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PHARMACEUTICAL ENGINEERING®

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DECEMBER 2014

Project Management

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Project Management

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Improving Project Management

This supplement features seven articles on project management, each offering ways to improve project management through a variety of methods that include: communication and collaboration; team work; design-assist; effective strategies; recognition of difficulties; time and efficient management; and Electronic Batch Record Keeping (EBR).

Communication and collaboration are project management leadership essentials, says **Alandra Strain**. All successful projects include leadership with clear and concise communication skills. Communications skills in a project manager are essential because pharmaceutical project management "has grown into a highly complex balance of time, money and quality." Good communications skills also mean active and effective listening; communications must be interactive. Managers must model and engage team members with up-to-date information to make decisions based on accuracy, she recommends.

Mark Mathis lays out methods and tools for managing projects successfully using "hybrid teams," teams comprised of players " cherry picked" from different organizations, but who work together to complete a project. "The rationale is simple," says Mathis. "Smaller, more diverse and focused teams will bring a wide breadth of experience without significantly adding overhead costs." Mathis advocates ways to: identify team players; identify the project culture and; identify technical resources. He offers a case study. Creating a culture of collaboration to align with project goals will build trust among team members, he counsels.

In "Practice What You Preach," **Trish Melton** discusses the process of developing the *ISPE Good Practice Guide: Project Management*. Melton describes how good practice project management begins with engaging a variety of stakeholders, developing an understanding of customers' needs, and assessing risk. A 'sneak peak' into the guide is included that introduces the "Stage Gate" approach to project management good practice.

What is Design-Assist? When do you use it? Why does it work? **Raj Vora** compares the benefits of *design-assist project delivery* versus *design-bid-build delivery*. There are pitfalls to design-bid-build projects; these include quality, design safety factors, schedule impacts and project harmony. Design-assist (a highly successful model becoming more commonly used) allows the owner to maintain control over the project. "The owner's quality requirements are met more efficiently through the design-assist project delivery process because it is more collaborative," advises Vora. A case study is included to illustrate the benefits to be found in the design-assist approach.

Mick Lynam and **Alf Penfold**, with a combined 56 years in the pharmaceutical industry, explain what to do when a project gets into difficulty. Being able to recognize that a project is in difficulty is the first hurdle. Getting a project in difficulty back on track is the second. They recommend and describe a "recognition-intervention-implementation" process with an emphasis on identifying "root cause" as opposed to "apparent cause." Once a recovery option is selected in principle, it must be implemented. After the project is back on track, the learning from the situation needs capturing.

A *path to enlightenment* for efficient project management is laid out by **Keith D. Gibbs**, an active ISPE educator for a decade. For Gibbs, a 'sacred truth' is that there are only four project outcomes that can be achieved: probable success goals will be met; possible success if things go your way; improbable that your project will be successful; success impossible. "The straight path to success is fictitious," says Gibbs. "All projects weave around." Gibbs describes the importance of time (time IS money) in project success and inefficiencies that are "built in" to how we work. "Make you project efficient by smarts, not muscle," he recommends. "People make projects happen and the best people make projects happen better."

"Paper on Glass" is a productivity game changer for paper-driven pharmaceutical production says **Robert Harrison**. He discusses how technology has advanced *electronic batch record* keeping (EBR) into solutions that compete one-to-one with paper flexibility. EBR, says Harrison, opens the door to 'game changing' production efficiencies in pharmaceutical production. Image no mountains of paper to be stored in secure locations and instant batch analysis. "Paper's history in pharmaceutical production is a little like a religion and its scriptures," says Harrison. "Paper is deemed paramount and never questioned."

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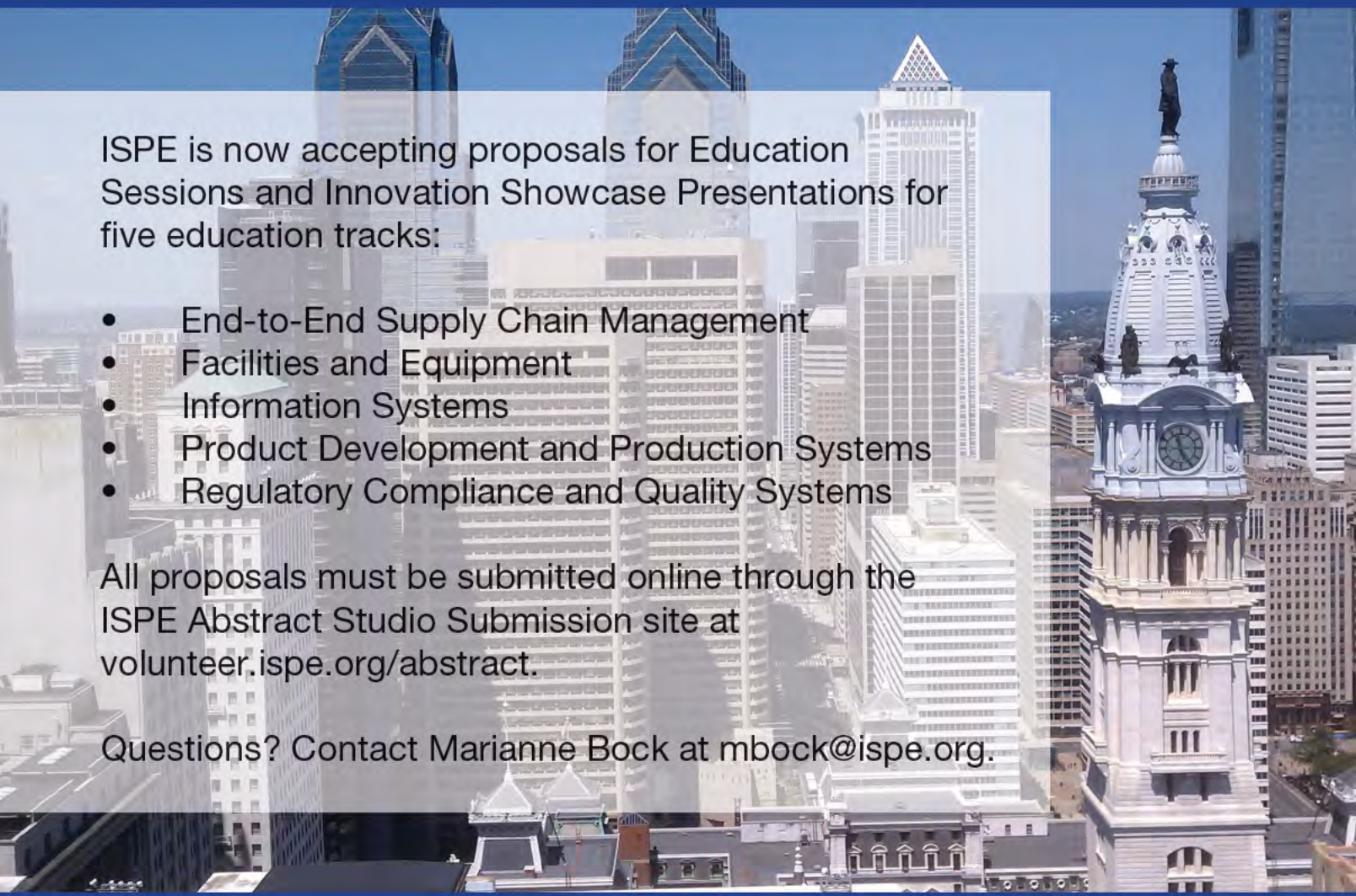

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Communication and Collaboration – Leadership Essentials in Pharmaceutical Project Management

by Alandra Strain

This article focuses on communication and collaboration as essential leadership traits leading to a successful project delivery.

Project management is the execution of a distinct goal with definite objectives. From beginning to end, a project manager is expected to possess the highest level of organizational and managerial discipline to artfully balance time, cost, and quality. A project manager is the ultimate facilitator responsible for monitoring, controlling, and reporting on all aspects of a project's lifecycle.[1] The primary responsibilities of project leaders is managing communication, knowledge transfer, project goals, and conflict resolution to successfully deliver a project. A project team is continuously evolving as are the professional relationships required to achieve in the complex industry of pharmaceuticals. Whether a project manager is chosen for experience or expertise, communication and collaboration can directly influence the following essential capabilities and criteria for a project manager:[2]

- **Knowledge**
  - Obtain knowledge of regulatory context and critical pharmaceutical processes
  - Compile teams' expertise
  - Understand drivers
- **Skills**
  - Manage all skill levels with good political and cultural awareness
  - Develop a robust project delivery strategy with accurate cost, schedules, risk management, techniques, and negotiation
  - Facilitate, motivate, and influence achievement
  - Apply sound judgment based on accurate and current information
  - Resolve conflict and manage key business relationships
- **Behavior**
  - Encourage innovative thinking and exploration of ideas
  - Drive engagement while maintaining focus
  - Vertically manage project stakeholders and team
  - Maintain an environment for exploration of concepts
  - Demonstrate honesty and integrity

Communicate Clearly

Peel back the layers of a successful project and you will find a leader with clear and concise communication skills. Communication, in the pharmaceutical industry, is vital to a company's success and more importantly to the health of a global population. Although many project leaders are knowledgeable in organization and capital budgets, no project can survive with an unclear vision and undecided direction. Leaders should approach the communication of objectives and timeline goals knowing their message may be subconsciously misinterpreted by team members. This is not

a malicious sabotage or a lack of professional expertise on the team's part, but a natural trait of humans as individual thinkers. The goal of project leaders is to align and direct a team to focus on the essential objectives. Accepting the notion that interpretation is highly dependent on a listener's perceptions is a proactive step toward more efficient communication.[3]

Relaying the Mission

Clear communication can have a measurable effect on project timelines and continuous quality, but communicating can mean different things at each level of manufacturing. Although an experienced project leader is assumed to be highly skilled in connecting team members and directing them toward specific goals, misinterpretation of the core objectives gathered from executives may be a hindrance. A disconnect between stakeholders (Figure 1) and project leaders can break down project strategies and execution. A fundamental responsibility for a project leader is a clear understanding of the company's mission and strategies for success. Without first understanding the expectations, a project leader may be clearly relaying a misinterpreted message. Taking the time to consistently reaffirm project goals and seek answers from company executives will trickle down clear expectations for the entire team. Understanding the company's mission and ultimate goal for a project can give a project leader the ability to make complex decisions quickly without disrupting timelines or budget requirements. Insufficient information will hinder a project leader's ability to align potential outcomes with the project's objectives. When possible, a project leader must take the time to gather the pertinent data to make an informed and rational decision. This background information can ease any negative fallout and direct team members back on track.[3]

All stakeholders are responsible for communicating goals and objectives to each other in a clear and concise fashion. The Project Sponsor is accountable for guidance, project support, and confirming process parameters. The Customer is responsible for expressing the benefits of the project and relaying the acceptance criteria for project completeness. The End User is the customer's representative accountable for communicating how a project's key deliverables should perform during operation. Key End Users have specific knowledge and expertise which is highly valuable to the success of a project team. Project Managers should develop a Stakeholder Management Plan to manage stakeholders and communication guidelines.[2]

Lost in Translation

Effective project leaders also recognize language as a critical aspect of successful project management. First and foremost, managers should consider the language of project implementation. Language miscommunication and misinterpretation can be found throughout projects with industry specific keywords or working with team members who are not communicating in their native language. Scientists, engineers, and operators have their own stock phrases and identifiers used throughout the life cycle of a project. When working with a multi-cultural or multi-departmental team, terms should encompass true meanings. Decreasing departmental specific acronyms and cultural-centric terms will assist in team communication and understanding. A project leader can work toward assimilation by developing a project glossary to be included in the project development plan. By setting a common terminology standard, a project manager can assure a more effective communication chain. Jargon and inconsistent terms should be replaced with commonly understood language. Project managers are expected to stay current and understand new industry terms applicable to the project. In addition, efficient leaders should not only accept the responsibility of explaining innovative tools, techniques, and terminology, but also ensure the project team understands and implements industry modernizations correctly.[3]

Active Listening

Efficient project leadership includes active listening as part of the overall communication process. Project leadership requires adequate convergence of the internal workings of a project's communication. Taking the time to communicate effectively means leaving out the dictative pattern for team directives. Communications must be interactive with the project leader dedicating time to team member input. By

Figure 1. Stakeholder Relationship Map: All stakeholders should be committed to constructive collaboration in order to generate solutions that reduce time, effort, and cost.[2]

surveying team members' collective interpretation of goals and responsibilities, a project leader can clear up missed concepts or realign strategies and responsibilities of project executions in timely manner.[3]

Knowledge Management

A top responsibility of project managers in any industry is knowledge management. A leader must handle any incoming data and communicate any analyses or outcomes to the project team. The communication of knowledge within a team is fundamental to a project's success. As with some pharmaceutical projects, confidentiality and the protection of intellectual property is a top priority. Project leaders must always clearly define processes to manage data as it is transferred to team members, contractors, and other key stakeholders. Project managers are responsible for developing and communicating a clear and precise Knowledge Management Plan.

Project leaders also must successfully streamline the integration of newly acquired data while maintaining fundamental project requirements. There are two principal terms in knowledge management: explicit knowledge and tacit knowledge. Explicit knowledge is captured and recorded in documents, databases, or websites. This knowledge is tangible and easily identified. Explicit knowledge can be gathered through regular reporting and consistent distribution. Tacit knowledge is the knowledge people possess through experience and personal learning. This knowledge is difficult to access, but is an important aspect in regard to the contribution of team members' insight and ideas. Effective leaders recognize the importance and usefulness of this knowledge and have developed highly specific and purposeful questioning techniques to take advantage of its full value. It is up to a project's leader to develop a team culture in which background knowledge and industry experience provide an advantageous instrument of success. Knowledge management within a project's lifecycle can be divided into the start, during, and ending phase.[2]

Start Phase

At the beginning, a project's objectives should be defined, but flexible in processes needed for achievement. Loosely defined paths to success need team based, explicit and tacit knowledge to bring specificity and definition. A project manager should encourage team members to gather knowledge from varied sources and integrate findings into process planning and set-up. Knowledge gathered may include:

- Data from previous and relevant projects
- Success factors from similar projects
- Team members expertise survey
- Collaborative options for review or critiques

During Phase

In the midst of a project's progress, information and data grow and challenges come to fruition. A project leader must maintain data organization and analyze the accuracy and relevance of incoming knowledge. Knowledge management and change control processes should be determined and enforced. Team members must be confident they are working with up-to-date knowledge. Project leader's responsibilities regarding the growing knowledge base include:

- Maintaining communication
- Sharing knowledge
- Addressing issues
- Maintaining alignment

End Phase

The end phase of the project inevitably contains the highest amount of knowledge. The project leader is encouraged to conduct a project review to capture new experiences which may assist in future projects. Guided conclusions may include:

- Compare differences between expectations and results
- Establish new processes resulting from project positives or negatives
- Identify industry peers' interests in project findings

A knowledge base and its management should be established by project leaders early within project planning. It is also the manager's responsibility to maintain the knowledge base and make it accessible to team members in an organized way. Upholding a well set knowledge cycle can continuously assure open lines of communication, mitigate project risks, and shorten timelines for project completion. Project managers should set up guidelines for contributing, maintaining, and accessing the knowledge cycle. Education and critical problem solving occurs freely within collaborative and well-informed teams facilitated by leaders who support and find value in sharing informational ownership. Success in today's project management is found within the ability of a team to openly share information and align on common ground.[2]

The Evolution of Team

Pharmaceutical projects are evolving into a new system of management as innovative leaders move toward a more open and collaborative approach. Today's leaders are recognizing the power that comes with team building and the shared ownership of responsibility. A collaborative team shares information and freely exchanges ideas enriching every member's understanding of the overall vision resulting in optimal results for key stakeholders.2 Collaboration within project management is creating a new business model that stands up to the complexity of the pharmaceutical in-

dustry and allows for increased productivity and efficiency.

Efficient leaders recognize strength in numbers. Successful project leaders are instrumental in building a high standard of collaboration between team members. Encouraging and engaging all levels of project teams allow multiple solutions and processes to be considered. Collaboration ensures team members' commitment to the project's common goals and focuses their energy to successfully completing objectives based on a community of high standards. Proficient project management requires a leader's buy in to collaborations among team members. Although working within a group requires team members to compromise, it also allows interactive learning between experts resulting in a more knowledgeable project team. In every team a project leader has gathered, every member has an expertise and every member has something new to learn.[3] Implementing a collaborative approach, project leaders increase the possibility of industry innovation and professional progress.

Conventional Project Leaders	Today's Innovative Leaders
Value hierarchical power	Value the power of collaboration
Depend on preset ideas and processes	Survey team as a valuable knowledge base for innovative processes and solutions
Information is guarded	Information is shared openly and continuously
Team members work strictly within their assigned roles	Roles are based on applicable experience and retain flexibility
Resources are given when need is proven worthy	Resources are immediately available as team decides on need
Reactive problem solving	Proactive problem solving based on continuous engagement with project team
Rules independently on challenges and conflicts	Brainstorms with team to agree on best actions

In a truly collaborative environment, every member of a project team has a valued voice and an aligned commitment to project objectives. The basis of this environment is trust. Trust among consultants and contractors can be established through clear terms of deliverables and expectations sanctioned within a collaborative working environment. The responsibility of communicating and managing relationships within the team, consultants, and contractors falls on the project leader. Project environments should be conductive to finding a common ground toward progress and challenged resolution. When mediating team conflicts, project managers should facilitate information sharing and assist in identifying resolution alternatives. Characteristics of a collaborative working environment:[2]

- Reciprocal respect of team members and managers viewpoints and professional experience
- Continuous engagement of entire team
- Joint decision making and idea development
- Equally familiarity of project goals and objectives between team
- Productive and accurate communication channels[2]

Leaders are involved in the entire process and engaged with every level of decision making. Managers facilitating a collaborative project are often faster at recognizing the root cause of problems and dealing with challenges quickly and efficiently. Project managers in a collaborative environment are open to the needs and required resources. Allowances are given proactively to cut implementation time and ensure rapid implementation of developed ideas. Since a collaborative team is centered on shared knowledge, resource allocations are justified and agreed upon for the success of the entire project.

Conclusion

Pharmaceutical project management has grown into a highly complex balance of time, money, and quality. Global resourcing and high regulator standards drive the need for multi-skilled project teams led by managers with communication and collaborative skill sets. Success depends on a team's knowledge convergence. Effective project managers recognize the need for strong teams willing to learn and grow from one another. Communication is no longer on a "need to know basis." Managers must model and engage members with up-to-date information in order to make decisions based on accuracy. One leader cannot be all things. Collaboration and clear channels of communication resulting in groundbreaking processes and innovative solutions are essential to keep up with industry progress.

References

1. Gibbs, Keith D., "Between Love and Madness Lies Obsession: Project Management in the Pharmaceutical Industry," presented at Boston Area Chapter, Cambridge, MA, 16 February 2012.
2. *ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry,* International Society for Pharmaceutical Engineering (ISPE), First Edition, November 2011, www.ispe.org.
3. Martin, C., *Tough Management,* New York: McGraw-Hill, 2005.

Alandra Strain is an independent technical writer from Tampa, Florida.

How to Manage an Efficient Project

by Keith D. Gibbs

This article candidly describes how to efficiently manage a project with the right people, the right process, and the right schedule.

Right out of the gate, I am going to tell you that I despise writing technical articles. It isn't the effort involved, or the rules of syntax and structure; it is the painful weariness of transferring information I am psyched about into dull text. I like to think that my ideas are organic, and they grow and blossom with discussion with colleagues and analysis. Over my inverse half-life of 43 years (meaning I am more radioactive now by at least twice what I was at birth, although my explosive potential is greatly diminished), I have not been the most focused individual, so a hopscotch jumping of thought from spot to spot in the direction of a goal is my norm. It has worked well, allowing creativity to blend to science in a way that has been exhilarating. I love to explore the fine points, debate miniscule mathematical similarities, drop a half dozen pop cultural references, and then go for coffee. It was only in the last decade that I slowed down enough to divert attention to managing my Attention Deficit/Hyperactivity Disorder (ADHD), Obsessive Compulsive Disorder (OCD), spatial contextual hyper-awareness and Tourette's syndrome. And for those that know me well, there may be additional items that they would add to this list. Yet, I digress ...

The point being is this; a hyperactive approach to everything often crashes against schedules (or formats, e.g., technical articles), as it is so difficult for some like me to stay paced. There are clear "Turtle" and "Hare" analogies, but so often we move further from the path with diversions, and need controls to bring us "back on track." I work primarily now on "specialty" projects, and these are often intricate, detail-oriented deliverables that are planned way in advance of execution, and then get turned topsy-turvy by outside unknowns. I try to get them back on track, by triage and often without being able to examine what got the project derailed in the first place. One of my favorite actors of all time is Alan Alda, and his role as Benjamin "Hawkeye" Pierce on M.A.S.H. is a model for a performance under pressure, work hard, play hard approach to life. Yet again, I digress ...

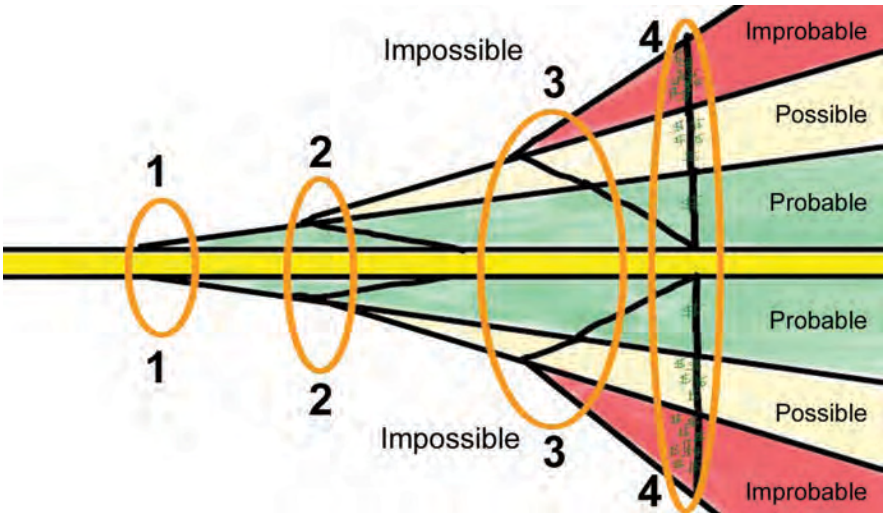

Figure 1. Project lifecycle turning points.

When I do get the opportunity to rewind and review, pause and zoom in on the documentary of a project, I have been blessed with 20/20 hindsight so often clichéd. Here is the first sacred truth I will share. When looking down the path of a project from start to finish, there are only four outcomes that can be achieved:

1. Probable success that goals will be met
2. Possible success if certain things go your way
3. Improbable that your project will achieve success
4. Impossible that any success will ever be achieved

Figure 2. The glamorous world of the PM – more trace matrix than matrix.

All projects should start as having a high probability of success, because after all, you haven't started, and you can freely define scope in your favor at this point. You can plan, map, schedule, apply constraints, get approvals; everything you need to succeed. Therefore there must be a point, a distinct singularity where your project goes from "probable" to "possible." Not a group of small things, but that first precarious domino. At this point, you would hope there is a way to get back on track since you are not that far off your plan, even if it takes time and money. You can health check and force the fall of the "bones" back onto your designed Rube Goldberg machine of a project. Google it, watch some videos and you will get the irony implied and the slight insult applied to typical project planning. Was a digression scheduled here? What is my contingency?

As more time goes by and the path isn't corrected, you will go from "possible" to "improbable" and again from "improbable" to "impossible." This is the truth of projects. The straight path is fictitious, all projects weave around at least a little bit, and it is everyone's responsibility to get back on the straight and narrow. Rarely will you have more than four chances to health check your project or you will divert too far away from your planned path, get your project team lost in the weeds and quite possibly miss supper. You may finish "a" project, but it is not the project you started. Yet, once again, I digress...

All this path analogy has roots in my recently initiated study of Buddhism, not as a religious ideology, but as a philosophical platform for project management. I am trying to visualize the affect of choice at distinct project point times, and the understanding of resource assignment and productivity needs to achieve tasks defined at a time or during a defined period of time. It is very much science fiction rooted in my brain, very Morpheus and Neo in the Matrix. Choice always has consequence, hopefully more positive than negative. What is the consequence if I choose to digress and consider that Trinity (the love interest, yet protagonist on her own merits) means group of three, and there are three phases to most projects, and 0111100101100101011101000010110000100000010010010010000001100100011010010110011101110010011001010111001101110011001000000010111000101110001000101110

So, choosing to apply resources available at certain times is a strategic conundrum. Typically, we are very battle tradition rooted in throwing bodies at the need. Might makes right, stronger not smarter. However, when watching it all unfold in the valley below, the generals watching the live drone-feed may see patterns evolve. Effort hours needed are

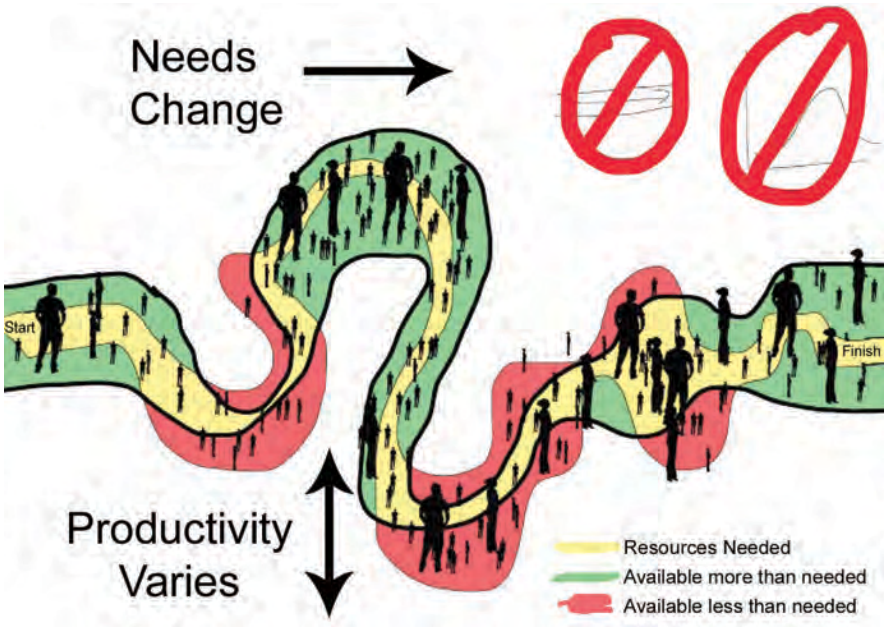

Figure 3. More Goldilocks than gold. Sometimes your resource load is too big, too small or just right.

different at different points along a project path, and rarely are the balanced harmonically to support the needs. Resources are many or few. Tasks are too many or spread too thin. Productivity is usually under, rarely over expectations. You expected me to digress, but ...

I have always believed that working faster would get me ahead, and working longer would keep me there. I willingly ignore that somewhere outside of my effort, the hours click by. Tick, tock, digress. Tick, tock, digress.

So, oxymoronically for me, I am currently immersed in a study of time, and specifically the management of this finite resource, to assure that project's move steadily toward scope completion without unplanned rate change or diversion. Do not get me wrong; I enjoy time travel paradox discussion as much as the next comic book fan-boy, and a Pi Day birthday of 3.14 is not the only thing I have in common with Einstein (the interests in quantum mechanics and relativity, not the brilliance or great hair). Time may slow at light speed, and although project execution is often now referred to as hyper-track, I can assure you that on the ground, in the trenches, time itself seems to fly away. Except in meetings, where it often grinds to a painful, repetitive forced review of a juxtaposed past and present, muddled by opinion and conjecture. I loathe meetings with more than four people, and in many cases, that is three too many. Yet, as is becoming the norm, I digress.

Time in a Year									
Value	Unit	Value	Unit	Value	Unit	Value	Unit	Value	Unit
1	second								
1	minute	60	seconds						
1	hour	3600	seconds	60	minutes				
1	day	86400	seconds	1440	minutes	24	hours		
1	year	31536000	seconds	525600	minutes	8760	hours	365	day

Working Time Potential			
8	hours	possible	per day
40	hours	possible	per week
173.3333333	hours	possible	per month
2080	hours	possible	per year
Working Time Subracted			
80	hours	Vacation	per year
80	hours	Holiday	per year
40	hours	Sick	per year
Working Time Potential (Actual)			
1880	hours	possible	per year

Working Time based on 1880 hours per year									
Value	Unit	Value	Unit	Value	Unit	Value	Unit	Value	Unit
1	second								
1	minute	60	seconds						
1	hour	3600	seconds	60	minutes				
1	day	28800	seconds	480	minutes	8	hours		
1	year	6768000	seconds	112800	minutes	1880	hours	235	day

Table A. Time may not always equal money, but it does on a project.

Figure 4. Game theory applies so my game clock is applicable.

I am a seeker, an explorer. I have been searching for something, and over the last several years, I have been more and more frustrated that I have been unable to find it. I want the universal productivity equation, the project anti-life equation as it is. I want to know, by the numbers, exactly what can be accomplished in a given period, to give perfect prediction of effort and outcome. For those that know me, this is one of those personal windmills that I tilt at in a Quixotic fashion. I like to tackle impossible tasks, not in the hope of success against great odds, but in the learning that comes with the attempt, the knowledge element. I like to plan and sort and analyze. And to be able to do that, and be successful at it, I need access to raw data, and be able to access that information on the fly, from anywhere, from anyplace. I used to carry dozens of notebooks, with sketches and notes and lists, using multiple colors of pen and highlighter to group data and tie information together with arrows and circles. Now, there should be an app for that, and one of its features should be to alarm when I digress. BEEP. BEEP. BEEP.

I know the complexity of the question will prevent me from boiling it down to a simple equation. There is no $E=MC^2$ when people are involved. However, when I started listing variables and constants and limits and unknowns on the board, the pattern that appeared was simple. Hours are either productive or they are not. The question is what percentage of non-productive time are you willing to accept on your project, and how do you manage your resources into that expectation. So, I kept track for a couple weeks using a game clock. Wikipedia (the obvious authority on everything until we really get a Hitchhiker's Guide to the Galaxy) defines a game clock as follows. "A game clock consists of two adjacent clocks with buttons to stop one clock while starting the other, so that the two clocks never run simultaneously. Game clocks are used in two-player games where the players move in turn. The purpose is to keep track of the total time each player takes for his or her own moves, and ensure that neither player overly delays the game." I am not sure how to reference this since it is open source

Time Calculations				
	Productive	Non-Productive	Total	Daily Percentage
Day 1	6:14	1:46	8:00	71.7%
Day 2	7:12	0:48	8:00	88.9%
Day 3	6:02	1:58	8:00	67.4%
Day 4	5:55	2:05	8:00	64.8%
Day 5	7:21	0:39	8:00	91.2%
Day 6	6:34	1:26	8:00	78.2%
Day 7	7:01	0:59	8:00	86.0%
Day 8	6:28	1:32	8:00	76.3%
Day 9	6:45	1:15	8:00	81.5%
Day 10	7:19	0:41	8:00	90.7%
TOTALS	**66:51:00**	**13:09:00**	**80:00:00**	**79.6%**

Table B. Productivity measured/repeatability questionable.

and therefore you can't prove I didn't write it originally. Ding. Timer expired, digression complete.

Back on track or as close to it as I can be. Game clocks can just as easily track productive time, that is, time spent on in-scope tasks, against non-productive time, meaning time spent not on in-scope tasks. Examples include taking calls, surfing the web, email, bathroom breaks, coffee breaks or writing disconnected, disjointed diatribes on project management for probable non-publication. Over the two weeks I tracked, I found I was about 80% "productive" over an eight-hour working period. The hardest part was limiting and tracking to eight hours (a forty-hour week) instead of my normal work whenever the work needs to be done type of day. Anyways, that being said, I was not focused on task 20% of the time. My gut tells me it is worse for most people, not through fault of their own, but because of the inefficiencies we build into how we work. My work-weeks were spent writing specifications and protocols, from home, without co-workers, meetings, trainings, or travel. I was shooting for 87.5% (seven productive hours out of eight) so I feel I got pretty close. I completed everything I had scheduled to complete in those 80 hours, the budget I had. I billed 66.5 hours to the project. The remaining 13.5 hours will be reserved for contingencies during execution, where I know I will see some delays and overages. Should I have just billed 80 hours? Well, I have a T&E contract, and not a lump sum. How does my efficiency affect the overall schedule? It doesn't. I still delivered on the expected day as promised. Could I have delivered it a day-and-a-half earlier? No, it wasn't complete. I wasn't 100% productive through the 80 hours. And nobody is, yet most are paid as if they were. I see I am getting off-track, and with 13.5 hours additional compensation I could afford to stay on track, and keep the train from getting de-railed like my stream of "digress-ionary" consciousness.

I hope to take one lesson from this study. If it is that in 80 hours, 10 working days, 9 to 5, you can't expect to be 100% productive, or expect that of others, then I have gained a PM Zen Merit Badge. If it is that every budget based on effort hours is immediately off by 20% and the schedule will slip one day in five, then a hard lesson is taught. The point being, you need to be brutally honest about time and productivity or the stress itself of hustling right out of the gate, knowing that you will never catch up, will burn

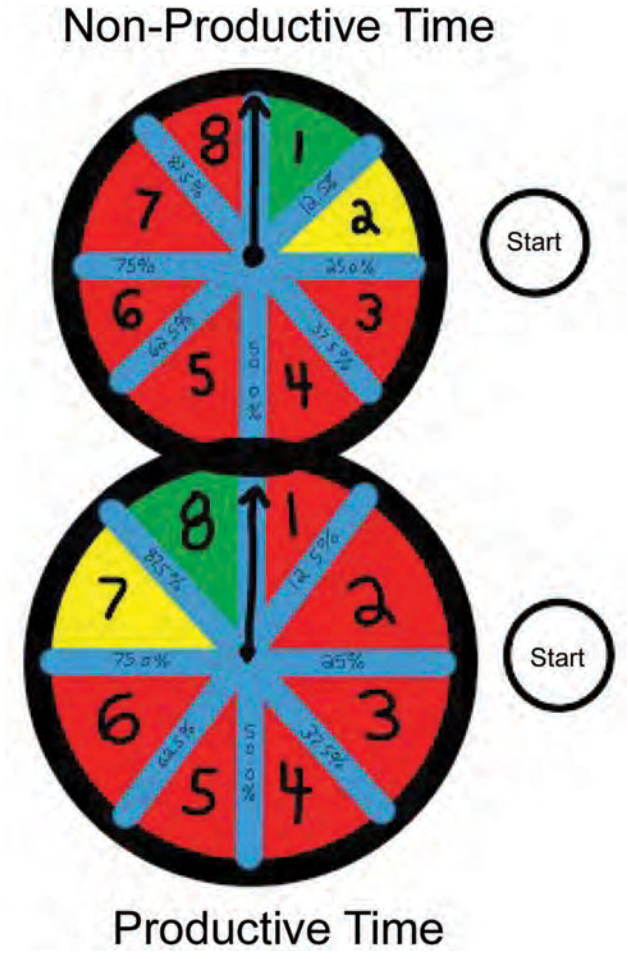

Figure 5. Productivity drawn out.

you out fast. I get burnt all the time, and it is taking longer and longer to recharge between races. This is the way of it, so watch out. You need to determine ways to keep away from digressing yourself away from your schedule; I have none for this thought so I digress freely and with confidence.

> *"Time is money; spend it wisely. Make your project efficient by smarts and not muscle. People make projects happen, and the best people make projects happen better.*

Time. Time to make a point. Time is money. If you pay me as a consultant to deliver 80 hours of work at $80/hr, your cost will be $6400.00. I finished in 67.5 hours and billed you $5400. I "saved" you $1000. However, I could have billed all of it, if I was under some different contract constraints. And next time, you may only offer me $5400 for the task. And if it takes a little longer, I am not as profitable. There is an ethic here so I offer in conclusion this non-conclusive argument, that is a total digression from anything up to this point.

Time is money; spend it wisely. Make your project efficient by smarts and not muscle. People make projects happen, and the best people make projects happen better. Use systems to map your position, don't get in the weeds, stay the course, be honest and have some fun.

About the Author

Keith Gibbs has been active as an ISPE educator for more than a decade, and promotes the concept that practice makes perfect so continuing education should be a practice of skills. Through the hard work of an amazing team of talented industry professionals, the ISPE Annual Meeting Project Management track "Real World" offerings have been a mainstay in execution of that concept. Professionally, he serves as the Director of Project Delivery for Innovative Process Solutions, a dynamically innovative project support group headquartered in Waltham, MA. Gibb's expertise is in strategic development of project delivery plans for cGMP projects.

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When a Project gets into Difficulty

by Mick Lynam and Alf Penfold

This article presents an approach to recognizing when a project is in difficulty and suggests a model for getting it back on track.

Organizations deliver strategic change through their portfolio of capital projects. Effectively delivering these projects is critical for businesses to grow and improve as they keep pace with the rapid changes in the market place.

Successful organizations have skilful project teams working to structured project processes supported by appropriate systems and tools. Each project also will have a proactive and supportive business sponsor who provides the business level direction and mentoring for the project team.

However, projects are inherently risky ventures given that they involve making a change to the business. Even the best project organizations will run into difficulty on some of their projects. The capability and maturity of the business sponsor is a key success factor in the early recognition and recovery from these situations.

This article provides an approach to recognizing when a project is in difficulty and suggests a model for getting it back on track.

Business Context/Project Environment

Modern business is characterized by an ever increasing speed of change, increasing global competitiveness and the need to "do more with less." Project teams in these environments have to cope with tougher regulatory requirements, tighter schedules, less available capital and with many opportunities in emerging markets requiring the use of virtual project teams. These factors put increasing pressure on project leaders as they define, scope, plan, deliver and close out their projects to deliver "success."

Project Characteristics

Every project is different, but there are characteristics that fundamentally define them,for example:

- Project type, e.g., capital project or organization change project
- Complexity (technically, organizationally, culturally, regulatory)
- Project delivery model, i.e., in-house team or using external services providers and contractors
- Project life cycle as seen in Figure 1

Project Success Factors

Delivering a project successfully and avoiding significant problems depends on success factors such as:

- It's the "right project" for the business to be executing.
- It has a solid business case and User Requirements Specification (URS).
- Project has a business sponsor who links the project to the business and proactively mentors and supports the team.
- Project has a clearly identified "end user" who will take over and own the asset.

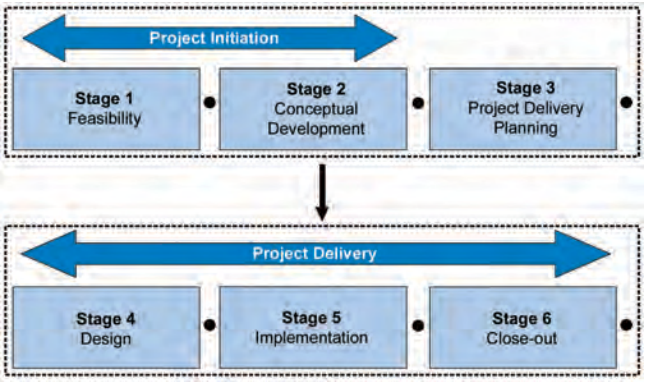


Figure 1. Project life cycle.

- Project is properly resourced.
- The team is competent and experienced with a strong leader.
- The team has a healthy, open culture with an ability to discuss contentious issues.
- Project is executed to a clearly defined life cycle with comprehensive reviews between stages to ensure that the project is ready for the next stage.
- Planning is thorough resulting in plans that are easily communicated.
- Estimating is comprehensive and realistic.
- Project has a strong project controls culture with a focus on real time measurement and prompt corrective actions.
- Change is managed with the implications of significant or multiple changes understood by the business sponsor.
- The team clearly communicates the project status both internally and externally ensuring that risks, decisions, priorities and actions are unambiguous.
- Risks are identified, communicated and mitigated.

To ensure a project doesn't get into difficulty requires the leadership to adhere tightly to these success factors.

Two Levels of Project Success

Assessing if the project is a success is not as straightforward as it might first appear because project success can be defined at two levels:

1. Business case level – delivering business benefit by selecting and delivering the "right" project
2. Project execution level – delivering on the project's specific goals for scope/performance, safety, schedule and cost

The "right project executed reasonably" is a better outcome for the business than the "wrong project executed brilliantly."

Two Levels of Project Difficulty

Business Case Difficulty

The business sponsor maintains the link between business case and project and must ensure that there is continuous alignment between both. Where a business case weakens or fails, e.g., because of a market shift or a change in the organizations strategy, this must be clearly communicated to the project leadership and the necessary adjustments or wind down of the project initiated immediately.

The irony in these situations is that a project may actually be executed successfully, but perceived negatively due to the business case difficulty fundamentally altering its direction or result or its ultimate termination and failure.

Project Execution Difficulty

Assuming that the business case is robust, project execution difficulties will then manifest themselves as identifiable problems with one or more of the primary goals:

- Scope is not being fully delivered or is not performing as it should.
- Safety is poor.
- Schedule is slipping.
- Costs are over running.

These are some of the visible symptoms of underlying root causes:

- The work done in the previous project stage was inadequate.
- Scope has grown due to change not being managed.
- The team does not have a clearly defined plan or have an unrealistic plan.
- The team is not controlling to their plan.
- Human factors, e.g., poor team culture, wrong skills, not enough people, personality clashes, team confidence is low, team is defensive, etc.

The project team may or may not be aware of these issues.

Degree of Difficulty and Trend

The sponsor needs to understand the difference between normal deviations from the plan and those that put a project in difficulty. Every project deviates from its plan at some stage, the deciding factors are by how much, when it happens in the life cycle and what it will take to get it back on track. A useful concept is to picture an organization's portfolio of projects and to identify both the particular zone that each is located in and also the direction in which it's trending, i.e., success, difficulty or ultimate failure as seen in Figure 2.

A key success factor is to be able to identify the current

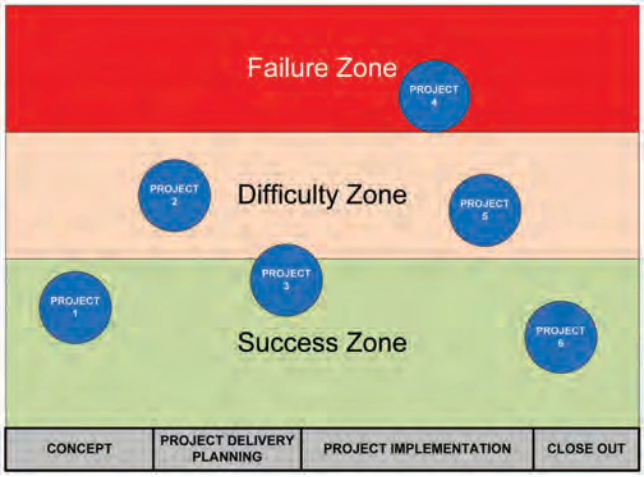


Figure 2. Success, difficulty and failure zones.

zone that a project is in and understand its trend. With small or normal deviations, the project will still be in the success zone albeit the team need to keep alert to keep it there and ensure it doesn't trend toward difficulty. More significant deviations will start to move the project into the difficulty zone and the need for more significant interventions to get it back on track.

A Model for Dealing with Projects in Difficulty

Business sponsors need to have a framework for dealing with a project in default. The framework should form part of the organization's project delivery process. The basic model has three steps:

- Recognition
- Intervention
- Implementation

Recognition

The earlier a sponsor can sense that something is not right the better. Early identification should assist in an easier and less painful fix. To be able to recognize a project in difficulty, the sponsor needs to know what to look for and where to find it. Good sponsors develop that sense of what to look for and the key questions to ask.

Life Cycle

Throughout the life cycle (Figure 1), the sponsor must stay in regular contact with the project and hold frequent steering or governance meetings with the project team leadership and end user.

The stage in the project life cycle is a key aspect. The problems that arise in the conceptual development and project delivery planning phases will tend to be different in nature and scale than those during project delivery. Problems in the earlier project stages are more likely to be strategic failings that can stay hidden unless they are actively sought out, e.g., insufficient design has been completed, the schedule is unrealistic, or the cost estimate is too low, etc. In these situations, the project is actually in mortal difficulty even before implementation starts, but it may not be evident.

To safeguard project delivery, sponsors must put great emphasis on the reviews between project stages to identify both evident and hidden difficulties; this is a key check before allowing a project to progress to the next stage as seen in Figure 3. These gates are opportunities for the sponsor to get a proper assessment of the project's current health and its readiness to move to the next stage. Very often the ultimate root cause of a project that gets into difficulty has been allowing it through a stage gate without a proper appreciation of its actual readiness.

Human Factors

One of the main challenges for a project that has difficulties is the inability of the project team to recognize or admit that there is a serious problem. The analogy of the frog in the saucepan that is continuously heated is relevant, i.e., the team may be gradually getting deeper and deeper into trouble, but they can't sense it happening. The following factors, mostly human or cultural, tend to influence this behaviour:

- People are too close to the detail and cannot see the reality of the situation.
- Team leadership may be inexperienced.
- Over optimism, a belief that everything is ok or that the issue can still be recovered without a major intervention.
- Culture in the location, admitting to "failure" is not culturally acceptable.
- Company culture, fear of repercussions result in the team "keeping their heads down."

An honest conversation may not be held because of the team's perception of how bad news will be received by their sponsor. The sponsor needs to create the environment where the team can talk openly about their concerns.

Plan vs. Actual

Sponsors should insist on good quality planning and estimating. Time should be spent with the project team to understand their planning basis, logic and assumptions. Plans which are very optimistic can set the project on the road to failure and need to be challenged. The sponsor should be particularly alert to plans which set out to beat previous best performance, i.e., the concept of "planning fallacy." It may

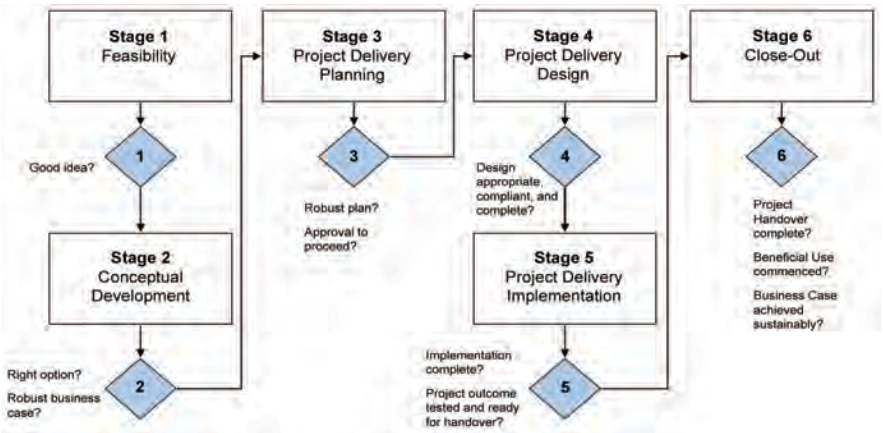


Figure 3. Reviews between stages.

be appealing to set world beating targets, but these need to be assessed to have a proven planning basis with the corresponding risk of failure clearly understood.

The sponsor must have high confidence in the alignment of scope, time and money before the project is approved for delivery.

With a robust project plan in place the sponsor should then insist on regular progress updates from the team. These are key touch points which allow a problem to be recognized early. Reporting and communication should be kept simple and focussed. Measurement and communication of actual performance against plan through earned value, etc., will provide key progress indicators that can be trended. Good examples are progress of team resource mobilization, design, PO award, construction, equipment deliveries, etc. The sponsor should insist on having project schedules summarized and progressed at the highest level for sponsor meetings to ensure that the big picture is visible and understandable.

The sponsor needs to be alert to the warning signs when a key parameter is showing a negative trend. For example, a simple yet accurate indicator is the inability to mobilize resources from the internal team or external service providers. Challenging and understanding the implications of this delayed mobilization becomes vital. The team may be over optimistic about their ability to recover from this.

Intervention

After recognizing that the project has a difficulty, an "intervention" must be made. A common failing with a project in difficulty is that the issue gets discussed regularly enough, but no definitive intervention takes place resulting in the situation deteriorating even further. The business sponsor must take ownership of the situation and establish a clear plan for the recovery effort.

Making a definitive intervention involves the typical steps outlined in Figure 4. This process can be executed in a number of days for a small project, a few weeks for a large complex project.

Ideally, the project status review should happen in parallel with the project delivery and try to avoid too much disruption. Depending on the scale of the difficulty, the sponsor may have to stop the project until the recovery option and plan is developed and approved.

The difficulty identified must be properly understood before a permanent fix can be put in place. The sponsor should engage the support of someone experienced from outside the project team to assist them as they assess and understand the issues and get to the true root cause(s). In setting up the assessment, the underlying business case/project drivers must be reviewed and unambiguously agreed, e.g., is the business value in the quality and speed of delivery or in the quality and cost of delivery, etc.

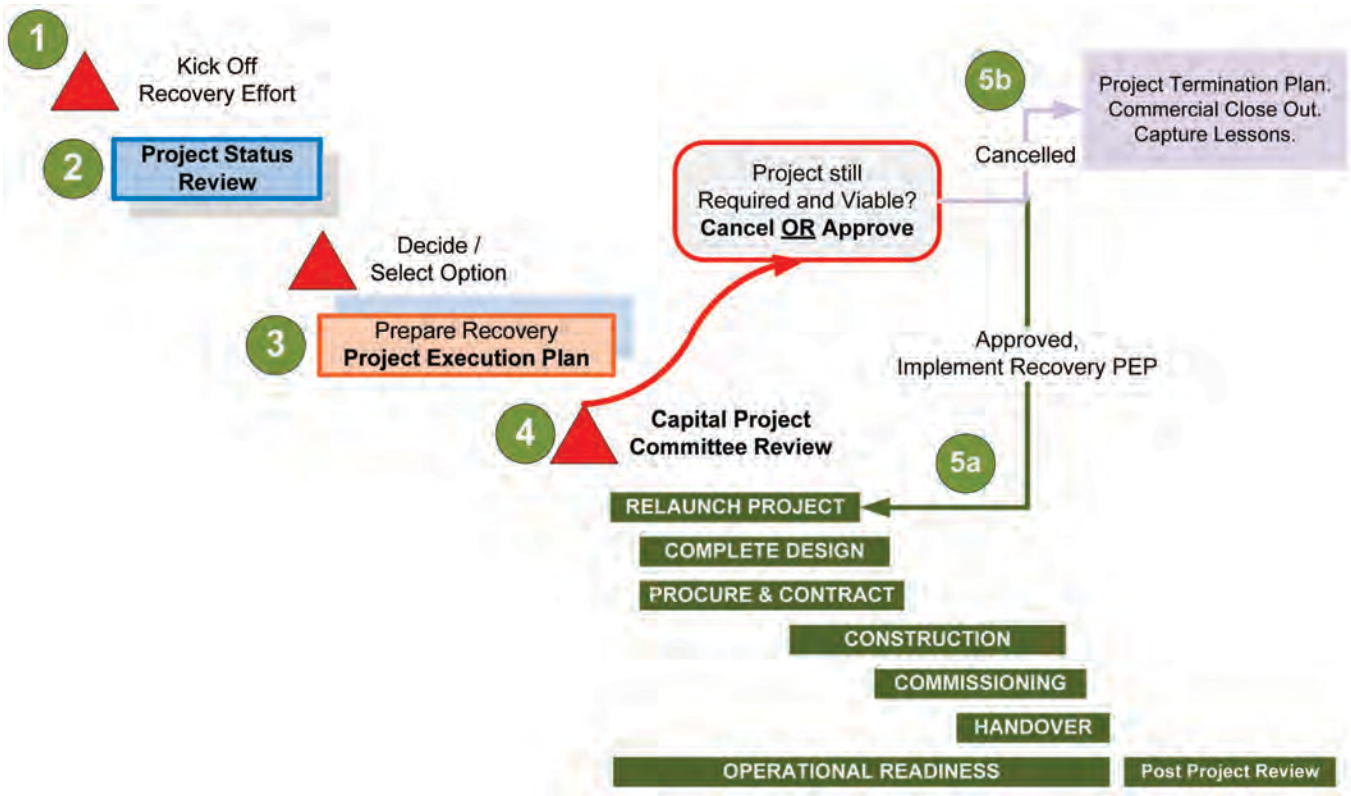


Figure 4. Project intervention and recovery methodology framework.

Kick Off

The intervention must be formally kicked off and the project team informed that the intervention is underway. The review should take place quickly, but in a structured and well communicated manner. It will usually involve a combination of documentation reviews and face to face meetings with key stakeholders.

Those leading the review should act professionally and courteously and avoid laying blame. The atmosphere should be business-like with a clearly communicated focus on getting the project back on track as quickly as possible. The review team are there to help and not criticize.

✓	Project Status Review
	Business Background/Context
	ROI Sensitivity
	Stakeholders
	Project Scope (and Changes)
	Project Execution Plan
	Project Org, Roles, and Responsibilities
	Project Governance and Sponsorship
	Regulatory and Permitting
	Site
	Design
	Procurement – Equipment
	Procurement – Trade Contracts
	Construction
	C&Q
	Cost
	Schedule
	Risk
	Root Cause(s)

Figure 5. Project status review checklist.

A comprehensive project status review checklist should be followed under the areas identified in Figure 5.

Understand the Root Cause(s)

When looking for the root cause, care needs to be taken not to take the "apparent: cause as being the root cause. Jumping to a conclusion too quickly can often increase rather than decrease the problem. Table A gives examples of apparent and actual root causes.

It's also useful to categorize the causes as either internal or external to the project and also if they are within the team's control or not.

Identify and Select Recovery Options

Most problems have more than one solution, the available recovery options need to be quickly identified, assessed and ranked. Inevitably, recovery will mean changing some aspect of the project delivery plan or structure, including:

- Project scope changes
- Personnel changes [which need to be handled sensitively]
- Training or team building
- Service provider changes
- Re-baseline the project schedule and budget

These potential changes will have the following implications:

- Business case re-assessment
- Additional capital sanction
- Extended project completion date
- Communication/negotiation with external/third parties
- Contractual/commercial negotiations with service providers/contractors
- Regulatory body notification
- People's reputation and careers

Symptom	Apparent Cause	Actual Root Cause
Project is behind schedule	Team not able to hit their dates	Project Manager is not dedicated to the project
		Team is under resourced
		Personality clash at senior level, project culture is dysfunctional
		Decision Making process is inadequate
		Project culture is poor due to personality clash at senior level
		Contractor has underbid the project and is losing money
Project is over budget	Team is not controlling the project costs	Changes being made without understanding implications
		Project URS was poorly defined
		New team members changing the decisions made in last life cycle stage
		Project Delivery Planning was inadequate
		Work done in the previous project stage was inadequate
		Contracting market conditions have changed since estimate was done
Safety onsite is poor	Site Team performance	Contractors were selected on lowest price

Table A. Identify the root cause.

These implications must be considered and factored into the decision making process as a preferred option is selected.

A doomsday scenario is where the scale of the problem and lack of acceptable options results in the project being recommended for termination.

Plan the Recovery

Once an option is selected in principle, a plan for its implementation must be put in place to address:

- How the project goals will be re-baselined (scope, cost, schedule, safety)
- How the project team will be restructured
- New roles and responsibilities
- Preparation of the updated project delivery plan
- Stakeholder engagement plan
- Communication plan
- Project control plan (to ensure it stays on track)

In preparing the recovery plan, the following must be understood:

- The recovery plan must not fail, the team will get one chance to do this.
- Don't be over optimistic, be realistic about the re-launch and the required time and money.
- The project will get a lot more senior management attention now that it has been in difficulty, a recovery plan must include a very strong project controls, reporting and communication component.

Recovery Plan Review, Approval and Communication

When the project execution plan has been sufficiently developed, the appropriate review should be carried out with the business leadership to confirm that the project is still required and viable. At this stage, the project might be terminated if the confidence level in the recovery plan is not high.

When the recovery plan is approved, communication with the project leadership, and with the key stakeholders, must be very clear. This is essential when the selected recovery option requires a new scope, date and budget for the delivery of the project.

Project Re-Launch and Implementation

With the plan approved, it now must be effectively implemented. Communication of the project re-launch is a critical element of a successful implementation. The sponsor needs to ensure that all of the key stakeholders in the project are engaged to ensure that they understand and commit to the new plan, roles, responsibilities and project objectives.

Organizational Learning

After the project has been put back on track, the learning from the situation needs to be captured. The valuable insights are those systemic improvements which can be built into the organization's capital sanction and project delivery processes. The immediate focus of a sponsor is on getting the project back on track, but the more strategic focus is to ensure that the organization learns from the experience and avoids a repeat.

Summary

- Projects do get into difficulty.
- The role of the business sponsor is key.
- The sponsor must take clear ownership when a project starts to get into difficulty.
- A structured intervention should be carried out.
- Corrective actions should be made decisively and followed through.

About the Authors

Mick Lynam has 28 years of experience in leadership roles on major projects in the pharmaceutical, mission critical, ICT, oil and gas and energy sectors. During his 19 years with PM Group, he has held a variety of roles in the areas of project management, design management, construction management, and operations management. He is currently Director of Business Development. Lynam's particular area of interest is the management of complex projects. He was a member of the core team responsible for the ISPE Project Management Good Practice Guide and is a member of the advisory board of the Centre for Project Management at the University of Limerick, Ireland.

Alf Penfold has 28 years of experience in the pharmaceutical and biotech industry with the last 10 years with Pfizer. He has led the ISPE Project Management Community of Practice and presented on project management at various ISPE events in Europe and the US. He has managed capital projects in Europe, the US and Asia and co-authored the ISPE Project Management Good Practice Guide. In addition to his experience in project management, he has been Head of Engineering at manufacturing sites in Europe and the US. During his time with Global Engineering at Pfizer, he has held a number of different roles including regional responsibility for engineering for Latin America, the US and Canada. More recently, he has led a number of regional and global teams for programs such as integrated facility management and serialization.

Project Management Strategies for Multi-Company Project Teams

by Mark Mathis

This article presents methods and tools for successfully managing projects where team members are from multiple and sometimes competing organizations.

With the growth of smaller, single-industry focused corporations and single-employee regionally based companies, clients in the pharmaceutical/biotech industry have come to enjoy the advantages of assembling project teams with exactly the individuals they need from multiple sources. There are risks and liabilities that accompany such decisions, but overall, this helps keep the market competitive for all service providers. This shift in resource availability brings a paradigm shift in how all companies must execute projects.

For those who have worked in large and small Architecture and Engineering (A&E) firm environments, there is a significant adjustment made when switching between the two. Larger firms have more established guidelines on how work is to be performed and by what criteria specific deliverables are completed. These work practices can span several industries that the larger firm services with the idea of creating continuity in a diverse, more project flexible workforce. Smaller firms have the flexibility and freedom to cross over inter-disciplinary boundaries and by necessity, must sometimes execute work outside of their comfort zones or technical background.

What seemed a great divide 10 years ago in the two operating philosophies has now been pulled together to form the hybrid project team. This is the team where several players from different organizations are made to work together to complete projects as a group. While it does happen that these hybrids form at the larger $100 million plus projects, it is more common to see it at the less than $50 million Total Installed Cost (TIC) jobs. The rationale is simple, smaller, more diverse, and focused teams will bring a wide breadth of experience without significantly adding overhead costs. By "cherry picking" individuals with backgrounds best suited to the scope, clients can offset the risks of a single company's shortfalls in personnel.

This scenario does not always provide for a lower capital cost for services. To the contrary, choosing select professionals from multiple firms will result in the highest Time and Materials (T&M) rates per person. What is diluted is the need for excessive overhead and administrative cost. Clients with a solid administrative infrastructure can offset this cost by including direct personnel to help with establishing and managing travel guidelines and expense reimbursements. Also, integrating members of a client's internal project team with the group will result in increased efficiency in communications and schedule alignment among all team members.

In this environment, projects can be derailed by taking the wrong approach to managing the team early on. Risks include larger firms trying to force their own governing work protocols on everyone else, individuals acting as lone-wolfs working in bubbles and not communicating with the group, and an increased likelihood of defection from key personnel. Much of this comes down to the personalities of those involved, but there are practical and successful strategies that if implemented early on will result in more managed scope control, higher retention of the core team, and a significant reduction in encountering the aforementioned risks along the way.

The concepts address in this article are as follows:

1. Identify Team Players
2. Identify the Project Culture
3. Identify Technical Resources
4. Communication

Strategy 1 – Identify Team Players

Encountering non-qualified individuals on project teams and realizing it a little too late is one of the more common risks all clients try to avoid. Overstated or embellished resumes can appear from large and small companies alike. Be on the lookout for inter-corporate nepotism as well. This can be especially common in projects where large project teams are relocated to jobsites. Corporate teams will naturally want to surround themselves with friends and their own known quantities. Don't assume that educational background was verified and check if the background seems appropriate for the positions held within the company or on the project. There can be managers of engineering staff who do not have an engineering degree, or other applicable experience other than the relationships with senior staff. In some states, you cannot add "engineer" to a title unless there is a relevant engineering degree and in some cases a regional license. This is not to say that all positions require degrees, but be discriminating with relocating project teams. The A&E's goal is to provide the right person, but often has to choose from a shallow pool of those employees who are willing to relocate. Set a project standard for background checks and degree verifications for everyone regardless of affiliation. This helps minimize what has become known as "empire building" on projects where the priorities tend to shift away from the project and more toward the individuals involved.

Another risk common in this scenario is personnel hired solely for the purpose of relocating. If you are considering a contract with any firm that includes relocating staff, you should expect personnel that are experienced with that company's policies and loyal to representing them even when away from the corporate home front. A senior executive brought on to pad a job with years and years of experience but no ties to the organization and a history of jumping companies can quickly poison the well for other members of the team. This too can turn into empire building which will only serve the goals of the empire and not the project.

Smaller firms will have every motivation to put their best face forward, but may not realize the advantages of integrating with others. It is easy to default to posturing and exaggeration of capabilities instead of identifying areas where they need support from others. Be aware of those that would propose to hold any technical role on a project. A small firm or individual should be flexible, but should have some area of expertise and a willingness to shore up the places where they are not as experienced. In fact, this is the primary advantage of assembling a team from multiple organizations.

There should be one flag for any project team. Since team members may originate from several different entities, a single governing set of directives that is aligned with the project objectives should be in place and managed by the team leader. If possible, become familiar with what the internal goals or employee incentives that may be in place at the different firms. Make sure these will align with project expectations. There are several technical strategies to defining the way a project will be executed but first, the hard part; identifying the project team's culture.

Strategy 2 – Identify the Project Culture

What is it about our industry that remains constant regardless of the company you work for or the products you help produce? It is the culture of that organization that defines, enhances, or limits the ability of the group to achieve success. There are many unique characteristics of the pharmaceutical, and more specifically, the biotech arena that set it apart from other multi-billion dollar industries. One that stands out is the fact that biotech itself is still an ever expanding and new marketplace. Having not been around near as long as the food and beverage, polymer, semiconductor and a host of other similar product driven groups; biotech has quickly set the pace of continually redefining itself every few years. Existing drug products are being manufactured more efficiently and becoming safer to produce and consume; and new drugs are pushing the envelope of what manufacturing and design tools are out there to formulate the product and increase speed to market.

If a hierarchy of culture were assembled for the biotech industry, it would include the fact that our media age continues to be one of the youngest, second only to Ecommerce; our workers and service providers can quickly set themselves apart as generators of new ideas and specialists in new areas of expertise; that the very core products are themselves a generous payback to those that work in the industry, striving to better the quality of life for friends, families and in most cases strangers around the globe. When speaking to those still in school, this culture is the easiest to convey because there are just a few professions that are as exciting and fulfilling as the pharmaceutical/biotech industry. No student can resist even the very basic principles of GFPs Green Fluorescent Protein (GFPs) and watching mice and other mammals glow under a black light. Combine that and other exciting technological advancements with the fulfillment of serving the sick and reducing the spread of disease worldwide, and you have an interested and engaged pupil.

Underneath the culture of the industry resides the culture of the individual company. This can be a manufacturer, a consulting group, or any number of service providers that work in the field. The first major challenge of working with a new client is determining what their culture is. This is more than a mission statement, it defines their community and ultimately what their priorities are. There are vast differ-

ences between company cultures that become evident after spending time with many of the larger drug makers. There are regional influences in west and east coast businesses and depending on the drugs produced; there are differences in attitudes about manufacturing; there are campuses that resemble colleges and parties and events that would impress even the coolest Facebook employee. Working at an acetaminophen plant will highlight the extreme difference between making aspirin additives in large bulk quantities and making a drug that only applies to a select market of consumers. The employees, the packaging, and very processes are all very distinct to the culture of the company where the drug is made.

The reason all of this becomes important to consider as part of a Team Leadership paradigm is that the culture of operations extend throughout all unique companies, but none is more challenging and ever changing than that of the small business consultant. Larger engineering firms that service multiple industries where biotech is but a small sector, cannot afford to greatly deviate the process by which they execute projects. An engineer or manager working in the biotech sector one day may be working in the petroleum group the next, especially those who work on the infrastructure or non-process driven side. However, the smaller companies, specifically those that choose to focus on the pharmaceutical/biotech industry alone, must constantly reevaluate the respective client's culture with every project. This is a more intimate environment where more often than not, consultants are brought into the fold of a clients operating group. Even going so far as to integrate them into site specific training, access to facilities and perks, and internal metrics by which performance is rated along side of full time employees.

So in this rapidly changing environment, how does a small company navigate the different modes of operation within a changing client roster, while simultaneously establishing a unique identity in this environment? Something that becomes apparent when an engineer leaves the fold of a big company, is that the workload and responsibility matrices begin to flatten. The lines of segregating interdisciplinary tasks and objectives are no longer clearly marked. A process engineer must now understand equipment and procurement; a mechanical design engineer must now route pipe and duct alike; a controls engineer has to step outside of the programming bubble to consider people and material flow and locate shared, multi-purpose operator interface stations or OITs.

Identifying and understanding the client's culture is a key first step in any team's success. It is equally the responsibility of the client to communicate this to the group, understanding that those not in the fold may not be aware of what happens behind the scenes. The leadership of the team should take an active part in making sure everything is communicated and consider it a primary responsibility to keep the team involved and engaged with a client's culture.

Strategy 3 – Identify Technical Resources

This article considers the challenges of smaller jobs, those under $50 million. These are the projects where overhead and administrative support is cut extremely thin. The project manager also may hold a technical design lead role in addition to managing the client interface and schedule.

For these type of jobs, efficiency in operation is everything. There is no time to waste on shoving the metrics and tools for $100 million plus projects down the throat of the team who is not staffed to manage those tools and whereby the larger output is not relevant to the smaller project needs. The team needs tools that are designed appropriately for smaller, faster paced jobs with flattened levels of communication throughout.

Common challenges that surface on almost all of these projects are how to manage the project's technical deliverables with the design and procurement of material. Often a smaller team that would include a process engineer, an architect and a project manager will conceptualize the project with the owner's team. This results in a rough budget and general plan for facility and equipment. Material and personnel flows, square footage and throughput are critical to establish and set the groundwork for the preliminary and detailed design teams to gather information for their respective disciplines. Where large groups of engineers maintain a respectable catalogue of past projects, computer programs, and other resources to draw from, it may be cost prohibitive for a client to bring them on board, or more likely, teams are now cherry picked from a variety of organizations where issues of intellectual property prohibits an open and sharing environment. In the absence of more traditional resources, coming up with unique project tools for the team can be challenging. These tools need to not only streamline the more mechanical operations (like datasheet and specification assembly), but make communication of technical and commercial data more efficient.

The relative cost of failure was mentioned in one of this year's earlier articles on risk assessment and also has great relevance for this topic. The primary goal of a project team is not to execute perfectly, but to properly evaluate risk and identify problems as early in the project as possible, knowing that failure costs increase exponentially with time.

A. Multi-User Project Database

For process engineers who must now manage equipment, a customized database application can be a good place to start. The days of Excel's large, multi-layer worksheets with countless embedded calculations referencing obscure and sometimes hidden cell locations are phasing out. As these programs are passed on or reused, they can't help but bring

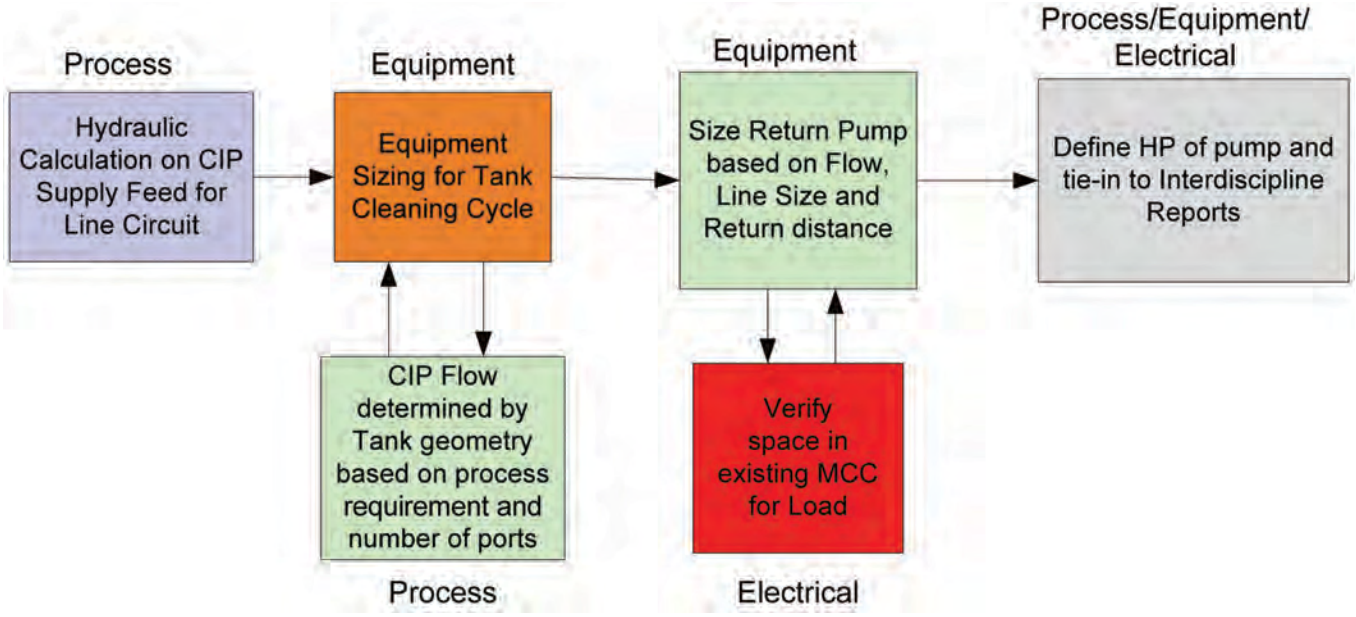


Figure 1. HP Calc for CIP return pump.

the old project problems into the new project. Too often there is only a single individual who may no longer be with the organization that even knows the details of the programs design, fudge factors, or macros. While creating a database management system does come with its own set of challenges and frustrations, a very powerful advantage is the ability to properly name variables and protect formulas from modification –accidental or otherwise. After all, there are certain laws of fluid dynamics that will never change with regard to line hydraulics as there are other constants and calculations that can be placed into a controlled environment.

Many of the project deliverables can be rolled into a common database management tool to not only provide a single source location of information, but act as a gate check for shared properties. As an example, Figure 1 is a flow path for acquiring the information regarding the HP load for a CIP Return Pump. Assumption is that for this return pump there is only a tank and line circuit.

This is simplified and meant to demonstrate a linked chain of communication and output from three disciplines working on a common piece of information. If the horsepower changes, process may have trouble returning the CIP fluid back to the skid, equipment may have undersized the pump, and electrical may not have accounted for the load. Instead of these groups acting in individual bubbles, they are working from a common technical matrix where each has a part to update and maintain. It is not to say that large companies don't communicate well. More to the point is that on a project with a small amount of equipment resulting in a smaller electrical scope, there may not be a budget for a design lead to remain on the project full time throughout its duration. This lands the detail in a common room with links to quickly coordinate design impact when project changes occur.

With a database application such as Microsoft Access or Oracle based products, it is common to have a primary interface screen or "Main Menu." Projects should be divided by tasks or a minimum by discipline lead. The separation can be as simple as process, equipment, and electrical. For each of these primary categories, subcategories will fall per the deliverables of the project. It may look like this shown in Figure 2.

In practice, the main discipline categories will be populated with many more subcategories, most of which may not be interconnected, but all of which should serve as a data resource area for the project team.

B. Technical Design Templates

Something that works well with one discipline may not be successful in another, but from a process perspective, design templates are a must have. Design templates are meant to identify and define boiler plate technical areas that would be repeated several times through the course of a project. As an example, P&IDs can be split up into many different categories such as upstream, downstream, process support equipment, utility, etc. The foundation of these drawings can have several design modules in common. A trick brought over from the automation side is to find groups of valves, instruments, components, or equipment that serve a common function and keep the operation and representation of those items consistent. This allows the automation team to easily reproduce and troubleshoot areas of their program that were similar.

From the process side, keeping the grouping of small components consistent is also an advantage, but branching out into larger modules of tanks, heat exchangers, and pumps can not only simplify the entire flow of the P&IDs, it can help bring consistency of operation to the finished product. Low hanging fruit would be things like vessel temperature control whereby buffer tanks, media tank, fermentation vessels, product pool tanks, and other similar vessels can all represent the respective heating/cooling operation the same way. There may be different setpoints, but the component cast of characters is often identical. This also branches out into instrumentation choices. There will be times when to preserve consistency, a common manufacturer or instrument model number may be used even though it is overqualified for its operation.

Plant steam and process steam traps are another area where consistency will add a lot of value. Producing the design template for each type of steam system along with the slight variations of horizontal, vertical, and high/low flow trap installations will not only make it easy for multiple P&ID owners to have similar drawings, but the piping designer doing the CAD work will have a lot less guess work to do when interpreting markups.

Here are some other design templates to consider:

- media feed through a filter
- dual CIP Sprayball arrangement for a vessel
- shell and tube heat exchangers
- chilled water/glycol inlet and outlet valves and instruments to a room or tank
- vent line drip legs
- transfer panel jumper design
- block and bleed arrangements

There are more, and the nice thing is that you can make use of these on future projects also. There are differences in design philosophies around equipment, but the basic mechanics will remain constant.

Note that this is not the same as just using an old set of P&IDs, to the contrary, this should protect against inheriting the mistakes of previous jobs and setting a design standard for future projects.

C. Simulators and File Share Software

One of the first considerations on a process driven project is how best to define scale. Defining this for the small project team is critical since the schedule is shorter and the need for consistency in deliverables is of greater importance. Give a centrifuge design to three different companies and you will get three different designs back. Documenting scale in the conceptual phase serves as the foundation for process equipment sizing, what options are needed, required utility services, and production support equipment. A popular method is to use a simulator and/or time and motion study to define and document scale. It would be good to research whether there are existing industry products out there that may serve the same purpose as an internal or custom program even if it is done with Excel worksheets. A turnkey software product sounds like a good idea; however, in practice, tends to implement more successfully on larger jobs. These types of tools

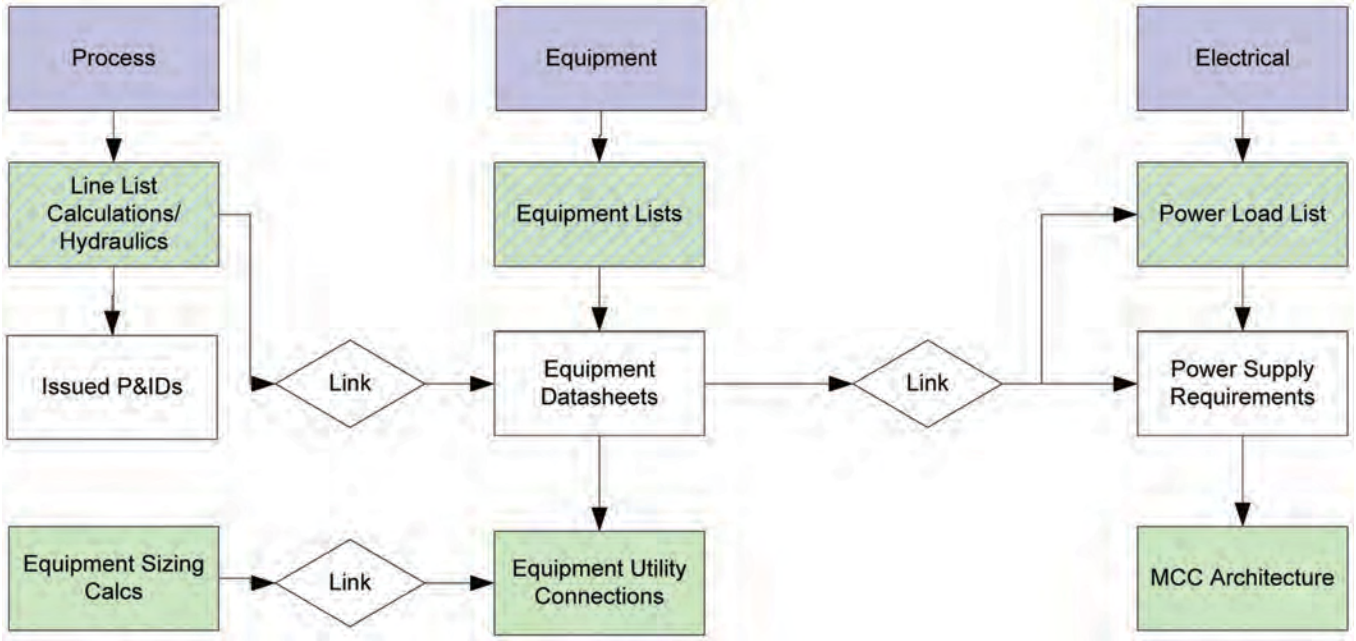


Figure 2. Inter-disciplinary project database flowchart.

are often designed for use in multiple industries and sometimes lack the necessary customization options to form fit to a smaller work protocol.

A good example is looking at the simulation platforms that are out there. Regardless of which platform used, Aspen, SuperPro, etc., each of them could be manipulated in some way to produce the desired result or graphic and more often there were very few people trained to make use of the available customization for their respective disciplines. It sometimes results in bringing a nuclear weapon to a knife fight. By keeping it simple and multi-use, each discipline lead can create and manage their deliverables and information on a common database platform with links for high priority detail throughout. The current versions of software for Access and Oracle have very good HTML options for reporting whereby weekly updates can be sent automatically through email or on a secure Web site for the whole project team. This negates the need for everyone to service the database for common and frequently updated information. This will not take the place of communication, but will bridge the gap between multiple disciplines on a small fast-paced job.

A software platform that is increasingly popular at job sites is that of the fileshare. Products like Autodesk's Constructware and many others profess to provide the kind of seamless information exchange on a common interface, but can easily morph into an endless sea of data in an even more endless sea of structured file folder locations. Constructware is no longer manufactured; whether this is due to user problems or a lack of market demand is debatable. This type of program does serve a purpose and is instrumental in the review, distribution, markup, and archiving of project documents, but tends to favor the construction teams more so than the early design teams. It becomes too easy to simply throw a document out there supposedly for everyone to have input on only to find out that if collected intranet dust for weeks without moving forward. The proposed database tool in this article will not take the place of a service like Constructware. However, it will fill in the need for a fluid design tool interface which serves the discipline lead's calculations and sizing of equipment and components during the design phases of the project. The reporting structure of the database can still be archived in a platform like Constructware or a simple project folder on the intranet.

Another positive aspect of this type of tool is the similarity between a typical PLC/DCS interface and the database interface itself. By keeping the database user friendly and implementing push button functions on the main screen and sub screens, it should serve as familiar territory for anyone who has run process or utility equipment in the field.

In keeping with the "less is more" aspect of smaller projects, it is important not to overload your project database with ancillary functionality that is already done better elsewhere. A good example of this is smart P&IDs. If properly managed, smart P&IDs can be effective in managing the valve, instrument and material lists for the project. These lists can be produced from the Smart P&ID platform in a database format which can either stand on its own or sync with your project database. The advantage of syncing this data is reducing the chance of double dipping on procurement with regard to equipment boundaries, such as: where does the shutoff valves scope lie? It also would allow related discipline leads to append to the information things that may be important to them, such as unusual power supplies for instrumentation, or special conduit requirements.

Strategy 4 – Communication

Communications within small project groups tends to have both advantages and disadvantages when compared to the larger teams. The advantages are that it spreads quickly and by companies being small and/or having a small role on the project, there is inherent motivation to stay in the loop. Small project teams can push the boundaries of current technology using smart phones and Web based protocols for faster and more seamless interface with the team. Disadvantages are case dependent, but problems can arise in the event where team members are remote or perhaps not full time on the project. Engineers with several projects going on at the same time are often forced to place a pecking order for their projects to meet their respective deadlines.

This forces the need for a more frequent and standing interface between the team. During FATs Factory Acceptance Tests (FATs), the small project scenario plays out in short periods of time. Here exists the likelihood of team members who are from different firms and backgrounds, interfacing with a vendor's sub-team and working remotely sometimes for several weeks. The first thing a successful FAT team sets up is the schedule and tasks to complete per the protocol. This may involve starting off with a daily safety meeting, followed by splitting up to inter-disciplinary protocol sections, touching base at lunch, and doing a final wrap up at the end of the day to set the next day's agenda.

For small project work, while it does not necessarily have to be this packed with meetings, the basic theory is sound. More communication will equal better alignment and performance by all team members. For the first few weeks of the job, having a standing morning meeting for your project team on site with telecommunication video capability. If people can't attend due to schedule conflicts, or move the meeting earlier until you can guarantee attendance, make it mandatory. This helps set the priorities and allows team members from separate companies to get to know one another better. Spread out the meetings throughout the week as deliverables begin to fall into place, but try not to just meet once a week. With people juggling travel schedules, remote operations, and other project workloads, it won't take much to hit a conflict. As a project manager, don't fall into

the trap of being reactive and calling the fire brigade every time something goes astray. Things will go wrong. Put in a system of regular, but brief meetings, email/text updates, and one-on-ones with team members to help anticipate problems and respond accordingly.

Clearly communicate the chain of command. Clients and consultants alike can tend to break out the corporate org chart and use this as a guideline for how the project is going to run. If a person two bars up is never going to be present at the meetings or play an active daily role on the job, they should not be listed in the chain. Let your team have one point of contact for communication and keep your org chart as flat as possible. This will encourage doing what needs to be done instead of what team members are just supposed to do as a scope or contractual requirements.

Encourage communication by applying incentives to shared deliverables between different leads within the team. Incentives should be built around time spent on the job to help with mid-project defection. When single employees are seconded to a jobsite, they are more at risks for taking the next best thing in job opportunity. Straddling a time and milestone type incentive will help identify the advantageous to sticking with the project until completion.

Case Study

Here is an example of a executing a job in a multi-company project team. In 2008, Biotech Company A and Biotech Company B partnered to produce a Biotech Company A product using production capacity from one of Biotech Company B's plants. The project's engineering company had approximately 17 process engineers on site, from two office locations that assumed responsibility for project management, process, commissioning and validation. Working side by side were multiple firms, including a large A&E firm and several one-person contract employees selected by Biotech Company B to manage the engineering and construction side of the project. Total project team size between all organizations involved was approximately 50 engineers and commissioning staff.

The clients also provided their own project staff to manage the technology transfer and to establish continuity in the drug's manufacture. Culturally, there could not be a more different match up. California with New England; large engineering firm with small; and several one-person 1099s to fill in the staff where needed; and nice heavy snowstorm filled winter to be based out of for a year. What appeared disastrous from the onset went very smooth. Strong client team leaders on both sides kept the staff meetings to a minimum and utilized technology to communicate pertinent information to the team. Each client provided an A-team of players who were intimately familiar with the product and the process and shared information through a common internet based fileshare platform. All project staff worked and housed in the same trailers and many travelled back to their home base every week or every other week. Per diems for travelers were kept consistent and fair and non-discriminate based on the company you worked for or your position. By establishing uniform project directives from the client's leadership and filtering priorities across all companies on the job, a common focus (flag) was maintained and executed as a seamless team. Project staff were screened prior to joining the project for all stated education credentials through a common background agency that everyone utilized. Teams were purposely divided to include several people from different companies in each group. This helped to ensure no silos could form and become cut off from the team or project communication.

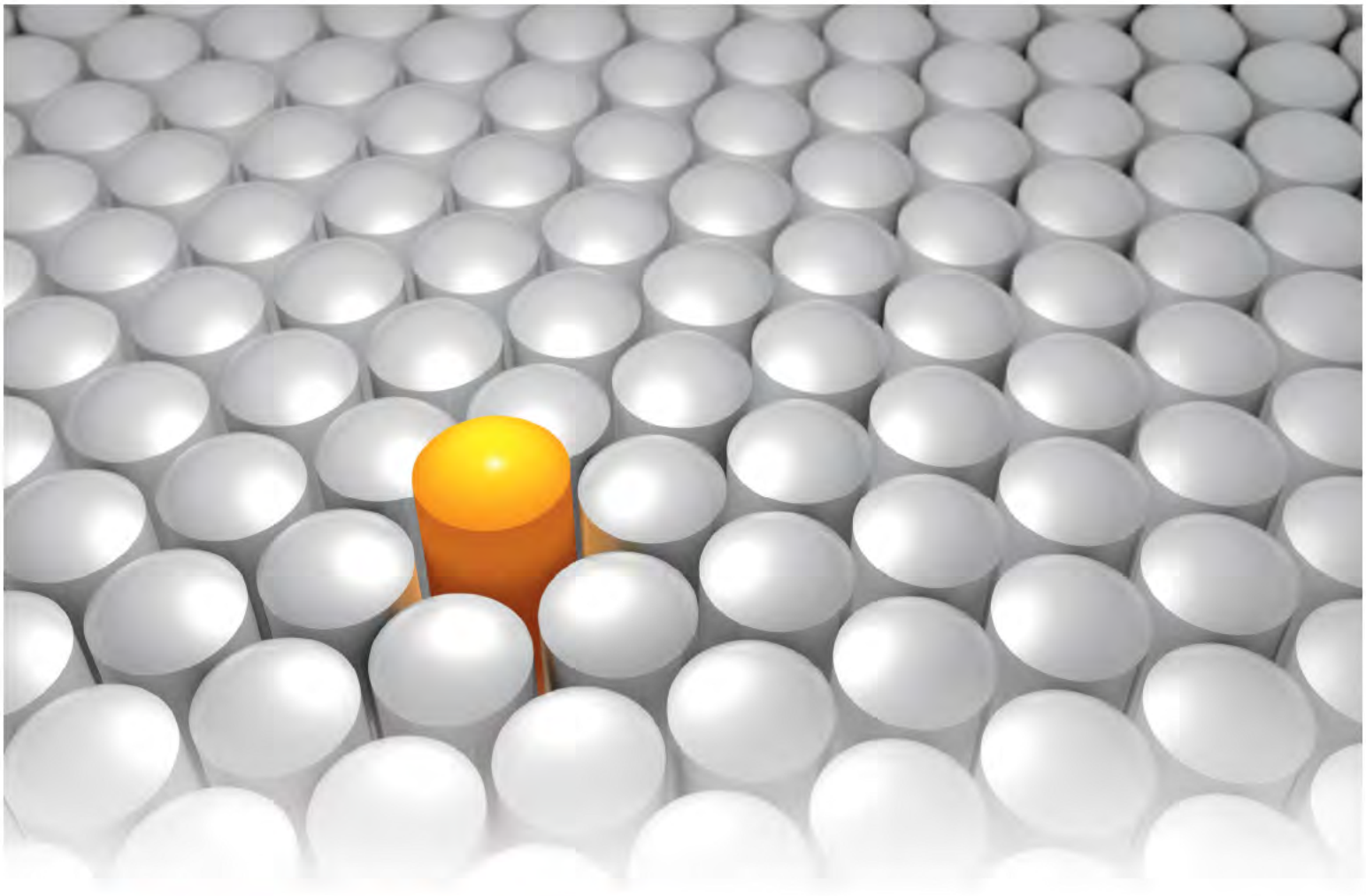
Daily safety meetings and client regimented regular training protocols provided a platform for continuity among the project team and eliminated much of the concerns over intellectual property between competing firms. Social functions were common and designed to be non-exclusive.

Conclusion

The culture of our industry is ever changing and impacts everything from the latest drug on the market to the way small projects are executed with multi-company teams. By thoroughly vetting the proposal team ahead of time, utilizing a flexible, custom, but powerful tool like an interdisciplinary database, project design templates, and a good fileshare platform, a small, multi-company project team can be more efficient in execution and identify problem solutions much sooner in the timeline. Creating a culture of collaboration to align with project goals will build trust amongst the team members and help to retain valuable resources for longer durations on the job.

About the Author

Mark Christopher Mathis is co-owner of PACE, Inc., a firm specializing in providing process, automation, and commissioning services to clients in high tech industries. Mathis holds a BS in chemical engineering and has 22 years of experience in the pharmaceutical/biotech industry with recently completed projects in the nanotech sector. He has performed as a Project Manager and Process Lead in the design, construction, and validation of large scale multi-product manufacturing facilities with a specialty and focus on design of large-scale bioreactors and chromatography systems for a worldwide list of clients. As a member of ISPE for the past 16 years, he has held several local positions including Chairperson of Programs and Communications Committees, Treasurer, Vice President and President of the Carolina South-Atlantic Chapter. His most recent position with ISPE was as Chair of the North American South American Advisory Council (NASAAC). He may be contacted by telephone: +1-919-345-4044 or email: mark.mathis@pac-engineers.com.



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Practice What You Preach!

The Project Management of the Project Management Good Practice Guide (PM GPG)

by Dr. Trish Melton on behalf of the Guide Core Team

When the PM GPG became a reality what was the first thing we did:

- Appoint a Chair (effectively the Project Director) and a Project Manager
- Form a core steering team of key stakeholders
- Develop a vision of success for our "project"

With this key structure in place we all agreed that if we were to achieve success that a fundamental concept was that we had to behave as project managers, use our combined project management expertise, and deliver excellent content in an effective value add way: we had to "practice what we were about to preach" – good practice project management.

People

Key to our success was the engagement of a variety of stakeholders: Guide chapter writers and other contributors; reviewers and those involved in the governance of such documents within ISPE (the Guidance Document Executive Committee – GDEC).

Our chapter teams were all led by a member of the core steering team and contained ISPE members with both interest and expertise in selected subjects. The desire to share knowledge was critical to effective management of the content generated.

Benefits

Developing an understanding of the needs of our customers (you – the ISPE membership) was fundamental in developing the scope of the Guide. We relied on each member of our extended team to consider why content should or should not be included and continually challenged the benefit it would bring.

Risk

The Guide was managed using a risk-based approach. All areas of uncertainty were identified and managed. A good example is the way that *chapter content* and *schedule adherence* was reviewed:

Each chapter was given a Red, Amber, Green (RAG Rating) dependent on these two factors enabling the core steering team to predict likely success (development of a value add guide able to be launched at the 2011 ISPE Annual Meeting – 18 months from start to finish!!).

Team Ways of Working

Control of the project schedule and risk profile was managed through regular virtual meetings allowing a "one-team" approach no matter where in the world a team member was located.

Most of us would attribute our success to having working sessions via a Webex platform:

- Action logs were generated "live" with no need to write lengthy minutes after the fact.
- Chapters were written and reviewed "live" avoiding the need for team members to have extended writing sessions outside of the virtual environment.
- Work was available on a shared area thus avoiding revision issues and emailing large documents.

Success

The Guide will be released at this year's Annual Meeting as a part of the PM COP Track and I hope to shake the hand of everyone who has contributed to this success. A real team effort born out of a combined desire to:

- share knowledge
- provide good practices to improve project outcomes
- demonstrate the value of project management

Sneak Peak into the PM GPG

Stage Gate Approach

A stage gate approach is a project management good practice. Figure 1 shows an example of a project life cycle which has been divided into discrete stages.

Each stage is a bounded set of activities which deliver data to a stage gate decision. The stage gate decisions are go/no go points: A project has to pass through each stage gate to proceed to the next stage.

For this approach to be effective, each stage gate should have:

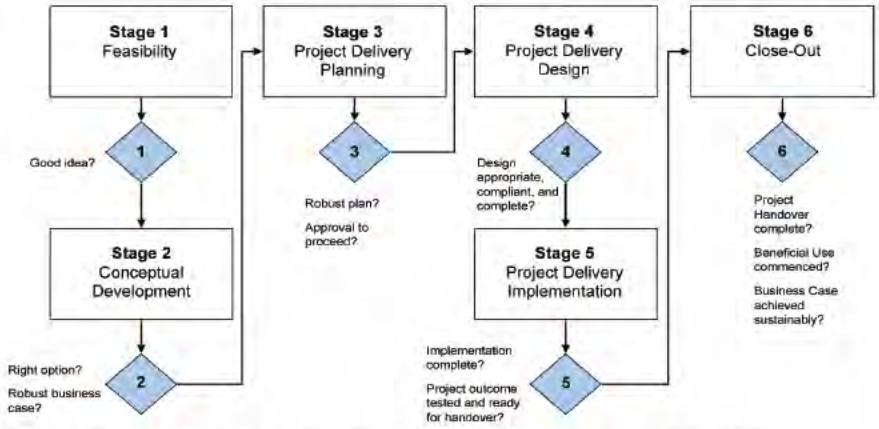

Figure 1. A Typical Project Stage Gate Approach (Figure 1.6 from the PM GPG).

- Inputs: what needs to have been achieved before a decision can be made.
- Acceptance Criteria: the level at which the achievements are deemed to have been sufficient.
- Value: a reason why the hold point is required; why it adds value to an organization.

A project stage-gate approach can be used to develop clarity of scope and approach for a project team and key stakeholder groups. It can be used to develop an early view of the overall project time-line based on the key data needed at each stage gate and the decisions that the data can support.

This approach has been used throughout this Guide and Figure 2 expands upon Figure 1 making links to the contents of the Guide and the stage gate decisions within each part of the project life cycle.

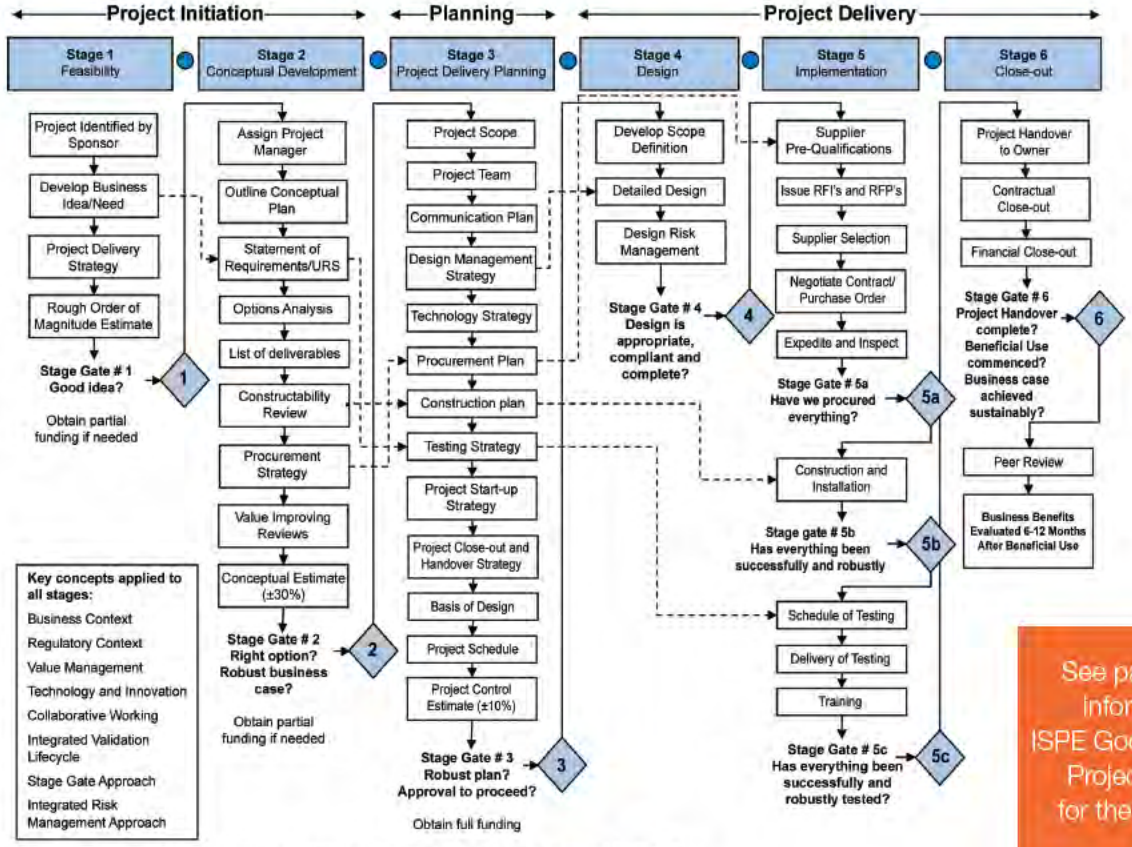

Figure 2. Project Management Flowchart (Figure 1.7 from the PM GPG).

See page 39 for more information on the ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry.

Fast-Track Life Sciences Projects: When to Use Design-Assist and Why It Works

by Raj Vora, P.E.

This article presents strategies to engage in life science projects from a schedule, quality, and budget standpoint – all with "speed to market" in mind.

End-user organizations are constantly searching for the "best" ways to engage in life science projects from a quality, schedule, and budget standpoint, while keeping "speed to market" in mind. In this article, the benefits of design-assist project delivery versus design-bid-build delivery will be examined. The article will demonstrate how design-assist project delivery contributed to the success of a fast-track life science project. Examples of project execution tools utilized to overcome specific challenges will be provided and the article will conclude with an itemized list of the "rules of engagement" for successful design-assist life science projects.

The selection of a proper construction delivery method for capital construction projects can ensure successful execution, while simultaneously meeting overall business goals. While choosing the right approach needs to be evaluated on a case-by-case basis, selecting the right delivery method should be based on a number of factors, including budget, schedule, cash flow, project complexity, risk, project goals, and most importantly, project team composition. Due to the weak economic climate, companies that had large in-house engineering and project management staffs have reduced resources and are opting to outsource these critical project roles. This is a key consideration in selecting the right project delivery method.

Project Delivery Methods

The most commonly used project delivery method is Design-Bid-Build (DBB). In DBB, the owner functions as the overall project manager and hires external engineers, consultants, and contractors to deliver the project. The owner typically starts by retaining an architect to program and develop a scope of work. The architect then hires a consulting engineering firm, who is the engineer of record, to develop the project plans and specifications. Once the detailed design effort has been completed, mechanical and plumbing contractors are invited to submit pricing to meet the owner's competitive bid requirements. Although this seems like the most cost-efficient method for securing a specific scope of work, design-bid-build has several pitfalls as follows:

1. **Quality:** the goal of the competitive bid process is to get the lowest upfront cost for the owner's scope of work and the general contractor may invite several mechanical contractors to bid on the project. As a result, the quality of the project could suffer if the owner/general contractor selects the mechanical contractor only on the basis of low price.

2. **Design Safety Factors:** in design-bid-build projects, the design usually includes safety factors, some as high as 20% excess capacity to ensure that the engineering design is adequate for the project scope. In traditional design-bid-build projects, designers don't want the liability of a design that may not work so they often overcompensate by incorporating excess capacity into the scope of the project. These safety factors lead to over-

sized building systems and equipment and unnecessary cost to the project. In fact, oversized building systems can lead to underperforming buildings through lack of efficiency and high energy consumption. In a design-assist, the approach is collaborative from the start with all parties working toward the same goals, allowing them to design based on actual project scope, and avoid costly changes down the road.

3. **Change Orders:** in design-bid-build, the contractor, based on the construction plans and specifications, assumes all construction and performance risks. Any scope variations from the bid documents result in change orders and schedule delays. The mechanical contractor does not influence the project design and opportunities for alternative approaches at bid time are minimal. Design-bid-build procurement by its nature is set up to create an atmosphere of silo entities with little contractual reason to collaborate to solve design gaps or resolve cost issues.

4. **Schedule Impacts:** in addition to the scope impacts mentioned above, the submittal review process can impact the project schedule. The mechanical contractor is required to submit shop drawings for each component of work per plans and specifications for formal review and approval by the architect, engineer, and owner. This process takes time and has to be repeated should there be scope changes or additions. All of this can negatively impact the owner's project schedule, leading to additional cost throughout the duration of the project.

5. **Project Harmony:** the nature of design-bid-build projects can lead to adversarial relationships among the owner, architect, designers, and contractors, especially if the owner's intent is not fully captured in the bid documents. Owners run the risk of expending significant project funds and time for detailed design only to find out the final project does not meet the project budget and schedule parameters.

Conversely, a highly successful delivery method is design-assist, which is becoming more commonly used. A design-assist project allows the owner to maintain control over his project, but key contractors are selected early in the project's lifecycle to achieve schedule and budget goals. Design and construction are integrated in the design-assist method, rather than compartmentalized, as is the case in design-bid-build. The owner still procures the general contractor, architect, and engineer of record, but instead of completing the design documents before soliciting pricing and procuring contractors, the mechanical contractor is brought on board early, usually as part of schematic design, to help finish the design process while simultaneously providing real-time pricing feedback.

There are many advantages to utilizing the design-assist project delivery method in lieu of design-bid-build:

1. Reduction of system cost through:
    a. Correct system application
    b. Use of innovation
    c. Right-sizing of systems
    d. Intelligent procurement
    e. Early coordination with other trades
    f. Enhancement of field productivity
    g. Near elimination of change orders
2. Early firm cost with updates at design revisions
3. Single source accountability for mechanical and plumbing system cost and performance
4. Quality installed system and equipment
5. Time/schedule savings through:
    a. Doing things right the first time
    b. Integrated design and coordination
6. Reduced administrative burden through reduced change order processing
7. Improved risk management

The goal of the design-assist method is to totally integrate the design and build processes in order to design, build, and commission high-quality systems within budget and on or ahead of schedule through designing things once. This collaborative approach reduces design costs and time, in addition to encouraging the design of systems that fully meet the owner's requirements. Design-assist also produces constructible documents that allow design errors to be detected and corrected early in the process, maximizing productivity in the field and saving time. Design-assist enables projects to ramp up to a completion date faster than traditional design-bid-build.

Case Study – Private Lab Facility

A national design-build and design-assist mechanical contractor teamed with a general contractor on a private lab facility project located in Maryland. The building is specially designed for breeding rodents for research purposes. The 54,000-square-foot facility is primarily used for animal holding, but it also includes administrative space, mechanical equipment spaces, lab support areas, and future tenant fit-out space. Specialized HVAC, plumbing, and process systems include 100% outside air handling units, lab exhaust, industrial and animal watering systems, compressed air, vacuum discharge, humidification steam, and services to several cage washers and autoclaves.

This project commenced in early 2007 based on a traditional design-bid-build project delivery. However, problems quickly arose. The owner had budget concerns, the facility design was incomplete and tenant leases had already been signed for May 2008. This created the need for an extremely aggressive project schedule of eight months. With critical time constraints facing the project, the mechanical contractor was brought on board in August 2007 in a design-assist contract delivery.

The project team held weekly meetings to complete the design while developing early cost guarantees. Due to the compressed schedule, construction had to begin while the design was still being finalized. The mechanical and plumbing design was completed in phases to best support the fast-track schedule. As the aboveground services were being finalized, design and installation of underground plumbing got underway. The team was able to keep the mechanical and plumbing equipment off of the critical path by procuring the equipment during the detailed design phase. Simultaneously, the entire project team held regular coordination meetings to ensure a smooth installation of services in the field. Frequent meetings and daily communication led up to the bulk of the mechanical and plumbing rough-in occurring in just four months, between February 2008 and May 2008. This equated to 11,000 hours of sheet metal labor, 15,000 hours of piping labor, and 11,000 hours of plumbing labor performed within this time frame.

How did the team achieve their goal of delivering the project within eight months? As outlined below, it was the combination of design-assist, frequent communication, and project execution tools that made it possible:

a. **Project Delivery Plan:** this is a document developed to detail the "plan-of-attack" for executing specific scopes of work for the project. This document contains all of the relevant project information; key personnel, safety contacts, etc., in addition to the project's milestone schedule dates, prefabrication opportunities, and tasks lists. This document compartmentalizes and plans the execution of the project into deliverable portions of work - *Figure 1.*

EXAMPLE PROJECT DELIVERY PLAN
UNDERGROUND PLUMBING

PROJECT NAME	Project Anywhere
SHORT PLAN SCOPE	Underground plumbing – all systems
PROJECT NUMBER	7118273
LOCATION/ADDRESS	Anywhere, USA
GENERAL CONTRACTOR	General Contractor, Inc.
MAILING ADDRESS	
BILLING ADDRESS	

PROJECT DIRECTORY (MAIN POINTS OF CONTACT FOR SHORT CP)

NAME	COMPANY	ROLE	TELEPHONE	E-MAIL
John Doe	GC, Inc.	Project Manager	703-555-1212	
Cara Doe	Mechanical Contractor	Project Manager	703-555-2433	

SAFETY/EMERGENCY INFORMATION

CONTACT	COMPANY	ROLE	TELEPHONE
Joe Safety	Mechanical Contractor	Division Safety Manager	703-555-7748

ACTIVITY HAZARD ANALYSIS (AHA)

SI AHA	GC JHA	DESCRIPTION OF ACTIVITIES ASSOCIATED WITH THIS SHORT PLAN
X		Excavation
X		Inhalation

DIRECTIONS TO NEAREST MEDICAL EMERGENCY TREATMENT FACILITY

FACILITY NAME & ADDRESS	
DIRECTIONS FROM PROJECT	1.
LINK TO INTERNET MAP SITE	

LOCATION OF JOB-SPECIFIC SAFETY PLAN

GC, Inc. – Trailer

SOUTHLAND SCOPE OF WORK (SHORT PLAN)

SHEET METAL	None
PIPE FITTING	None
PLUMBING	Underground sanitary, storm, water and industrial waste piping

OPTIMUM SEQUENCE OF INSTALLATION (SHORT PLAN)

SHEET METAL	1. N/A
PIPE FITTING	1. N/A
PLUMBING	1. Start at mains exit point on building working towards east wall. Complete A side first before moving down to B side.

OPEN ITEMS OR TASKS TO COMPLETE TO MAKE STATED PLAN

WHO?	DESCRIPTION OF ITEM, TASK OR PREDECESSOR ACTIVITY	DATE CHECKED
Detailing	Drawings for Area A to be completed by Friday	09/04/07

CREW SIZE & MANPOWER

TRADE	CREW SIZE	# OF CREWS	START	COMPLETE	WEEKS	FOREMAN
Plumbing	2	2	09/10/07	10/11/07	5	Mike Plumber

SCHEDULE & CPM ACTIVITIES

COMPANY	MAJOR CONTRACTUAL MILESTONES FOR THIS SCOPE	FINISH DATE
SI	Complete UG before concrete pours	10/11/07

PRE-FABRICATION PLAN

SHEET METAL	N/A
PIPE FITTING	N/A
PLUMBING	N/A

PROCUREMENT

EQUIPMENT/MATERIAL TYPE	TAG NO.	QTY	SUBMITTAL STATUS	REQ'D ON-SITE
Chem Drain Pipe Material	IW	1976	Approved	09/11/07

OUSTANDING DESIGN OR COORDINATION ISSUES

SHEET METAL	N/A
PIPE FITTING	N/A
PLUMBING	Coordination drawing from detailing (SIDE A COMPLETED)

POTENTIAL ROAD BLOCKS (RISKS) THAT SHOULD BE WATCHED

SHEET METAL	N/A
PIPE FITTING	N/A
PLUMBING	1. Power – We may need to rent a generator if no power present. (COMPLETED)

OPPORTUNITIES

VALUE ($)	TRADE	DESCRIPTION

COST CODES REQUIRED FOR THIS SCOPE

TRADE	SCOPE	HOURS
Plumbing	Detailing	299
Plumbing	Supervision	239
Plumbing	Material Handling	131
Plumbing	Underground – PVC (Including Drains)	373
	Underground – Chem Drain (Inc Drains)	1054
Plumbing	Material (UG Portion Only)	N/A
Subcontracts	Excavation – T&M Subcontractor Only	N/A

APPLICABLE DRAWINGS & SPECIFICATIONS

TRADE	SPEC SECTIONS	DRAWINGS
Plumbing	Standard Submittals	P-101 and P-102

CONTRACT OR SPECIFICATION ITEMS OF INTEREST

CONTRACT/SPEC CLAUSE	APPROVED INTERPRETATION

Figure 1. Project Delivery Plan: document used to plan and organize execution of projects by compartmentalized specific scopes of work into deliverable portions of work.

Figure 2. Prefabricated Racking of Services: prefabricated racks in the service corridor that includes all major utilities and services.

b. **Equipment Delivery Log:** this is a spreadsheet that captures all of the equipment on the job, associated lead-times and delivery dates. By understanding when equipment is needed on site, the project team can drive design decisions to achieve associated construction milestones.

c. **Trend Log:** in a design-assist delivery, owner generated scope changes will occur as the design progresses. The trend log is a tool used to capture owner design decisions that increase scope or cost in addition to capturing contractor ideas that help maintain a net zero impact of those changes. The project team uses the trend log to make educated decisions with an understanding of project schedule and budget impacts. It is a great communication tool that is used by the owner to realize the value in the design-assist process and to ensure involvement of the project team in maintaining project budgets. The log includes a description and the quantity of an item, its location, critical dates – planned/actual including lead times, plus the vendor name, contact person, and phone.

d. **Prefabricated Racking of Services:** the project contained an extremely congested service corridor running down the center of the facility. All major utilities and services were located in this corridor and hung from several different locations along the route. The team utilized coordination and modeling capabilities in conjunction with weekly coordination meetings with the project team to design the building to allow prefabricated racks for all the utilities, rather than individual piping distribution for each utility service. The coordinated racks were built off-site and delivered to the site in 20-foot sections for field installation, which helped meet the aggressive schedule - *Figure 2*.

Conclusion

The selection of the right project delivery method and the right configuration of roles, responsibilities, and relationships are more crucial than ever. The ability to define and develop project requirements and scope early, in order to deliver a successful project, is the key challenge that will continue to face project teams today. Choosing a collaborative delivery-method will ensure a good project experience by all.

These "Rules of Engagement" should serve as a guideline for determining when design-assist should be considered.

Design-Assist "Rules of Engagement"

1. Schedule: the project has an accelerated timeline that cannot be achieved by using the traditional design-bid-build method.

2. Budget: the project's budget is in jeopardy or the owner wants cost certainty and needs early cost validation.

3. Risk: minimize owner's and mechanical contractor's risk through early involvement in the design process.

4. Owner's Team: the owner wants to utilize their architect and engineer from past projects.

5. Project Complexity: a more complex greenfield or renovation project requires early mechanical contractor involvement and more team collaboration to meet the overall project goals.

Outcome: the owner's quality requirements are met more efficiently through the design-assist project delivery process because design-assist is more collaborative – the budget is shared up front and either through an open-book or lump sum process, the contractors and project team are working together toward a common budget goal as opposed to the negative competitive aspects of design-bid-build.

About the Author

Raj Vora has more than 15 years of industry experience ranging from campus-wide master planning and manufacturing expansions to renovation and retrofits of facilities during operations. At Southland Industries, Vora is responsible for the strategic growth of the enterprise through new project and customer development by guiding the company on the type and size of projects to pursue. He can be contacted by telephone: +1-703-834-5570 or email: rvora@southlandind.com.

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"Paper on Glass" User Centric Batch Operations – A Productivity Game Changer for Paper Driven Pharmaceutical Production

by Robert Harrison

This article presents how technology has advanced electronic batch record into solutions which compete one-to-one with paper flexibility, opening the door to game changing production efficiencies in pharmaceutical production.

People deal with complexity and abnormality very well. The flexibility an operator gives to the nature of production in the lifescience industries is an extremely valuable resource. However, production complexities and quality demands continue to increase, using paper to drive the operator and record events may have outlived its welcome. We all feel comfortable with paper; it is something we can touch, see, and feel progress as it grows during the batch. Because you can touch it, it makes you feel like you have full visibility on the process and people's activities, paper's history in pharmaceutical production is a little like religion and its scriptures, they are deemed paramount and carry with them emotion which is never questioned.

Challenges of Managing Paper Based Production Operations

Paper and its long term storage has a large effect on pharmaceutical production cost. Pharmaceutical production requires that significant post batch analysis and reporting must be carried out. Manually extracting and analysing paper production data is an intense and demanding activity which involves highly educated and experienced people. The major cause of rejects and reworks in paper-based batches are the result of 1. missing entries and 2. errors in paper documentation. The batch ran physically perfect, only the recording of this perfect execution failed, and proving its innocence costs serious revenue. Each batch can involve about 1000 manual entries with a human failure rate of 1×10^{-2} (i.e., one in on hundred)[1] – the probability of significant failure is too high. Each of these manual paper records require Standard Operating Procedures (SOPs) from each process, which amounts to a long paper audit trail and needs to be stored in a secure location. The risks to keeping such an inefficient system are great, the cost of quality is high, which is reflected in the cost of production.

We can identify many areas where human error can enter into the system: a person generates and issues the paper documentation, the operator reads the SOP, then reads the equipment, and writes the result on the batch record. The records are then read by another person and inputted into a computer for analysis and reporting as seen in Figure 1. With each human activity, the risk of failure is increased.

When investigations are carried out, the whole paper documentation needs to be obtained and analysed once again. What happens with missing entries? What happens with entries entered incorrectly? What happens with lost paper or paper delivered to the wrong person, or the wrong SOP is issued for a particular batch?

"*Benchmarks for Pharma vs. Other Industries,*"[2] the

1.	The operator: • Read the SOP → Execute the command(s) on the equipment • Requested to read process values → Read the equipment process values • Record the information in the correct location on the batch record sheet • Sign the record A potential violation is noticed → the violation is flagged, the operator contacts the quality responsible. ! Or the operator makes a judgement call that the violation is only minor → and continues.
2.	Post batch • All batch records are manually transferred to a computer system • Individual machine data is time-lined as a process • The process data is analysed • A batch report is generated
3.	The whole paper documentation, analysis, batch reports and supporting documents are secured in a large air conditioned and protected storage unit. The documentation remains in storage, in some cases for many years.

Figure 1. A basic workflow for a paper based execution of production.

"first pass yield – zero defects" indicates right first time with a value of 60%, this hints that pharmaceutical production has significant benefits to gain from the addition of technology. Right first time in paper driven production environments is far less estimated to be at 47% with the major causes of rejects or reworks being 1. errors in paper documentation 38% and 2. missing entries 29%.

Manual paper-based processes record and store production data in a disconnected and difficult to access medium. Decisions need to be made on these manual processes and with paper systems, there is a significant time delay to get the data into a usable format. This is an area where EBR aims to improve.

Current EBR limitations

Electronic Batch Record (EBR) systems are designed to gather accurate and complete information critical to compliance. With paper-driven processes, the operator and his or her memory is crucial to completing the batch information. EBR avoids mistakes common in manual transfer and integrates manual operations with automated processes.

The problem with EBR is the static workstation and its focus to the mechanical process. It relies on the operator to prove the flexible interface between what is required by quality and operations management; in some instances, this can be a large cognitive activity that the production operator needs to carry out. Paper on glass aims to be user centric and portable with the right tools available to understand how the person is linked to the process, and produce batches with little variation.

How EBR Evolves to Paper on Glass

Paper on glass is not a revolution in technology, rather a progression together of known technologies that easily interface in a high usability application to embrace the user centric environment it operates in. The key functionalities for paper on glass are:

- Mobile tablet usage is paramount for the application. Paper is portable and the application that replaces it also must be portable. With a client – server infrastructure to safeguard process information and keep a central control. The tablet can get lost or broken and the data remains secure.

Measure	Pharma	Automotive	Aerospace	Computer	Consumer Packaged Goods
Overall equipment effectiveness	10% to 60%	70% to 85%	50% to 70%	80% ti 90%	70% to 90%
Annual productivity improvement	1% to 3%	5% to 15%	5% to 10%	1% to 3%	5% to 15%
First-pass yield – zero defects	60%	90% to 99%	70% to 90%	90% to 99%	90% to 99%
Production lead times in days	120 to 180	1 to 7	7 to 120	5 to 10	3 to 7
Finished goods inventory in days	60 to 90	3 to 30	3 to 30	5 to 580	10 to 40
Labor value-add time	20%	60% to 70%	60% to 70%	60% to 70%	60% to 70%
Direct/indirect labor ratio	1:1	10:1	10:1	10:1	10:1
Pharma is decades away from achieving the performance, on key OpEx benchmarks, reached by other industries. But, experts say, pharma is still three to five times more profitable than they are. Chart source: McKinsey & Co., quoted in The Gold Sheet, December, 2009.					

Table A. Benchmarks for pharma vs. other industries.

- A batch control system which is compliant to the industry batch standard ISA 88, this gives flexibility to drive the process and usability to interact with the operator.
- Usability is of great importance as mobile tablets don't have large screens, and a batch system contains much information. Intuitive presentation of data is needed, multi-touch is an essential element linking the user to a known interface common to tablets and smart phones.
- Historian to archive batch operation data, weight dosing and media information, equipment usage, and operator events. The historian is central to batch compliance, automated archiving of recorded data provides data integrity.
- Complete batch documentation must be reported with automated analysis and clear information identifying weighing information, equipment usage, operator events, alarms, Critical Quality Attributes (CQAs) violation and electronic logbook.

To be able to stand on your own feet is a test of character, and the system outlined here supports this. However interaction with outside and connected systems is an equally important function. John Steinbeck, in his novel "East of Eden"[3] quotes *"Maybe a specialist is only a coward, afraid to look out of his cage. And think what any specialist misses—the whole world over his fence."* In pharmaceutical production, there are many sources of information that build up a batch record and additional information needs to be included. Standard industrial interfaces exist with for example SQL connectivity, MES and ERP have native mechanisms to embrace the whole supply and manufacture chain. This automates the batch record to accommodate specific batch needs.

Making the Move, What Are the Advantages and Challenges to "Paper On Glass?"

To replace paper with software requires an application with diverse behaviour. Mobile technology allows for intelligent and portable applications to be with the operator, high usability swaps their clipboard to a mobile workstation. EBR forces strict execution of the batch recipe, stage by stage requesting the operator to execute tasks and record information. The operator is not allowed to miss entries, each user input can be automatically verified to ensure correct entry of data, and violations are signalled in real-time through the correct channels. More importantly, potential violations can be alerted, key people then intervene to mitigate the situation. Batch analysis and reports need not be manual activities, these can be instant and automatic.

Any activity affecting how direct production is executed falls directly under quality management's scrutiny. The system proposed here makes no changes to the physical equipment and no changes to the current automation of the process. It does aim to replace the paper driven operator instructions, and replace the operator batch record, then digitally store the complete record. The process hasn't changed, only closer control of manual operations has been achieved with live verification of inputted information.

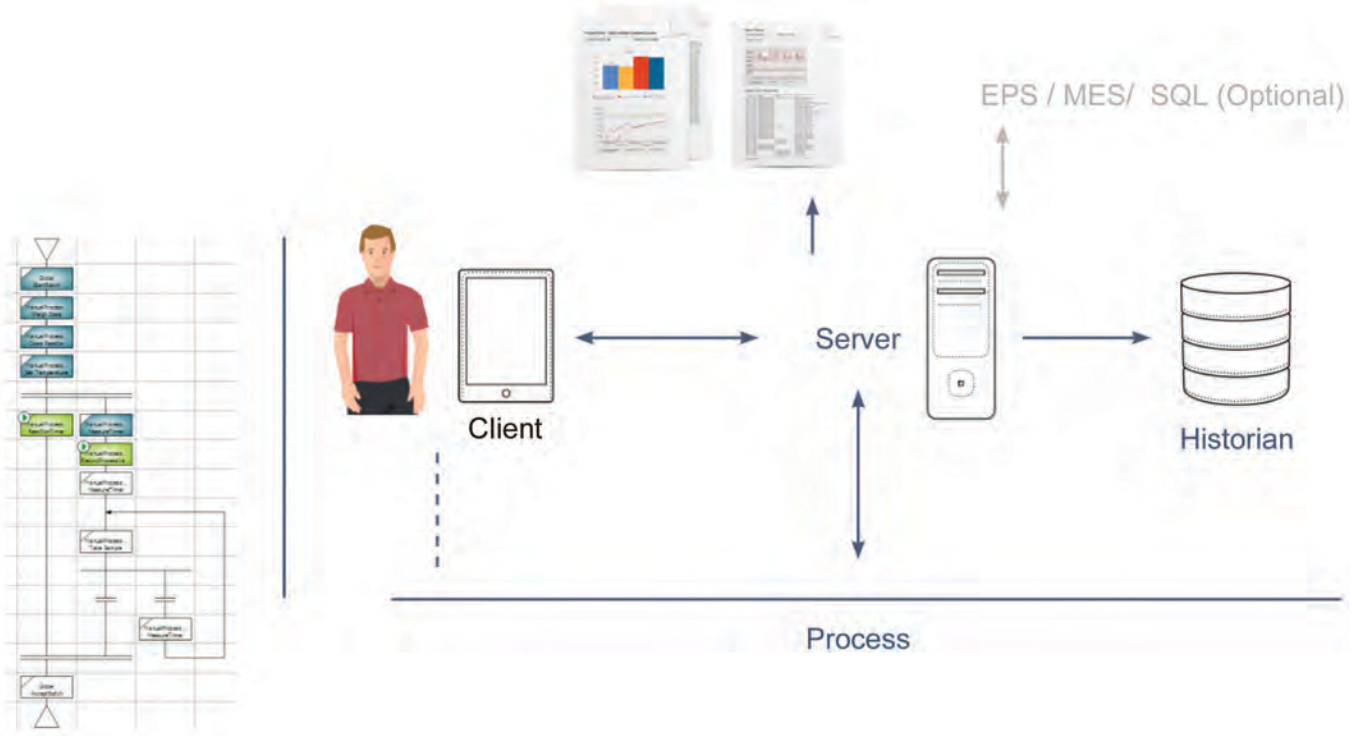

Figure 2. A simplified system overview demonstrates the linkage of the functionalities.

- Multiple batches operating concurrently
- Flexible visual recipe management
- Agile to different equipment, hardware and products
- Check, recheck, and query the operator
- Alert on violations and warnings, e.g. via SMS, email, or telephone
- Archive CQA's
- Automate analysis, Review By Exception (RBE), alarms
- Automated reporting
- Digital storage and retrieval

Figure 3. Paper on glass is more than EBR, it provides logic and intelligence to the operator.

As there are no changes to production processes, the current paper method can be executed concurrently with the digital "paper on glass" system; this would allow for several stages of production quality acceptance to be examined and tested without risk or stoppage to production.

Another challenge is that perhaps the current automation solutions in place today are not flexible enough to bring the required functions together in one portable system: Mobile tablet application, batch process understanding and operation, secure archiving of data, analysis, sophisticated reporting, real-time communication, FDA 21 CFR Part 11 compliance. Fortunately automation technology is an industry which never sleeps, these crucial individual mechanisms do exist in the market place, and can be configured to create an all-in-one mobile electronic batch record system.

Accuracy and Consistency

People are open to a wide array of influences: stress, lack of attention, attitude, sleep (the lack of it), or just having a bad day. Automated batch-driven processes repeat the same strict sequence each time and every time. Software can interrogate each user input within limits, determining at the point of entry if a human error has occurred, and with time-stamped accuracy. Electronic logbooks manage the abnormality with automated alerts and workflows enforcing the correct execution on violations.

Strict point-of-entry requirements and clarity of data is paramount to complete batch documentation and right first time. Missed entries and incorrect entries are minimized for consistent production and release.

Productivity

People and their motivation go a long way to achieve production success. Providing a familiar human interface with access to correct and complete information are the tools to work faster, smart companies create the perfect environment for increased productivity.

Production cycles can be reduced. Typical batch release cycle times of around 10 to 40 days can double in non-conformance situations. EBR forces consistent execution of the manufacturing sequence on a platform which provides

accurate real-time view of process and deviation data. Time associated with detecting, tracing, and documenting deviations in the manufacturing process is much reduced. Analysis and reporting is automated, which accelerates batch release and reduces the head count of persons involved in this critical exercise.

Reduce Cost of Quality, Full Quality Compliance

Paper on glass ensures the batch documentation is correct and comprehensive. Compliance requires repeatability of batches, capturing information accurately, organizing and retaining the information, then efficiently analysing and presenting it. Do it right first time prevents errors through pro-active checks. Such mechanisms improve the demonstration of compliance to meet Good Manufacturing Practice (GMP) regulations.

Master recipe development and control recipe creation is on a graphical system with version control and recipe state control to managing GMP compliant processes. Automated batch reports easily separate production data, e.g., material weighing and dispensing data, equipment usage, CQAs and process values, user instructions and actions, electronic signatures, alarms and violations, audit trail and electronic logbook. Production is monitored as a process and not individual machines, allowing focused reports with specific analysis.

Critical Quality Attribute (CQA) deviations can be handled through automated workflows, and don't need to rely on the operator to flag violations. With automated alerts, the equipment can signal warnings via remote system such as SMS, email, or telephone. Post batch analysis can be made on non-conformities through Report by Exception (RBE) reports generated automatically from production data. Access to all information decreases the effort required to investigate product deviations.

Having data stored electronically has several advantages: information is readily available, it requires so little storage area in comparison to paper, digital data can be stored on redundant systems, and the information is widely available for example the progress status of each batch is visible across the company.

Cost Avoidance

Costs are mitigated on many fronts with 'paper on glass'. 1. Rejects and reworks are much reduced due to correct data entry and consistent production sequence. 2. Head count is reduced, as the batch information doesn't need to be re-entered into a computer system; therefore, data alignment of individual machines in to a process is automatic. 3. Paper doesn't need to be generated with automated master and control recipes. 4. Large volumes of paper don't need to be stored in a secure and controlled environment, the storage can be digital and redundant.

Improve Right First Time

Improvement in RFT comes from strict operator workflow and point of entry verification, which creates more consistent and repeatable batches with shorter release time. Paperless recipe systems reduce manufacturing errors, provide investigations with easy access to all required data, and instant batch analysis.

Conclusion

"Paper on glass" transforms a paper-based production system into something quite remarkable – without change to any production equipment or process. Automating the operator and production reporting means post batch analysis is reduced to an absolute minimum by removing the manual heavy element of batch analysis. Products are released to the market potentially faster than paper production methods. Quality is optimized and risk is mitigated as production flow is consistent between batches, execution is strict and no information is missing from the record. With errors in recording information as far as humanly possible eliminated, reworks and rejects are significantly reduced. The benefits of a complete batch control system, integrated on mobile tablets, avoids cost and is a game changer for pharmaceutical production efficiency. No paper needs to be generated with no mountains of paper to be stored in secure locations – instant batch analysis means instant revenue. Production activities are aligned in real-time to the gravity of business.

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About the Author

Robert Harrison leads the pharmaceutical industry division at COPA-DATA, Salzburg, Austria. With more than 20 years of international experience, Harrison has served in varying management and engineering roles across industry and research, gaining his BSc in electronic engineering while working at CERN, Geneva, Switzerland. He is currently responsible to drive strategy, technology development, global growth and worldwide performance of zenon technology in the life science industries. He may be contacted by telephone: +43 662 43 100 20 or email: RobertH@copadata.com.

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