

BUILD AN EFFECTIVE CMC FUNCTION

Insights from Pharmaceutical Leaders

In a recent project to optimise a pharma company's Chemistry Manufacturing and Control (CMC) function, we interviewed CMC leaders to gain insight into how they have built effective CMC functions and how they measure success. They concurred that CMC functions must be agile and deliver on a range of projects while not impacting the critical development timelines.

Building an Effective CMC Function

CMC leaders build CMC functions that react quickly to requests and deliver on time. They strive for agility and continuous improvement. The critical success factors for an effective function are:



Strong CMC leaders: Appoint dedicated and empowered CMC project leaders who are strategic and collaborate effectively with other functions. CMC project leaders:

- Find innovative ways to deliver projects on time
- Represent CMC in the R&D project core team
- Explain CMC issues to non-CMC stakeholders clearly
- Manage the CMC project sub-team
- Promote open communication within and beyond CMC

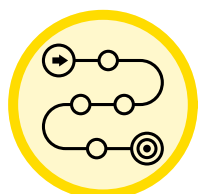


Clear, realistic plans: Align CMC plans with R&D strategy, follow and monitor them closely, and evolve them as required



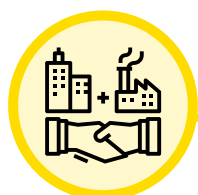
Appropriate mindsets: Ensure there are people with a mindset of agility, risk-acceptance, and continuous improvement at all levels

- **Agility** e.g. reacting to requests quickly, delivering milestones on time and in full
- **Risk-acceptance** e.g. running fewer studies or generating less data to arrive at an acceptable answer
- **Continuous improvement** e.g. optimising operating procedures



Standard processes: Enable CMC teams to deliver efficiently in an environment of constant change by standardising routine processes

- Ensure employees understand what their responsibilities are and how they deliver the standardised processes



Balanced outsourcing model: Outsource according to project needs and existing internal capabilities and capacity

- Manage vendors carefully via employees with the correct skills and mindset

Measuring Success

Key Performance Indicators are set up to ensure CMC reacts quickly to requests and delivers on time, in full, and at the right level of quality. They focus on agility (on time in full) and quality (right first time), and less on volume (batches released) and cost (development cost).