

1. Programme Planning

Effective biopharmaceutical development starts with detailed programme planning. This includes defining objectives, timelines & deliverables across functions. Leadership, flexibility & effective communication are essential in building a roadmap that reflects the program's complexity while aligning internal & external teams on deliverables.

2. Project Budgeting

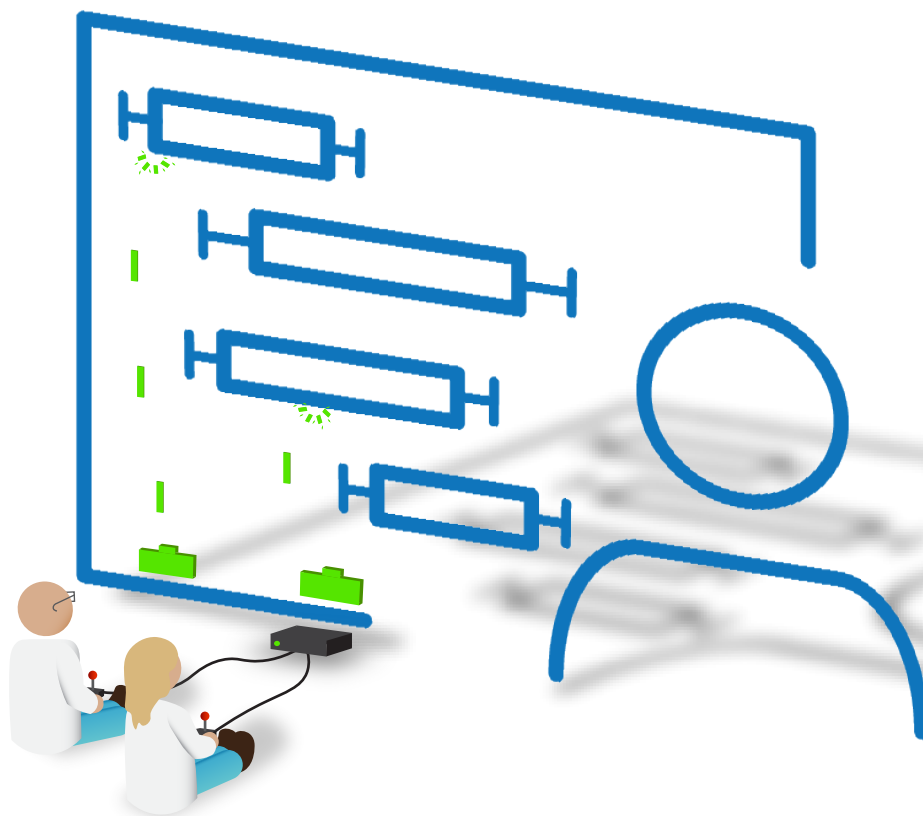
Budgeting involves forecasting costs across phases, identifying resource needs & managing risks. Effective budgeting & monitoring ensures that funds & resources are allocated efficiently & transparently. Resource optimisation and clear financial oversight are critical for maintaining programme stability & ensuring progress through each milestone.

3. Contracts & Agreements with CDMOs

Contracts define responsibilities, timelines, quality standards & risk-sharing models between sponsors & CDMOs. Agreements provide structure & accountability while maintaining flexibility for changes. Clear communication, shared expectations & trust underpin productive collaboration throughout development & manufacturing activities.

4. CDMO Proposals

Evaluating CDMO proposals requires understanding technical feasibility, cost drivers & timelines. Proposals must reflect realistic assumptions, resourcing capacity & phase appropriate regulatory requirements. A sound review process helps identify appropriate & reliable partners as well as ensuring alignment with programme requirements & goals.



5. Project plans & Gantt Charts

Structured project plans & Gantt charts map out interdependencies and timelines. These tools support risk management & enable teams to transparently track progress against defined deliverables. Adjustments, based upon real world situations, help keep projects on time and well-managed.

6. Risk Registers

Risk registers document known & potential risks across a programme, capturing likelihood, impact & mitigation strategies. They enable proactive risk management by ensuring all stakeholders are aligned on critical uncertainties. Regular review support timely, informed decision-making throughout development & well as capturing accountability.

7. CDMO Relationship Management

Beyond contracts, effective CDMO management involves trust, consistent communication & alignment on shared goals. Building collaborative, accountable relationships fosters resilience and adaptability. This is especially important when navigating changes, resolving challenges that are certain to arise during the clinical development pathway.