

Biography and Background

Stacy Price

Head of Pharmaceutical Development Operations at Shire

Stacy has over twenty years of experience leading operations and program management in corporations to build business capabilities across biotechnology disciplines

She has acted as Project Management Office (PMO) and Portfolio Manager for development, capital, remediation and operational project teams.

She has been with Shire for eleven (11) years leading manufacturing, pilot plant, and laboratory operations, CMC, Operations and Engineering program management offices and has been a champion to building IT solutions for the laboratory space. Prior to her time with Shire, Stacy has worked at TKT and Serono, focusing on process and automation engineering, development and manufacturing.

Stacy holds a Masters of Science in Biochemical Engineering from Tufts University, is a certified Project Management Professional (PMP) from the Project Management Institute, is a Lean Six Sigma Green Belt and has a certification in Business Process Management from Boston University.



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Biography and Background

Robert G Beane Jr

Director for the Barry-Wehmiller Design Group

Rob has over seventeen years of experience leading turn-key capital engineering, validation and quality projects for pharmaceutical, biotechnology, and medical device clients.

Has acted as Project Management Office (PMO) and Portfolio Manager for capital, remediation and operational project teams.

He has been with Design Group for four (4) years assisting to build the Regulatory Compliance business and service offerings for the company. Prior to his time with Design Group, Rob has worked for a small number of consulting companies, where his focus has been on efficient project delivery, total operational solutions and building QbD into the EPCMV process.

Robert holds a Bachelor of Science in Chemical Engineering from Villanova University and is a certified Project Management Professional (PMP) from the Project Management Institute



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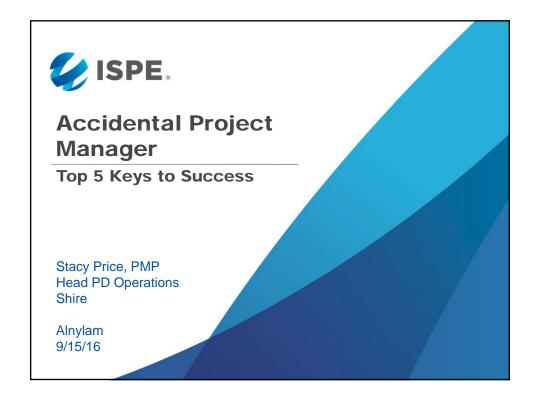
Barry-Wehmiller Design Group

DESIGN M GROUP

Barry-Wehmiller Design Group is a leading supplier of professional engineering and consulting services in the Pharmaceutical, Biotech and Medical Device Markets, providing thousands of hours of engineering design, construction management, system integration, process engineering and regulatory compliance solutions to leading Life Science companies each year.

Design Group has over 1100 engineers across 35 offices with extensive experience with technology transfer, new product introductions, process modeling, facility & critical utility engineering projects and quality remediation planning and execution.







Projects and Project Success

Key Points to Remember

Projects are started to fix a problem or build capability.



A Project by definition is finite. It has:

- · A defined end point and
- Defined success criteria.

Project Success is determined by whether and how well the problem was solved and how capable the new solution is



Projects & Project Success

The word on the street...

One in six IT projects have an average cost overrun of 200% and a schedule overrun of

70%. (Source: Harvard Business Review)

75% of business and IT executives anticipate their software projects will fail.

(Source: Geneca)

The United States economy loses \$50-\$150 billion

per year due to failed IT projects. (Source: Gallup **Business Review**)

33% of projects fail because of a lack of involvement from senior management. (Source: University of

Ottawa)

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The Project Management Institute that poor communication is at

has continually found the heart of most project failures.

Fewer than a third of all projects were successfully completed on time and on budget over the past year. (Source: Standish Group)

> Most Common Causes of Project Failure: Changing priorities within organization-

Inaccurate requirements – 38% Change in project objectives - 35%

Undefined risks/opportunities - 30% Poor communication - 30% Undefined project goals - 30% Inadequate sponsor support - 29% (Source: Wrike News)

High-performing organizations successfully complete 89% of their projects, while low performers complete only

36%. (Source: PMI.org)

Project Success

Key Points to Remember

As the Project Manager, you are responsible for delivering the project according to expectations of the stakeholders and for setting-up the final solution for success

Stakeholder = anyone affected by the project.

Expectations = problem/pain point & success criteria definitions



Agenda

Projects and Project Success

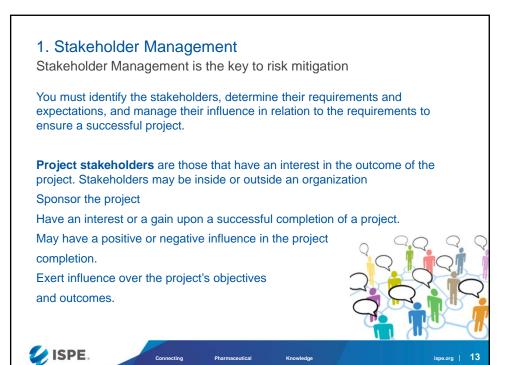
Bring your project in successfully, on-time, on-budget

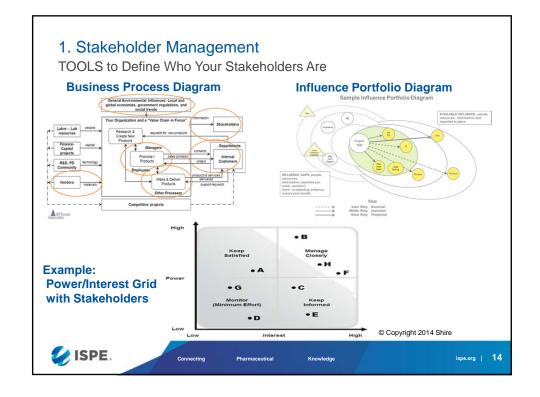
- 1. Stakeholder Management
- 2. Scope Management
- 3. Communication Management

Give your project longevity

- 4. Operations
- 5. Change Management



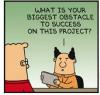






Who's your Sponsor?

Sponsors provide resources and budget for the project. Ensure requirements align with business objectives.







Stacy's PM rules:

- 1. If you don't have a sponsor, don't accept the job
- 2. If your project doesn't align with the corporate goals, don't accept the job

Stacy's PM Corollary:

- 1. Keep your sponsor engaged by active communication
- 2. Know the pulse of your sponsor and the corporate goal your project maps to



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2. Scope Management:

"deliver the project according to expectations"

What are the expectations?



- 1. Establish your vision
 - Describe your future state

2. Describe the current state



- Process map with metrics
- 2. Pain-point checklist and description (include current and future stakeholders)

3. Classify needs

1. Immediate, short tem, long term



What expectations are reasonable for the time and funding provided? Meeting Stakeholder priorities builds enthusiasm and adoption

Stacy's third PM Rule:

Write a charter for EVERY project



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3. Communications Management

The key to Stakeholder Management

When stakeholders feel that they are being heard and their needs are being considered, they become engaged in the project.

When stakeholders are engaged in the project they truly take ownership of the outcome!

TOOLS:

- Governance model
- RACI
- Meeting agendas, minutes
- Reporting





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Project Execution

Bring your project in successfully, on-time, on-budget

- 1. Stakeholder Management
- 2. Scope Management
- 3. Communication Management

But what about the following practices?

- Schedule Management?
- Risk Management?
- · Cost Management?
- Team Management?

ALL are important and contribute to a successful project.

BUT... if you don't have the first three topics covered well, (stakeholder, scope & communication management), the practices listed above won't bring your project to a successful completion.



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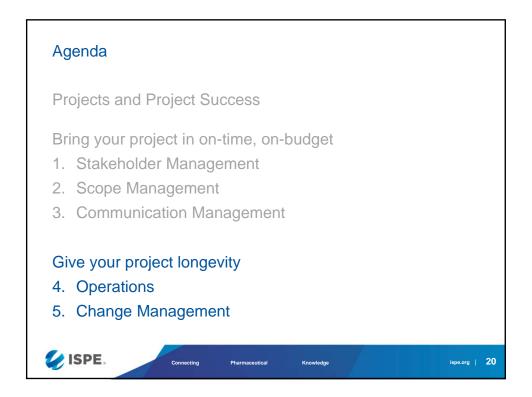
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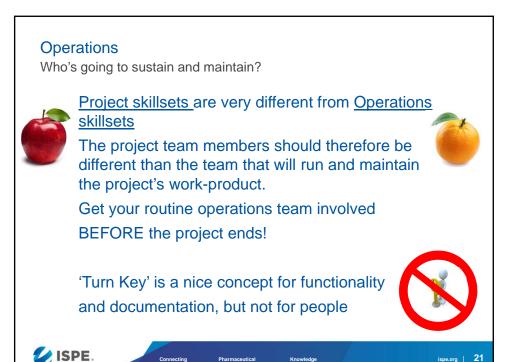
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Project Success How capable is the solution/capability your project delivered? Remember, projects are intended to fix problems or build capability And also RememberEntropy takes over and undoes whatever was 'fixed' by the project implementation Order Disorder UNLESS – you planned for success Key to success: Operations planning, Change management ENTROPY TRANSPORTED TO SUCCESS ENTROPY TRANSPORTED TO SUCCESS We success: Operations planning, Change management





Operations Business Processes All successful projects require new/revised business processes to keep the intended solution running well Your operations team are the ones to define and document those business processes. The project team or Operational Excellence/continuous improvement teams offer the skillset to help the operations team define those processes. Look holistically, not just at the individual pieces. This scope is always bigger than initially perceived!







Engaged stakeholders = adoption

Find quick wins
Advertise success



Continuous improvement – the project team needs to stay engaged after go-live

Hyper-care

Measure against your success criteria and don't stop until finished (and the Sponsor declares success)!



Summary – Top 5 Keys to Project Success

Bring your project in successfully, on-time, on-budget:

- 1. Stakeholder Management
- 2. Scope Management
- 3. Communication Management

Give your project longevity:

- 4. Operations
- 5. Change Management



Summary

Stacy's Checklist

- √ Know your sponsor, know your stakeholders
- ✓ Link your project with the corporate goals
- √ Scope it right-sized!
- ✓ Communicate, communicate, communicate
- ✓ Integrate your operations team during project execution
- ✓ Build sustainable business processes for post go-live
- ✓ Market your project, communicate expectations for all stakeholders, including end users



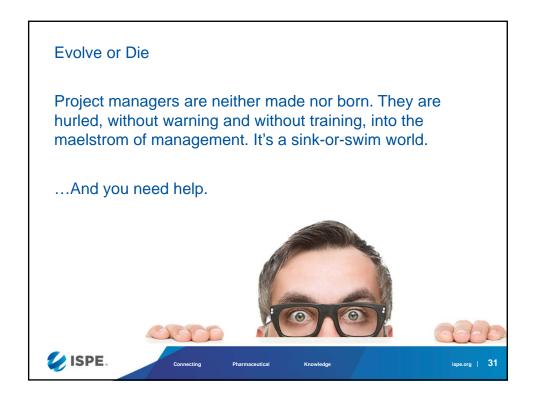
For further information, please contact

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IT'S SO IMPORTANT THAT SHE MENTIONED IT FOUR TIMES IN HER SUMMARY!

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So, Communication's pretty important? Communication Management

What is it?

The processes required to ensure timely and appropriate generation, collection, dissemination, storage and ultimate disposition of project information.

Why is it important?

The most crucial success factor in project management is effective communication. On an average, **two in five** projects do not meet the project's original goal or intent and one-half of those unsuccessful projects are related to ineffective communications.*



*PMI's 2013 Pulse of the Profession report

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Ok, that's great, but definitions and scare tactics don't help

Communication is work

Work is tough

Effective Communication is more work and more tougher

The greater the project, the more stakeholders it will have

The more stakeholders, the more points of communication

How you gonna do it?

What information? Media?

Audience? Frequency?

Ugh, too many questions.

Let's get a little tactical...

Project Team

The Connection Parameterical Stakeholders and more tougher

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