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Reconciling the design process

Meeting the challenge of competing stakeholder priorities requires continuous assessment



The design process for a pharmaceutical manufacturing facility is dynamic, frequently disjointed, and often cyclical. Differing stakeholder perspectives can be a challenge to reconcile. A number of different priorities can all struggle for dominance. From regulatory considerations to building material characteristics, corporate leadership, quality assurance, production and facility management, opposing concerns can lead to a divergent design process, despite guidance from project managers.

Since the stage gate process has been the “way of the world” for over 25-years, few remember when it was the norm for the A/E team to be responsible for estimating to ensure the design was on budget. Significant value engineering efforts, or course correction, were not originally intended to be part of the design process and while they can be used effectively and with good results, they tend to be disruptive and cause inefficiencies for the project team.

With so many unique circumstances in pharma facilities, it can be useful to reflect on the challenges associated with competing priorities and the fundamental approach to reconciling them.

Define success

The table of goals with carefully considered and weighed priorities done at the outset of a project is familiar and a good start, but it should be considered a living document.

The design process naturally reveals opportunities and consequences that may not have been

understood, appreciated or even known at the beginning of a project. Knowing all the stakeholders as well as their motivations helps to anticipate what outcomes they will advocate for and which they may cede. Keeping the goals for “success” simple is relatively easily done for cost and schedule but quality can be defined by a wide range of characteristics. Therefore, agreement by all stakeholders on what the specific goals are, as opposed to how to achieve those goals at the start of a project, will keep evaluations simple and allow the team to approach the dynamic process with guidance and not constraints.

Control the “wish list”

Almost every project is seen as an opportunity to secure enhancements cut from the last project, address ongoing operational or maintenance issues, or introduce upgrades. The “wish list” should identify every possible function, capacity, feature, improvement, or “fix” that each stakeholder might desire. The list should be developed in a brainstorming session with all participants and no limitations. While many items may not be within the project charter, identifying and discussing them will set the ground rules to control them.

By agreeing on which wish list items are to be included in the project and which are not, a line in the sand is established with all parties as the starting point. Things will change as a function of design development — as management priorities, budget allocations, and alternate solutions for the original

business driver develop. The process is dynamic and the line in the sand will shift after thoughtful assessment of project goals. New ideas will emerge and priorities will shift over the course of a project and being flexible in the approach and methodology to accommodate those shifts will help ensure all stakeholders’ highest priorities are achieved.

Put the project’s priorities in order

To deliver on the highest priorities of the team, employ methods to assess each component of the facility for operational benefits, estimated first versus life-cycle costs, reliability within the overall operations, and other factors. This assessment should facilitate agreement among all stakeholders on priorities ranked in terms of their impact on the shared definition of success for the project. Each stakeholder should realize that not all of their priorities will be accommodated but a process that allows for thoughtful consideration will deliver a successful operation — the highest priority of the project team.

These activities are familiar to everyone who has participated in a project to design and build a pharma manufacturing facility. Continuously assessing the priorities as part of the dynamic process allows the team to make better informed decisions about the resulting facility and operation. While every project will be operational at some point, the ones that align and address all stakeholders’ priorities will deliver true success for the manufacturer. 