**1. Introduction**

**Data to include:**

* Project context (e.g., study goal, product candidate, stage of development).
* Purpose of the report (e.g., process development, technology transfer, scale-up).
* Any key questions or hypotheses guiding the study.

**Note:** You might frame hypotheses explicitly or describe more general objectives.

**2. Summary / Overview**

**Data to include:**

* A concise high-level description of the process.
* Process flow diagram (either an image reference or step list).
* Summary of critical unit operations (thaw, seed train, production, harvest, purification).

**Note:** Pull this from either textual descriptions in Notebook entries or structured metadata of operations.

**3. Materials and Methods**

**Data to include:**

* Media compositions or identifiers (lot numbers, supplier, custom formulations).
* Cell bank source and expansion protocols.
* Equipment details (bioreactors, flasks, filtration skids).
* Operating conditions (e.g., pH setpoints, DO, temperature, agitation).
* Sampling and monitoring plans.

**Note:** Media might be described with detailed recipes or only by general type or name if off the shelf or in-house, standardized “platform” media.

**4. Process Description**

**Data to include:**

* **Cell Bank Thaw:** parameters, media, monitoring.
* **Seed Train:** shake flask and bioreactor expansions, setpoints, additions, and monitoring strategy.
* **Production Bioreactor Operations:** parameters, control strategies, additions (feeds, supplements), and sampling.
* **Harvest and Downstream Preparation:** harvest conditions, clarification, viral inactivation, chromatography steps, filtration, UF/DF, and solution prep.

**Note:** Not all studies perform downstream steps – omit or note if no data is provided or can be found.

**5. Results and Discussion**

**Data to include:**

* Viability, growth, and productivity results (raw data, averages, comparisons).
* Analytical results (e.g., metabolite concentrations, product titer, yield).
* Comparisons across runs (development vs. transfer, control vs. test).
* Multivariate analysis or design space exploration if available.
* Observed deviations, trends, or anomalies.

**Note:** May only have include basic viability and titer data; might also include detailed omics or other analytical assay data.

**6. Bill of Materials**

**Data to include:**

* Complete list of raw materials used upstream (media, feeds, supplements).
* List of materials used downstream (resins, buffers, filters, excipients).
* Quantities, suppliers, catalog numbers if available.

**Note:** For early-phase studies, this may be sparse; for later stage or GxP tech transfers, it will be detailed.

**7. Conclusion**

**Data to include:**

* Key findings (e.g., best-performing conditions, achieved titers).
* Recommendations for next steps (e.g., scale-up, optimization).
* Any transfer-ready process parameters.

**Note:** Phrase conclusions relative to the data available (e.g., emphasize feasibility vs. robustness depending on maturity).

**8. References**

**Data to include:**

* Literature cited.
* Internal SOPs or protocols referenced.

**Note:** May or may not be provided. Omit or leave unfilled if not found.

**9. Appendix**

**Data to include:**

* Abbreviation list.
* Media derivations or recipes (if shared).
* Tables of run conditions.
* Supporting data/figures not in the main text.

**Principles for filling out this template:**

1. **Flexibility:** Sections should be filled only if data is available; otherwise, omitted or left as placeholders.
2. **Standardization:** Encourage consistent formatting (tables for setpoints, graphs for growth curves, structured lists for materials).
3. **Traceability:** Preserve source identifiers (lot numbers, run IDs, SOP references) where available.