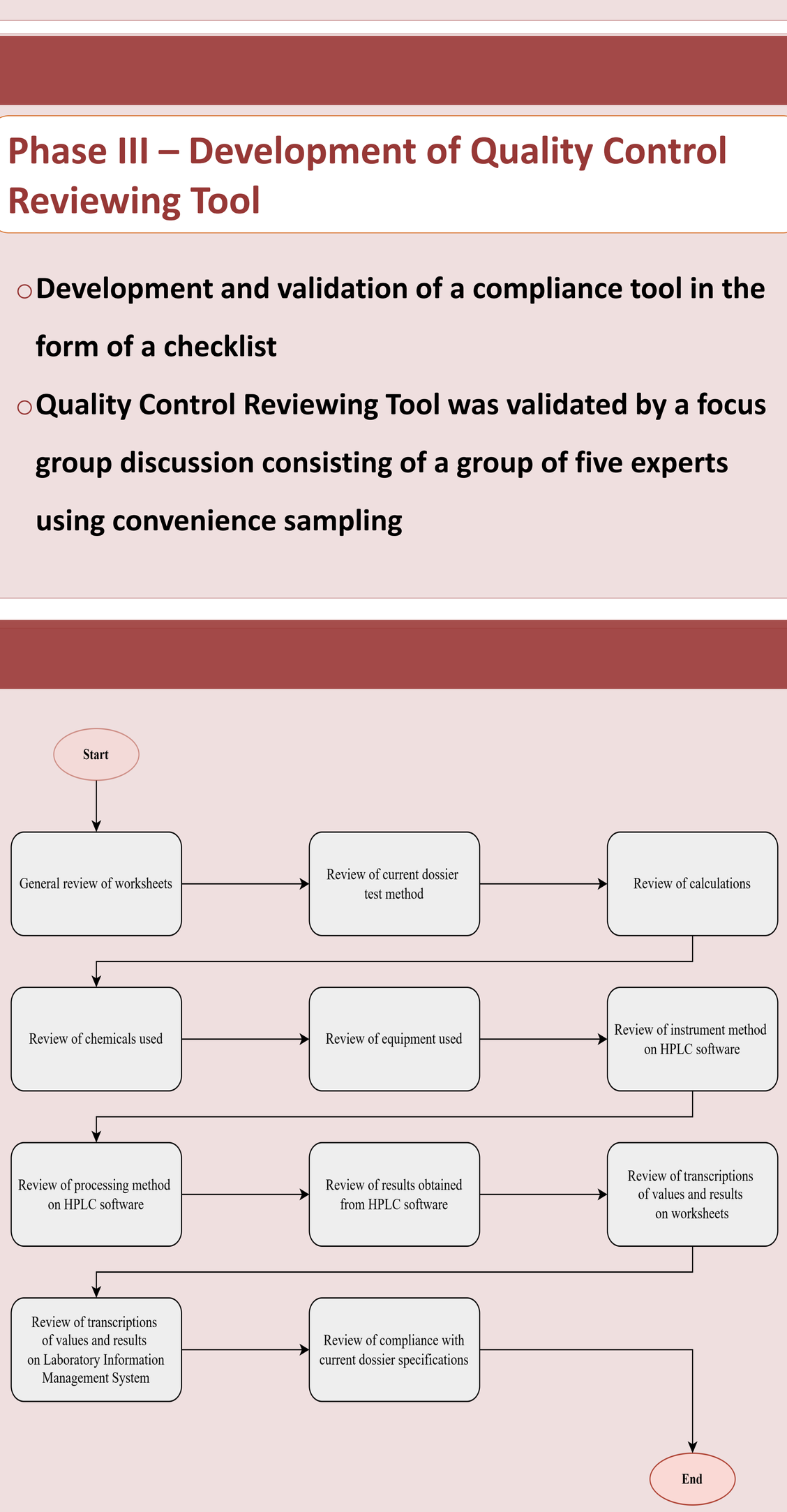

Figure 1: Process Flow for Reviewing QC Documentation

CONCLUSION

The QCR-Tool addresses the gap identified in the study and reduced risk priority numbers of failure modes related to human omission or commission errors. The QCR-Tool is adaptable yet standardises the QC documentation reviewing process and provides a means of documenting the process and actions taken.

REFERENCES

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