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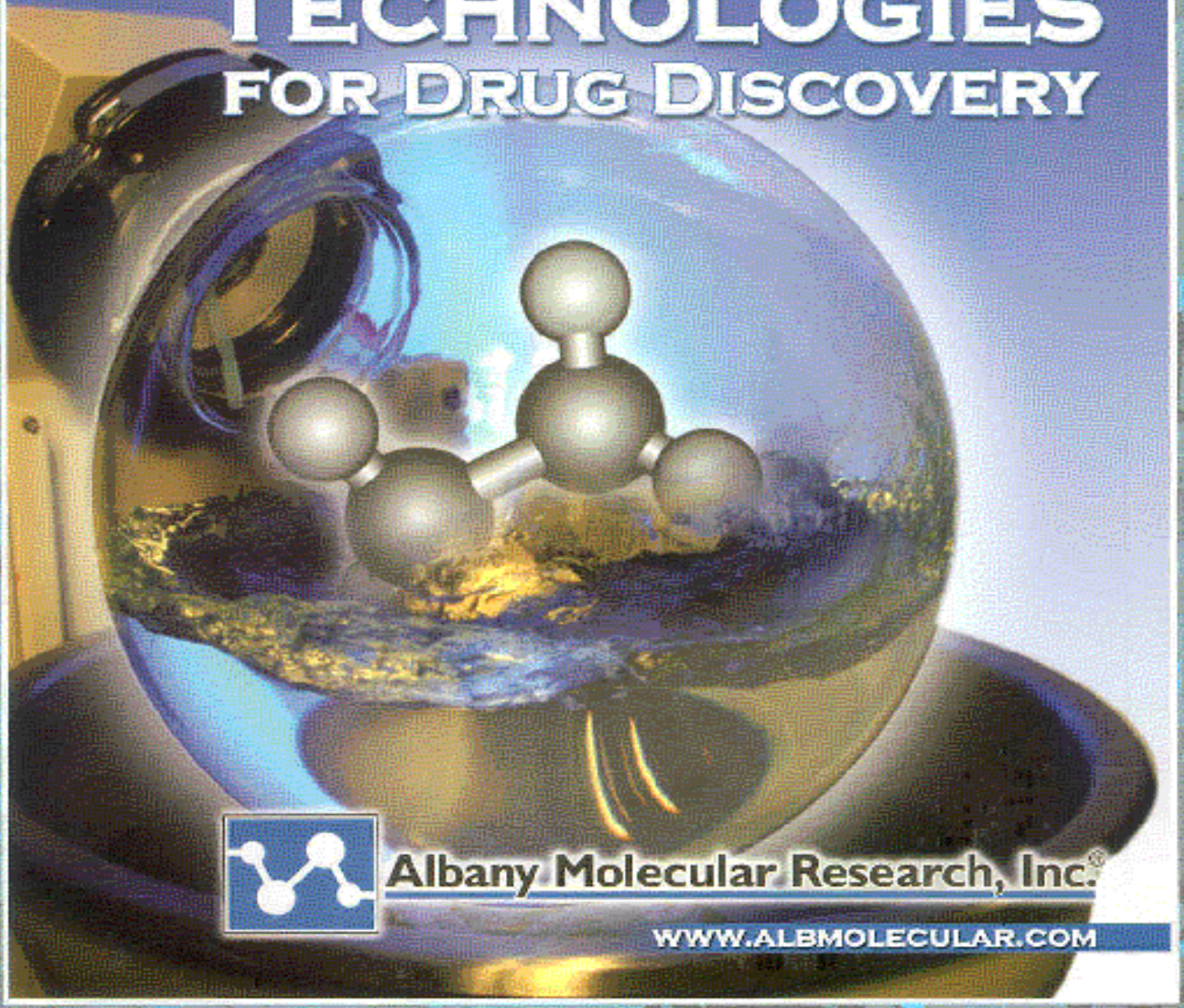

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EFFECTIVE PROJECT MANAGEMENT…the key lean components in a regulated environment by Larissa Potapchuk and Patrick Lucansky

INTRODUCTION

As organizations identify opportunities for growth and improvement, successfully managing activities to realize these opportunities is critical for achieving results and benefits. Effective project management starts with the application of key principles and tools fin order to increase the likelihood of success of the initiative, regardless of whether the intended improvements are focused on strategy, products, processes, or technology.

Most growth and improvement initiatives are, by definition, outside of the usual tasks comprising the organization's daily business functions and processes; hence, the implementation of these opportunities is structured as a project, where unique activities are defined, developed, and executed to meet objectives and realize benefits. Realizing benefits from achieving the intended objectives is the ultimate measure of a project's effectiveness.

Effective project management is supported by proven guidelines and principles. These can be applied to any type of project, such as those focused on implementing lean management practices, to those focused on launching new products, developing new drugs, and even those focused on software development and system's implementation. These and other types of projects, while differing in their objectives, resources, and required activities, all have components common to the definition of 'project' and will benefit from the same effective project management principles. Effective project management becomes more challenging as project complexity increases due to any number of factors such as project design, scope, and reach. The principles of Lean present a further challenge due to its cross-functional involvement and scope. ***[Lean projects are specifically addressed and noted in Italics.]***

OVERVIEW OF A 'PROJECT'

A project is defined as a set of specific activities intended to produce predetermined results and is identified by:
- a specific start and end point with clear objectives,
- resources dedicated to meeting objectives and achieving specific results.

PROJECT…… designed for the purpose of accomplishing a specific goal

A set of activities that:
- **support a defined objective**
- **are performed by people appointed to be responsible for meeting that objective**

Projects are identified by:
- **a specific scope**
- **a well defined start and completion point**
- **unique objectives**

A project is also defined by the existence of limited resources to be managed throughout the duration of the project. Schedules, resources, and controls cannot be applied without time constraints to manage against; project resources are identified as time, money, people, and equipment that need to be applied as effectively as possible. Timeframes are critical for responsible resource management and deadlines should be viewed as key opportunities to highlight activity completion, identify achieved results and recognize successes. Project reviews can provide 'lessons learned' for enhancing management effectiveness for future projects.

As projects differ from each other, there will be variations in the resources, tools and methods needed to accomplish project activities. However, there are common elements critical to success of any project like, focus, discipline and communication. The model for successful project management requires a disciplined approach to methodically plan tasks, monitor and manage activities and resources, communicate, and track results.

Due to the breadth of change required in a lean initiative, a clear understanding of Lean concepts, involvement, support, and commitment are required by all those either directly or indirectly affected by the initiative.

PROJECTS FOCUSED ON IMPLEMENTING LEAN PRINCIPLES ENCOMPASS…

- organization strategy	***- leadership***	***- processes***
- collaboration	***- reporting***	***- communications***
- customers / suppliers	***- systems***	***- teamwork***

PROJECT SUCCESS COMMON ELEMENTS

The Project lifecycle encompasses critical elements necessary to support the success of the project; guidelines exist at each phase in a project and ensuring these are fully addressed is key for building a foundation for success in the next phase of the cycle. Methods and tools exist to enhance the effectiveness of each project phase and can be customized by project type.

An overall set of guidelines should be included in a fully developed and comprehensive Project Plan. These guidelines are the governance tool for effective project management. A comprehensive project plan is comprised of high level activities or tasks. Project activities consume most of the time and resources spent on a project. These activities, as documented in the Project Plan, should ensure that deliverables are met and milestones are attained.

KEY COMPONENTS FOR EFFECTIVE COMPLETION OF A PROJECT

1. **Definition of the project**
2. **Involvement of the right resources**
3. **Development of detailed activities / tasks required to achieve project results**
4. **Estimation of time and cost**
5. **Development of change procedures and criteria for acceptance**
6. **Development of communication strategy and a 'dashboard' for tracking project status.**

PHASE I PROJECT INITIATION AND DEVELOPMENT

The key elements for success in any project start in the Initiation and Development phase where agreement and understanding for the project is obtained as a result of the project definition and project scope.
For projects to be successful, they should contain the following:

- identification of the opportunity,
- definition of needs,
- documentation of scope,
- involvement of management and identification of a sponsor(s),
- Identification of expected results and benefits.

Projects are identified by the need to achieve a specific result or accomplishment; prior to the start or 'kick-off' of a project, discussions to identify and verify the opportunity must occur. From the outcome of these discussions and reviews, the project is further defined and intended results are drafted. A Project Charter is developed in order to document the opportunity and outline the intended high-level project results. This information is used to define the Project Scope.

Project Scope

A concise and accurate description of the end products or deliverables to be expected from the project and that meet specified requirements as agreed between key people in the organization. Scope defines the processes and functions where the project activities occur, extent of action, and boundaries of work. The scope describes the project's deliverables, outlining the activities performed, the resources consumed and the resulting end products.

Once the Project Scope is developed, the Project Sponsor is identified; the Sponsor represents the interests of the ‘sponsoring organization’, or ‘funder’. The Sponsor is the owner of the project’s business case, its primary ‘risk taker’,

and can be the 'customer' for the project; this Sponsor acts as management's representative on behalf of the company. The Sponsor (or the Sponsoring Team) provides the funds to complete the project and is responsible for ensuring that the strategic direction of the organization is considered and integrated into the project. The project manager and project team (appointed by the Sponsor) share the responsibility for integrating the organization strategy into the project goals and objectives.

Project Sponsor

The individual or body for whom the project is undertaken, providing the funding for the project and to whom the project manager reports. The person concerned with defining the project objectives in the context of the sponsoring organization.

Project Stakeholders

People or organizations who have a vested interest in the scope, performance, and/or outcome of the project.

The development of the Project Scope also facilitates the identification of Project Stakeholders. These Stakeholders are individuals or groups that are involved in or may be affected by project activities and have a 'stake' in the successful completion of the project. Since Stakeholders are not directly accountable for the project success, they may be a barrier or obstacle in achieving project objectives.

Project Manager

The person designated by the Sponsor or management to lead the Project Team and be responsible for ensuring the project objectives are met, managing project resources and leading the Project Team.

Project Team

The group of people organized for the purpose of executing a project or set of project activities. The Project Team comprises the central management group of the project that shares responsibility for the accomplishment of project goals and carrying our project activities.

Members of the Project Team may be fully dedicated to the project or involved in executing the project plan as necessary, hence becoming 'ad hoc' team members.

Since many 'Lean' projects involve multiple functions in an organization, it is important to ensure that the Project Sponsor is dedicated to the concepts of Lean and can be considered a 'Lean Leader' for the rest of the organization. The Sponsor is the high level contact point for the Stakeholders and needs to have assurance from the Project Manager that the Stakeholders concerns are being addressed. In addition, as many Lean projects involve groups external to the organization such as customers and suppliers, the Stakeholder may be responsible for strategic business negotiations and communicating to senior management.

Once these key factors have been identified, the detailed project plan can be developed and the start up phase for the project can be undertaken. Guidance is provided by the Project Sponsor. This solidifies the decision to 'launch' the project and subsequent activities, including planning, organizing, mobilizing, and importantly, executing.

RESULTS FROM PROJECT INITIATION AND DEVELOPMENT

- Identification of the Project Definition
- Identification of the Project Scope
- Identification of the Project Sponsor
- Creation of the Project Charter
- Identification of Project Stakeholders

TOOLS SUPPORITING PROJECT INITIATION AND DEVELOPMENT

- Project Charter
- Statement of Scope
- Project Organization Chart
- Project Responsibility List

Once the purpose of the project has been identified and documented through the Scope, the Project Plan can be developed. The Project Plan is where the activities and tasks to accomplish the project's objectives are defined and appropriate resources are assigned. The Plan documents the work content of the project and supports the Scope through the identification of all activities to be perfumed, resources consumed, and the expected result.

'Project planning and start up' is comprised of the sequence of activities that is required to:

- obtain agreement on the project's objectives,
- develop a road map for meeting the project's objectives,
- define the project activities in detail, and,
- mobilize the resources or project team.

The development and implementation of the Project Plan provides the basis for managing the project, including addressing the objectives, procedures, organization, guidelines, finance, and chain of activities required to support the objective of achieving the project's intended results.

Since lean projects generally involve external business partner resources the project planning process needs to address their concerns and issues which may be barriers or obstacles to success.

Case Study:
A business unit of a large U.S. Pharmaceutical Company that makes Medical Devices recently brought two of its key suppliers to a planning session with its own Project Team members; the purpose for this was to define scope and solicit collaboration for their Lean project. The group, including the two suppliers, completed a Value Stream map of the current processes and communications between the organizations and identified each process step as Value Added, Non Value Added, or Sustaining Non-Value Added [those activities supporting Regulatory Requirements but not 'Adding Value' to the process from the customer's perspective]. This planning and process mapping activity highlighted the importance in working with external business partners in the early stages of implementing Lean Principles and developing a project plan collaborating with external partners. Jointly, the group developed a future business state by designing the future 'to be' business processes together, employing lean principles. As a result of partnering early in the planning process, the two suppliers are currently collaborating with the Medical Device company on their lean project by ensuring understanding and responsiveness to lean management tools and signals, facilitating improvements and changing their own organizations, in order to support their customer and to achieve improved business processes.

Detailed activities to accomplish project objectives are developed during the Project Planning phase. Project activities are short-term actions that are defined to support the accomplishment of project objectives. Milestones are defined for the purpose of tracking the completion of these project activities and ensuring achievement of project objectives. Milestones are the key measures to track the project's progress on activity completion and resource utilization.

Activity:
An element of work performed during the course of a project, defined by an expected duration, an expected cost, and expected resource requirements. Activities are often subdivided into tasks and can be a series of tasks completed over a period of time whose purpose is to ensure objectives of a project are met.

Milestone:
A measure of completion for an activity or set of activities which is identified as critical points in meeting project objectives.

During the process of defining project activities, an assessment of barriers should occur, in order to address whether there are issues preventing activities from being completed successfully. Barriers are defined as any item which may hinder or prevent the completion of activities or reaching intended project results. Some examples of barriers may be:

- reliance on a legacy computer systems for 'timely' reporting of data
- limited knowledge and understanding on concepts, tools, and methods
- any organization restructuring affecting resources
- impending labor strikes or similar 'external' items which may inhibit production or work flow.

For most projects and especially for Lean projects, it is critical to consider any competing demands on resources or issues with collaborative partners [internal or external to the organization] that may have an impact on meeting milestones and objectives. This consideration should be done prior to defining time constraints for activity completion in order to ensure ample time to complete activities and address concerns on resources. By engaging external partners early in the process, the project will have greater chances of meeting its objectives and garner credibility and support from Stakeholders and Partners.

Lean Projects may engage more resources on a part time basis due to the breadth of scope with the process; to address inter-organizational needs it is important to identify functional barriers.

Once all project activities, resources, requirements, and milestones have been addressed, a project start date is identified and the Project Plan / Schedule is developed. The development of a detailed Project Plan is necessary to ensure that all project objectives are assessed and supported by activities resulting in measurable project deliverables. The Plan outlines the work activities, appropriate resources and tasks necessary to meet the project objectives. This becomes the daily, weekly, and high level set of guidelines that directs the activities of the Project Team, documents resource requirements, sets project tracking guidelines, and supports the monitoring of project milestones. All of these items encompass Project Planning and identify organizational requirements for the project. The Project Schedule communicates the timeframe for accomplishing project activities. This is the core document that guides the Project Team on a daily basis for completing required activities.

In developing a project plan for implementing Lean Principles, one of the biggest barriers to success identified may be the incomplete understanding of lean concepts. Education and 'training' on lean concepts, methodology, and tools may be necessary; development of related training materials needs to be considered as a primary project activity and addressed in the project plan prior to the completion of other project activities; this is to ensure that the Project Team is utilizing the right lean tools.

Project Planning
- **the combination of all project goals and activities, along with the identification of work requirements and resources necessary to accomplish them**
- **the sum of the products and services to be provided as a project**
- **the bounded set of verifiable end products or outputs, which the project team undertakes and is provided to the Project Sponsor**

Project Schedule
- **planned dates for starting and completing activities and milestones**
- **timelines for the project defined by activities, milestones, and resources**

Once the resources for the project are identified and confirmed as either full time or 'as needed' [ad-hoc] and time frames necessary to complete the activities are identified, communication of the project can occur with the Project Sponsor, Stakeholders, and key functions in the organization. The result of this and the detailed project plan is the finalization of the Project Schedule.

In order to complete preparation for the project during this phase of the project lifecycle, the Project Manager/Team develops the working procedures and business rules for executing the project. These tools and methods are:

1. Project Rules / Procedures - the policies, rules, and practices that will be followed throughout the project life cycle; these are a set of management and administrative procedures needed for the project, including expectations, rules for communications, procedures for issue resolution, reporting objectives and plans, procedures for managing change, and a process for milestone reviews.

2. Project Processes - the process and activities that encompass the project tools, methods, and techniques, enabling project success

3. Project Plan - the documented list of activities necessary to successfully complete the project, with identified resources, and time frames for completion assigned. The use of a computerized tool is recommended as a method for documenting, sharing and adjusting the plan, as this will provide for ease of use in developing and maintaining the plan, project tracking, management of milestones, and change / impact assessment.

4. Communication strategy - the plan for managing and implementing the sharing of project information within the team, to the Sponsor and Stakeholder, throughout the organization and to management. This is critical for ensuring

the Sponsor, Stakeholders, Project Team, external collaborators, and organization are engaged and committed to the project.

These business procedures may encompass daily, weekly, and periodic activities in order to ensure the effective completion of project objectives and activities. Review of these procedures with the Project Sponsor is recommended to ensure support, confirm understanding and commitment on the scope, gain 'buy in' and 'approval' with the approach identified in the Plan.

For projects that are cross functional in objectives or impacting most of the organization, stakeholder review for the Plan is recommended during the project initiation and throughout the project lifecycle, highlighting milestones and addressing issues.

Once these elements have been identified, the project execution phase can be initiated, where the actual completion of project activities and milestones occurs. This is where the effectiveness of the Project Plan and Resources is realized.

RESULTS FROM PROJECT PLANNING AND START-UP

- Development of the Project Pan / Schedule
- Identification of the Project Activities
- Identification of Resources
- Identification of Project Milestones and start / completion dates
- Development of the Communication Strategy

TOOLS SUPPORITING PROJECT PLANNING AND START-UP

- Project Plan
  - Project Schedule
  - Resource / Responsibility List
  - Communication Strategy
- Project Procedures Operations / Business Rules
- Statement of Scope
- Project Organization Chart

PHASE III. PROJECT EXECUTION

Implementation of project activities in accordance with the requirements and procedures identified in the project plan is critical to the attainment of success and expected results of the project. Work requirements have been broken down into manageable activities and tasks with well-defined completion times [in the Project Planning and Start-Up phase] that need to be implemented in order to reach milestones, meet objectives, and obtain results.

The effectiveness and success in executing the project is based on various items, including the effectiveness of Project Manager, Project Team, Project Plan, external collaborations, internal support, and various unmanageable items [generally external to the functional management supporting the initiative]. Most successes in executing projects occur when there is a strict discipline surrounding adhering to project rules, plan, and schedule; this discipline includes ensuring timely completion of activities, prompt action and reaction to events, effective stakeholder management, accurate status reporting, flexibility in adjusting to issues and initiating change, and consistent monitoring and reporting on activities and milestones.

The Project Rules/Procedures are developed by the Project Manager and the Team in accordance with the framework of the Project Plan; this should outline the project discipline for executing activities, obtaining feedback, addressing issues, status reporting, tracking progress, and communicating. The Project Plan/Schedule and Project Rules/Procedures should provide the direction for implementing activities and obtaining results. The Project Team completes activities and tasks according to the plans and procedures as defined by the project. Additionally, team members are responsible for completing project requirements, addressing issues and documenting results.

Although support tools and methods are developed in Planning, the team should remain flexible to adjust, revise, or supplement methods for the most effective completion of project activities.
As tools and methods are developed and utilized, the procedure to implement and use these should be documented to ensure sharing knowledge across the project.

The Project Leader monitors project progress, supports the communication and tracks the meeting of objectives. Project progress reports generally occur weekly or bi-weekly, ensuring logical completion of activities and task, with the objective of tracking the progress of meeting milestones

Project Plan Execution
- **the act of carrying out activities as stated in the Project Plan**

Project Progress Report / Project Status
- **structure and formal statements that compares the project progress, achievements, and expectations with the project plan act of carrying out activities as stated in the Project Plan**
- **the timely comprehensive measurement of project progress against the plan to identify variances and the seriousness of the variances if not controlled by corrective action**
- **a report on the status of accomplishments and any variance to spending and schedule plans**

Progress reports are part of the quality management of a project; this ensures that the objectives and activities of a project are being satisfied in accordance with the Project Plan. After a Quality review is completed it may be necessary to take actions to address items hindering of project progression.

RESULTS FROM PROJECT EXECUTION

- Completion of project activities
- Communications
- Tool development and methodology implementation
- Objective reporting
- Benefits tracking

TOOLS SUPPORITING PROJECT EXECUTION

- Statement of Scope
- Project Organization Chart
- Project Responsibility List
- Quality Management review
- Status report
- Communication plan

PHASE IV. PROEJCT COMPLETION AND REVIEW

Effective completion of any project should be applauded as a success in an organization considering the magnitude of variations and potential complications associated with executing project activities. Review of the execution of the project should be completed as a project status review and reported to:
- capture the project success and milestones achieved,
- understand any variance in expected results,
- identify opportunities for improvement,
- ensure credit is applied to the appropriate resources, and
- document project management knowledge for leveraging in future projects

The final result should be communicated to the organizations, highlighting team member's participation, benefits and continuous support for the newly implemented project objectives.

Success in projects should encourage a culture of urgency and continuous business improvement with principles enabling success becoming part of the organizations 'project management tool set'. Sharing the tools, plans, and methods for managing projects effectively would become a 'working library' where organizational knowledge will increase and improve with experience.

RESULTS FROM PROJECT COMPLETION / REVIEW

- Completed project activities with objectives met, results obtained, and benefits accruing
- Project completion review with assessment of project plan effectiveness, review of benefits, lessons identified
- Final project communication with highlighting success
- Overview and documentation of new tools, reports, methodology for new operating concepts.

TOOLS SUPPORITING PROJECT COMPLETION / REVIEW

- Project completion review
- Method / Tool review and documentation
- Documentation for project tools supporting the processes resulting from the Project

CONCLUSION

The key elements for effective project management are applicable across all projects, with differences accounted for by type of project scope and functional reach. A disciplined approach to the implementation of key elements of project management and a well-developed project plan will support the attainment of project objectives and benefits. These principles are valid for projects of all sizes and across most organizations and industries. The complexity of a project will determine the resource [time and effort] requirements necessary for completing each element and activity stream and consequently meeting milestones. Projects with cross functional scope and changes in operating strategies (like those implementing the principles of Lean Management) require high levels of resource requirements, management support, communications, and teamwork; these projects present significant risk to the organization and therefore require a highly disciplined approach to support a successful implementation. The concept of continuous project flow, timeliness and effective communications is a key enabler in supporting the success of the project. The management commitment, participant 'buy-in', tracking and reporting on project results are critical elements in sustaining organization focus. Visibility of the project, its team, and completion of milestones are also useful in supporting the initiative and focus of stakeholders and partners.

TOOLS and CHECKLISTS

Tools to support effective project management guidelines vary by project type, scope, cost, complexity, and technology platform. Key elements to support the decision on choice of tools have been identified above; the ultimate choice of tools depends on the organization, its objectives, resources, project type and scope, and its current business state.

The Project Leader and team members may create their own tools and checklists, as formal methods to support the completion of project activities or as useful lists to ensure tasks are being completed and issues are being addressed. Use of tools and methods should be documented for effective use and future project deployment. Common support tools are listed by purpose in the box below.

PURPOSE	TOOL
Project Planning, Project Management Cost tracking	- **Various software tools and project management tools, developed by notable software companies [ex: MS Project]** - **GANT charts** - **Spreadsheets [ex: MS Excel]**
Process Flows, Process Mapping	- **Value Stream Maps** - **Software vendors [ABC Flowcharter, Visio, PowerPoint]**
Role and Responsibility charting	- **RACI charts / Roles and Responsibility Matrix** - **Resource allocation functions in Project Planning tools** - **Job descriptions, performance evaluation forms**
Communications / Project Tracking	- **Scorecards, 'dashboards'** - **Project status reports** - **Newsletters, 'e-rooms', emails, company intranet** - **Bulletin boards, posters, periodic conference calls** - **Surveys** - **'Town meetings', organization announcements** - **Presentations, periodic update meetings,** - **'Project Thermometers', 'Fever Charts'**

For question or comments relating to the article or Lean tools and techniques, please email authors**.** Value Innovation Partners, Ltd. is an operations improvement consulting firm specializing in the delivery of value through implementation of Lean Manufacturing and Supply Chain Management tools and techniques in a variety of industries from discrete parts to continuous flow, from distribution to assembly, from aerospace to pharmaceuticals. We have enjoyed equal success deploying these tools and techniques in non-traditional settings like offices, regulated environments and retail settings. Visit our website at www.vipgroup.us.

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