



Supply Readiness

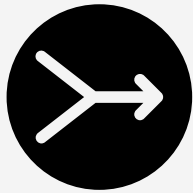
Establishing a Risk-Based Framework to Enable Seamless

Transition from Clinical Development to Commercial Launch

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EPO Summit 06 June 2025

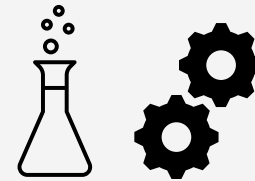
Context: asset acquisition via M&A transaction, with multi-formulation, full external value chain, and legacy CDMO network



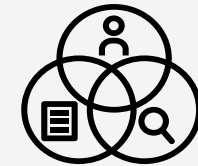
Setting



E2E external value chain



Product and process complexity



CDMOs attributes

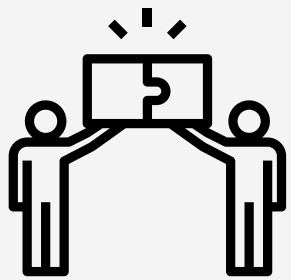
M&A, late Phase II / Phase III product acquisition

End-to-end external value chain, “from plant to product”

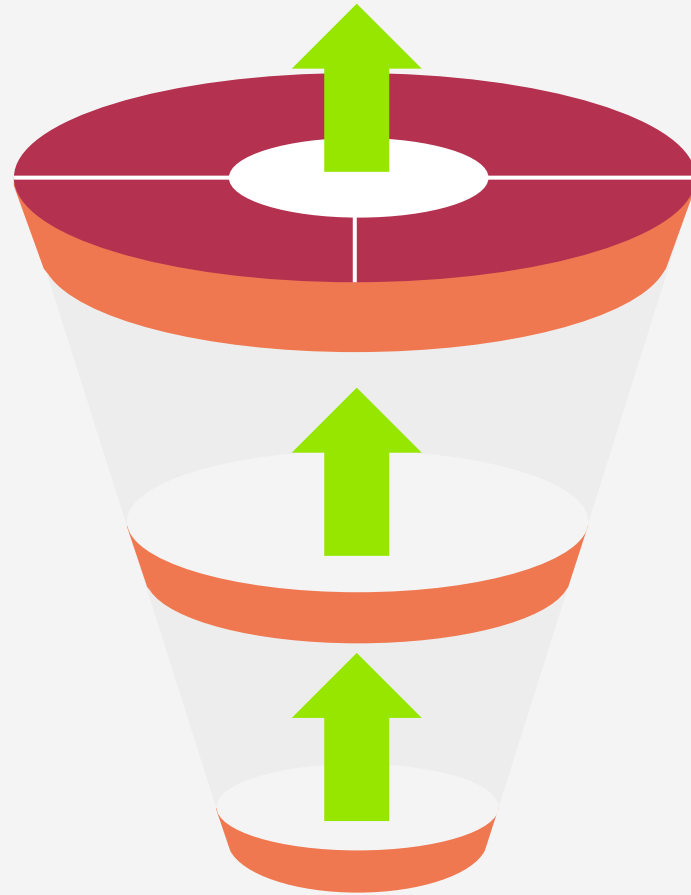
2 different formulations
Tech transfers (within CMO and to new CMOs)

Clinical-focused
Different commercial supply maturity across CMOs

First, establishment of a **Virtual site** to enable optimal management of the external value chain; supply readiness launched under this setting to support prioritization of actions



Virtual
Site
Set up



Operation – full execution mode

Team formed and fully operative

Defined governance, RACI / decisions and information flows

Incorporated into the ways of working

Evolution – governance set-up

New internal and CDMOs governance

Clearer roles & responsibilities

Second round roll-out

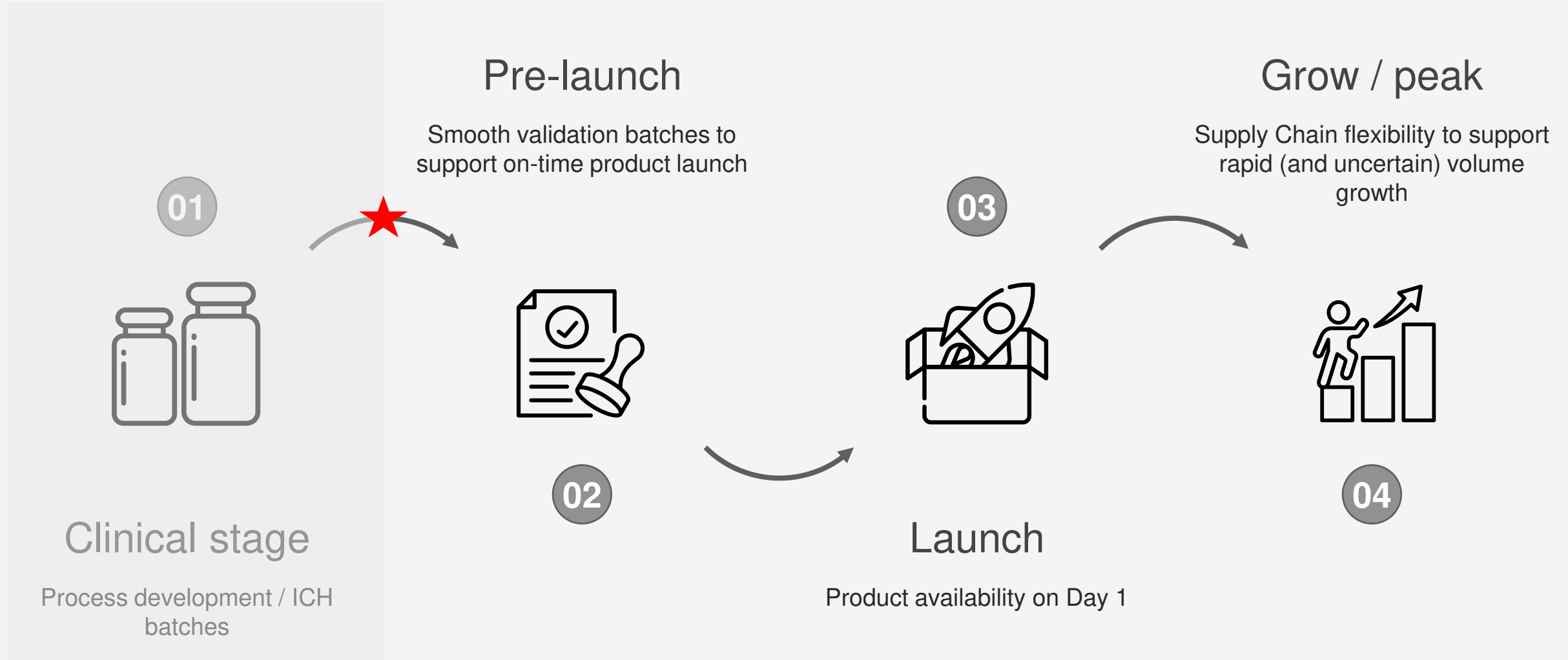
Formation – team set up

Transition from Development to Operations

Overlap and handover processes with R&D

First round of supply readiness with CDMOs

Supply Readiness Assessment should be executed as early as possible to identify weak points in the future commercial product value chain



Supply Readiness to consider the time horizon of product lifecycle during the review with the CDMO partner

Pre-launch

End of development / tech transfer

- Technical expertise
- Process definition / “lock”

Validation

- Established processes
- Critical for launch dates

Launch

Product nuances

- Shelf-life / stability limitations
- Product release risk assessment
- Novelty processes

Site nuances

- Launch expertise
- Capacity to react / respond
- Personnel

Grow / Peak

Volume growth

- Long-term capacity
- Production flexibility

Resilience

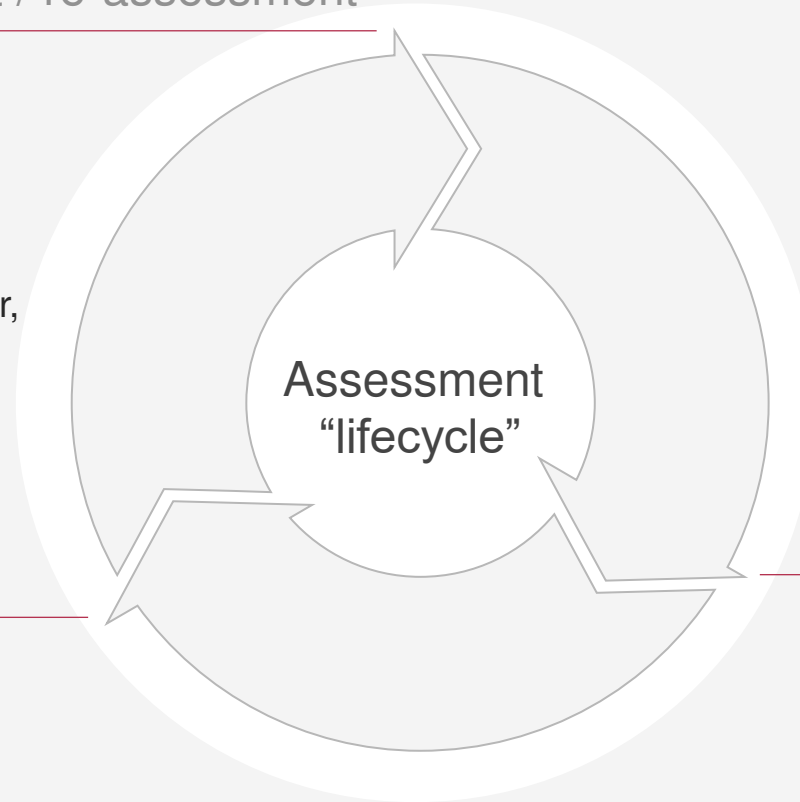
- Business Continuity Planning
- Supply risk mitigation (e.g. 2nd source; 2nd line – E2E assessment)

Supply Readiness as a circular process to mitigate supply risks on short, medium and long term

Supply Readiness Assessment / re-assessment

Circular process on readiness journey

- Assessment, not audit;
- Collaborative in nature. agreed on observations on site
- Multi-day, focus vary based on partner, product impact and lifecycle



Implementation of Action plan

Short, medium and long-term actions

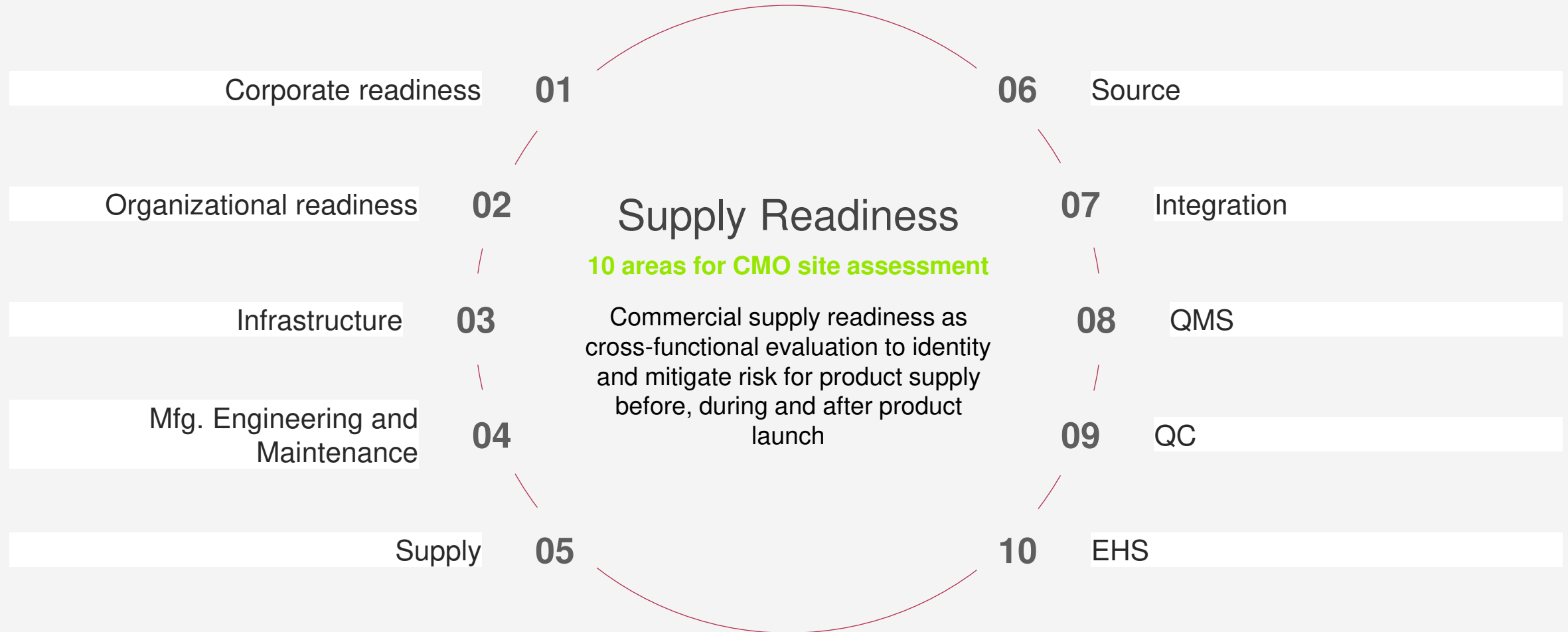
- Support from Client on best practices / internal know-how
- Governance (SteerCo, 1-2-1s) to support action implementation

Jointly Agreed Action Plan

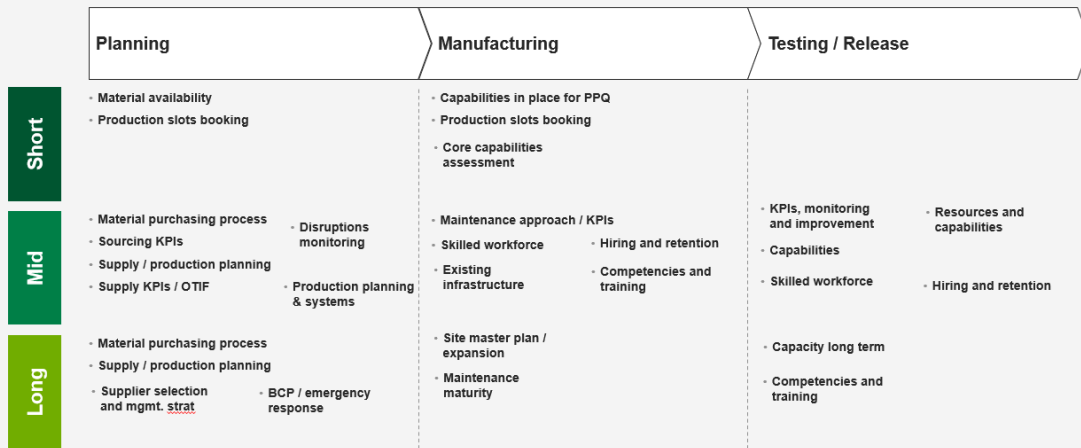
Outcome of observations, divided on prioritization / criticality level

- Agreed on owners and timing
- Partner to use assessment on internal processes

CDMO assessments provides broad review on partner site's ability to supply; 10 different areas identified to be assessed



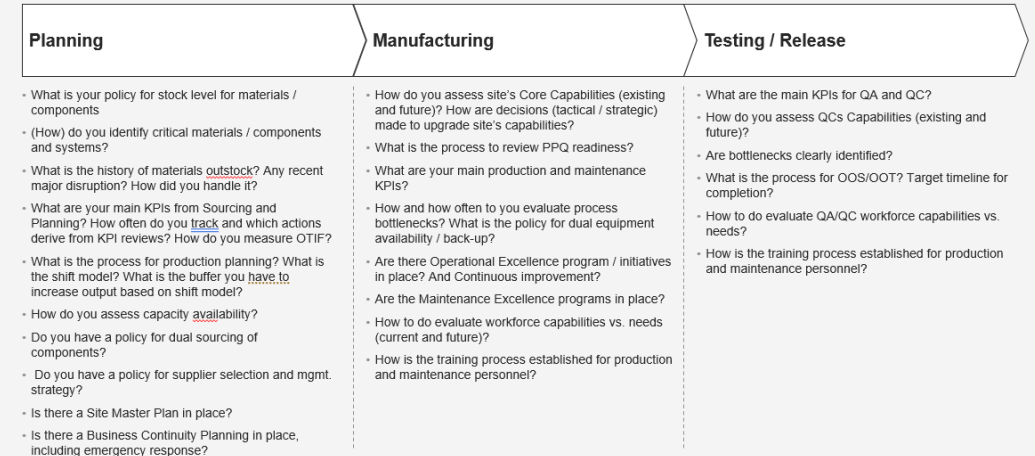
Assessment to follow actual product flow, from Planning to Release, identifying actions on short, medium and long horizons



Themes to be assessed

Each “theme” is a sub-stream of one of the previously 10 areas identified for review;

Due to overlap, following process flow enables cross-functional evaluation



Interview mode as preferred approach

Best assessment execution is done in interview mode, with experts sitting with functional areas to understand the processes and identify improvements

Assessment can though be adapted (e.g. questionnaire, check-list) depending on CDMO traits and level of openness

Assessment to follow actual product flow, from Planning to Release, identifying actions on short, medium and long horizons

Organization is currently set up for development work; broader capability mapping needed to ensure site is ready for a larger share of commercial supply

Score	Description	Justification
1	CMO capabilities (performance)	... XXXXXX
2	Process and integration	... XXXXXX
3	Compliance and safety	... XXXXXX

CMO presented a low maturity score for commercial supply, heavily influenced by focus / share of development vs. commercial supply (~80/20)



Action plan will be monitored for completion; progress on activities should improve commercial supply maturity for CMO and reduce risk for RTX Commercial Supply

Priority action description

Action number	Action description	Who	Target completion date
1		1	15-ago-24
2		1	15-ago-24
3		1	15-ago-24
4		1	15-ago-24
5		1	20-ago-24
7		1	16-oct-24
8		1	15-oct-24
9		2	31-oct-24
10		2	31-oct-24
11		2	31-oct-24
12		2	31-oct-24
13		2	31-oct-24
14		2	31-oct-24
16		2	21-oct-24
18		2	30-mar-25
17		2	21-mar-25
18		2	30-mar-25
19		2	30-mar-25
20		2	30-mar-25
21		2	30-mar-25
22		2	30-mar-25
23		3	31-oct-25
24		3	31-oct-25
25		3	31-oct-25
26		3	31-oct-25
27		3	31-oct-25

Next steps

- Meeting to present results and action roll-out within CMO
- Action plan alignment and execution - supported by GRT whenever possible
- Second round of Supply Maturity assessment
- (Additional actions can be identified as project evolves and GRT identifies areas of support)

Assessment results

First, still on site, long list of observations reviewed and agreed across the parties

Maturity scoring per functional area reflects observations

Action plan to follow

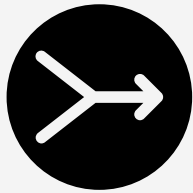
Action plan following observations

Actions by criticality

Clear owner from CDMO for each action; client (GRT) to support with expertise and best practices

Keywords: comparison, comparisons, percent, percentage, barometer, gauge, gauges

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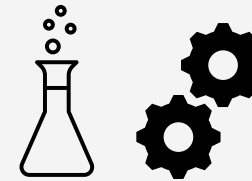
Setting

Use of Supply readiness on
Clinical vs. Commercial launch
Support partners selection



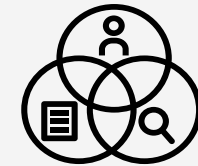
E2E external value chain

Highlight weak points and
long-term mitigation actions
Improve active collaboration



Product and process complexity

Identify investment and
technology needs



CDMO attributes

Consider partner size (small
vs. large CDMOs)
Consider level of openness
Assess based on criticality to
Finished Goods

