Product Requirements Document (PRD)

Product: Regulatory Submission Checklist App

1. Executive Summary

The Regulatory Submission Checklist App is a lightweight, web-based tool designed to help pharmaceutical regulatory teams streamline the preparation and tracking of submission requirements (e.g., new product registrations, renewals, and variations). The app centralizes regulatory checklists, provides progress tracking, and enables exportable reports for compliance documentation. By digitizing and standardizing checklists, the tool reduces manual errors, ensures completeness of submissions, and improves team efficiency.

2. Background & Context

Problem Framing: Regulatory submissions require strict documentation. Current methods rely on spreadsheets, emails, or manual trackers, leading to incomplete submissions and delays.

Current Solutions & Gaps: Manual checklists are not standardized, large suites are too complex and costly. Gap: A simple, accessible tool tailored for pharma regulatory teams.

3. User Personas & Needs

Persona 1: Regulatory Affairs Officer – needs quick way to check documents, ensure completeness, and track timelines.
Persona 2: Regulatory Affairs Manager – needs visibility into team progress, timelines, and standardized checklists.
Persona 3: Pharma Executive – needs timely approvals and cost-effective compliance tools.

4. Product Scope

In-Scope:
- Dropdown for submission type (New Registration, Renewal, Variation)
- Input field for Drug Name
- Start date and End date fields per submission
- Checklist progress tracked per drug
- Each item can be marked as Backlog, In Progress, or Completed
- Progress tracker (% bar per drug)
- Export checklist to Excel/PDF with drug, submission type, dates, and status
- Add custom requirements

Out-of-Scope (Phase 1): Multi-user accounts, regulator system integration, advanced analytics.

5. Detailed Requirements

User Stories:
1. Select submission type and view checklist.
2. Enter a drug name with start and end dates to plan submissions.
3. Move checklist items between Backlog → In Progress → Completed.
4. Export checklist per drug with full details.

5. Add custom checklist items.

Acceptance Criteria: Dropdown displays correct checklist, dates required, export includes all details, progress bar updates only with Completed items.

6. Competitive Landscape

Excel/Word: familiar but error-prone.
Veeva Vault: comprehensive but expensive and complex.
Local trackers: customizable but not digital/cloud-ready.

Differentiator: simple, pharma-specific, affordable.

7. UX & Design Notes

UI elements:
- Input fields for Drug Name, Start Date, End Date
- Checklist displayed per drug in labeled card
- Three columns (Kanban-style): Backlog, In Progress, Completed
- Drag-and-drop or dropdown status updates
- Progress bar reflects only Completed items

8. Technical Considerations

Tech Stack: Python + Streamlit + Pandas.
Data: JSON/CSV file for checklists.
Deployment: Streamlit Cloud.
Dependencies: streamlit, pandas, openpyxl, reportlab.

9. KPIs & Success Metrics

- % of submissions completed within planned dates
- % of checklist items completed by deadlines
- Number of overdue submissions flagged
- User adoption of task status workflow
- Overall user satisfaction feedback

10. Risks & Mitigations

Risks:
- App too simple for large companies → Roadmap includes advanced features
- Regulatory requirements change → Easy updating of checklist data
- Adoption resistance → Simple UI and training docs

11. Timeline / Roadmap

Phase 1 (Month 1–2): Core app with drug-level tracking, dates, status workflow, export
Phase 2 (Month 3–4): Multi-drug dashboard view with filters by date/status
Phase 3: Multi-user support, reminders/alerts, regulatory integrations

12. Open Questions

- Should MVP support multiple authorities (EMA, FDA) or only PPB?
- Multi-language support needed?
- Should exports follow regulator templates or generic?