CDMO PLAYBOOK SERIES

CLIENT ORDER TO RELEASE

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1. ORDER TO RELEASE OVERVIEW

The Order to Release process for a Contract Development and Manufacturing Organization (CDMO) encompasses several critical stages from initial proposal to the final shipment and invoicing. Here's an overview of each step involved.

Proposal

The proposal preparation process is a structured approach to crafting compelling proposals that meet client needs while optimizing internal efficiencies. Additionally, this approach to proposal development ensures a thorough understanding of the customer's needs, efficient use of internal resources, and the creation of high-quality proposals that meet customer expectations. By following these steps, organizations can improve their proposal success rates and foster stronger client relationships.

Demand Planning

Demand planning is a strategic process used by businesses to forecast future customer demand and ensure that products are available to meet that demand. It involves the collection and analysis of historical sales data, market trends, and other relevant information to predict future sales. By accurately forecasting demand, companies can optimize their inventory levels, reduce the risk of stockouts or overstock situations, and improve customer satisfaction.

The demand planning process typically includes several key steps: data gathering, analysis, demand forecasting, and collaborative planning. Data gathering involves collecting relevant data from various sources, such as sales history, market research, and economic indicators. Statistical analysis is then used to identify patterns and trends within the data. Demand forecasting involves generating predictions based on the analyzed data, while collaborative planning involves working with different departments, such as sales, marketing, and supply chain, to align on the forecast and develop strategies to meet projected demand. This holistic approach helps businesses to be more proactive and responsive to market changes, ultimately enhancing their operational efficiency and competitiveness.

Supply Planning

Supply planning is a crucial component of supply chain management that focuses on ensuring that a company has materials, documentation, facilities, equipment, and resources available to meet customer demand. This process involves the coordination of various activities, including technical transfer, process development, analytical development, documentation development, materials management, production scheduling, procurement planning, and distribution logistics into an integrated Program Plan. By effectively managing these elements, supply planning helps to balance supply with demand, minimize costs, and optimize the use of resources.

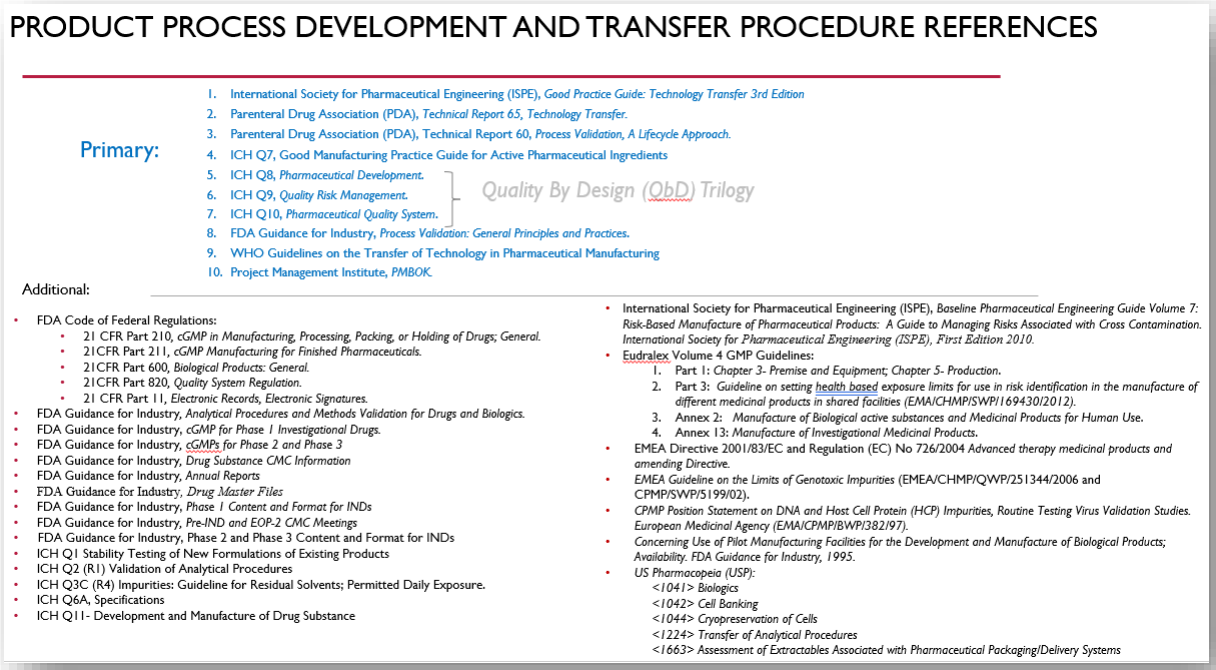
The supply planning process typically begins with demand forecast output, which provide an estimate of the future customer needs. These forecasts are then used to create supply plans that outline the quantity and timing of production and procurement activities. Supply planning also involves identifying and addressing potential constraints, such as production capacity, lead times, and supplier reliability. By continuously monitoring and adjusting the supply plan, companies can respond more effectively to changes in market conditions, reduce the risk of stockouts or excess inventory, and improve overall operational efficiency.

Technical Transfer + Process & Analytical Development

The Technical Transfer and Process/Analytical Development phase is a foundational component in establishing manufacturing readiness. This phase draws on critical inputs such as the Tech Transfer Process SOP, Quality Target Product Profile (QTPP), and deliverables from both process and analytical development. Standardized MPR templates and a clear understanding of material inventory position enable structured knowledge transfer and seamless progression through development stages. Through coordinated efforts between technical, analytical, and operational teams, process understanding and control strategies are established to ensure product consistency, compliance, and scalability.

Activities span from technical transfer and initial process characterization to full development and scale up. This results in the development of Master Production Records (MPR), culminating in the release of finalized bills of materials (BOM), facility and equipment readiness, and operator training. Outputs also include finalized process and analytical documentation (Process Control Strategy, Aseptic Processing Strategy, Process Flow Diagrams, pFMEA), released material specifications, and trained staff prepared to support GMP operations. This phase is reviewed regularly through weekly readiness and finance reviews, core team meetings, and steering committee oversight. Metrics mirror those of the supply plan, focusing on schedule adherence, risk mitigation effectiveness, and client satisfaction to ensure a robust and timely launch into manufacturing.

- **Technical Transfer**: process of transferring the manufacturing process and analytical methods from one site to another, ensuring consistency and compliance with regulatory standards. This involves detailed documentation, validation, and collaboration between the sending and receiving units to ensure a smooth transition and maintain product quality. Technical Transfer is governed by many different Regulatory regulations and industry guidance (eg. ISPE, PDA) with emphasis on Quality by Design. Reference below table for reference summary.



- **Process Development:** Refining and optimizing the production processes to meet customer specifications. This includes scale-up from laboratory to production scale.
- **Analytical Development:** Developing and validating analytical methods to ensure product quality and compliance with regulatory standards.
- **Materials Management:** Sourcing and procuring raw materials, reagents, and other necessary components.
- **Documentation:** Preparation and management of all necessary documentation, including SOPs, batch records, product + process characterization, risk assessments, and regulatory filings.
- **Facilities and Equipment:** Ensuring that the facilities and equipment are ready for production, including any necessary maintenance, calibration, or upgrades.
- **Resourcing:** Allocation of human resources, including training and assignment of production, quality, and support staff.

SEE Technical Transfer Guidance Document + Training Slide Deck for additional details

Manufacturing

The manufacturing process involves Production Execution, where the product is manufactured according to specified processes and standards; Quality Control, which includes ongoing monitoring and testing to maintain product quality and regulatory compliance; and Batch Records, which are comprehensive logs of each production batch ensuring traceability and adherence to compliance requirements.

Release

The release process in pharma manufacturing involves the final MPR review, quality release testing, quality event closure (eg. Deviations) and approval of the product by the quality assurance team ensuring that the product meets all regulatory standards and securing necessary certifications. Once these steps are completed, the Product Release phase officially authorizes the product for shipment to the customer.

- **Manufacturing:** Final MPR review and quality event closure
- **Quality Assurance:** Final review and approval of the product by the quality assurance team.
- **Regulatory Compliance:** Ensuring that the product meets all regulatory requirements and obtaining necessary certifications or approvals.
- **Product Release:** Official release of the product for shipment to the customer.

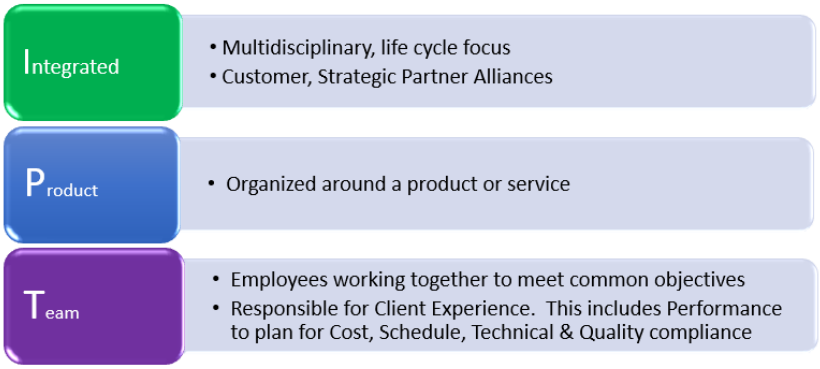
Shipment + Invoice

- **Logistics Planning:** Coordination of logistics for the shipment, including packaging, labeling, and transportation arrangements.
- **Shipment:** Dispatching the product to the customer's specified location.
- **Invoice Generation:** Preparation and issuance of the invoice to the customer, detailing the costs incurred as per the agreement.
- **Payment Collection:** Tracking and managing the payment process, including following up on outstanding invoices and ensuring timely receipt of funds.

Enablers:

Clinical Integrated Product Team

Throughout the Order to Release process, effective integration and coordination among various departments—such as sales, production, quality assurance, supply chain, and finance—are crucial for ensuring smooth operations and customer satisfaction. Integrated Product Team construct is effective in achieving this.



Integrated Product Teams (IPTs) are cross-functional, collaborative teams established to deliver a defined product, process, or service, with a clear focus on performance, quality, cost, and schedule. These teams are composed of representatives from multiple disciplines—such as R&D, manufacturing, quality, regulatory, and supply chain—and are formed early in the lifecycle to ensure consistent engagement with customers and end-users from concept through completion.

Each IPT operates under a governance structure defined by executive leadership (ELT), which outlines budget authority, decision-making boundaries, and strategic objectives. Led by a Team Leader who also participates in the next higher-level governance body, IPTs are empowered to manage their own planning, execution, risk mitigation, and issue resolution. The teams meet regularly to review progress, address roadblocks, and coordinate integration with other IPTs to support broader

site or enterprise goals. Benefits of this structure include improved accountability, faster decision-making, early risk identification, and better alignment across departments. Effective IPTs maintain open communication, foster strong team dynamics, and are supported by adequate and qualified resources to deliver results.

CHALLENGE

Case for change to Vertically Integrated Team model:

- ✓ Client Experience is inconsistent and not best in class
- ✓ No clear common or shared team vision of product success
- ✓ Goals (i) tracked at Site level, (ii) tiering left to department Managers, (iii)communication of progress is infrequent
- ✓ KPI's primarily tracked at Site level, not representative of individual areas
- ✓ Conflicting priorities within and across organizations
- ✓ Lack of responsible/accountability around quality, product cost, performance, technical, and measures
- ✓ Inadequate planning
- ✓ Inadequate risk opportunity management
- ✓ Vastly different product/service portfolio requirements

Characteristics of IPT:

- ✓ Has early and consistent involvement of Customers
- ✓ Multi-functional and responsible for delivering a product or service
- ✓ Has governance doc's, budget, and boundaries established by the Site Leadership Team and empowered to make decisions within these boundaries
- ✓ Plans, performs, tracks, and manages tasks and associated risks
- ✓ Responsible for product performance, quality, cost, and schedule
- ✓ Led by a Team Leader who is also a member of the next higher tier team
- ✓ Meets regularly and frequently to discuss issues, identify barriers and make decisions
- ✓ Plans integration with other IPT's toward overall site goals
- ✓ Maintains open communication both within the team and with other IPT's
- ✓ Have sufficient qualified resources to enable success
- ✓ Balance task, process, and team relationships

Model of Team Effectiveness:

- **Strategies**- a clear set of plans, actions and goals that outlines how a business will compete in a particular market, or markets, with a product(s) and/or or service(s).
- **Goals**- Shared understanding of what the team is to accomplish and how it supports the overall site goals.
- **Roles**- Shared agreement on whole will do what part of the work so the sum of the team effort is successful achievement of stated goals. In the course of IPT maturity team members will further establish
- **Procedures**- A shared agreement on what processes and procedures the team will use to coordinate and integrate the work, make decisions, and resolve issues.

- **Plans and Schedules**- Detailed tiered schedules (annual, Qtr, Mo, Wk) developed by team members to manage ongoing work.
- **Relationships and Teamwork**- Mutual respect and trust on which effective collaboration is built

Roles and Responsibilities

Each role has specific responsibilities that contribute to the successful completion of the Order to Cash process in a CDMO setting. Effective collaboration and communication among these roles are essential to meet customer requirements and ensure the smooth execution of projects.

Process Step	Role	Responsibilities
Proposal	Business Development	Engaging with customers, understanding requirements, drafting proposals, and negotiating terms.
	Program Management	Coordinating with internal teams to gather necessary information and ensure proposal feasibility.
	Commercial Operations	Supporting the creation of cost estimates and pricing strategies.
	Quality	Providing input on regulatory requirements and quality assurance aspects.
Order	Program Management	Confirming order details, ensuring alignment with the proposal, and managing customer communications.
	Supply Chain	Assessing demand and planning for necessary resources and materials.
	Finance	Verifying financial terms, setting up invoice schedules, and monitoring budget allocation.
Readiness	Manufacturing	Preparing facilities and equipment and ensuring process readiness.
	Supply Chain	Procuring materials, managing inventory, and coordinating logistics.
	Quality	Developing and validating analytical methods, ensuring compliance with regulatory standards.
	Program Management	Overseeing readiness activities, coordinating between teams, and tracking progress.
	Commercial Operations	Ensuring all commercial aspects are in place, including contracts and customer agreements.
Manufacturing	Manufacturing	Executing production processes, maintaining records, and ensuring timely completion of batches.
	Quality	Conducting in-process quality control and ensuring product meets specifications.
	Program Management	Monitoring production progress, addressing issues, and updating the customer.
	Supply Chain	Managing material flow and ensuring availability of necessary resources during production.
Release	Quality	Final product testing, quality assurance, and regulatory compliance checks.
	Manufacturing	Providing final batch records and production documentation to Quality.

Process Step	Role	Responsibilities
	Program Management	Coordinating release activities, ensuring all release criteria are met, and communicating with the customer.
	Finance	Confirming cost allocations and preparing for invoicing.
Shipment + Invoice	Supply Chain	Arranging logistics, packaging, and transportation for product shipment.
	Finance	Generating and issuing invoices, tracking payments, and managing financial transactions.
	Program Management	Ensuring timely delivery to the customer and resolving any post-shipment issues.
	Commercial Operations	Managing customer relationships and addressing any commercial concerns.

Phase Gate Process + Timeline

This timeline provides a structured approach to managing the Order to Cash process, ensuring that each critical milestone is achieved in a timely and organized manner. Key is that as part of the integrated program plan exists a tailorable master schedule template that includes modules that can be incorporated into the schedule dependent contract scope of work: Process Development, Analytical Development, Engineering Batch, GMP Batch (s), Release, Shipment, Stability, PPQ validation activities. Below is Phase-Gate Timeline for reference.

P0: Pre-Award Phase

- ☑ **Day (-50)**: Proposal preparation
- ☑ ****GATE 0****
  - Approved- Proposal Submission to Client
  - Conditional Approval- Actions documented and implemented prior to submission
  - No Go- No Bid

P1: Award Phase

- ☑ **Day 0: Proposal Award**. The client awards the contract to the CDMO
- ☑ ****GATE 1****
  - Approved- Signature Executed Contract
  - Conditional Approval- Actions documented and implemented prior to proceeding

P2: Planning Phase

- ☑ **Day 4:** Integrated Program Plan Developed
- ☑ **Day 5:** Contract Internal Core Team Kickoff. Internal kickoff meeting with the core team to review the contract and plan execution
- ☑ **Day 7:** Client and CDMO PM(s) review and align on program management governance
- ☑ **Day 10:** Joint Client + CDMO Kickoff. Joint kickoff meeting with the client to align on goals, timelines, and responsibilities
- ☑ ****GATE 2****
  - Approved- Internal Program Plan
  - Conditional Approval- Actions documented and implemented prior to proceeding

P3: Technical Transfer Phase: Process and Analytical Development

- ☑ **Day 75** Process Control Strategy Complete
- ☑ **Day 75** Aseptic Processing Strategy Complete
- ☑ **Day 75** pFMEA Complete
- ☑ **Day 90**: Process and Analytical Development Complete

Materials

- ☑ **Day 10**: Materials for process and analytical development defined and plan in place to ensure material availability
- ☑ **Day 30:** Manufacturing long lead-time material analysis complete with any material non-supports reconciled
- ☑ **Day 30**: Manufacturing schedules updated based upon IPP
- ☑ **Day 60**: Manufacturing BOM finalized for the manufacturing process
- ☑ **Day 60**: Master Data Updated in the ERP system with the defined BOM
- ☑ **Day 60**: Demand Loaded into ERP, WO created based on the Demand Purchase Requisition (PR) created for materials that need to be ordered
- ☑ **Day 75**: Purchase Order (PO) Placed for materials that need to be ordered
- ☑ **Day 140**: Material Received from suppliers, tested, and released to inventory
- ☑ **Day 150**: Pick List Created + Material Issued to the production floor based on PL

Facilities and Equipment Readiness Phase

- ☑ **Day 30:** Assign production suites for the manufacturing process
- ☑ **Day 90:** Revise room layouts if necessary to accommodate the production process
- ☑ **Day 90:** Assign necessary equipment to the production suites
- ☑ **Day 130:** Rooms Staged with required equipment and materials
- ☑ **Day 140:** Complete Environmental Monitoring and Process Qualification (EMPQ) and/or risk assessment as required
- ☑ **Day 145:** Equipment Calibrated
- ☑ **Day 150:** Room Disinfected, Cleaned, and EM completed
- ☑ **Day 159:** Room Released for production after final inspection and approval

Resourcing Readiness Phase

- ☑ **Day 90**: Resource Utilization Analysis Completed to ensure efficient use of personnel and equipment
- ☑ **Day 120**: Load Level resource loads to avoid over- or under-utilization and ensure smooth operations
- ☑ ****GATE 3****
    - Approved- Technical Transfer Complete
    - Conditional Approval- Actions documented and implemented prior to proceeding

P4: Manufacturing Phase

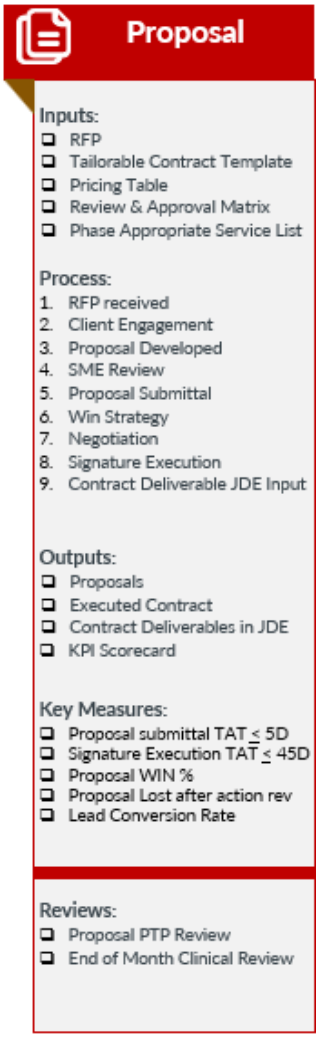
- ☑ **Day 160+**: Manufacturing Batch(s) Complete
- ☑ **Day MFG batch record completion +20d**: All MPR Internal Review Complete

- ☑ **Day MFG batch completion +30d**: All Batch DV Investigated and Closed
- ☑ **Day MFG batch completion +45d**: Release Testing complete
- ☑ **Day Release Testing complete +5d:** CofA issued
- ☑ **Day CoA issued +14d:** Shipment complete
- ☑ ****GATE 4****
    - Approved- Manufacturing Complete
    - Conditional Approval- Actions documented and implemented prior to proceeding

P5: Successful Contract Completion + Closure

- ☑ **Day P4 completion + 30d:** Contract review and closeout- Risk Log, Change Control Closure, SOW milestone completion verification, QMS open actions closed, Client provided equipment dispositioned, Invoices all reconciled and paid, Client Net Promoter Score assessment, Joint After Action Review, Follow-on Campaign planning.
- ☑ **GATE 5**
    - Approved- All Contract Deliverables met + Contract closeout on track
    - Conditional Approval- Actions documented and implemented prior to proceeding

2. PROPOSAL PREPARATION & WIN STRATEGY



Input(s)

1. **Request for Proposal (RFP)**

   Document received from a client outlining project requirements and expectations.

2. **Tailorable Contract Template**

   A flexible contract template that can be customized to fit specific project needs.

3. **Pricing Table**

   A detailed table listing the costs associated with various services and deliverables.

4. **Phase Appropriate Service List**

   A list of services appropriate for different phases of the project lifecycle.

5. **Review & Approval Matrix**

   A framework outlining the necessary steps for review and approval of the proposal.

Process

1. **RFP Received**

   The RFP is received from the client and logged into the system.

2. **Customer Engagement**

   Establish initial contact with the Client to understand their requirements & project scope. Schedule a kick-off meeting or call with the customer. Gather preliminary information about the customer's objectives, project requirements, and any specific preferences. Assign a dedicated account manager or point of contact to oversee the proposal development process.

3. **Proposal Developed**

   A proposal is developed based on the RFP, using the tailorable contract template and pricing table. Include a clear and detailed cost estimate, timeline, and list of deliverables.

4. **SME Review**

   Subject Matter Experts (SMEs) review the proposal to ensure accuracy and feasibility.

5. **Proposal Submittal**

   The final proposal is submitted to the client for consideration.

6. **Proposal Success Probability (Psuccess)**

   This is a combination of the both the Probability that the Client will proceed forward with the campaign (Pgo) and the Probability that CDMO will win the business (Pwin)

   $$Psuccess = Pgo * Pwin$$

7. **Win Strategy**

   Document the win strategy for each client proposal, including key actions, milestones, and responsible team members. The win strategy should provide the most advantageous CDMO Pwin and would typically focus on competitive pricing, industry leading turnaround time, technical expertise, Client experience.

8. **Negotiation**

   The negotiation phase begins with the client to refine terms and conditions.

9. **Signature Execution**

   The contract is finalized and signed by both parties.

10. **Contract Deliverable JDE Input**

    The executed contract and its deliverables are input into the JDE system.

Output(s)

1. **Submitted Proposal**

   The proposal that has been reviewed and submitted to the client.
2. **Executed Contract**

   The contract that has been signed by both parties.
3. **Contract Deliverables in JDE**

   The contract deliverables that have been input into the JDE system.
4. **KPI Scorecard**

   A scorecard that tracks key performance indicators related to the proposal process.

Key Measures (tailorable)

Key Measure	Description	Target
Lead Conversion Rate	The % of leads that are converted into proposal submission	≥ 60%
Proposal Average Time to Submit	The average time taken to develop and submit a proposal	≤ 5 Days
Signature Execution TAT	The time taken to execute the contract signature	< 45 Days
Proposal WIN Rate	The ratio of proposals won to the total proposals submitted	≥ 60%
Proposal Hit Rate by Value	The ratio of total $ won proposals to total $ submitted proposals	≥ 80%
Proposal Lost After Action Review	The process of reviewing + analyzing proposals lost reasons	N/A
Proposal % Submitted On Time In Full	The % of proposals submitted on time and in complete form	100%
Proposal Right First Time	The % of proposals that did not require revision before submittal	≥ 90%
Proposal to Close Cycle Time	The duration of the proposal submission to contract closure	≤ 40 Days
RFP % No Bid	The % of RFPs received that are not pursued with a bid	≤ 5%
Cost per Proposal	The average cost incurred in developing + submitting proposals	≤ $3500
Client Feedback Score (1-10)	The rating or score provided by clients based on their satisfaction with the proposal process and outcome	≥ 9

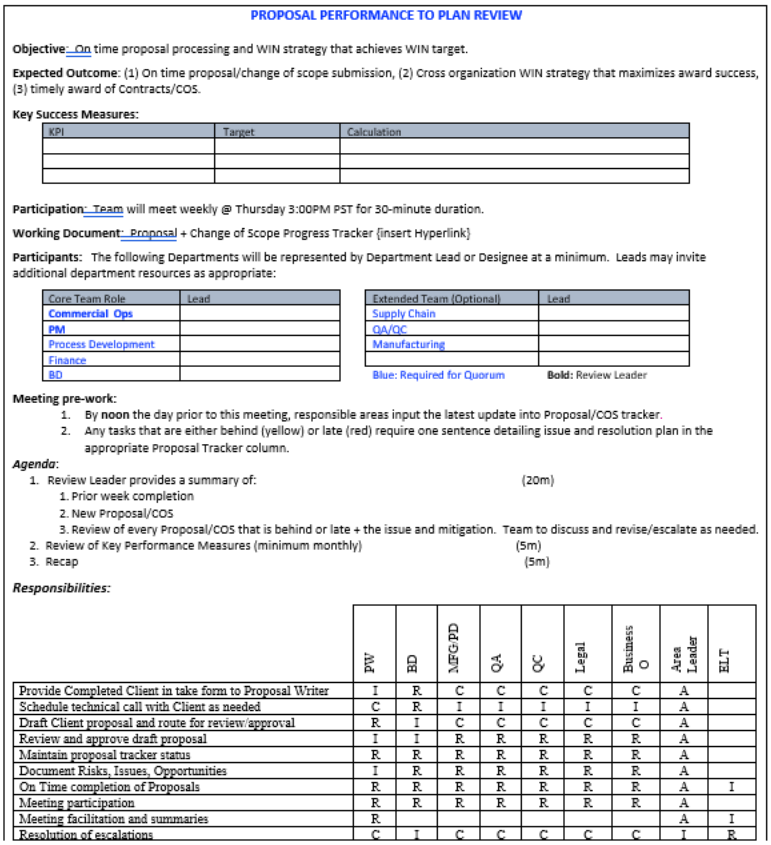
Reviews

- **Proposal PTP Review (Weekly) Proposal Status Performance to Plan**

  Objective: Provide a detailed summary of the proposal status from RFP intake through development, SME review, to issuance.

- **Clinical Review (Monthly)**

  Objective: Comprehensive evaluation of: KPI scorecard, financial performance, proposal execution, program readiness, manufacturing and quality adherence to plan, CAPEX progress, and goal progression to ensure strategic and operational success.



PROPOSAL PERFORMANCE TO PLAN REVIEW

Objective: On time proposal processing and WIN strategy that achieves WIN target.

Expected Outcome: (1) On time proposal/change of scope submission, (2) Cross organization WIN strategy that maximizes award success, (3) timely award of Contracts/COS.

Key Success Measures:

KPI	Target	Calculation

Participation: Team will meet weekly @ Thursday 3:00PM PST for 30-minute duration.

Working Document: Proposal + Change of Scope Progress Tracker {insert Hyperlink}

Participants: The following Departments will be represented by Department Lead or Designee at a minimum. Leads may invite additional department resources as appropriate:

Core Team Role	Lead
Commercial Ops	
PM	
Process Development	
Finance	
BD	

Extended Team (Optional)	Lead
Supply Chain	
QA/QC	
Manufacturing	

Blue: Required for Quorum **Bold:** Review Leader

Meeting pre-work:

1. By **noon** the day prior to this meeting, responsible areas input the latest update into Proposal/COS tracker.
2. Any tasks that are either behind (yellow) or late (red) require one sentence detailing issue and resolution plan in the appropriate Proposal Tracker column.

Agenda:

1. Review Leader provides a summary of: (20m)
   1. Prior week completion
   2. New Proposal/COS
   3. Review of every Proposal/COS that is behind or late + the issue and mitigation. Team to discuss and revise/escalate as needed.
2. Review of Key Performance Measures (minimum monthly) (5m)
3. Recap (5m)

Responsibilities:

	PW	BD	MFG/PD	QA	QC	Legal	Business O	Area Leader	ELT
Provide Completed Client in take form to Proposal Writer	I	R	C	C	C	C	C	A	
Schedule technical call with Client as needed	C	R	I	I	I	I	I	A	
Draft Client proposal and route for review/approval	R	I	C	C	C	C	C	A	
Review and approve draft proposal	I	I	R	R	R	R	R	A	
Maintain proposal tracker status	R	R	R	R	R	R	R	A	
Document Risks, Issues, Opportunities	I	R	R	R	R	R	R	A	
On Time completion of Proposals	R	R	R	R	R	R	R	A	I
Meeting participation	R	R	R	R	R	R	R	A	
Meeting facilitation and summaries	R							A	I
Resolution of escalations	C	I	C	C	C	C	C	I	R

PROPOSAL PERFORMANCE TO PLAN 1-PAGE REVIEW CHARTER

Effectiveness Check (Do's and Don'ts)

DO's

- ☑ **Leverage CDMO Expertise**. Client's approach CDMO's for services and expertise. Part of the expertise is having a tailorable phase appropriate drug development list of services to assist Client. From CDMO de-risking perspective, list the required services by Phase per CDMO QMS with others for Client to select. This will assist in the development of more robust proposals and minimize disconnects between CDMO and Client. For example, it is preferred to understand strategy well in advance of IND and BLA filing to prevent a disconnect whereby Client needs for filing (eg. Method Validations, E&L, Characterization Studies) but was not performed.
- ☑ **Understand Requirements**: Thoroughly understand the client's needs and requirements. Tailor your proposal to address these specifics.
- ☑ **Acknowledge Promptly**: Confirm receipt of the order promptly to reassure the customer.
- ☑ **Clarify Details**: Ensure all order details are clear, including quantity, specifications, delivery dates, and any special requirements.
- ☑ **Verify Information**: Double-check the customer's information and the details of the order to avoid errors.
- ☑ **Document Everything**: Keep thorough records of the order confirmation and any communication with the customer.
- ☑ **Set Expectations**: Clearly communicate the next steps, including timelines for delivery and any potential delays.

- ☑ **Research**: Conduct thorough research on the project, industry standards, and any previous similar projects to provide relevant and insightful content.
- ☑ **Clear Structure**: Use a clear and logical structure with sections like Executive Summary, Introduction, Objectives, Scope, Methodology, Timeline, Budget, and Conclusion.
- ☑ **Highlight Benefits**: Clearly articulate the benefits of proposal to the client. Show how it solves their problem or meets their needs.
- ☑ **Visual Aids**: Use charts, graphs, and diagrams to illustrate key points and make your proposal more engaging and easier to understand.
- ☑ **Proofread**: Ensure your proposal is free from errors. Proofread multiple times and consider having a colleague review it.
- ☑ **Concise Writing**: Be concise and to the point. Avoid unnecessary jargon and ensure that every word adds value.
- ☑ **Customization**: Customize each proposal for the specific client. Avoid using a one-size-fits-all approach.
- ☑ **Professional Appearance**: Use professional formatting and design to make your proposal visually appealing.
- ☑ **Follow Guidelines**: Adhere to any guidelines or templates provided by the client or organization.
- ☑ **Showcase Experience**: Highlight your relevant experience and past successes to build credibility.
- ☑ **Include a Call to Action**: End with a clear call to action, specifying the next steps the client should take
- ☑ **Internal Proposal Performance to Plan Reviews**: Hold periodic proposal performance to plan reviews highlighting any turnaround time gaps, reconciliation actions, and performance to key measures.

DON'TS

- ☒ **Overpromise**: Avoid making promises you can't keep. Be realistic about what you can deliver.
- ☒ **Be Vague**: Do not include vague or generic statements. Be specific and clear about your proposal's details.
- ☒ **Ignore Feedback**: Don't ignore previous feedback. Use client feedback from past proposals to improve your current one.
- ☒ **Neglect the Executive Summary**: This is often the first section a client reads, so make sure it's compelling and summarizes the key points effectively.
- ☒ **Skip the Budget Details**: Provide a detailed and transparent budget. Ambiguity here can lead to distrust.
- ☒ **Forget Deadlines**: Ensure you meet all deadlines, both for submission and for any milestones within the proposal.
- ☒ **Use Unreliable Sources**: Ensure all data and references come from reliable and reputable sources.
- ☒ **Be Inconsistent**: Avoid inconsistencies in formatting, terminology, and information. Consistency builds trust and professionalism.
- ☒ **Neglect Client Perspective**: Focus on the client's needs rather than just your capabilities. Show how you are the solution to their problem.
- ☒ **Overcomplicate**: Don't overcomplicate your proposal with too much technical detail. Ensure it's understandable for all stakeholders, including those without technical backgrounds.

3. DEMAND PLANNING

This process framework ensures a structured approach to handling proposals and contracts, with a focus on efficiency, accuracy, and continuous improvement.

Demand Plan

Inputs:
- ❑ Executed Contract
- ❑ Capacity Analysis
- ❑ Historical Utilization Rate
- ❑ Contract Deliverable in JDE
- ❑ Revenue Recognition Playbook
- ❑ Secured Revenue
- ❑ New business probabilities
- ❑ S&OP charter + templates
- ❑ KPI Site Dashboard

Process:
1. Develop time phased Demand Plan (Secured, P>70%, P>50%)
2. Assess against Mfg, Fac, Material, Equipment Capacity
3. Prepare and conduct managerial S&OP
4. Prepare and conduct executive S&OP

Outputs:
- ❑ Time Phase Demand Plan
- ❑ Revised Capacity Plan
- ❑ Managerial S&OP
- ❑ Executive S&OP

Key Measures:
- ❑ Forecast Accuracy
- ❑ Book to Bill Ratio
- ❑ PTP Revenue (1Q,2Q,3Q)
- ❑ Capacity Utilization
- ❑ Inventory Turns
- ❑ Scrap as % of Sales

Reviews:
- ❑ Mid Month Forecast Review
- ❑ Managerial S&OP
- ❑ Executive S&OP

Input(s)

1. **Executed Contract**
   Signed agreement outlining the binding terms and deliverables.
2. **Capacity Analysis**
   Evaluation of available manufacturing and operational resources.
3. **Historical Utilization Rate**
   Insight into past resource usage trends to guide capacity planning
4. **Contract Deliverable in JDE**
   Tracked contractual commitments entered into JDE System.
5. **Revenue Recognition Playbook**
   Guidelines for recognizing revenue based on contract terms and milestones.
6. **Secured Revenue**
   Income that is guaranteed based on executed contracts.
7. **New Business Probabilities**
   Forecasted likelihood of acquiring new contracts.
8. **S&OP Meeting Charter & Templates**
   Defined structures, agendas, and documents for both Managerial and Executive S&OP sessions.
9. **Site Dashboard**
   Real-time performance data, including personnel, safety, manufacturing delivery, quality, financial, innovation

Process

1. **Develop Time Phased Demand Plan**
   Create demand forecasts categorized by probability tiers (Secured, P>70%, P>50%).
2. **Assess Against Capacity**
   Compare demand forecasts with manufacturing, facility, material, and equipment constraints.
3. **Prepare and Conduct Managerial S&OP (Monthly)**
   Facilitate managerial level Sales and Operating Planning meetings for operational alignment.
4. **Prepare and Conduct Executive S&OP**
   Hose executive level S&OP meetings to review high level strategy, capacity planning, risk mitigation plans, and address any key escalations/decisions pending from managerial S&OP.
5. **Incorporate Site Dashboard Insights**
   Utilize site level data to adjust capacity utilization, resolve bottlenecks, and align on demand forecast.

Output(s)

1. **Time Phased Demand Plan** (included within site dashboard)
   A detailed schedule mapping demand against specific time periods.
2. **Revised Capacity Plan**
   Updated resource plan addressing identified risks with mitigation plans + opportunities with realization plans.
3. **Managerial S&OP + Outcomes** (S&OP KPI included within site dashboard)

Actionable outputs from managerial -level planning sessions.

4. **Executive S&OP + Outcomes** (S&OP KPI included within site dashboard)
   Strategic insights and decisions from executive level planning review.
5. **Refined Site Dashboard Updates**
   Continuous updates and tracking of site-specific performance indicators providing timely insights, guide future reviews, and have resources focused on recovery actions as opposed to administrative KPI updates.

Key Measures

Key Measure	Description	Target
Book to Bill Ratio	A metric comparing new orders booked to the amount billed within a specific period.	> 1.2 Annual
Bookings to Target (1Q, 2Q, 3Q)	Quarterly targets for bookings and performance measurement against these targets.	100% of $ target booked and scheduled 1Q out, 2Q out combination of bookings + proposal Psuccess >75% greater than $ target, 3Q out combination of booking + proposals Psuccess >50% greater than $ target.
Forecast Accuracy	The alignment of demand forecasts with actual outcomes.	>95% MAPE
Capacity Utilization	The % of total production capacity actively employed	75% < X < 90%
Operational Labor Effectiveness	Tracks efficiency of personnel against available capacity	> 0.85 FTE
Inventory Turns	Frequency of inventory replenishment or cycled through within a specific period	> 6
Inventory Aging/Obsolescence	Measures extent of inventory by quantity and value that is at risk of scrap due to expiration, decreased demand, overorder, or redundancy.	< 1% of total inventory value
Months Of Supply (Raw Materials, Finished Product)	Represents the amount of inventory available to sustain operations over a defined period.	100% within ERP established Economic Order Quantity target
Scrap as % of Sales	Quantifies the proportion of sales revenue lost due to defective or excess inventory.	<1%
S&OP Meeting Effectiveness	Assesses the overall impact and alignment of S&OP meetings based on Weighted KPI Scorecard value and trends.	> 95%

Reviews

1. **Mid-Month Forecast Review**
   Evaluates performance to plan for secured revenue milestones for the month, along with WIN strategy execution for Psuccess >75% and Psuccess >50%, ensuring that risks are documented, and mitigation plans are in place. Frequency of meetings can range from Daily-Weekly-Biweekly based upon successful performance to plan and risk management.
2. **Managerial S&OP**
   (1) Aligns the Operating Plan reconciling any gaps between Commercial Demand Plan and Business Supply Plan documenting risks + mitigation actions. (2) Review of KPI with recovery to goal plans for any Yellow/Red, (3) Determine related strategic priorities.
3. **Executive S&OP**

Reviews and finalizes strategic direction, approves mitigation strategies to address risks impacting key measure targets, and addresses any escalations/decisions pending from Managerial S&OP.

SEE ADDENDUM FOR 1 PAGE REVIEW CHARTERS

Effectiveness Check (Do's and Don'ts)

Do's:

☑ **Use Accurate Data**: Base your demand planning on accurate and up-to-date data.

☑ **Collaborate Across Departments**: Involve multiple departments (sales, operations, finance) to get a comprehensive view of demand.

☑ **Adjust for Variability**: Consider potential variability in demand and have contingency plans in place.

☑ **Optimize Inventory Levels**: Aim to balance inventory levels to avoid both shortages and excess stock.

☑ **Regularly Review and Adjust**: Continuously monitor demand and adjust plans as needed to reflect real-time changes.

☑ **Forecasting:** Using historical data, market trends, and customer input to forecast demand and plan production schedules.

☑ **Create a Stacked Revenue Tracker:** Use a time-phased approach to track and visualize revenue. This includes:
- Current Quarter: Track revenue secured.
- One Quarter Out: Track secured revenue + Probability > 75% revenue.
- Two Quarters Out: Track secured revenue + all Probability > 50% revenue.
- Beyond Two Quarters: Track secured revenue + all probabilities.

☑ **Collect Client Details:** Gather and compile details for each client, including their current status, win probability, and associated revenue.

☑ **Win Strategy:** Document the win strategy for each client, including key actions, milestones, and responsible team members.

☑ **Leverage Technology**: Use advanced forecasting tools, software to improve accuracy, and Dashboard applications (Tableau, Power BI) to automate KPI report out.

☑ **Incorporate Various Inputs**: Use a mix of historical data, market analysis, and customer input for robust forecasting.

☑ **Scenario Planning**: Develop multiple scenarios to prepare for different potential outcomes.

☑ **Track Performance**: Monitor forecasting accuracy and adjust methods as needed.

Don'ts:

☒ **Ignore Historical Data**: Failing to use historical data can result in inaccurate demand forecasts.

- ☒ **Isolate Planning**: Don’t plan in a silo; collaboration is key for accurate demand planning.
- ☒ **Neglect External Factors**: Don’t ignore external factors like market trends, economic conditions, and seasonality.
- ☒ **Overlook Lead Times**: Always factor in lead times for procurement and production.
- ☒ **Be Inflexible**: Avoid rigid plans; be adaptable to changing circumstances.
- ☒ **Rely Solely on One Method**: Avoid relying on a single forecasting method; use a combination for better accuracy.
- ☒ **Ignore Market Trends**: Stay informed about market trends and incorporate them into forecasts.
- ☒ **Disregard Feedback**: Customer feedback is valuable; don’t overlook it in your forecasting process.
- ☒ **Overcomplicate**: Keep the forecasting process as simple as possible while still being effective.
- ☒ **Neglect to Review**: Regularly review forecasting performance and make improvements as necessary.

4. SUPPLY PLANNING

This structured process ensures a comprehensive approach to managing projects, with a focus on alignment, readiness, and continuous monitoring of key performance indicators.

Supply Plan
[Readiness]

Inputs:
- ❑ Tailorable Project Schedule
- ❑ Program Plan Templates
- ❑ Material Inventory
- ❑ Fac_Equip Utilization Tracker
- ❑ Ready To Execute Tracker
- ❑ Document Tracker
- ❑ Revenue Recognition Tracker

Process:
1. PS and Revenue Recognition Tracker inclusive of all CLIN
2. Program Plan Developed
3. Document, Fac_Eq, Material trackers Updated
4. Internal Core Team Kickoff
5. Client Core Team Kickoff
6. Ongoing Core + Steering Committee PTP meetings

Outputs:
- ❑ Integrated Program Plan
- ❑ Readiness +Revenue Trackers
- ❑ RTE Tracker
- ❑ Client Scorecards
- ❑ Integrated Risk Log

Key Measures:
- ❑ % OT milestone + SA
- ❑ Revenue PTP
- ❑ Schedule Performance Index
- ❑ Cost Performance Index
- ❑ Critical Path Length Index
- ❑ Risk Mitigation Effectiveness
- ❑ Client Sentiment (NPS)
- ❑ SOW Change Management

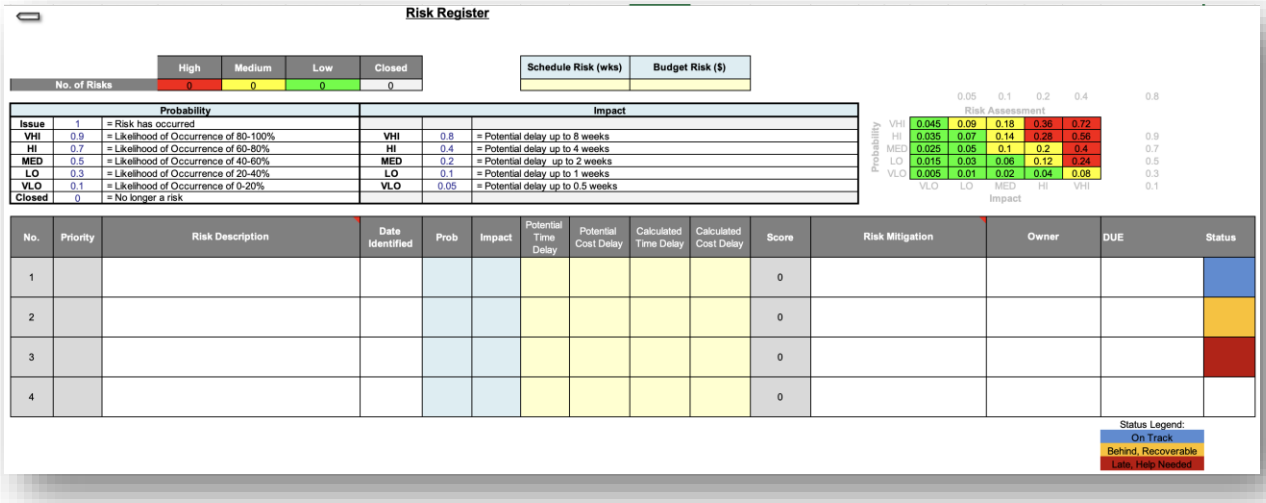
Reviews:
- ❑ Wkly Readiness + Release
- ❑ Wkly Performance to Finance
- ❑ Core Team Meetings
- ❑ Steering Committee Review

Input(s)

1. **Material Inventory**
   The current stock of raw materials and components required for projects.
2. **Facilities and Equipment Requirement + Utilization Tracker**
   A tool to monitor the usage and availability of facilities and equipment.
3. **Tailorable Project Plan**:
   Integrated Master Schedule (IMS): Customizable project schedule tailored to specific project timelines and milestones. At a minimum this should include all the CLIN deliverables, owners, % Complete, Dependencies, Durations, Baseline, Schedule Variance, Status Indicator.
   Revenue Tracker: A Revenue Tracker is a tool used to monitor and manage the financial performance of a project or business. It helps in tracking the revenue generated from different sources, ensuring that the income aligns with the expected or forecast figures. The tracker typically includes:
   - Revenue Streams: Details of various income sources.
   - Milestone Payments: Scheduled payments tied to project milestones.
   - Actual vs. Forecasted Revenue: Comparison of actual revenue against projected figures.
   - Trends and Variances: Analysis of revenue trends over time and identification of any variances.

Reference Smartsheet for IMS Template +Deliverables

Risk Log: A Risk Log is a document or tool used to identify, assess, and manage risks associated with a project. It includes:
- Risk Identification: List of potential risks that could impact the project.
- Risk Assessment: Evaluation of the likelihood and impact of each risk.
- Mitigation Strategies: Plans and actions to reduce or eliminate risks.
- Status Updates: Regular updates on the status of each risk and the effectiveness of mitigation efforts.



Risk Register

	High	Medium	Low	Closed
No. of Risks	0	0	0	0

Schedule Risk (wks)	Budget Risk ($)

Probability		
Issue	1	= Risk has occurred
VHI	0.9	= Likelihood of Occurrence of 80-100%
HI	0.7	= Likelihood of Occurrence of 60-80%
MED	0.5	= Likelihood of Occurrence of 40-60%
LO	0.3	= Likelihood of Occurrence of 20-40%
VLO	0.1	= Likelihood of Occurrence of 0-20%
Closed	0	= No longer a risk

Impact		
VHI	0.8	= Potential delay up to 8 weeks
HI	0.4	= Potential delay up to 4 weeks
MED	0.2	= Potential delay up to 2 weeks
LO	0.1	= Potential delay up to 1 weeks
VLO	0.05	= Potential delay up to 0.5 weeks

Risk Assessment

Probability \ Impact	VLO	LO	MED	HI	VHI
VHI	0.045	0.09	0.18	0.36	0.72
HI	0.035	0.07	0.14	0.28	0.56
MED	0.025	0.05	0.1	0.2	0.4
LO	0.015	0.03	0.06	0.12	0.24
VLO	0.005	0.01	0.02	0.04	0.08

No.	Priority	Risk Description	Date Identified	Prob	Impact	Potential Time Delay	Potential Cost Delay	Calculated Time Delay	Calculated Cost Delay	Score	Risk Mitigation	Owner	DUE	Status
1										0				
2										0				
3										0				
4										0				

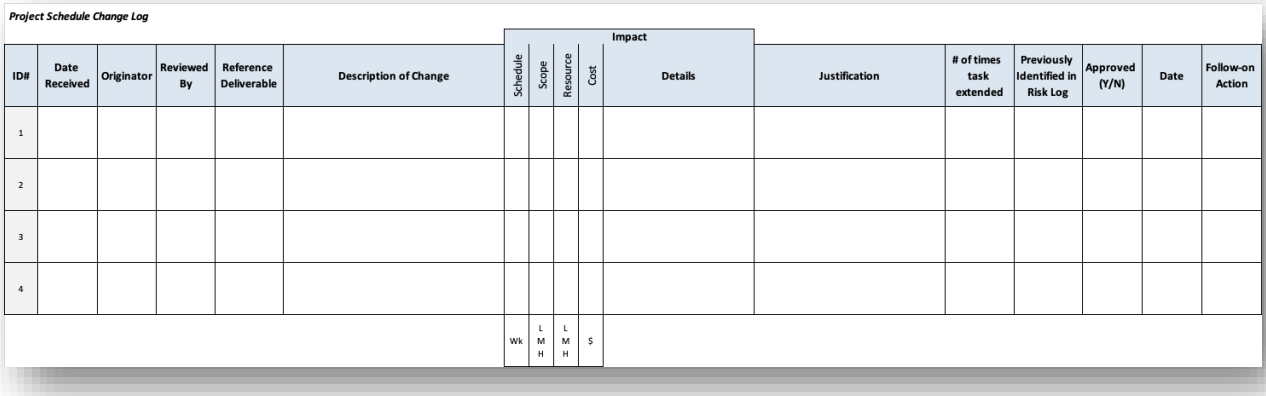
Status Legend:
On Track
Behind, Recoverable
Late, Help Needed

Action Log: An Action Log is a detailed record of actions that need to be taken to progress a project. It includes:

- Action Items: Specific tasks or activities to be completed.
- Responsibility: The person or team responsible for each action.
- Due Dates: Deadlines for the completion of each action item.
- Status: Current status of each action (e.g., pending, in progress, completed).
- Notes: Additional comments or updates related to the action items.

Schedule Change Log: A Schedule Change Log tracks any changes made to the project schedule. It includes:

- Change Description: Details of the change made to the schedule.
- Reason for Change: Explanation of why the change was necessary.
- Impact Assessment: Analysis of how the change affects the overall project timeline, milestones, and deliverables.
- Approval Status: Record of approvals from relevant stakeholders.
- Date of Change: When the change was made.



Project Schedule Change Log

ID#	Date Received	Originator	Reviewed By	Reference Deliverable	Description of Change	Impact: Schedule	Impact: Scope	Impact: Resource	Impact: Cost	Impact: Details	Justification	# of times task extended	Previously Identified in Risk Log	Approved (Y/N)	Date	Follow-on Action
1																
2																
3																
4																
						Wk	L M H	L M H	$							

Change of Scope Log: In a CDMO environment, scope changes can occur due to various factors such as client requests, regulatory updates, scientific discoveries, or technical challenges. The Change of Scope Log ensures that any modifications to the project are systematically evaluated and managed, supporting the delivery of high-quality, compliant

products and services. By meticulously maintaining a Change of Scope Log, CDMOs can enhance their ability to adapt to changes while minimizing disruptions and ensuring that all project goals and regulatory requirements are met. Key elements of a Change of Scope Log:

- Change Request ID: A unique identifier assigned to each scope change request for easy tracking and reference.
- Date of Request: The date when the scope change request was submitted.
- Requested By: The name and role of the person or team requesting the change.
- Description of Change: A detailed description of the proposed change, including what aspects of the project scope are affected and why the change is needed.
- Justification for Change: The rationale behind the requested change, explaining the reasons and expected benefits or necessity of implementing the change.
- Impact Analysis: An assessment of how the proposed change will affect the project in terms of time, cost, resources, quality, and risk. This analysis should be comprehensive and include input from relevant stakeholders.
- Priority Level: An indication of the urgency or importance of the change request (e.g., low, medium, high).
- Review and Approval Status: A record of the review and approval process, including dates and names of individuals or committees who reviewed and approved or rejected the change.
- Decision Details: The outcome of the change request, such as approved, rejected, deferred, or requires more information. This section should include any conditions or comments from the approvers.
- Implementation Plan: A detailed plan outlining how the approved change will be implemented, including timelines, responsible parties, and any required resources or adjustments to the project plan.

Change of Scope (COS) Log

ID#	Date Received	Originator	Reviewed By	Description of Change	Impact				Details	Justification	Priority	Approved (Y/N)	Date	Implementation Plan
					Schedule	Scope	Resource	Cost						
1														
2														
3														
4														
					Wk	L M H	L M H	$						

Communication Plan: A Communication Plan outlines the strategy for effectively communicating with all stakeholders involved in a project. It includes:

- Stakeholder Identification: List of all stakeholders and their communication needs.
- Communication Methods: Various channels and methods to be used (e.g., email, meetings, reports).
- Frequency: How often communication will occur.
- Responsibility: Who is responsible for each type of communication.
- Content: Key messages and information to be communicated.
- Feedback Mechanisms: Ways to gather feedback from stakeholders.

Core Team Communication Plan Template

Last Update: 00/00/20x

#	Description	Person Responsible	Intent /Objective	Message/Agenda	Audience	Prework	Documents	Communication Type	Frequency	Documented Summary Location
			(Why)	(What will be communicated)	(Who)			(How-- email, 1:1,		
1	Internal Core Team Meeting	Project Manager	Team focus on Performance to plan (i) Schedule Adherence, (2) timely communication and resolution of project Risks/Issues, (3) Timely completion of Actions	- Project Schedule Adherence: All tasks scheduled to complete and/or start over the prior and current week occurred. ID any upcoming tasks that are @ risk. - Risk Register Review: New Risks & Risks/Issues with resolution plans @ completion risk - Schedule Change Log: Any Scope or Schedule Changes or other variances - Change of Scope Log: All COS are on track to complete by dates. - Project Plan KPI's: recovery plans for any that are below target - Document any notable Assumptions and/or Decisions Pending for Escalation resolution - Team Action Item log review - Monthly review of Core team KPI	Core Team Members	Core team to update Documents where member is listed as activity owner: 1. Project Schedule % Complete for deliverables Owned. If the deliverable is @ risk or late, add line to Risk Register 2. Risk Log with any new risks, Risk Update, and Mitigation Plan update 3. Change of Scope latest status 4.	- Baselined Project Schedule - Risk & Issue Log - Schedule Change Log - Change of Scope Log - Project Plan KPI's - Assumptions and/or Decisions Pending Log - Action Item log - Doc readiness Tracker -Material Readiness Tracker -Fac-Equipment Requirement tracker	MS Teams	Weekly 30 minutes	Smartsheet Team SharePoint
1	Joint Client Core Team Meeting	Project Manager	Team focus on critical path deliverables and associated timely communication and resolution of project Risks/Issues	- Project Schedule Adherence: All tasks scheduled to complete and/or start over the prior and current week occurred. ID any upcoming tasks that are @ risk. - Risk Register Review: New Risks & Risks/Issues with resolution plans @ completion risk - Schedule Change Log: Any Scope or Schedule Changes or other variances - Change of Scope Log: All COS are on track to complete by dates? - Project Plan KPI's: recovery plans for any that are below target -Document any notable Assumptions and/or Decisions Pending for Escalation resolution - Team Action Item log review	Joint Core Team Members	The output from internal Core Team meeting will be what is discussed in this meeting	- Baselined Project Schedule - Risk & Issue Log - Schedule Change Log - Change of Scope Log - Project Plan KPI's - Assumptions and/or Decisions Pending Log - Action Item log	MS Teams	Weekly 30 minutes	Smartsheet Team SharePoint
2	Extended Team Meeting	Project Manager	Project Plan progress review with extended team for alignment, understanding, escalations (decision pending).	4-Panel: - Notable Accomplishments & KPI status - Key upcoming milestones and status - Significant Risks & Issues along with resolution - Notable new Assumptions - Escalations for Decision Making Additional Project Deliverable Communication Slides as relevant	Extended Team Members	PM to update 4-Panel from Weekly update material	- 4-Panel - Additional project communication details slide(s)	MS Teams	Biweekly	Team SharePoint
3	Monthly SLT Steering Committee Review	Joint Team Leaders	Provide ELT with summary level update, provide directions for any decisions pendng and risks/issues requiring additional focus.	4-Panel: - Notable Accomplishments & KPI status - Key upcoming milestones and status - Significant Risks & Issues along with resolution - Notable new Assumptions - Escalations for Decision Making	- CDMO SLT - Project Manager	PM to update 4-Panel from Weekly update material	4-Panel	MS Teams	Monthly 10 min per Client	Team SharePoint
3	Joint Leadership Team Meeting	Joint Team Leaders	Provide Joint ELT with summary level update, provide directions for any decisions pendng and risks/issues requiring additional focus.	4-Panel: - Notable Accomplishments & KPI status - Key upcoming milestones and status - Significant Risks & Issues along with resolution - Notable new Assumptions - Escalations for Decision Making Select Topics (as needed to be decided by Team)	- Client - CDMO SLT - Project Manager	- PM to update 4-Panel from Weekly update material - SME to prepare 1-2 slides for given select topic	- 4-Panel - 1-2 Slides for each select topic	MS Teams	Quaterly 1 hr	Team SharePoint
4	PD/MSAT SME Progress Review	Joint Team Leaders	SME collaboration, prioritization, and deliverable alignment with timely communication and resolution of Risks/Issues	PD/MSAT Related detailed SME review: - PD/MSAT Deliverables Schedule Adherence - Risk Register Review: New Risks & Risks/Issues with resolution plans @ completion risk - Technical Discussion - Schedule Change Log: Any Scope or Schedule Changes or other variances - Document any notable Assumptions and/or Decisions Pending for Escalation resolution - Action Item log review	- RU/SU Leaders - Project Manager - ENG Core and select extended team	Leverage existing updates from core team meeting	- Baselined Project Schedule - Risk & Issue Log - Schedule Change Log - Document Readiness Tracker - Action Item log	MS Teams	Weekly	Team SharePoint
5	MFG SME Progress Review (Optional)	Joint Team Leaders	SME collaboration, prioritization, and deliverable alignment with timely communication and resolution of Risks/Issues	- MFG Related detailed SME review: - Deliverables Schedule Adherence - Risk Register Review: New Risks & Risks/Issues with resolution plans @ completion risk - Schedule Change Log: Any Scope or Schedule Changes or other variances - Document any notable Assumptions and/or Decisions Pending for Escalation resolution - Action Item log review	- RU/SU Leaders - Project Manager - MFG Core and select extended team	Leverage existing updates from core team meeting	- Baselined Project Schedule - Risk & Issue Log - Schedule Change Log - Project Plan KPI's - Assumptions and/or Decisions Pending Log - Action Item log	MS Teams	Weekly	Team SharePoint
6	QA/QC SME Progress Review	Joint Team Leaders	SME collaboration, prioritization, and deliverable alignment with timely communication and resolution of Risks/Issues	- QA/QC Related detailed SME review: - Deliverables Schedule Adherence - Risk Register Review: New Risks & Risks/Issues with resolution plans @ completion risk - Schedule Change Log: Any Scope or Schedule Changes or other variances - Document any notable Assumptions and/or Decisions Pending for Escalation resolution - Action Item log review	- RU/SU Leaders - Project Manager - QA/QC Core and select extended team	Leverage existing updates from core team meeting	- Baselined Project Schedule - Risk & Issue Log - Schedule Change Log - Project Plan KPI's - Assumptions and/or Decisions Pending Log - Action Item log	MS Teams	Weekly	Team SharePoint
7	Team Heath Review	Project Manager	Periodic 1:2:1 between Joint team leaders and Project Managers with focus on what is working well (+) and not(-), with plan to address (-).	Project Manager to bring summary for discussion of what is working well and not. Discussion focus on team recognition for (+) and additional focus for (-)	- Joint Leaders - Project Manager	Complete Team Health Assessment Tool	Summary of Assessemnt results. Start with (+) and then (-). Action plan for (-)	MS Teams	Weekly	Team SharePoint

Key Decision & Assumptions Log: A Key Decision & Assumptions Log records important decisions made during a project and the assumptions underlying those decisions. It includes:

- Decision Description: Details of the decision made.
- Decision Date: When the decision was made.
- Rationale: Reasons for the decision.
- Assumptions: Assumptions that were considered when making the decision.
- Impact: How the decision affects the project.
- Approval: Record of who approved the decision.

Decision Tracker

Last Update: 00/00/00

#	Notable Project Decisions & Key Points	Forum	Date Communicated	Method of Communication
1				
2				
3				

Resourcing Plan: A Resourcing Plan outlines the allocation of resources required to complete a project. It includes:

- Resource Requirements: Identification of the types and quantities of resources needed (e.g., personnel, equipment, materials).
- Resource Allocation: Assignment of resources to specific tasks or project phases.
- Availability: Analysis of resource availability and any constraints.
- Resource Scheduling: Timeline for when resources will be needed and for how long.
- Contingency Plans: Plans for dealing with resource shortages or conflicts.

Core Team Operating Management Guidelines: Provide a framework for how the core team should operate and interact to ensure efficient project management. They include:

- Roles and Responsibilities: Clear definition of each team member's role and responsibilities.
- Meeting Protocols: Guidelines for how meetings should be conducted (e.g., frequency, agenda setting, minute-taking).
- Decision-Making Process: Procedures for making and documenting decisions.
- Communication Protocols: Standards for how team members should communicate with each other and with stakeholders.
- Conflict Resolution: Methods for resolving conflicts within the team.
- Performance Monitoring: Criteria and processes for evaluating team performance and individual contributions.

4. **Ready To Execute (RTE) Tracker**
   A tracker to ensure all prerequisites are met before project execution.
5. **Document Tracker**
   A system for tracking and managing project-related documents.
6. **Revenue Recognition Tracker**
   A tool for tracking revenue recognition based on project milestones.
7. **Program Plan Templates**
   Standardized templates for developing comprehensive program plans.
8. **Core Team Integrated Program Team Training**
9. **PM Program Leadership Training**

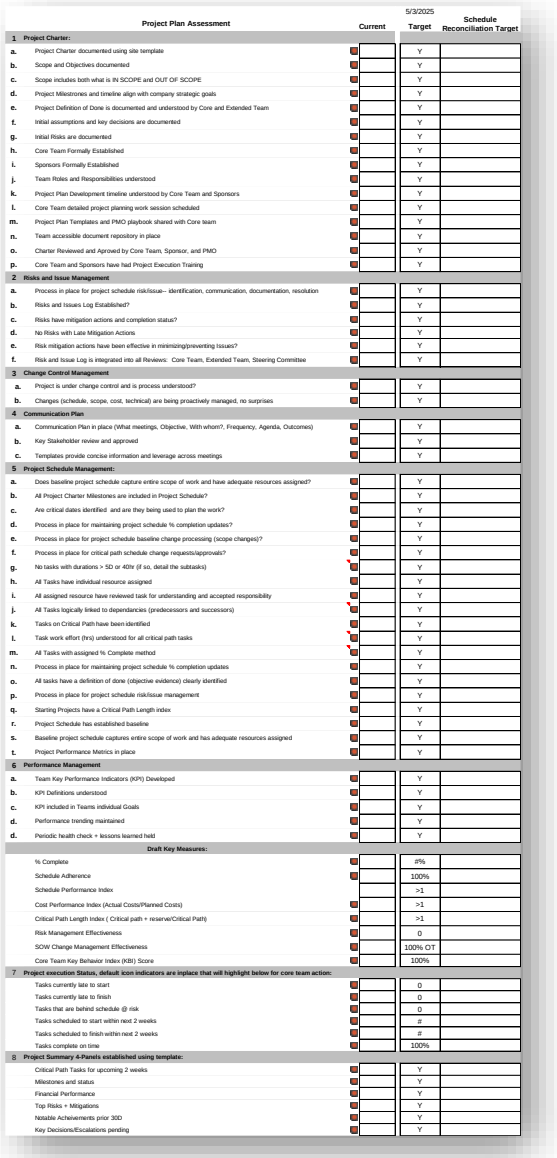
Process

1. **Integrated Master Schedule (IMS) and Revenue Recognition Tracker Inclusive of All CLIN**
   Incorporating all Contract Line-Item Numbers (CLIN) into the project and revenue recognition tracker.
2. **Integrated Program Plan Developed**
   Creating a detailed program plan outlining project scope, timelines, resources, and deliverables.
3. **Readiness Trackers Updated**
   Updating all relevant trackers with the latest information on documents, facilities, equipment, and materials.
4. **Internal Core Team Kickoff**
   Initial meeting with the internal core team to align project objectives and responsibilities.
5. **Client Core Team Kickoff**
   Initial meeting with the client's core team to review the program plan and align project goals.
6. **Ongoing Core + Steering Committee PTP Meetings**
   Regular meetings with the core team and steering committee to review progress, address issues, and make decisions.

Output(s)

1. **Integrated Program Plan**
2. **Readiness + Revenue Trackers**

3. **RTE Tracker**
4. **Client Scorecards**
5. **Integrated Risk + Action + Issues + Key Decision Log (RAID)**
6. **Completed & Reconcile Project Plan Robustness Assessment:**



	Project Plan Assessment	Current	5/3/2025 Target	Schedule Reconciliation Target
1	**Project Charter:**			
a.	Project Charter documented using site template		Y	
b.	Scope and Objectives documented		Y	
c.	Scope includes both what is IN SCOPE and OUT OF SCOPE		Y	
d.	Project Milestrones and timeline align with company strategic goals		Y	
e.	Project Definition of Done is documented and understood by Core and Extended Team		Y	
f.	Intial assumptions and key decisions are documented		Y	
g.	Initial Risks are documented		Y	
h.	Core Team Formally Established		Y	
i.	Sponsors Formally Established		Y	
j.	Team Roles and Responsibilities understood		Y	
k.	Project Plan Development timeline understood by Core Team and Sponsors		Y	
l.	Core Team detailed project planning work session scheduled		Y	
m.	Project Plan Templates and PMO playbook shared with Core team		Y	
n.	Team accessible document repository in place		Y	
o.	Charter Reviewed and Aproved by Core Team, Sponsor, and PMO		Y	
p.	Core Team and Sponsors have had Project Execution Training		Y	
2	**Risks and Issue Management**			
a.	Process in place for project schedule risk/issue-- identification, communication, documentation, resolution		Y	
b.	Risks and Issues Log Established?		Y	
c.	Risks have mitigation actions and completion status?		Y	
d.	No Risks with Late Mitigation Actions		Y	
e.	Risk mitigation actions have been effective in minimizing/preventing issues?		Y	
f.	Risk and Issue Log is integrated into all Reviews: Core Team, Extended Team, Steering Committee		Y	
3	**Change Control Management**			
a.	Project is under change control and is process understood?		Y	
b.	Changes (schedule, scope, cost, technical) are being proactively managed, no surprises		Y	
4	**Communication Plan**			
a.	Communication Plan in place (What meetings, Objective, With whom?, Frequency, Agenda, Outcomes)		Y	
b.	Key Stakeholder review and approved		Y	
c.	Templates provide concise information and leverage across meetings		Y	
5	**Project Schedule Management:**			
a.	Does baseline project schedule capture entire scope of work and have adequate resources assigned?		Y	
b.	All Project Charter Milestones are included in Project Schedule?		Y	
c.	Are critical dates identified and are they being used to plan the work?		Y	
d.	Process in place for maintaining project schedule % completion updates?		Y	
e.	Process in place for project schedule baseline change processing (scope changes)?		Y	
f.	Process in place for critical path schedule change requests/approvals?		Y	
g.	No tasks with durations > 5D or 40hr (if so, detail the subtasks)		Y	
h.	All Tasks have individual resource assigned		Y	
i.	All assigned resource have reviewed task for understanding and accepted responsibility		Y	
j.	All Tasks logically linked to dependancies (predecessors and successors)		Y	
k.	Tasks on Critical Path have been identified		Y	
l.	Task work effort (hrs) understood for all critical path tasks		Y	
m.	All Tasks with assigned % Complete method		Y	
n.	Process in place for maintaining project schedule % completion updates		Y	
o.	All tasks have a definition of done (objective evidence) clearly identified		Y	
p.	Process in place for project schedule risk/issue management		Y	
q.	Starting Projects have a Critical Path Length index		Y	
r.	Project Schedule has established baseline		Y	
s.	Baseline project schedule captures entire scope of work and has adequate resources assigned		Y	
t.	Project Performance Metrics in place		Y	
6	**Performance Management**			
a.	Team Key Performance Indicators (KPI) Developed		Y	
b.	KPI Definitions understood		Y	
c.	KPI included in Teams individual Goals		Y	
d.	Performance trending maintained		Y	
d.	Periodic health check + lessons learned held		Y	
	Draft Key Measures:			
	% Complete		#%	
	Schedule Adherence		100%	
	Schedule Performance Index		>1	
	Cost Performance Index (Actual Costs/Planned Costs)		>1	
	Critical Path Length Index (Critical path + reserve/Critical Path)		>1	
	Risk Management Effectiveness		0	
	SOW Change Management Effectiveness		100% OT	
	Core Team Key Behavior Index (KBI) Score		100%	
7	**Project execution Status, default icon indicators are inplace that will highlight below for core team action:**			
	Tasks currently late to start		0	
	Tasks currently late to finish		0	
	Tasks that are behind schedule @ risk		0	
	Tasks scheduled to start within next 2 weeks		#	
	Tasks scheduled to finish within next 2 weeks		#	
	Tasks complete on time		100%	
8	**Project Summary 4-Panels established using template:**			
	Critical Path Tasks for upcoming 2 weeks		Y	
	Milestones and status		Y	
	Financial Performance		Y	
	Top Risks + Mitigations		Y	
	Notable Acheivements prior 30D		Y	
	Key Decisions/Escalations pending		Y	

Reference PMO Performance Playbook for Additional Guidance

Key Measures

Key Measure	Description	Target
% OT Milestone + Schedule Adherence	The % of milestones achieved on time and schedule adherence.	>98%
Revenue PTP	Tracks performance to plan for revenue generation	≥ 98%

Schedule Performance Index	Assess schedule efficiency comparing earned value to planned value	≥ 1
Cost Performance Index	Evaluates cost efficiency by comparing earned value to actual costs	≥ 1
Critical Path Length Index	Calculating schedule flexibility by dividing critical path duration including reserve by baseline duration	≥ 1
Risk Management Effectiveness	The effectiveness of risk actions to mitigate the risk	≥ 95%
SOW Change Management Effectiveness	Measures on how effective changes to the SOW are managed and implemented	≥ 98%
Core Team Key Behavior Index Score	Tracks adherence to critical team behaviors that drive project success and alignment	> 95%
Client Sentiment (NPS)	Captures client satisfaction and project performance through Net Promoter Score (NPS)	≥ 9
Capacity Utilization	The extent to which facilities and equipment are utilized effectively.	75% ≤ X ≤ 90%

Reviews

1. **Monthly S&OP (Sales & Operations Planning)**
   Monthly review meetings to align sales forecasts with operational plans.
2. **Weekly Readiness + Release**
   Weekly meetings to assess project readiness and release schedules.
3. **Weekly P2F (Plan to Forecast)**
   Weekly review of plans and forecasts to ensure alignment with project goals.
4. **Core Team Meetings**
   Regular meetings with the core team to discuss project progress and address any issues.
5. **Steering Committee Review**
   Periodic meetings with the steering committee to review project status and strategic decisions.

SEE ADDENDUM FOR 1 PAGE REVIEW CHARTERS

Effectiveness Check (Do's and Don'ts)

Do's:

☑ Align with the finalized demand plan using accurate forecasts and capacity analysis.

☑ Verify that all contract "shall" requirements are included in the project schedule.

☑ Conduct a thorough line-item assessment of the project schedule to ensure completeness.

☑ Ensure the core team is trained and prepared to execute the project plan.

☑ Provide sponsors with a summary of their responsibilities and necessary training.

☑ Conduct an internal core team meeting to review the Project Plan within one week of contract execution.

☑ Host a joint client and CDMO meeting to review the Project Plan within the first two weeks of contract execution.

☑ Facilitate a meeting between client and CDMO Project Managers in Week 1 to align project plan templates, the project schedule, and the communication plan.

☑ Establish a joint CDMO and Client SharePoint site to centralize document sharing and collaboration. Use a cloud-based project planning tool, such as Smartsheet, for seamless joint updates and real-time project tracking.

☑ Incorporate facility, equipment, workforce, and material limitations into the supply plan. Collaborate with stakeholders to ensure supply readiness.

☑ Document risks and implement proactive mitigation strategies. Monitor KPIs such as inventory management, capacity utilization, and fulfillment rates.

☑ Align supply plans with GMP and USP compliance standards.

Don'ts

☒ Avoid rigid plans that don't account for demand variability or market shifts.

☒ Do not assume unlimited capacity; always validate against actual constraints.

☒ Never defer addressing identified risks, as this may lead to delays.

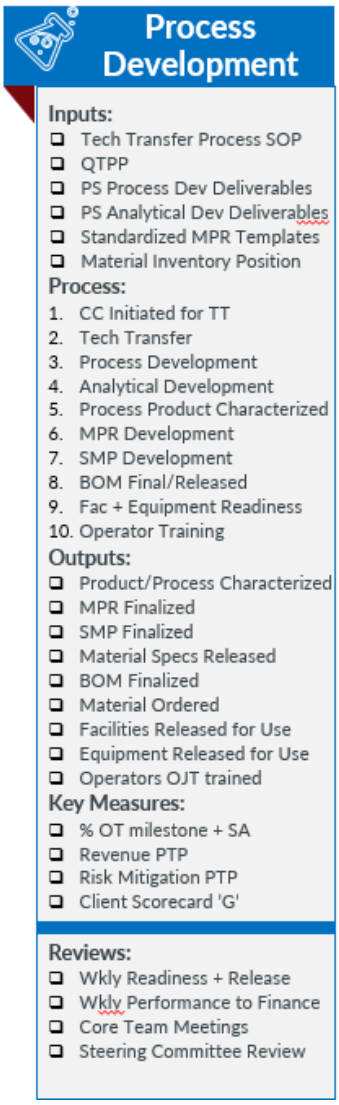
☒ Avoid isolating supply planning from cross-functional teams, which can cause inefficiencies.

☒ Do not overstock inventory, as this may lead to aging, obsolescence, or increased holding costs.

☒ Never compromise on quality to prioritize speed or cost.

☒ Ensure regular KPI reviews are conducted to enable timely interventions and continuous improvement.

5. TECHNICAL TRANSFER + PROCESS/ANALYTICAL DEVELOPMENT



The **Process Development** phase is a critical stage in the CDMO lifecycle, encompassing the technical transfer and development of manufacturing and analytical processes that will support clinical or commercial production. Key inputs to this phase include foundational documents such as the Tech Transfer SOP, Quality Target Product Profile (QTPP), and deliverables from Process and Analytical Development teams. These inputs enable structured execution of tech transfer, development, and readiness activities, with supporting templates like the MPR (Master Production Record) and current material inventory positions guiding planning accuracy and execution feasibility.

Core activities during this phase include formal initiation of change control for tech transfer, process and analytical development, and comprehensive process characterization—culminating in the finalization of the process control strategy. The goal is to ensure that all documentation, material readiness, facility and equipment staging, and operator training are complete and compliant. Success is measured through performance metrics such as on-time milestone achievement, revenue earned-to-plan (PTP), risk mitigation progress, and client satisfaction via scorecards. Weekly reviews of readiness, finance performance, and cross-functional team meetings ensure aligned execution and issue resolution in preparation for manufacturing readiness.

Input(s)

1. **Tech Transfer Process SOP**
   Standard operating procedure outlining the steps and requirements for technical transfer execution.
2. **QTPP**
   Quality Target Product Profile defining the desired product characteristics to guide development.
3. **Project Schedule Process Development Deliverables**
   Key documents and data outputs from process development required to support tech transfer.
4. **Project Schedule Analytical Development Deliverables**
   Analytical method development and validation outputs that characterize the product and ensure quality standards are met.
5. **Standardized MPR Templates**
   Predefined templates for creating Master Production Records to ensure consistency, accuracy, and compliance.
6. **Material Inventory Position**
   Baseline assessment of available raw materials and components required for development and initial production.

Process

1. **Change Control Initiated for Technical Transfer**
   Change control is formally opened to initiate technical transfer activities. This Change Control will include all the deliverables for the given clinical campaign. This is improve the overall efficiency in maintaining campaign history especially when Client returns to continue forward with next phase of clinical trials.
2. **Technical Transfer**

Knowledge and process responsibilities are transferred from Client to CDMO with the CDMO continuing the development to manufacturing.

3. **Process Development**
   The process is optimized and scaled to prepare for clinical or commercial production.
4. **Analytical Development**
   Test methods transferred from Client to CDMO and/or developed with agreed to plan on Qualification and Validation to ensure product quality and compliance.
5. **Process Product Characterized**
   Critical process and product attributes are defined and confirmed through studies. This would typically include a Process Control Strategy, Process Flow Diagram, Aseptic Process Strategy, pFMEA, and refining both Critical Process Parameters and Critical Quality Attributes.
6. **MPR Development**
   The MPR is drafted based on process design and manufacturing requirements.
7. **SMP Development**
   Standard Manufacturing Procedures are written to govern consistent shop floor execution.
8. **BOM Final/Released**
   Bill of Materials is confirmed and approved for use in manufacturing.
9. **Fac + Equipment Readiness**
   Facilities and equipment are staged, qualified, and ready for use in production.
10. **Operator Training**
    Operators are trained and OJT qualified on any new procedures, equipment, MPR's.

Output(s)

1. **Product/Process Characterized + Signed Off Supporting Documents**
   Key attributes and variability of the product and process are understood and documented.
2. **MPR Finalized**
   The Master Production Record is approved and ready for use.
3. **Master Data Finalized**
   All manufacturing procedures are approved and released.
4. **Material Specs Released**
   Specifications for raw materials and components are formally issued.
5. **Manufacturing BOM Finalized**
   The finalized list of materials required for manufacturing is approved.
6. **Material Released for Use**
   Materials necessary for production have been procured.
7. **Work Orders + Pick Lists Issued**
   Materials necessary for production have been procured.
8. **Facilities Released for Use**
   Manufacturing facilities are approved and ready for operations.
9. **Equipment Released for Use**
   Equipment is qualified, calibrated, and ready for GMP use.
10. **Operators OJT Trained**
    Operators have completed on-the-job training and are ready to execute.

Key Measures

Key Measure	Description	Target
% Complete Process Characterization	Track % Deliverables on time and total % complete	100%
% Analytical Methods Transferred	Track % Deliverables on time and total % complete	100%
% Analytical Methods Qualified	Track % Deliverables on time and total % complete	100%
% Documents Approved	Track % Deliverables on time and total % complete	100%
% Materials Released for Use	Track % Deliverables on time and total % complete	100%
% Facilities + Equipment Readiness	Track % Deliverables on time and total % complete	100%
% Operators Trained + Qualified	Track % of Operators that are trained and Qualified	100%
Revenue PTP	Tracks performance to plan for revenue generation	≥ 98%

Cost Performance Index	Evaluates cost efficiency by comparing earned value to actual costs	≥ 1
% On Time Invoicing	% of Invoices where completed deliverable is invoiced within 2D	100%
Risk Management Effectiveness	The effectiveness of risk actions to mitigate the risk	≥ 95%
Core Team Key Behavior Score	Track adherence to team behaviors driving project success+ alignment	> 95%

Reviews

1. **Weekly Readiness + Release**
   Weekly reviews of readiness activities and release tracking for deliverables.
2. **Weekly Performance to Finance**
   Financial performance is assessed weekly against planned targets.
3. **Core Team Meetings**
   Cross-functional team meetings to align, update, and resolve issues.
4. **Steering Committee Review**
   Governance-level oversight to review progress and strategic risks

SEE ADDENDUM FOR 1 PAGE REVIEW CHARTERS

Effectiveness Check (Do's and Don'ts)

Do's:

☑ Define and align early on the QTPP, CPPs, and CQAs to drive focus in both process and analytical development.

☑ Use standardized templates (MPRs, SMPs, BOMs) to streamline documentation and avoid ambiguity.

☑ Initiate Change Control (CC) promptly to formally trigger the transfer.

☑ Engage cross-functional teams (process dev, quality, manufacturing, supply chain, etc.) from the beginning to align goals and timelines.

☑ Conduct regular Core Team + Steering Committee reviews to escalate & resolve issues quickly.

☑ Ensure analytical methods are phase-appropriate and transferred or qualified early to avoid delays in release testing.

☑ Map out facility + equipment readiness timelines & coordinate with calibration/ validation teams.

☑ Validate material inventory position and lead times to prevent shortages or schedule delays.

☑ Track operator training and qualification status proactively to ensure readiness for execution.

☑ Document and track risk mitigation plans (PTP) with clear owners and due dates.

☑ Schedule and stick to weekly readiness reviews to catch misalignments early.

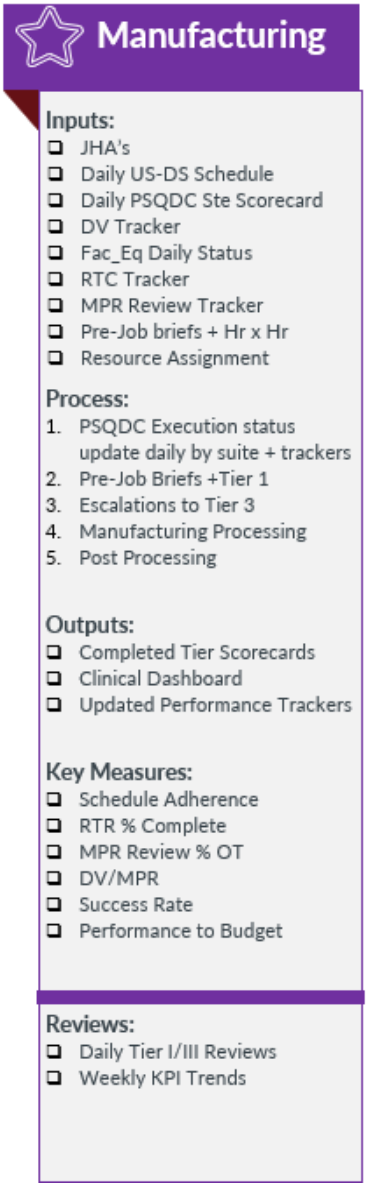
☑ Use a centralized risk log and continuously update it throughout development.

☑ Capture client feedback routinely via scorecards to guide course corrections in real-time.

Don'ts

- ☒ Delay initiating Change Control—this can stall dependent activities and misalign teams.
- ☒ Assume analytical methods are ready for tech transfer without verified method qualification or validation.
- ☒ Overlook BOM accuracy or materials readiness—incomplete BOMs or delayed orders can derail manufacturing readiness.
- ☒ Rely on informal communication—lack of documented alignment can lead to costly rework.
- ☒ Proceed with operator training too late—this creates risk for execution errors and deviation spikes.
- ☒ Underestimate facility or equipment lead times—ensure staging, calibration, and release are planned well ahead.
- ☒ Skip process characterization documentation—lack of defined CPPs/CQAs increases risk of process drift.
- ☒ Proceed without finalized specs or MPRs—doing so invites quality system gaps and audit findings.
- ☒ Let unresolved risks or open actions linger—close them before phase gate reviews.
- ☒ Ignore early warnings in performance metrics or weekly reviews—act promptly to address gaps.
- ☒ Leave client expectations unmanaged—lack of transparency can erode trust or delay approvals.

6. MANUFACTURING CAMPAIGN



This structured process ensures effective monitoring, execution, and review of manufacturing activities, with a focus on safety, quality, and efficiency in viral vector production.

Inputs

1. **Job Hazard Assessments (JHA's)**
   Evaluations of potential hazards associated with job tasks to ensure safety.
2. **Daily Manufacturing Schedule**
   Schedules for daily upstream (production) and downstream (purification) processes in viral vector manufacturing.
3. **Daily PSQDC Suite/Area Scorecards**
   Performance scorecards for daily updates on Productivity, Safety, Quality, Delivery, and Cost (PSQDC).
4. **Deviation (DV) Tracker**
   A tool for tracking deviations from standard processes or expected outcomes.
5. **Facilities and Equipment Daily Status**
   Daily updates on the status and availability of facilities and equipment.
6. **Real-Time Material Consumption (RTC) Tracker**
   Tracking the consumption of materials in real time during the manufacturing process.
7. **Master Production Batch Review (MPR) Tracker**
   A tracker for reviewing the overall status of MPR review.
8. **Pre-Job Briefs + Hour by Hour Schedule**
   Detailed briefs before starting jobs, including hourly schedules to ensure precise execution.
9. **Resource Assignment**
   Allocation of resources (personnel, equipment, materials) for daily tasks and activities.
10. **Pre + Post Line Clearance Check sheets Pre + Post Line Clearance Check sheets**
    Essential documents used in manufacturing environments, particularly in regulated industries like pharmaceuticals and biotechnology. These check sheets ensure that the production line is properly cleared and prepared before and after specific manufacturing processes. By thoroughly completing these check sheets, manufacturing facilities can maintain a controlled and compliant production environment, ensuring the safety and efficacy of their products. Here's a detailed description:

Pre-Line Clearance:

- **Removal of Previous Materials**: Ensuring all materials from the previous run are removed.
- **Material Readiness**: Ensuring that all materials needed for the shift activities are available and verified against the BOM for identification, count, expiry.
- **Cleaning Verification**: Confirming that the line has been cleaned according to standard operating procedures (SOPs).
- **Equipment Setup**: Verifying that all equipment is correctly set up and calibrated.

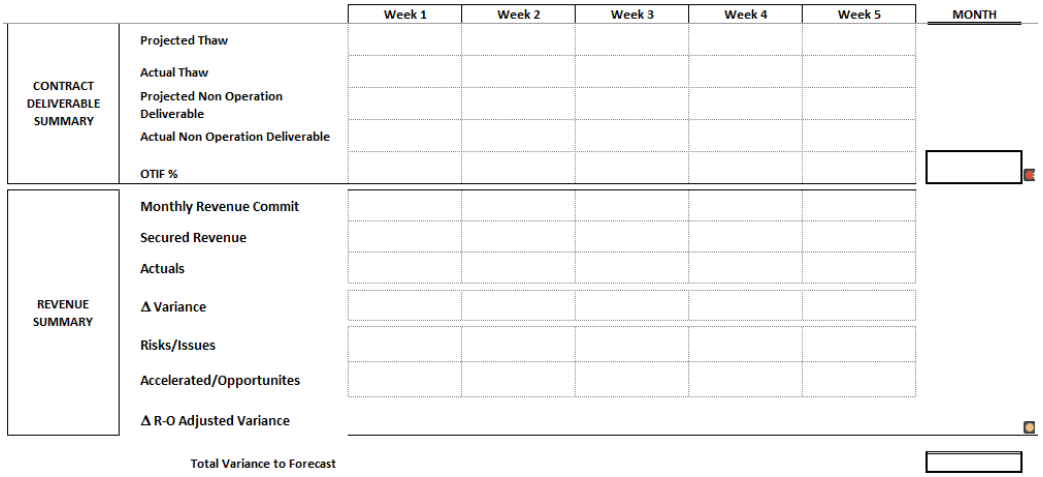
- **Documentation Check**: Ensuring that all necessary documentation for the upcoming run is available and correct.
- **Safety Checks**: Confirming that safety measures are in place and functional.
- **Approval**: Sign-off by a supervisor or quality assurance representative indicating that the line is ready for production.

Post Line Clearance:

- **Removal of Used Materials**: Ensuring all materials used during the production run are removed and properly disposed of.
- **Cleaning**: Confirming that the area has been cleaned + sanitized according to SOPs.
- **Equipment Inspection**: Verifying that all equipment has been cleaned, inspected, and reset as necessary.
- **Documentation Realtime Review**: Ensuring that all production documentation is complete and accurate.
- **Storage**: Confirming that any materials or products are correctly labeled and stored.
- **Safety and Compliance**: Ensuring that the line is left in a safe state, with no hazards or compliance issues.
- **Approval**: Sign-off by a supervisor or quality assurance representative indicating that the line has been properly cleared and is ready for subsequent processes.

Process

1. **PSQDC Execution Status Update Daily by Suite + Trackers**:
   Daily updates on the execution status of PSQDC metrics for each manufacturing suite using trackers.
2. **Pre-Job Briefs + Tier 1**:
   Conducting briefings before starting jobs, including Tier 1 meetings for immediate issue resolution.
3. **Escalations to Tier 3**:
   Escalating unresolved issues to Tier 3 for higher-level management and decision-making.
4. **Manufacturing Processing**:
   Execution of the manufacturing processes for viral vector production.



		Week 1	Week 2	Week 3	Week 4	Week 5	MONTH
CONTRACT DELIVERABLE SUMMARY	Projected Thaw						
	Actual Thaw						
	Projected Non Operation Deliverable						
	Actual Non Operation Deliverable						
	OTIF %						
REVENUE SUMMARY	Monthly Revenue Commit						
	Secured Revenue						
	Actuals						
	Δ Variance						
	Risks/Issues						
	Accelerated/Opportunites						
	Δ R-O Adjusted Variance						
	Total Variance to Forecast						

5. **Post Processing**:
   Activities following the manufacturing process, including cleaning, quality checks, and documentation.

Outputs

1. **Completed Tier Scorecards**
   Finalized scorecards reflecting the daily performance metrics and outcomes for each tier.
2. **Clinical Dashboard**
   A dashboard providing an overview of clinical metrics and performance.
3. **Updated Performance Trackers**
   Updated trackers reflecting the latest performance data and progress.

Key Measures

Key Measure	Description	Target
% On Time In Full	% of batches complete and on time as promised, in full quantity (Yield)	>98%
% Right First Time	% of batches, MPR's, tests, or outputs that are completed correctly without DV	>80%
Schedule Adherence	The degree to which the manufacturing process adheres to the planned schedule.	100%
RTR % Complete	Percentage completion of Real-Time Release (RTR) activities.	>98%
MPR Review % OT	Percentage of Master Production Record Reviews completed on time.	>98%
DV/MPR	Count of deviations (DV) and their impact on the Master Production Review.	< 0.25
Success Rate	The rate at which manufacturing processes meet their intended goals terminations.	>95%
Performance to Budget	Comparison of actual performance against the budgeted or planned performance.	100%

Reviews

1. **Daily Tier I+II+ III Reviews**
   Daily review meetings for Tier I (immediate team-level issues) and Tier II/III (higher-level management review).
2. **Weekly KPI Trends**
   Weekly analysis and review of Key Performance Indicator (KPI) trends to monitor ongoing performance and identify areas for improvement.

SEE ADDENDUM FOR 1 PAGE REVIEW CHARTERS

Effectiveness Check (Do's and Don'ts)

Do's:

☑ Detail 'A Day in the life of' with shift start + processing + exit Standard Work.

☑ Use Daily Schedules + PSQDC trackers to manage shifts and proactively identify issues by suite.

☑ Weekly schedule is resource allocated and leveled: Required Resources <=Assigned Resources.

☑ Conduct pre-job briefs to align teams, confirm readiness, and clarify roles and expectations.

☑ Have Performer + Verifier communicate activities in pre-job briefs.

☑ Utilize process FMEA in pre-job brief to bring awareness to and prevent failures.

☑ Include Client in pre-job brief.

☑ Prepare and utilize Hour x Hour schedule with Performer + Verifiers listed for activities along with Technical SME as needed during critical activities.

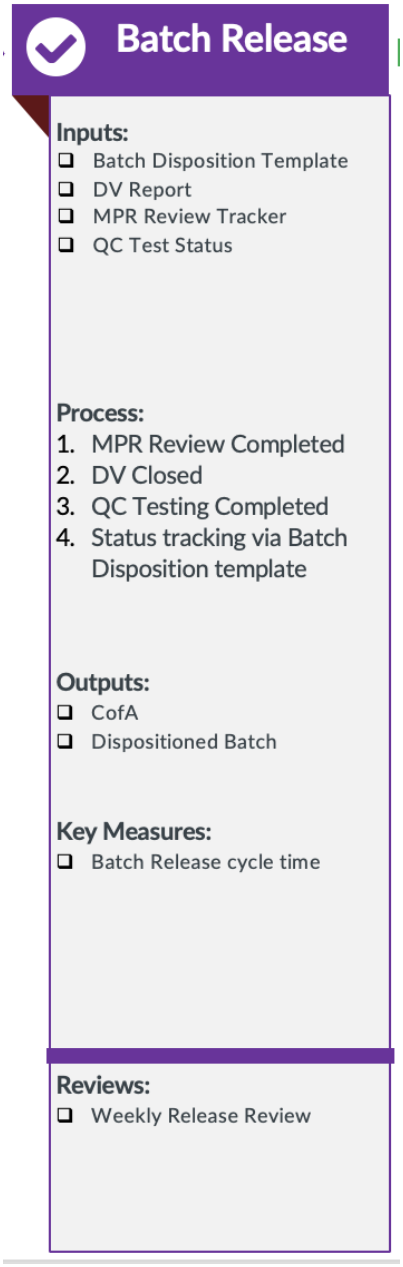
- ☑ Conduct daily shift real time review to verify MPR entries are ALCOA with no GDP/GMP issues.
- ☑ Link the daily shift change to the Tiered I,II, III PSQDC trackers.
- ☑ Focus Tiers on prior day + current day performance, plan, new DV, risk mitigations, KPI, and escalations.
- ☑ Complete Job Hazard Analyses (JHAs) before initiating operations to ensure safety compliance.
- ☑ Track performance to Hour x Hour schedule- did you start and stop within +- 2hrs of schedule.
- ☑ Monitor the DV + RTE trackers daily to stay ahead of DV, room turnover, and execution timing.
- ☑ Escalate issues to Tier 3 promptly using predefined criteria to prevent production delays.
- ☑ Ensure MPR reviews are completed on time and with clear documentation to support batch release readiness.
- ☑ Track schedule adherence and RTR (Ready-to-Release) % complete as leading indicators of processing efficiency.
- ☑ Review manufacturing success rates and budget performance weekly to identify trends or drift.
- ☑ Resource schedule has a 30D look ahead reconciling any discrepancies between Resources required vs available.
- ☑ Update clinical dashboards and tier scorecards consistently to maintain transparency and accountability.

Don'ts

- ☒ Bypass or delay JHA reviews—doing so increases risk to safety and compliance.
- ☒ Start manufacturing activities without completing pre-job briefs—misalignment can lead to execution errors.
- ☒ Ignore real-time data from PSQDC or DV trackers—small issues can compound if not addressed daily.
- ☒ Allow MPRs or documentation reviews to lag behind production—this jeopardizes release timelines.
- ☒ Rely solely on verbal escalations—document and route issues through established Tier processes.
- ☒ Treat Tier scorecards as a formality—they are key to understanding true performance and guiding decisions.
- ☒ Wait until weekly meetings to address deviations or bottlenecks—daily action is more effective.
- ☒ Overlook budget deviations—track cost performance regularly to prevent overrun surprises.
- ☒ Assume resource assignments are aligned without validation—confirm roles and handoffs clearly.

7. RELEASE

By following this process, the organization ensures that each batch undergoes thorough review and testing before being released, maintaining high standards of quality and compliance.



Inputs

1. **Batch Disposition Template**
   A standardized template used to document the final disposition of a batch, including quality status and release decision.
2. **Deviation (DV) Report**
   Documentation of any deviations from standard procedures that occurred during the batch production.
3. **Master Production Review (MPR) Tracker**
   A tool for tracking the review MPR.
4. **Quality Control (QC) Test Status**
   Reports on the status and results of all QC tests performed on the batch.

Process

1. **MPR Review Completed**:
   - The Master Production Review is conducted to ensure that all production steps were performed according to the predefined protocols and that the batch meets all required standards.
   - This includes reviewing documentation, production records, and any deviations.
2. **DV Closed**:
   - All deviations reported during the batch production are investigated, resolved, and closed.
   - This includes documenting the root cause, corrective actions, and preventive measures taken.
3. **QC Testing Completed**:
   - All necessary QC tests are performed on the batch to ensure it meets the specified quality criteria.
   - This includes chemical, physical, and microbiological tests.
4. **Status Tracking via Batch Disposition Template**:
   - The status of the batch is tracked using the Batch Disposition Template, which records the outcomes of the MPR review, DV closure, and QC tests.
   - This template provides a comprehensive view of the batch's readiness for release.

Outputs

1. **Certificate of Analysis (CofA)**
   - A document certifying that the batch meets the required specifications and quality standards based on the results of the QC tests.
2. **Dispositioned Batch**
   - The final decision on the batch (e.g., released, rejected, or put on hold) is documented and communicated. The dispositioned batch is either released for distribution, sent for reprocessing, or disposed of as per regulatory guidelines.

Key Measures

Key Measure	Description	Target
Batch Release CT	The total time taken from the completion of production to the final disposition and release of the batch. This metric includes the time required for MPR review, DV closure, QC testing, and any necessary approvals.	<30D
Schedule Adherence	The degree to which the manufacturing process adheres to the planned schedule.	100%
Success Rate	The rate at which manufacturing processes meet their intended goals terminations.	>95%
MPR Review % RFT	% of batches, MPR's, tests, or outputs that are completed correctly without DV	>95%
MPR Review % OT	Percentage of Master Production Record Reviews completed on time.	>98%
DV/Batch	Count of deviations (DV) and their impact on the Master Production Review.	< 0.25
Performance to Budget	Comparison of actual performance against the budgeted or planned performance.	100%

Reviews

1. **Weekly Disposition and Release Review**
   A regular review meeting where the status of all batches in the disposition process is discussed. This meeting includes reviewing the progress of MPR reviews, DV closures, QC test completions, and any bottlenecks or issues that may delay batch release. Key stakeholders such as quality assurance, quality control, production, and regulatory affairs typically attend these reviews.

SEE ADDENDUM FOR 1 PAGE REVIEW CHARTERS

Effectiveness Check (Do's and Don'ts)

Do's:

☑ Ensure MPR (Master Production Record) reviews are completed thoroughly before proceeding to quality disposition.

☑ Track MPR Review right first time at Manufacturing, Quality, and Client Review.

☑ Track MPR review schedule adherence for Manufacturing, Quality, and Client Reviews.

☑ Allow Manufacturing to investigate MPR review discrepancies prior to initiating DV.

☑ Triage DV with Manufacturing and Quality upon initiation.

☑ Have a communication feedback loop to Manufacturing Operators for DV and GDP issues discovered during MPR review

☑ Verify all deviations (DV) are closed and documented with QA-approved justifications.

☑ Confirm QC testing is fully complete and within specifications before initiating batch disposition.

☑ Use the Batch Disposition Template to track status consistently across departments.

☑ Maintain timely communication between QA, QC, +manufacturing to expedite release timelines.

☑ Conduct weekly release reviews to track cycle times, flag delays, and drive accountability.

☑ Archive DV reports, CoAs, and review trackers for audit readiness and traceability.

☑ Measure and trend batch release cycle time as a key indicator of operational efficiency.

☑ Ensure CoAs (Certificates of Analysis) are accurate, approved, and match batch records.

Don'ts

☑ Initiate batch release with open or incomplete deviation investigations.

☑ Overlook discrepancies in the MPR or rush the review process.

☑ Assume QC status is final—always confirm test completion and result approval.

☑ Release a batch without full documentation and review of critical process and quality steps.

☑ Allow incomplete Batch Disposition Templates to delay or misrepresent status.

☑ Skip cross-functional reviews—missed communication can lead to costly errors.

☑ Ignore trends in batch release delays—regular reviews should lead to corrective action.

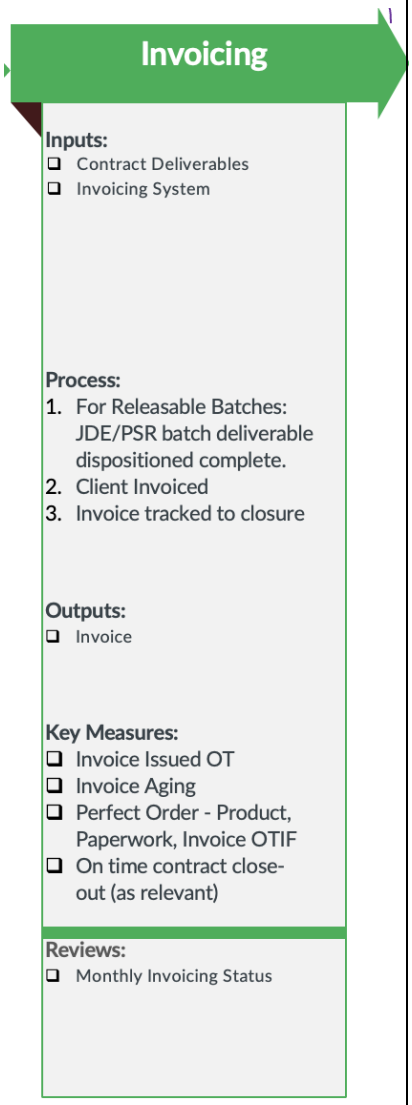
☑ Bypass QA approval on CoAs or disposition decisions.

8. SHIPMENT + INVOICE

By following this process, the organization ensures accurate and timely invoicing for completed batches, which helps maintain healthy cash flow and client satisfaction while ensuring compliance with contractual obligations.

Inputs

1. **Contract Deliverables**
   Detailed information and deliverables from the financial system of record related to the contract, including batch details, deliverable completion status, and client-specific requirements.
2. **Invoicing System**
   The system or software used to generate, track, and manage invoices.



Process

1. **For Releasable Batches: Finance system of record Batch Deliverable Dispositioned Complete**:
   - Ensure that all deliverables for the batch, as specified in the system are completed and documented.
   - Confirm that the batch is ready for release based on the completion of all required deliverables.
2. **Client Invoiced**:
   - Generate an invoice for the client using the invoicing system, based on the completion of deliverables and batch readiness for release.
   - Include all necessary details such as batch identification, deliverables completed, costs, and payment terms.
3. **Invoice Tracked to Closure**:
   - Track the status of the invoice from issuance to payment.
   - Follow up on outstanding invoices, manage any client queries or disputes, and ensure timely payment.

Outputs

1. **Invoice**
   A formal invoice issued to the client for the releasable batch, detailing the services provided, costs incurred, and payment instructions.

Key Measures

1. **Invoice Issued On-Time (OT)**

The timeliness of invoice issuance after batch deliverables are completed and the batch is dispositioned.

2. **Invoice Aging**

   The duration an invoice remains outstanding before payment is received. This measure helps track overdue payments and manage cash flow.

3. **Perfect Order** *Product +Paperwork+ Invoice On Time In Full (OTIF)*

   A measure of the completeness and accuracy of the entire order process, ensuring that the product, associated paperwork, and invoice are all delivered on time and in full, meeting all client and contractual requirements.

4. **On-Time Contract Close-Out (as relevant)**

   The efficiency and timeliness in closing out contracts once all deliverables are completed and invoiced.

Reviews

1. **Monthly Invoicing Status**:
   - A regular review meeting to discuss the status of all outstanding and recent invoices.
   - Review key metrics such as the number of invoices issued, invoice aging, on-time issuance, and any issues or delays in payments.
   - Address any client disputes, follow-up actions, and strategies to improve the invoicing process.
   - Participants typically include finance, accounts receivable, project management, and commercial operations teams.

SEE ADDENDUM FOR 1 PAGE REVIEW CHARTERS

Effectiveness Check (Do's and Don'ts)

Do's:

☑ Confirm all contract deliverables are complete before initiating the invoice.

☑ Issue the invoice within 24hrs of contract deliverable completion.

☑ Ensure client invoicing aligns with contractual billing terms (milestone, time-based, or deliverable-based).

☑ Include in the project schedule, columns for invoice amount and completion verification for all revenue related deliverables for core team tracking.

☑ Include a KPI for Invoices submitted on time and paid on time.

☑ Track each invoice through to closure using a centralized system to avoid lost or delayed payments.

☑ Review invoice aging regularly to flag overdue or at-risk payments.

- ☑ Perform periodic status reviews to reconcile open vs. closed invoice items. Frequency is based upon magnitude of open invoices.
- ☑ Include complete and accurate backup documentation (e.g., CoA, batch release forms, SOW references).
- ☑ Align with finance and program teams to ensure “Perfect Order” conditions are met (product, paperwork, invoice accuracy).

Don'ts

- ☒ Issue an invoice before batch disposition or documentation is fully complete.
- ☒ Assume invoice delivery equals payment—track confirmation and follow up as needed.
- ☒ Overlook mismatches between SOW terms and what is being invoiced.
- ☒ Delay invoicing—late billing can impact cash flow and client satisfaction.
- ☒ Send incomplete or error-prone invoices—this can result in payment rejection.
- ☒ Ignore aging invoices—lack of follow-up can lead to revenue leakage.
- ☒ Skip monthly reviews—unresolved issues can accumulate and disrupt end-of-contract reconciliation.
- ☒ Neglect cross-functional alignment—errors often arise from disconnects between ops, QA, and finance.

9. ADDENDUM

a) GATE 0- Proposal Approval

b) GATE 1- Contract Signature Execution

c) GATE 2- Program Plan Finalization

d) GATE 3- Technical Transfer + Process & Analytical Development

e) GATE 4- Manufacturing Campaign

f) GATE 5- Successful Contract Closure

g) Integrated Master Schedule Template (Project Schedule)

h) 1-Page Review Charters:

i. Proposal Performance to Plan

ii. Mid-Month Forecast Review

iii. End of Month Clinical Review

iv. Monthly S&OP (Sales & Operations Planning)

v. Weekly Readiness + Release Charter

vi. Weekly P2F (Plan to Forecast) Charter

vii. Core Team Meetings Charter

viii. Steering Committee Review Charter

ix. Daily Tier I+II+ III Reviews Charter

x. Weekly KPI Trends Charter

xi. Weekly Disposition and Release Review Charter

xii. Monthly Invoicing Status Charter

GATE 0: PROPOSAL APPROVAL

Overview:
Proposal qualification begins with evaluating the strategic, operational, and financial viability of pursuing an opportunity in response to a client Request for Proposal (RFP). The criteria below help determine if the proposal is positioned for success and if it is aligned with internal capabilities, resources, and business priorities.

KEY MEASURES	VALUE	TARGET
Clinical Phase		I/II/III
Total Proposal Value		$10M
Estimated Client Life Time Value		> $50M
Estimated Profitability (EBITDA)		> 30%
Probability Win		> 80%
Probability Go		> 75%
Complexity		Low/Med

Independent Review Results:

CRITERIA	YES/ NO	RISK (H,M,L)	MITIGATION	ADDITIONAL DETAILS	
Proposal approach and solution maximize probability of winning					
Competitive pricing strategy developed and benchmarked					
Turnaround time for deliverables meets or exceeds client expectations					
Proposal meets all mandatory ("shall") requirements of the RFP					
Work scope is within company capabilities (technical and operational)					
Organization has capacity (resources, infrastructure) to deliver if awarded					
Clear indication client will proceed w/ award (funding approved, committed timeline)					
Client financial stability confirmed (e.g. D&B SER rating, payment history)					
Major risks identified and addressed (e.g. timeline, cost, compliance)					

ACTIONS	OWNER	DUE	STATUS

SELECT ONE	GATE 0 REVIEW CONCLUSION
☐	Approved to proceed to next phase
☐	Approved to proceed @risk to next phase, pending completion of below actions
☐	Not Approved, do not proceed forward to next phase

Signatory

REVIEWER	DEPT	PRINT	INITIAL / DATE
	Operations		
	Supply Chain		
	QA		
	QC		
	Process Development		
APPROVER			
	GM		
	Commercial		
	Finance		
	Operations		
	Supply Chain		
	QA/QC		
	Process Development		

GATE 1: CONTRACT SIGNATURE EXECUTION

Overview:
The purpose of this Contract Review Checklist is to ensure that all terms and conditions outlined in the agreement between the Client and the CDMO are robust, clearly defined, and structured to effectively mitigate operational, financial, legal, quality, and compliance risks

KEY MEASURES	VALUE	TARGET
Clinical Phase		I/II/III
Total Proposal Value		$10M
Estimated Client Life Time Value		> $50M
Estimated Profitability (EBITDA)		> 30%
Probability Go		> 75%
Complexity		Low/Med

Independent Review Results:

CRITERIA	YES/ NO	RISK (H,M,L)	MITIGATION	ADDITIONAL DETAILS	
Scope of Work (SOW) • Clear definition of services: tech transfer, process development, DS & DP manufacturing, QC testing, and release. • Milestones and deliverables with acceptance criteria. • Roles and responsibilities (CDMO vs. Sponsor)					
Timeline & Scheduling • Project timeline realistic.					
Pricing & Payment Terms Fair and Transparent • Detailed cost structure. • Payment triggers (e.g., milestone-based, invoice date). • Terms for change orders, budget caps, or overruns. • Late payment penalties.					
Quality Agreement Established					
Standard Terms and Conditions					
Pricing meets internal Targets					
Governance Mechanism enable partnership and issue escalation					
Major risks identified and addressed (e.g. timeline, cost, compliance)					

ACTIONS	OWNER	DUE	STATUS

SELECT ONE	GATE 1 REVIEW CONCLUSION
☐	Approved to proceed to next phase
☐	Approved to proceed @risk to next phase, pending completion of below actions
☐	Not Approved, do not proceed forward to next phase

Signatory

REVIEWER	DEPT	PRINT	INITIAL / DATE
	Operations		
	Supply Chain		
	QA		
	QC		
	Process Development		
APPROVER			
	GM		
	Commercial		
	Finance		
	Operations		
	Supply Chain		
	QA/QC		
	Process Development		

GATE 2: PROGRAM PLAN FINALIZATION

Overview:
The objective of this gate is to ensure all foundational elements of the contract program are finalized, documented, and aligned across stakeholders prior to execution of project activities. This step acts as a critical control point to verify program readiness, enhance cross-functional transparency, and minimize downstream execution risk.

KEY MEASURES	VALUE	TARGET
Project % Complete		On Track
Schedule Adherence		100%
Cost Performance Index		> 1
Schedule Performance Index		> 1
Invoicing On Time in Full		100%
Critical Path Management (CPLI)		> 1
Risk Mgt Effectiveness		>95%
SOW Change Mgt Effectiveness		>95%
Core Team KBI Score		>95%

Independent Review Results:

CRITERIA	YES/ NO	RISK (H,M,L)	MITIGATION	ADDITIONAL DETAILS	
Project Schedule Finalized					
Any Contract SOW additions reviewed and dispositioned					
Risk Log Established- Major risks identified and addressed					
Communication Plan Finalized					
Schedule Change Control Initiated					
Key Decision Tracker Initiated					
Governance Alignment					
Core Team Launched					
Joint Kick-off Meeting Held					
Shared Doc Repository Established (Sharepoint)					
Project Plan Assessment Complete					

ACTIONS	OWNER	DUE	STATUS

SELECT ONE	GATE 2 REVIEW CONCLUSION
☐	Approved to proceed to next phase
☐	Approved to proceed @risk to next phase, pending completion of below actions
☐	Not Approved, do not proceed forward to next phase

Signatory

REVIEWER	DEPT	PRINT	INITIAL / DATE
	Operations		
	Supply Chain		
	QA		
	QC		
	Process Development		
APPROVER			
	GM		
	Commercial		
	Finance		
	Operations		
	Supply Chain		
	QA/QC		
	Process Development		

GATE 3: TECH TRANSFER + PROCESS/ANALYTICAL DEVELOPMENT

Overview:
The objective of this gate is to verify that all technical, analytical, facility, material, and operational elements have been transferred, developed, and qualified to support the initiation of GMP manufacturing. This gate ensures that product, process, and analytical readiness meet internal quality standards, client expectations, and regulatory compliance, thereby minimizing technical risk and ensuring robust execution during production.

KEY MEASURES	VALUE	TARGET
Project % Complete		On Track
Schedule Adherence		100%
Cost Performance Index		>1
% On Time Invoicing		100%
% Complete Process Characterization		100%
% Analytical Methods Transferred		100%
% Analytical Methods Qualified		100%
% Documents Approved		100%
% Materials Released for Use		100%
% Facilities + Equipment Readiness		100%
% Operators Trained + Qualified		100%
Risk Mgt Effectiveness		>95%
Core Team KBI Score		>95%

Independent Review Results:

CRITERIA	YES/ NO	RISK (H,M,L)	MITIGATION	ADDITIONAL DETAILS	
Process Characterization complete: • Finalized Process Flow Diagram (PFD) • Control Strategy documented • Aseptic Processing Strategy established • pFMEA reviewed and actions addressed • CPPs (Critical Process Parameters) and CQAs (Critical Quality Attributes) finalized • QTPP updated and aligned					
Batch Records (MPR/SMP) finalized					
Bill of Materials (BOM) finalized					
JDE Master Data Verified					
Material Specifications Released					
Materials Released for Use					
Analytical Readiness- • All required methods transferred to QC + qualified • Method validation completed (or appropriate bridging/risk-based rationale documented) • Analytical testing protocols approved • Release testing strategy defined					
Facility & Equipment Readiness • Facilities qualified+ released for intended use • Equipment staged, calibrated, released for use • Environmental monitoring strategy in place					
Operator Readiness • Operators trained and OJT qualified • Operators trained on MPR • Personnel gowning/training compliance confirmed for classified areas • Line clearance procedures in place and practiced					
Risk Management • Updated Risk Register including mitigations for technical and operational risks					
Change control • TT CC Implementation Actions Complete					

ACTIONS	OWNER	DUE	STATUS

SELECT ONE	GATE 3 REVIEW CONCLUSION
☐	Approved to proceed to next phase
☐	Approved to proceed @risk to next phase, pending completion of below actions
☐	Not Approved, do not proceed forward to next phase

Signatory

REVIEWER	DEPT	PRINT	INITIAL / DATE
	Operations		
	Supply Chain		
	QA		
	QC		
	Process Development		
APPROVER			
	GM		
	Commercial		
	Finance		
	Operations		
	Supply Chain		
	QA/QC		
	Process Development		

GATE 4: MANUFACTURING CAMPAIGN COMPLETION

Overview:
The objective of **Gate 4** is to verify that the manufacturing campaign has been executed in full alignment with GMP expectations, contractual obligations, and internal standards—ensuring all quality, technical, and operational elements are complete, reconciled, and reviewed. This includes closure of batch documentation, deviations, testing, and delivery commitments. Gate 4 provides a formal go/no-go checkpoint to confirm readiness for project continuation or closure, while mitigating residual risks and confirming compliance with the Statement of Work (SOW).

The gate criteria are evaluated based on a time-bound sequence of post-manufacturing deliverables, ensuring discipline and accountability. Outcomes of this gate include either full approval for campaign closure or conditional approval with documented actions required prior to progressing to product release, stability initiation, or subsequent phases.

KEY MEASURES	VALUE	TARGET
% Success Rate		>95%
% Batches On Time In Full		100%
% On Time MPR Review (<24 days)		100%
% MPR Review Right First Time		>95%
DV/MPR		<0.25
% On Time DV Completion (<30D)		100%
Cost Performance Index		>1
Client Net Promoter Score (NPS)		≥ 9
Risk Mgt Effectiveness		>95%
Core Team KBI Score		>95%

Independent Review Results:

CRITERIA	YES/ NO	RISK (H,M,L)	MITIGATION	ADDITIONAL DETAILS	
Batch Execution • Manufacturing batch(es) executed per approved MPR/SOP • Campaign summary report completed • In-process and final results within specification					
Deviation and Documentation • All deviations investigated, closed, w/CAPA as needed • Final executed MPR reviewed, with internal signoff					
Testing & Release • All release testing completed and reviewed within 45-day post-batch window • Certificate of Analysis (CoA) issued within +5 days of release completion • Stability testing in process (as applicable)					
Materials • Client furnished materials dispositioned • Unused Materials returned to Inventory • Materials on NCMR dispositioned in MRB					
Client & Regulatory Commitments • All Client communications and reports issued • Shipment completed within 14d post CofA					
Facilities & Equipment • Facility Changeover • Equipment Changeover • Client owned Equipment dispositioned					
Risk Management • Updated Risk Register including mitigations for technical and operational risks					

ACTIONS	OWNER	DUE	STATUS

SELECT ONE	GATE 4 REVIEW CONCLUSION
☐	Approved to proceed to next phase
☐	Approved to proceed @risk to next phase, pending completion of below actions
☐	Not Approved, do not proceed forward to next phase

Signatory

REVIEWER	DEPT	PRINT	INITIAL / DATE
	Operations		
	Supply Chain		
	QA		
	QC		
	Process Development		
APPROVER			
	GM		
	Commercial		
	Finance		
	Operations		
	Supply Chain		
	QA/QC		
	Process Development		

GATE 5: CONTRACT CLOSURE

Overview:
The final phase of the program, **P5: Contract Completion + Closure**, ensures that all contractual, operational, and quality-related obligations are fulfilled, enabling formal closure of the project. This includes a systematic review of deliverables, risk mitigation, financial reconciliation, and knowledge capture.

A comprehensive contract review confirms that all milestones outlined in the Statement of Work (SOW) have been completed and verified, all Quality System actions (e.g., deviations, CAPAs, QCA) are closed, and any change controls have been resolved. Client-provided assets are dispositioned appropriately, and financial closeout is confirmed through reconciliation and payment of all invoices. Additionally, client satisfaction is formally captured through a Net Promoter Score (NPS), and a Joint After Action Review (AAR) is conducted to extract lessons learned and inform potential follow-on campaign planning.

KEY MEASURES	VALUE	TARGET
On Time Contract Closeout		100%
% SOW Milestones Completed and Verified		100%
% Quality Event Closed		100%
% Risk Log Items Closed		100%
CC On Time Completion of Implementation Actions		100%
Invoice Reconciliation Rate		100%
Client Net Promoter Score (NPS)		≥ 9

Independent Review Results:

CRITERIA	YES/ NO	RISK (H,M,L)	MITIGATION	ADDITIONAL DETAILS
All Contract SOW milestones completed and verified (Contract 'Shalls')				
All Milestones closed out in JDE				
All Invoices reconciled and paid				
All Risk log risk + issues actions complete and closed				
All Quality Events (DV, QCA, CAPA) completed and closed				
Campaign Change Control Implementation Actions complete and CC closed				
Final Client Net Promoter Score collected and reviewed in detail with Client				
Joint After-Action Review (AAR) conducted, documented, with lessons learns communicated				
Follow-on Campaign Planning initiated, as applicable				

ACTIONS	OWNER	DUE	STATUS

SELECT ONE	GATE 5 REVIEW CONCLUSION
☐	Approved to proceed to next phase
☐	Approved to proceed @risk to next phase, pending completion of below actions
☐	Not Approved, do not proceed forward to next phase

Signatory

REVIEWER	DEPT	PRINT	INITIAL / DATE
	Operations		
	Supply Chain		
	QA		
	QC		
	Process Development		
APPROVER			
	GM		
	Commercial		
	Finance		
	Operations		
	Supply Chain		
	QA/QC		
	Process Development		

PROPOSAL PERFORMANCE TO PLAN REVIEW

Objective: On time proposal processing and WIN strategy that achieves WIN target.

Expected Outcome: (1) On time proposal/change of scope submission, (2) Cross organization WIN strategy that maximizes award success, (3) timely award of Contracts/COS.

Key Success Measures:

KPI	Target	Calculation

Participation: Team will meet weekly @ Thursday 3:00PM PST for 30-minute duration.

Working Document: Proposal + Change of Scope Progress Tracker {insert Hyperlink}

Participants: The following Departments will be represented by Department Lead or Designee at a minimum. Leads may invite additional department resources as appropriate:

Core Team Role	Lead
Commercial Ops	
PM	
Process Development	
Finance	
BD	

Extended Team (Optional)	Lead
Supply Chain	
QA/QC	
Manufacturing	

Blue: Required for Quorum **Bold:** Review Leader

Meeting pre-work:

1. By **noon** the day prior to this meeting, responsible areas input the latest update into Proposal/COS tracker.
2. Any tasks that are either behind (yellow) or late (red) require one sentence detailing issue and resolution plan in the appropriate Proposal Tracker column.

Agenda:

1. Review Leader provides a summary of: (20m)
    1. Prior week completion
    2. New Proposal/COS
    3. Review of every Proposal/COS that is behind or late + the issue and mitigation. Team to discuss and revise/escalate as needed.
2. Review of Key Performance Measures (minimum monthly) (5m)
3. Recap (5m)

Responsibilities:

	PW	BD	MFG/PD	QA	QC	Legal	Business O	Area Leader	ELT
Provide Completed Client in take form to Proposal Writer	I	R	C	C	C	C	C	A	
Schedule technical call with Client as needed	C	R	I	I	I	I	I	A	
Draft Client proposal and route for review/approval	R	I	C	C	C	C	C	A	
Review and approve draft proposal	I	I	R	R	R	R	R	A	
Maintain proposal tracker status	R	R	R	R	R	R	R	A	
Document Risks, Issues, Opportunities	I	R	R	R	R	R	R	A	
On Time completion of Proposals	R	R	R	R	R	R	R	A	I
Meeting participation	R	R	R	R	R	R	R	A	
Meeting facilitation and summaries	R							A	I
Resolution of escalations	C	I	C	C	C	C	C	I	R

A – Accountable: Owner of Task; R – Responsible: Performs Task; C – Consulted: Two way communication; I – Informed: One Way communication

Mid-Month Forecast Review Charter

Objective: {Objective}

Expected Outcome: {Outcome}

Key Success Measures:

KPI	Target	Calculation

Participation: Team will meet weekly @ DD TT PST for 30-minute duration.

Working Document: {insert Hyperlink}

Participants: The following Departments will be represented by Department Lead or Designee at a minimum. Leads may invite additional department resources as appropriate:

Core Team Role	Lead

Extended Team (Optional)	Lead

Blue: Required for Quorum **Bold:** Review Leader

Meeting pre-work:

1. {Prework}

Agenda:

1. {Item 1}
2. {Item 2}
3. {Item 3}

Responsibilities:

	PM	COM OPS	MFG	QA/QC	FINANCE	PD	SCM	Area Leader	ELT

A – Accountable: Owner of Task; R – Responsible: Performs Task; C – Consulted: Two way communication; I – Informed: One Way communication

End of Month Clinical Review Charter

Objective: {Objective}

Expected Outcome: {Outcome}

Key Success Measures:

KPI	Target	Calculation

Participation: Team will meet weekly @ DD TT PST for 30-minute duration.

Working Document: {insert Hyperlink}

Participants: The following Departments will be represented by Department Lead or Designee at a minimum. Leads may invite additional department resources as appropriate:

Core Team Role	Lead

Extended Team (Optional)	Lead

Blue: Required for Quorum **Bold:** Review Leader

Meeting pre-work:

2. {Prework}

Agenda:

2. {Item 1}
2. {Item 2}
3. {Item 3}

Responsibilities:

	PM	COM OPS	MFG	QA/QC	FINANCE	PD	SCM	Area Leader	ELT

A – Accountable: Owner of Task; R – Responsible: Performs Task; C – Consulted: Two way communication; I – Informed: One Way communication

Monthly S&OP (Sales & Operations Planning) Charter

Objective: {Objective}

Expected Outcome: {Outcome}

Key Success Measures:

KPI	Target	Calculation

Participation: Team will meet weekly @ DD TT PST for 30-minute duration.

Working Document: {insert Hyperlink}

Participants: The following Departments will be represented by Department Lead or Designee at a minimum. Leads may invite additional department resources as appropriate:

Core Team Role	Lead

Extended Team (Optional)	Lead

Blue: Required for Quorum **Bold:** Review Leader

Meeting pre-work:

3. {Prework}

Agenda:

3. {Item 1}
2. {Item 2}
3. {Item 3}

Responsibilities:

	PM	COM OPS	MFG	QA/QC	FINANCE	PD	SCM	Area Leader	ELT

A – Accountable: Owner of Task; R – Responsible: Performs Task; C – Consulted: Two way communication; I – Informed: One Way communication

Weekly Readiness + Release Charter

Objective: {Objective}

Expected Outcome: {Outcome}

Key Success Measures:

KPI	Target	Calculation

Participation: Team will meet weekly @ DD TT PST for 30-minute duration.

Working Document: {insert Hyperlink}

Participants: The following Departments will be represented by Department Lead or Designee at a minimum. Leads may invite additional department resources as appropriate:

Core Team Role	Lead

Extended Team (Optional)	Lead

Blue: Required for Quorum **Bold:** Review Leader

Meeting pre-work:

4. {Prework}

Agenda:

4. {Item 1}
2. {Item 2}
3. {Item 3}

Responsibilities:

	PM	COM OPS	MFG	QA/QC	FINANCE	PD	SCM	Area Leader	ELT

A – Accountable: Owner of Task; R – Responsible: Performs Task; C – Consulted: Two way communication; I – Informed: One Way communication

Weekly P2F (Plan to Forecast) Charter

Objective: {Objective}

Expected Outcome: {Outcome}

Key Success Measures:

KPI	Target	Calculation

Participation: Team will meet weekly @ DD TT PST for 30-minute duration.

Working Document: {insert Hyperlink}

Participants: The following Departments will be represented by Department Lead or Designee at a minimum. Leads may invite additional department resources as appropriate:

Core Team Role	Lead

Extended Team (Optional)	Lead

Blue: Required for Quorum **Bold:** Review Leader

Meeting pre-work:

5. {Prework}

Agenda:

5. {Item 1}
2. {Item 2}
3. {Item 3}

Responsibilities:

	PM	COM OPS	MFG	QA/QC	FINANCE	PD	SCM	Area Leader	ELT

A – Accountable: Owner of Task; R – Responsible: Performs Task; C – Consulted: Two way communication; I – Informed: One Way communication

Core Team Meetings Charter

Objective: {Objective}

Expected Outcome: {Outcome}

Key Success Measures:

KPI	Target	Calculation

Participation: Team will meet weekly @ DD TT PST for 30-minute duration.

Working Document: {insert Hyperlink}

Participants: The following Departments will be represented by Department Lead or Designee at a minimum. Leads may invite additional department resources as appropriate:

Core Team Role	Lead

Extended Team (Optional)	Lead

Blue: Required for Quorum **Bold:** Review Leader

Meeting pre-work:

6. {Prework}

Agenda:

6. {Item 1}
2. {Item 2}
3. {Item 3}

Responsibilities:

	PM	COM OPS	MFG	QA/QC	FINANCE	PD	SCM	Area Leader	ELT

A – Accountable: Owner of Task; R – Responsible: Performs Task; C – Consulted: Two way communication; I – Informed: One Way communication

Steering Committee Review Charter

Objective: {Objective}

Expected Outcome: {Outcome}

Key Success Measures:

KPI	Target	Calculation

Participation: Team will meet weekly @ DD TT PST for 30-minute duration.

Working Document: {insert Hyperlink}

Participants: The following Departments will be represented by Department Lead or Designee at a minimum. Leads may invite additional department resources as appropriate:

Core Team Role	Lead

Extended Team (Optional)	Lead

Blue: Required for Quorum **Bold:** Review Leader

Meeting pre-work:

7. {Prework}

Agenda:

7. {Item 1}
2. {Item 2}
3. {Item 3}

Responsibilities:

	PM	COM OPS	MFG	QA/QC	FINANCE	PD	SCM	Area Leader	ELT

A – Accountable: Owner of Task; R – Responsible: Performs Task; C – Consulted: Two way communication; I – Informed: One Way communication

Daily Tier I+II+ III Reviews Charter

Objective: {Objective}

Expected Outcome: {Outcome}

Key Success Measures:

KPI	Target	Calculation

Participation: Team will meet weekly @ DD TT PST for 30-minute duration.

Working Document: {insert Hyperlink}

Participants: The following Departments will be represented by Department Lead or Designee at a minimum. Leads may invite additional department resources as appropriate:

Core Team Role	Lead

Extended Team (Optional)	Lead

Blue: Required for Quorum **Bold:** Review Leader

Meeting pre-work:

8. {Prework}

Agenda:

8. {Item 1}
2. {Item 2}
3. {Item 3}

Responsibilities:

	PM	COM OPS	MFG	QA/QC	FINANCE	PD	SCM	Area Leader	ELT

A – Accountable: Owner of Task; R – Responsible: Performs Task; C – Consulted: Two way communication; I – Informed: One Way communication

Weekly KPI Trends Charter

Objective: {Objective}

Expected Outcome: {Outcome}

Key Success Measures:

KPI	Target	Calculation

Participation: Team will meet weekly @ DD TT PST for 30-minute duration.

Working Document: {insert Hyperlink}

Participants: The following Departments will be represented by Department Lead or Designee at a minimum. Leads may invite additional department resources as appropriate:

Core Team Role	Lead

Extended Team (Optional)	Lead

Blue: Required for Quorum **Bold:** Review Leader

Meeting pre-work:

9. {Prework}

Agenda:

9. {Item 1}
2. {Item 2}
3. {Item 3}

Responsibilities:

	PM	COM OPS	MFG	QA/QC	FINANCE	PD	SCM	Area Leader	ELT

A – Accountable: Owner of Task; R – Responsible: Performs Task; C – Consulted: Two way communication; I – Informed: One Way communication

Weekly Disposition and Release Review Charter

Objective: {Objective}

Expected Outcome: {Outcome}

Key Success Measures:

KPI	Target	Calculation

Participation: Team will meet weekly @ DD TT PST for 30-minute duration.

Working Document: {insert Hyperlink}

Participants: The following Departments will be represented by Department Lead or Designee at a minimum. Leads may invite additional department resources as appropriate:

Core Team Role	Lead

Extended Team (Optional)	Lead

Blue: Required for Quorum **Bold:** Review Leader

Meeting pre-work:

10. {Prework}

Agenda:

10. {Item 1}
2. {Item 2}
3. {Item 3}

Responsibilities:

	PM	COM OPS	MFG	QA/QC	FINANCE	PD	SCM	Area Leader	ELT

A – Accountable: Owner of Task; R – Responsible: Performs Task; C – Consulted: Two way communication; I – Informed: One Way communication