Pilot Trial Data Capture Checklist

For Fermentation & Bioindustrial Scale-Up

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1. Pre-Pilot Context (Complete Before the Run)

Objectives

- ☐ Primary objective of this run:
- ☐ Secondary objectives:
- ☐ Key decisions this pilot should inform (check all that apply):
  - ☐ Scale selection
  - ☐ Cost per kg
  - ☐ DSP route

Process Snapshot (As Planned)

- ☐ Planned batch size or throughput:
- ☐ Target yield / titer / conversion:
- ☐ Planned run duration:
- ☐ Key operating parameters (T, pH, DO, etc.):

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2. Equipment Documentation (Setup / Day 0)

Equipment Inventory (Actual Equipment Used)

For each major unit operation:

- ☐ Unit operation:
- ☐ Equipment type:
- ☐ Manufacturer / model (if visible):
- ☐ Nominal size:
- ☐ Working volume:
- ☐ Material of construction:
- ☐ Any visible constraints or modifications:

Photos Taken (Check All That Apply)

- ☐ Fermenter/reactor nameplate
- ☐ Agitation system
- ☐ Sensors/probes
- ☐ DSP equipment
- ☐ CIP/SIP setup
- ☐ Material handling steps
- ☐ Process materials (liquids & solids) before and after each major step

☐ Broth / reaction mixture
☐ Clarified streams
☐ Solids, cakes, pellets, or residues

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3. Raw Materials & Inputs (During the Run)

Feedstocks / Media

- ☐ Actual recipe used:
- ☐ Supplier(s):
- ☐ Lot numbers (if available):
- ☐ Deviations from planned recipe:
- ☐ Notes:

Consumables Used

- ☐ Filters
- ☐ Resins
- ☐ Membranes
- ☐ Chemicals
- ☐ Single-use items
- ☐ Unexpected consumables

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4. Operating Data Log (During the Run)

Time-Based Events

- ☐ Start time:
- ☐ End time:
- ☐ Phase changes (timestamps):
- ☐ Pauses / holds / delays:

Operating Conditions (Actual)

- ☐ Temperature range:
- ☐ pH range:
- ☐ DO range:
- ☐ Agitation speed(s):
- ☐ Aeration / gas flow:
- ☐ Pressure (if applicable):

Deviations & Interventions

- ☐ Any deviation from plan occurred?
- ☐ What happened:
- ☐ When:
- ☐ Action taken:

5. Performance & Output Data (End of Run)

Results

- ☐ Yield / titer / conversion:
- ☐ Measurement method:
- ☐ Confidence level:
  - ☐ High
  - ☐ Medium
  - ☐ Low

Throughput & Timing

- ☐ Actual cycle time:
- ☐ Bottlenecks observed:
- ☐ Manual steps required:

Losses

- ☐ Material losses observed?
- ☐ Where losses occurred:
- ☐ Estimated quantity lost:
- ☐ Likely cause:

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6. Downstream Processing (If Applicable)

- ☐ DSP steps used (list):
- ☐ Recovery yield per step (if known):
- ☐ Volumes handled:
- ☐ Fouling or filtration issues:
- ☐ Cleaning frequency required:
- ☐ Resin/membrane performance notes:

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7. Scale-Up & Cost Flags (Critical for TEA)

Scale Sensitivity

- ☐ Steps likely to scale poorly:
- ☐ Mixing concerns:
- ☐ Heat/mass transfer concerns:
- ☐ Manual operations that won't scale:

Hidden Cost Drivers Observed

- ☐ High labor intensity
- ☐ High consumable usage
- ☐ Long cleaning times
- ☐ Equipment changeovers
- ☐ Utility intensity

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8. Visual Evidence & Operator Insights

- ☐ Photos taken
- ☐ Sketches made
- ☐ Whiteboard notes captured
- ☐ Informal operator comments recorded

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9. Immediate Post-Pilot Reflection (Same or Next Day)

- ☐ Biggest surprise:
- ☐ Assumptions proven wrong:
- ☐ Data you wish you had captured better:
- ☐ One thing to change in the next run:

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10. Handover to TEA / Scale-Up Team

- ☐ Data ready for TEA:
- ☐ Key gaps remaining:
- ☐ Validations needed next:
- ☐ Confidence in current cost assumptions:
  - ☐ High
  - ☐ Medium
  - ☐ Low

Purpose of this checklist
This document is intended to support real-time data capture during pilot trials to inform techno-economic analysis and scale-up decision-making. It complements — but does not replace — formal pilot reports, SOPs, or regulatory documentation.

Developed from real-world scale-up experience and aligned with the **ScaleUpReady™** approach to manufacturing and techno-economic readiness.