


Connecting a World of
Pharmaceutical Knowledge

**Boston Area
Chapter**




Between Love and Madness Lies Obsession: Project Management in the Pharmaceutical Industry

Thursday, February 16, 2012
5:30 pm to 8:30 pm
Royal Sonesta Boston Hotel
Cambridge, MA

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Between Love and Madness Lies Obsession!

PART I

**An Introduction to the ISPE Good
Practice Guide:**

**Project Management for the
Pharmaceutical Industry**



Presented by:

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Yonkers Industries, Inc.

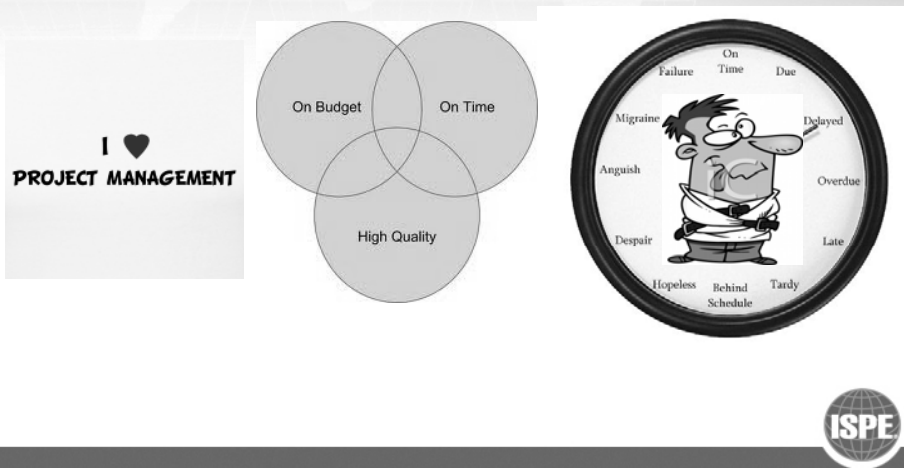
Corporate Manager of Technical Services



- Chairman of the ISPE Project Management Community of Practice (COP)
- ISPE PMGPG Core Team Member and Author
- Instructor, NC State University Biotechnology Education Center



Between Love and Madness Lies Obsession!

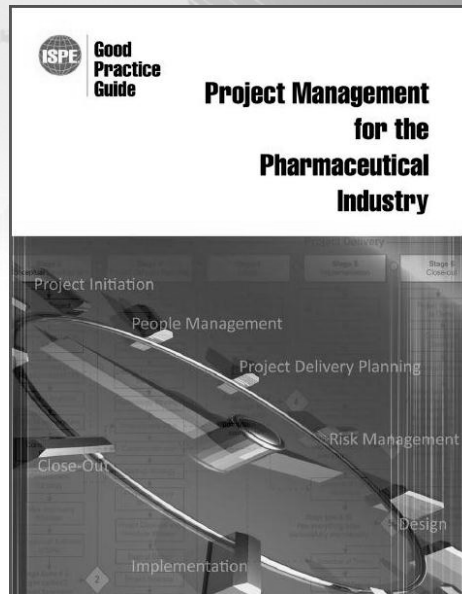


For the love of Project Management ...



5
years of
desire ...

18 months
of effort ...



Our Questions Started With ...

**PROJECT MANAGEMENT,
WHAT IS IT, REALLY?**



PROJECT MANAGEMENT 101

Project Management (Simple Definition)

The application of modern management techniques and systems to the execution of a project from start to finish, to achieve predetermined objectives of scope, quality, time and cost, to the equal satisfaction of those involved.



PROJECT MANAGEMENT 401

Project Management (Expanded Definition)...

is a critical skill required for execution. It is an essential organizing and managerial discipline in getting things done. The art of managing the product and service development cycle to achieve a balance of time, cost and quality is project management. Although project management requires the use of processes, tools and templates to manage and control work, **its real value is released when a project manager actively engages stakeholders to support and sponsor key work.**



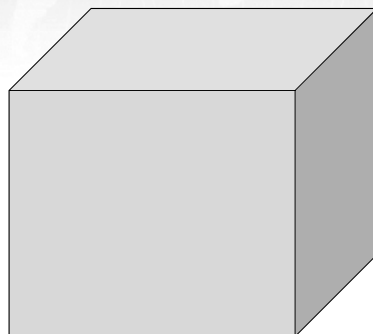
SO, WHAT THEN IS A PROJECT MANAGER?

The classic role of the Project Manager is to monitor, control and report on Scope, Schedule, Budget and Safety, or manage the programs and personnel in place to accomplish these tasks.

WHAT IS MISSING FROM THIS DEFINITION?



PROJECT MANAGERS SHOULD BE ABLE TO WHAT?

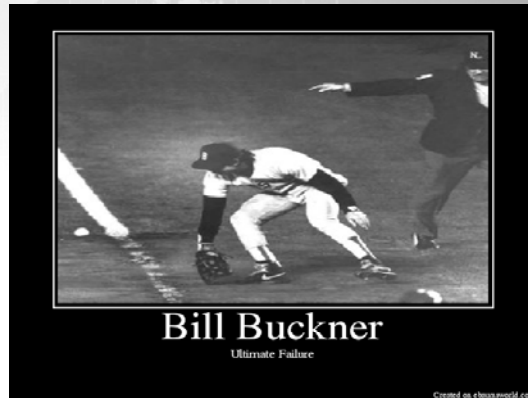


THINK



THE “REAL WORLD” PROJECT MANAGER

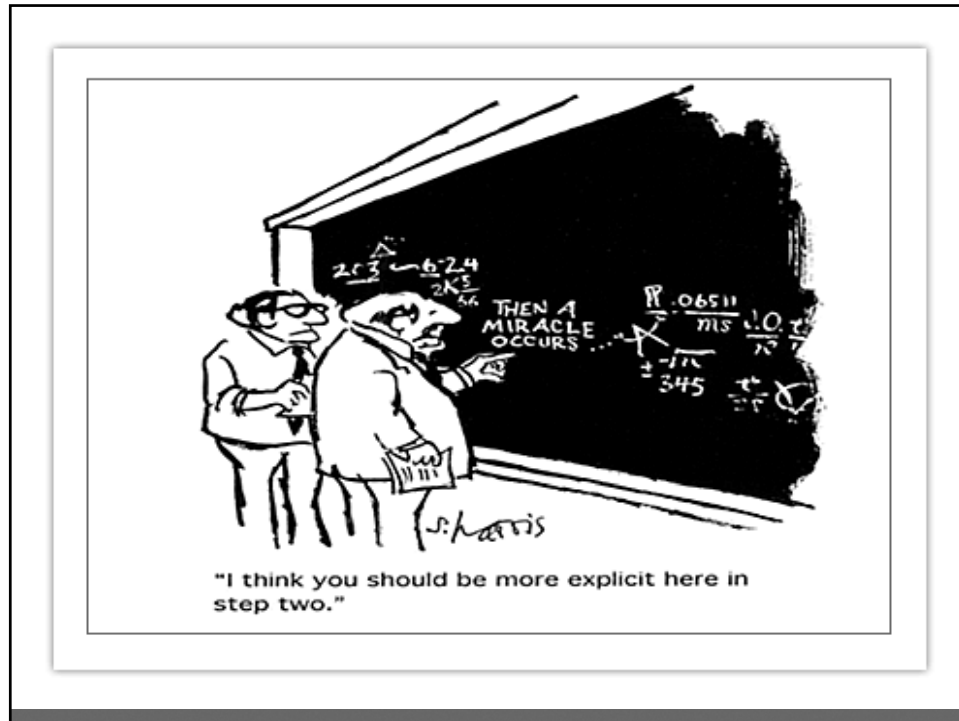
“Leader”
“Firefighter”
“Enforcer”
“Therapist”
“Deal Maker”
“Salesperson”
“Responsible Party”



So we launched an effort ...

To develop a PM GPG as
our “Playbook” for Project
Management within the
Pharmaceutical Industry





The Project Management Good Practice Guide (PM GPG)

WHAT?

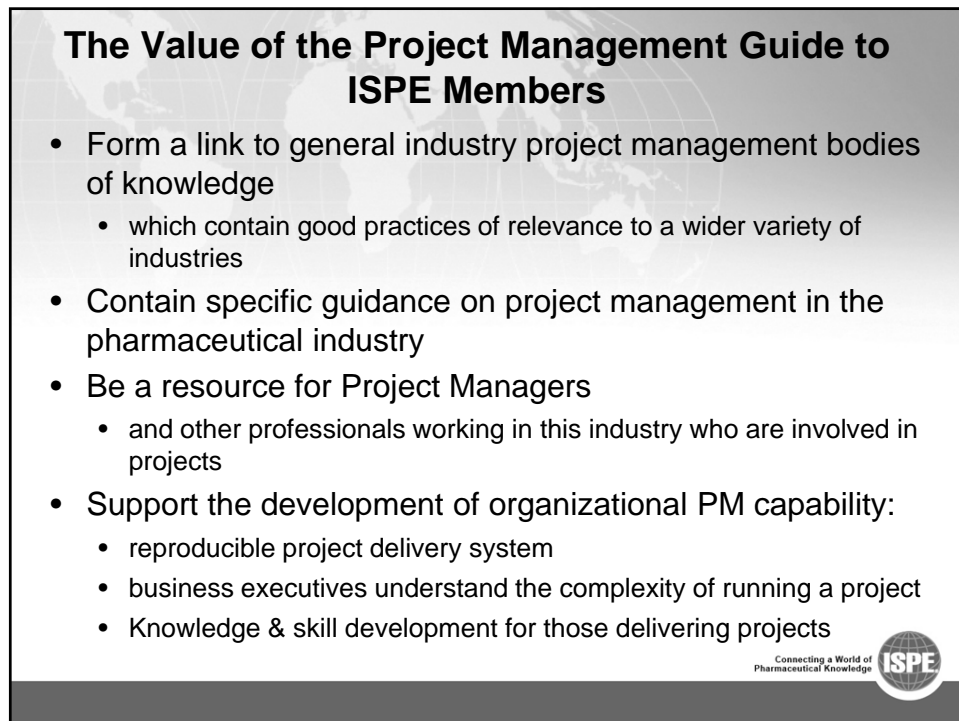
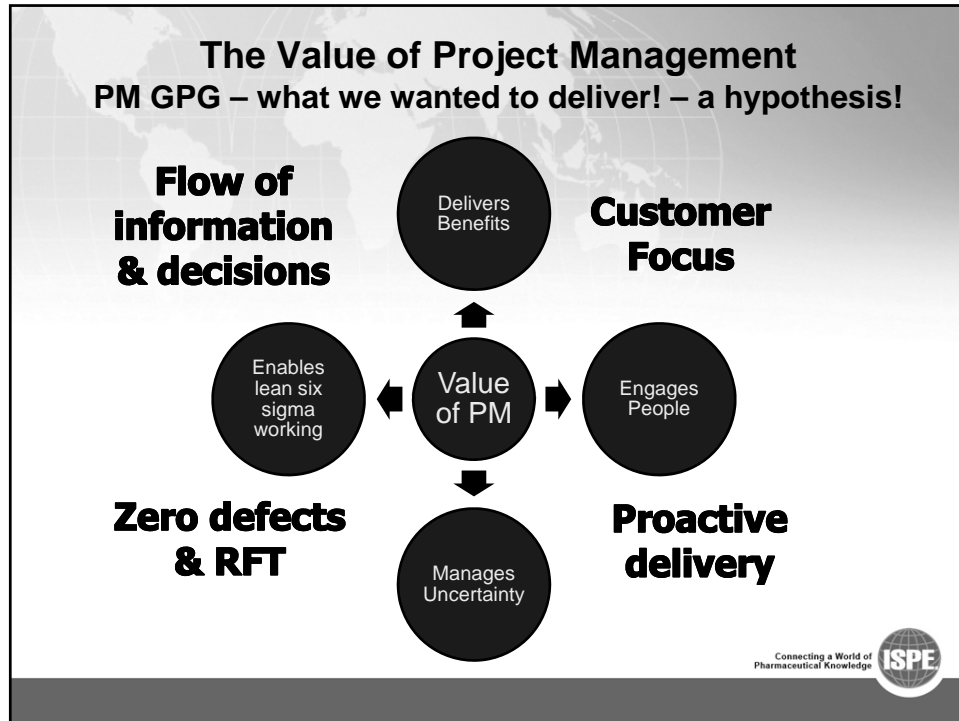
Should be addressed in the Guide

WHO?
Is it for

HOW?
Does it
deliver
something
of value

WHY?

**Do we need
a PM Guide**



ISPE PM Good Practice Guide Purpose

- To produce a document which enables *sharing of good practices*
- To support:
 - Development of a common language
 - Integration across discipline boundaries
 - Development of pharmaceutical Project Manager capabilities
- To be a link to other generic PM BoK

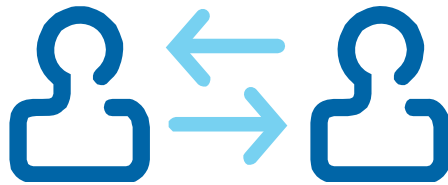


ISPE PM Good Practice Guide Key Concepts

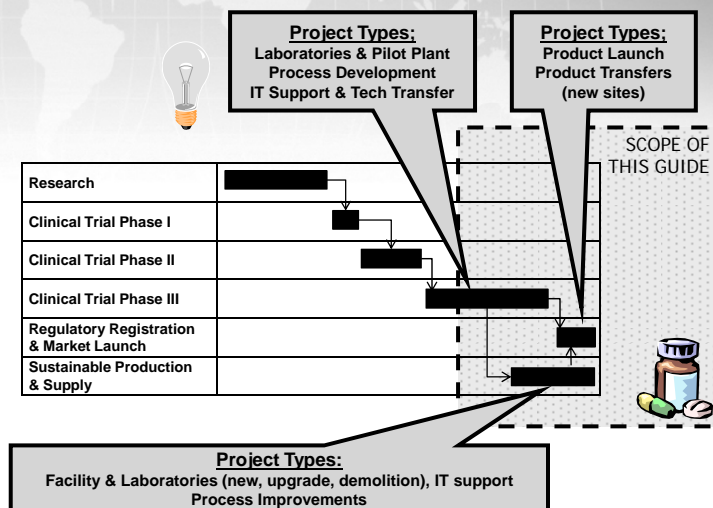


ISPE PM Good Practice Guide Audience

- Our audience is broader than Project Managers
- ALL professionals involved in the pharmaceutical projects



ISPE PM Good Practice Guide



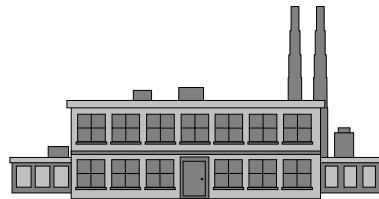
ISPE PM Good Practice Guide Project Types

- **Types**

- Facility
 - New & Retrofit
 - Demolition & Estate
- Improvement
 - Product & Facility
- Product
 - New Product & Product Transfer
 - Tech Transfer & Clinical
- IT

- **Differences**

- Scale
- Complexity
- Technical



ISPE PM Good Practice Guide Business Context

- Managing the development and delivery of a business case in a dynamic environment
 - The importance of a formal benefits management process
 - The process to react appropriately to changes in that environment whether economic, regulatory or technical



ISPE PM Good Practice Guide Regulatory Context

- Regulatory requirements drive almost everything within the pharmaceutical industry
 - specific industry regulations
 - compliance with local codes and legislation
- Failure to abide by these regulations can result in significant financial and operational penalties for a manufacturer.
- *Thus the importance of managing a product's compliance to the multitude of regulations is an essential undertaking to achieve success*

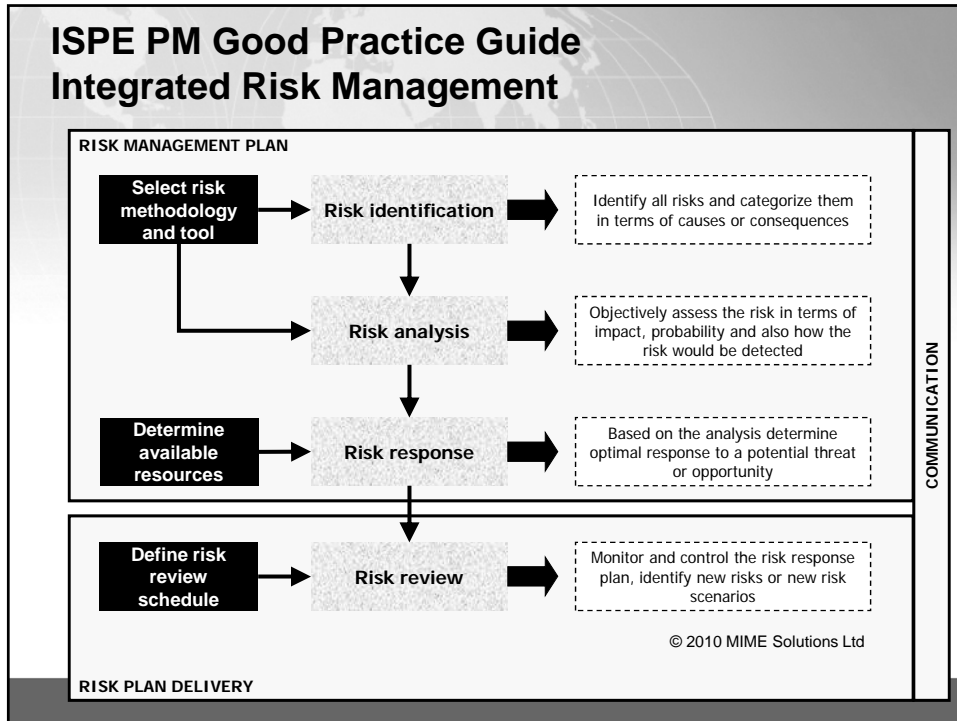


ISPE PM Good Practice Guide Collaborative Working

- Collaborative working promotes the sharing of information and exchange of ideas
- Characteristics of a collaborative working environment:
 - 2-way respect of each stakeholder's viewpoints and expertise
 - Reduced risk of individual stakeholder failure and reward early and continuous involvement of all stakeholders
 - Communal decision making and innovation generation
 - Avoidance of the duplication of effort and activities
 - Mutual perception of the project parameters and objectives
 - Appropriate, timely, informative and accurate communication



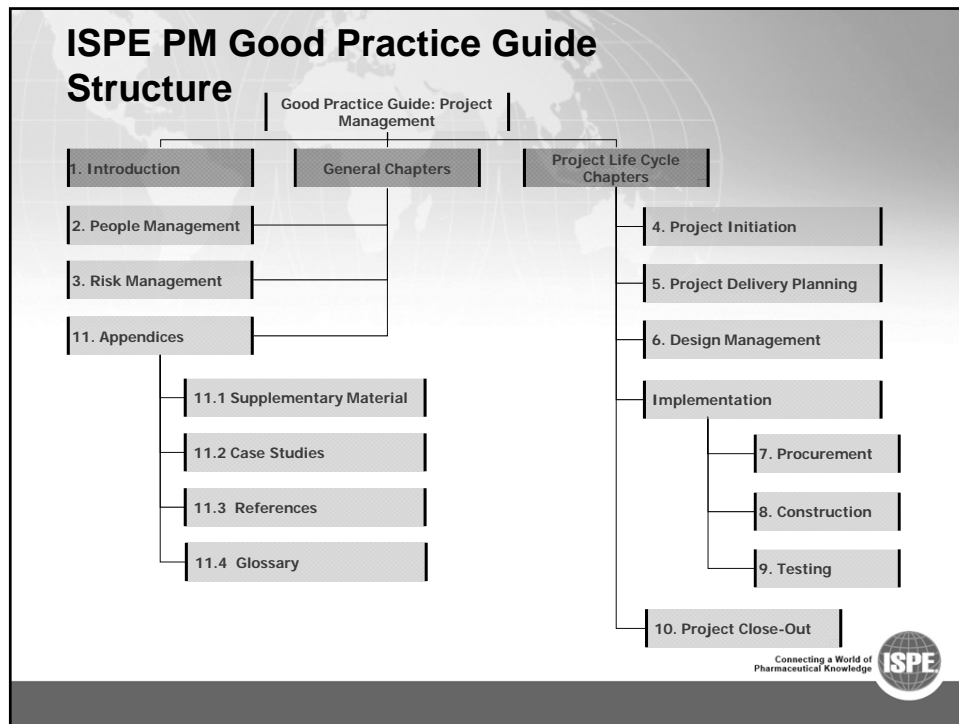
ISPE PM Good Practice Guide Integrated Risk Management



ISPE PM Good Practice Guide Guide Exclusions

- Generic project management tools and methodologies
 - that are not applied differently or have a different context within a pharmaceutical environment.
- The technical challenges within any part of the project life cycle:
 - Only the management of those aspects are covered NOT the technical solutions.
 - Other technical Guides will be referenced where applicable



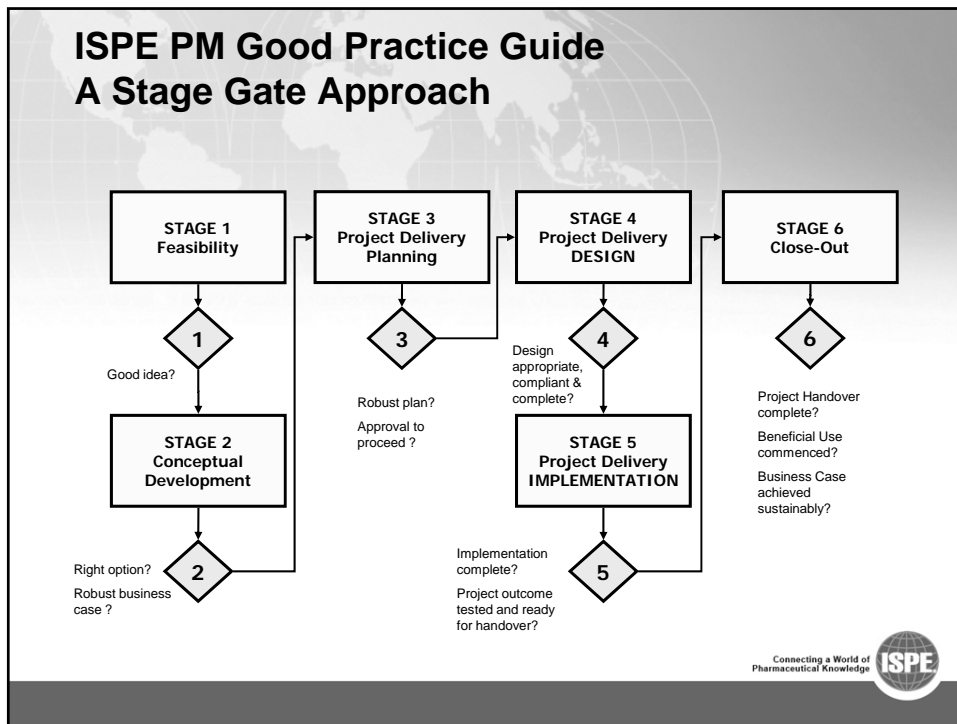


ISPE PM Good Practice Guide Integrated Validation Lifecycle

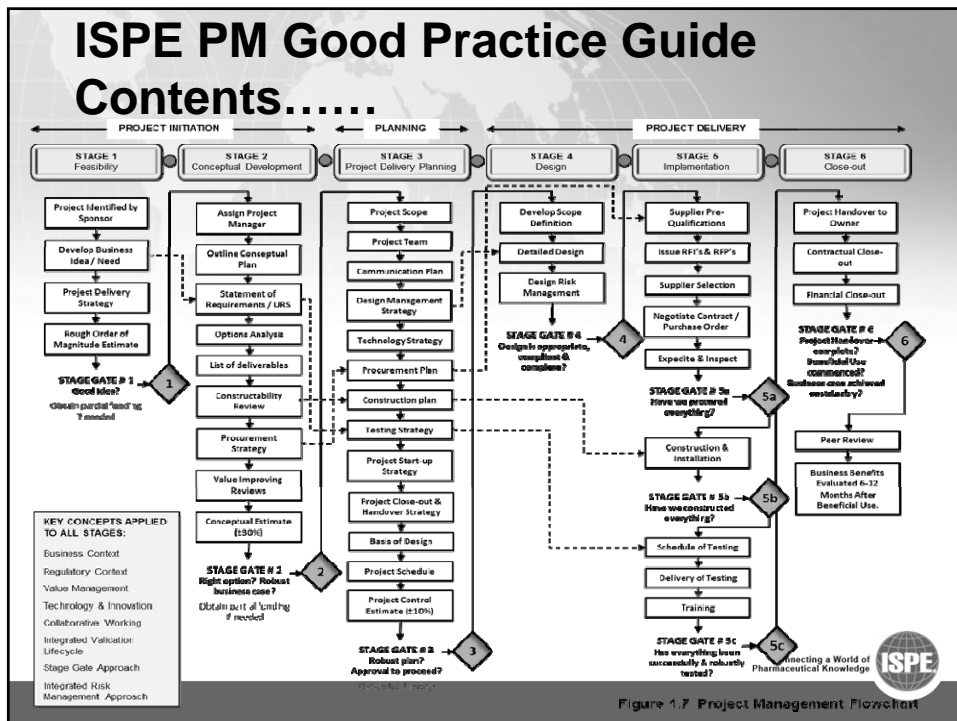
- Integration of validation & engineering
 - Incorporate the reviews, checks, and decisions which assure that the project is moving forwards appropriately
 - Validation requirements defined early and managed throughout the project lifecycle
- A stage gate approach supports this integration:
 - The definition of clear go-no go milestones in the project life cycle which need to be passed in order for the project to proceed
 - The integration, where possible, of validation activities into normal project activities

Connecting a World of Pharmaceutical Knowledge **ISPE**

ISPE PM Good Practice Guide A Stage Gate Approach



ISPE PM Good Practice Guide Contents.....



The Value of Good Project Management Hypothesis proved.....

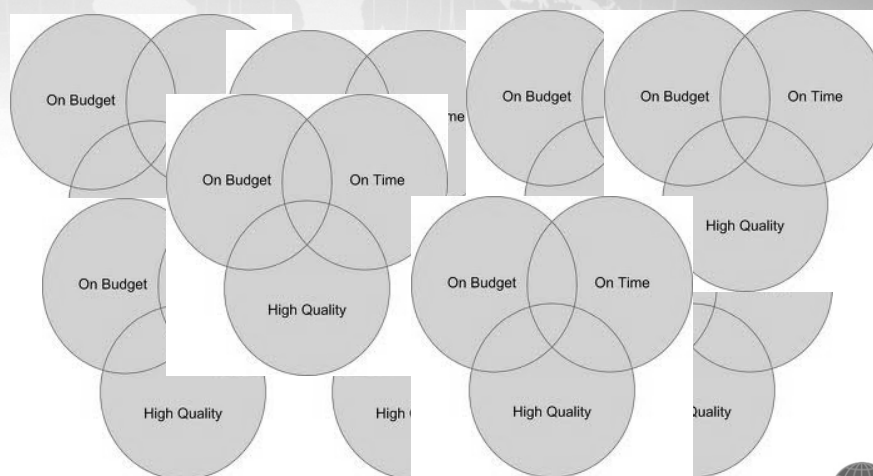


Practicing what we preach.... PM GPG CASE STUDY

- The PM GPG Team used the approaches and principles to develop the Guide and deliver it on time...
 - Delivered Benefits
 - Engaged people
 - Managed Uncertainty
 - Used a Lean Six Sigma Approach



The Obsession of Project Management!



When you suffer from Obsession:

Definition:

the domination of one's thoughts or feelings by a persistent idea, image, desire, etc.



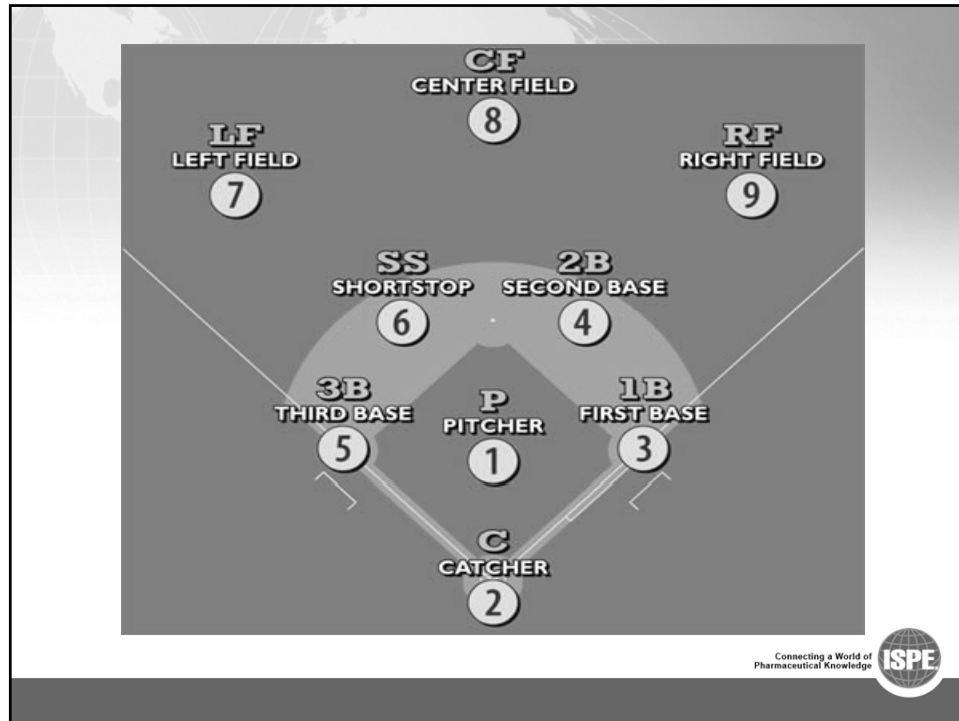
ONE THING THAT IS A PERSISTANT IDEA FOR ME THIS LAST YEAR:



SECTION REMOVED FROM PRINT VERSION

HOW IS MY PROJECT LIKE BASEBALL?

Let's assign the positions. Ask yourselves, on a typical project (Design, Construction, Verification) who would play what position if it was a Baseball Team?



How is a Project Like Baseball?

- *Game (nine or more innings) – Process (value chain)*
- *Game situations – Process and business risk events*
- *Changes in game strategy – Risk responses*
- *Game statistics and inning box score – Leading metrics*
- *Final box score – Lagging metric*

How is a Project Like Baseball?

Game strategies for negative game situations (threats) may be to

- **Avoid** – e.g., walk the next batter to remove the possibility of a slugger getting an odds-on-hit
- **Mitigate** – e.g., advise the pitcher how to pitch to the next batter to lower the probability of a hit
- **Transfer** – e.g., relieve the pitcher with someone from the bullpen



How is a Project Like Baseball?

Risk responses for negative process situations (threats) may be to

- **Avoid** – e.g., stage higher workloads to maintain a steady work pace
- **Mitigate** – e.g., add staff to handle additional workload
- **Transfer** – e.g., outsource additional workload



How is a Project Like Baseball?

Game strategies for positive game situations (opportunities) may be to

- **Exploit** – e.g., give a “steal a base” signal to a base runner to take advantage of the opposition’s slow windup delivery of a pitch
- **Enhance** – e.g., change the batter for a pinch hitter to increase the probability of a hit or change a base runner with a pinch runner that is faster to increase the probability of “stealing a base”
- **Share** – e.g., show team commitment by protesting a bad umpire call (perhaps get thrown out of a game)



How is a Project Like Baseball?

Risk responses for positive business situations (opportunities) may be to

- **Exploit** – e.g., implement new technology to eliminate task errors or quicken the process
- **Enhance** – e.g., certified workers become available to further ensure compliance to standards
- **Share** – e.g., obtain supplier commitment via a partnership to share success or offer a worker a bonus for process improvement suggestions



CLOSING OUT THE MONEYBALL THING ...

I don't need home runs to win if they
come with an equal amount of
strikeouts. I need base hits. A high on
base percentage. A game plan. I DO
NOT NEED HIGH PAID FREE AGENT
PRIMA DONNA'S.



And like every project ...

**The goal of
baseball is to get
home safe.**



The Madness of having a group of PM's writing a guide about PM!



The Value of Good Project Management PM GPG Development Project Case Study

- **Our Approach**
- The development of the guide was treated as a PROJECT
- The Team therefore had:
 - An approved business case
 - A robust project delivery plan
 - Succinct and appropriate project progress measures



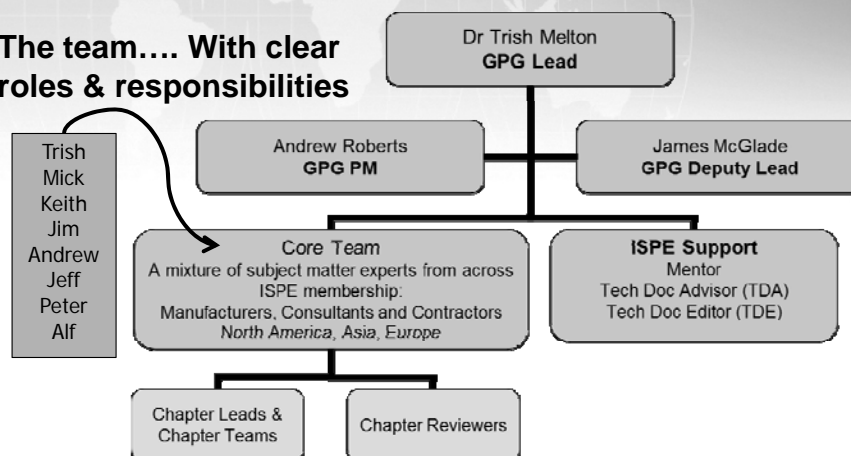
The Value of Good Project Management PM GPG Development Project Case Study

- **Challenges**
- Desire to launch by AM 2011
 - Follow GDEC process
 - Gain full industry review
- Need to focus on Pharma PM
 - Not be a generic PM BoK
- Ability to get a team of PM's together
 - Cross industry
 - Global



The Value of Good Project Management PM GPG Development Project Case Study

**The team.... With clear
roles & responsibilities**



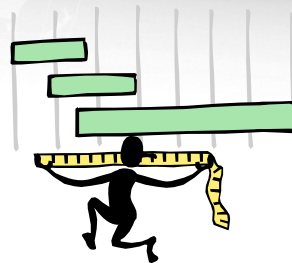
The Value of Good Project Management PM GPG Development Project Case Study

- **The Delivery Strategy**
- Review how other Guides had been delivered and learn from them
- Chapter one completed first
 - Issued to chapter teams as a set of consistent messages key to the Guide
 - Core team members became chapter leads or liaisons
- All chapter teams writing 'live' during meetings:
 - GoToMeeting platform
 - Eliminate need for minutes

Effective virtual working even though most of us will only meet face to face for the first time at this AM

The Value of Good Project Management PM GPG Development Project Case Study

- **Agreed Schedule**
- Project approved in March 2010
- Kicked Off June 2010
 - Core Team formed
 - Chapter One completed within a month
 - 50% of chapter teams started in August 2010
 - Remainder started by October 2010
- Launch AM 2011



The Value of Good Project Management PM GPG Development Project Case Study

- The target was to manage the development of chapters through the following stages with steering team review at key points to ensure alignment & direction

July & August 2010	Sept to mid November	Mid Nov to Mid Dec	Mid Dec 2011	Mid Feb 2011	April & May 2011
Chapter Concepts list (table of contents) with writers assigned	Chapter draft Writing (all leads will have draft Chapter 1 as guidance)	Chapter finalised	Chapter ready for Steering team Review	Chapter ready for industry review	Chapter edits based on industry comments
Stage Gate review August 31 st 2010	Steering progress review	Steering progress review	Steering progress review	Stage Gate review Feb 10 th 2011	Stage Gate review May 31 st

TDE requires a month followed by GDEC approval (month) before final edits by Core Team and then issue to printers (September 2011)

Chapter Development Schedule

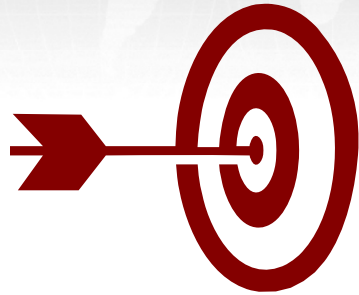


The Value of Good Project Management PM GPG Development Project Case Study

- Regular progress & Risk Reviews**
- Chapters reviewed every 2 weeks to give a chapter rating
- Core Team were able to focus on chapters needing mitigating actions
- Risk profile moved in the 'right' direction

Chapter		Meet #8	Meet #9	Meet #10
1	Introduction	1	1	1
2	People Management	2	4	4
3	Risk Management	2	2	2
4	Project Initiation	4	2	1
5	Project Delivery Planning	2	2	1
6	Design Management	4	4	4
7.1	Procurement	6	6	6
7.2	Construction	6	4	4
7.3	Testing	9	6	6
8	Close Out	6	6	6
9.1	Appendix 1 Glossary	2	2	1
9.2	Appendix 2 Case Studies	2	2	2
9.3	Appendix 3 Project Type Matrix	2	4	1
9.4	Guide Map	2	1	1

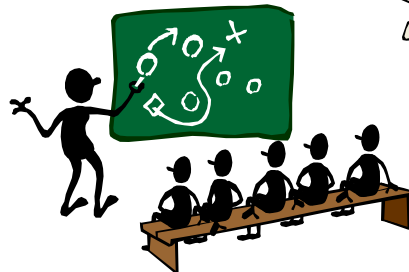
The Value of Good Project Management PM GPG Development Project Case Study



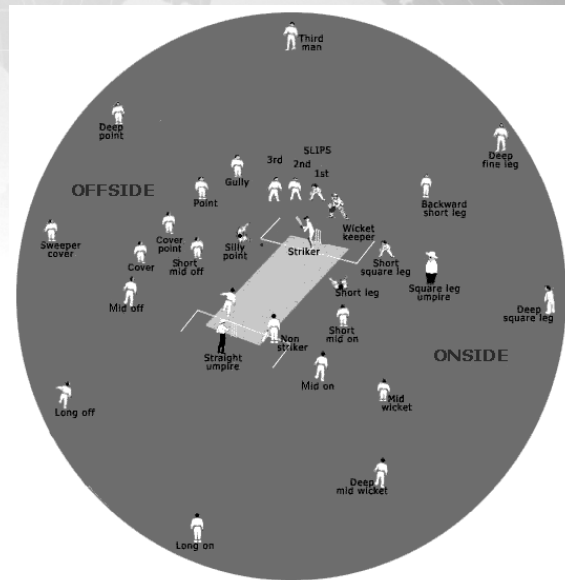
- PM GPG
 - Reviewed by Industry
 - Approved by ISPE GDEC
 - Launched at AM 2011 – SCOPE DELIVERED ON TIME



What's next....



If I had tried to tie Project Management to Cricket ...



Any Questions....



THANK YOU!

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