Functional Specification Document

Document ID: DOC^EX^FS-10255
Title: Functional Specification – Packaging Execution Application
Prepared by: Avirup Saha
Approved Date: June 14, 2025

---

1. Introduction

This application supports end-to-end digital execution of clinical trial packaging activities. This document specifies the expected behaviors, features and validations required to ensure compliance with operational standards.

---

2. Key Functional Modules

Module	Description
Operator	Validates operators using scan code and password. Prevents multiple user sessions.
Job Allocation	Allows job selection and allocation. Saves printer type for validation.
Room Allocation	Assigns cleanroom where packaging will occur.
Equipment	Validates presence of required devices. Printer type must match job specification.
Checklists	Pre-requisite validations before packaging. Must confirm "Yes" for all.
Manage SU (Open SU/Label SU/ Close SU)	Open/ Label SU to start with labelling and require to close SU that are opened before labelling after the labelling activity.
Packaging	Matches scanned barcodes to expected order qty. Tracks visual progress.
Reconciliation	Validates actual packaging output. Requires IPC login for shortfall.
SOP	Lists downloadable SOP documents.
Credits View	Acknowledges contributors.
Refresh	It will refresh the ongoing session

Module	Description
Restart Application	It restarts the application refreshing the session.
Shutdown	It will close the application
End Job	It releases the Room, Job and equipment after completion of packaging and labeling

---

3. Workflow Summary

- Operator logs in
- Job is selected and validated
- Room is assigned
- Equipment is scanned
- Checklist is filled
- Packaging begins
- Reconciliation is performed
- Job is closed

Flow: Operator → SOP(If required)→ Job Allocation → Room Allocation → Clean Room(If required) → Equipment → Checklists→ Manage SU → Label SU → Open SU → Packaging → Close SU → Reconciliation → End Job → Shutdown/ Restart Application

---

4. Validations

- Printer mismatch → Error
- Checklist incomplete → Packaging blocked
- Reconciliation < 100% → IPC login + reason mandatory

Data Sources and Storage

- JSON-Based Static Files stored in /DB_records/:
    - o Operator.json
    - o Job.json
    - o Room.json
    - o Equipment.json
    - o Checklists.json
- LocalStorage:
    - o Persists active session information (e.g., logged operator, allocated job, scanned equipment).

---

5. User Roles

Role	Access
Operator	Responsible for executing assigned jobs and following all checklist and packaging steps.
IPC/Supervisor	Validates reconciliation shortfalls and signs off on deviations.
Administrator	(Future scope) – Role-based access and audit capabilities.

6. Key Functional Validations

Condition	Expected Behavior
Printer Type mismatch	Registration blocked with a descriptive error.
Checklist not fully marked "Yes"	Confirmation button disabled. Packaging cannot proceed.
Reconciliation < 100%	Requires IPC login and deviation reason.
Duplicate login attempt	Shows alert and blocks second login.
Attempting packaging without equipment or checklist	Shows error; does not allow progress.

7. Navigation Flow

1. Operator logs in
2. Allocates a job
3. Allocates a room
4. Registers equipment
5. Completes checklist
6. Performs packaging
7. Conducts reconciliation
8. Ends session

8. Success Criteria

- ☑ 100% checklist compliance before packaging

- ☑ Accurate scanning and tracking of packaging quantities
- ☑ Successful printer type validation
- ☑ Proper deviation logging and approval for reconciliation mismatches
- ☑ All activities traceable via local state

---

9. Assumptions

- Operator JSON credentials are correct and pre-loaded.
- The application is used on supported devices (desktop/tablet).
- All modules are accessed in the prescribed order.

---

10. Limitations

- No server-side persistence — browser storage only.
- Cannot handle concurrent multi-user access.
- JSON mock DB (no actual API).

---

11. Future Enhancements

- Role-based authentication (Admin, IPC, Operator).
- API-based database CRUD operations.
- Reconciliation audit logging and PDF reports.
- Offline mode with local sync support.

---

12. Contributors

- **Avirup Saha** – Lead Developer, Architect & UX Refinement