

Improving Patient Health and Safety

Case Study: CMC Program Management

A rapidly growing biotech company was concerned about the plan and approach to the CMC section of a CAR T-cell therapy program. The experienced CMC program management consultant led the development of a product development plan (PDP), working closely with the product team lead, cross-functional team members and appropriate vendors to develop and maintain the plan. Once the plans were completed, the program manager played a critical role in facilitating the use of processes and tools for risk assessment and mitigation, strategic plans, cross-functional communication and planning, and timelines across the program. Other key activities completed by the expert program manager were:

- Tracking the progress of the product development plan (PDP) and timeline and anticipating upcoming activities in advance, bringing them to the attention of the product team and/or joint CDMO team, while leading the initiation of appropriate actions to maintain the timeline.
- Working collaboratively with product development lead (PTL) and CDMO vendor PMs to build agendas and ensuring that agenda topics for internal and joint CDMO meetings were well planned with structured presentations available in advance, working closely with team members to drive the preparation as needed.
- Working closely with vendor CDMOs to ensure development of joint plans and ensuring that vendor CDMO activities are carried out in accordance with target timelines and within budgeted costs/resources.

As a result of the consultant's effort, the product team and vendors were able to successfully shift from a disorganized state to a structured, methodical team utilizing a common plan and strategy for execution. The communication greatly improved between the product development team and the vendor CDMO for the CAR T-cell program. The number of emails and time spent in meetings was greatly reduced for the product development team. Overall, the team was more efficient, and the dollars spent on the vendor CDMO were more productive.

