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Title: SOP – Packaging Execution for Clinical Trial Supplies
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1. Objective

To standardize the packaging process for clinical trial supplies using a web-based tool, ensuring accuracy, traceability and compliance with operational procedures.

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2. Scope

Applies to all packaging technicians, supervisors and QA personnel involved in primary and secondary packaging activities in cleanroom environments for clinical trial kits.

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3. Responsibilities

- Operators must scan and register correct equipment, perform packaging and log output accurately.
- Supervisors (IPC) must validate shortfalls, approve deviations and oversee completion.

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4. Procedure

1. Operator logs in using scan code and password.
2. Job is allocated and assigned from approved job list.
3. Room is assigned based on cleanroom mapping.
4. Equipment (label printer, workstation, etc.) is scanned and validated.
5. SOP documents are reviewed as reference.
6. Checklist items are completed prior to packaging.
7. Packaging is performed using barcode scanner.
8. Progress is tracked; order quantity is matched.
9. Reconciliation is done:
    - If 100%, job is marked complete.
    - If <100%, deviation is logged and IPC must approve.

10. Final confirmation and job closure.

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5. **Documentation**

- All actions are logged in browser storage.
- SOPs are available for download under /docs/.

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6. **References**

- Job.json, Equipment.json, Checklist.json
- Regulatory packaging guidelines (ICH GCP)

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7. **Contributor**

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