



Pharmaceutical SIG NEWSLETTER

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Dare to Innovate with 90 Days, 1 Project Prenup and 7 Determined People

by Victoria Tucker



Introduction

In one business quarter or 90 days, with a project charter (the prenup) and 5-7 focused people, constructive change is uncovered, the brain trust of the organization is grown, attributes of leadership are seeded and know-how is transferred. In very real terms, mid level managers learn leadership by doing, gathering a repository of learning artifacts rather than happy face evaluation sheets. Workers from different functions collaborate with one another to tackle tough challenges facing their organization now. And if passing along some of that tribal knowledge weren't enough, or the skill sets of leadership populated in true boot camp style, consider the magnitude of impact when newer, more creative improvements are

discovered. Be careful when you dare a bright group to innovate... you just might get a lot more than you bargained for.

You Want Burgers and Fries with that Innovation?

The grouping of managers to identify and implement better practices is not without some historical basis. The concept of a disciplined based community of practice is straightforward. It stems from the days when it was fairly common for a bunch of professionals to get together over burgers and fries and talk about what worked and what didn't in their fields of practice, and more importantly, pass along nuggets of wisdom that had been unraveled.

The version presented here suggests that a handful of mid level managers, from cross functional areas of the (Continued on page 6)

Applying PMBOK Principles to Clinical Submissions Utilizing Medical Imaging

by Lance Wolf, RadPharm

Editors Note: The Pharmaceutical SIG Newsletter is always interested in case studies which demonstrate the practical application of project management practices. This article is one such example. If you have a case study to present, please send your article to Sue Fisher at sfisher.pps@sbcglobal.com.

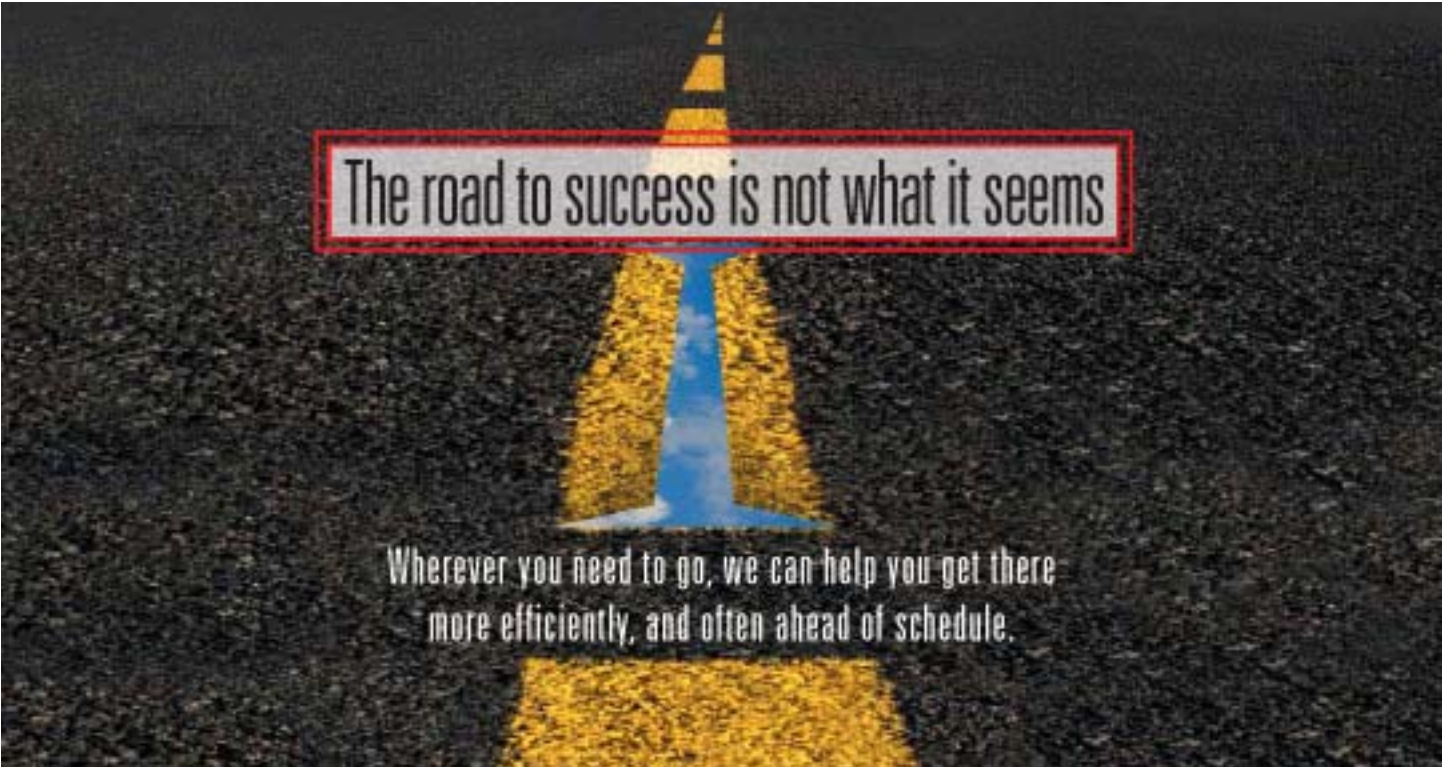
Introduction

RadPharm, an Imaging Core Lab, is a leader in image assessment for clinical trials designed to take advantage of diagnostic imaging. Unlike many other Imaging Core Labs, RadPharm's unique approach includes utilizing on-site, board certified, subspecialty diagnostic radiologists, radiation oncologists and medical oncologists to perform all measurements, image interpretation and quality assessment. In the past ten years, RadPharm has participated in over 250 global clinical trials, in 50 countries, supporting 5,000 sites.

Supporting clinical trials from Phase I to Phase IV, several factors in recent years have contributed to an increased need to aid RadPharm's sponsors in clinical submissions. These have included:

- A growing acceptance of biomarkers as surrogate end points for clinical studies. For many of the cancer treatment studies that RadPharm supports, this means making a determination of efficacy based upon measurable tumor activity (shrinking, growing, or stabilized) rather than waiting for mortality or cancer-free survival as an end-point.
- The FDA Modernization Act of 1997, including the centralization of imaging review at CDER's Division of Medical Imaging and Hematology Products (DMIHP).

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Help to expand the knowledge of project management practitioners by presenting at the PMI Global Congress 2008—EMEA scheduled for May 2008, in Marrakech, Morocco.

Submit your topic for consideration to the Call for Presentations website (<http://congresses.pmi.org/introduction.cfm>) by 8 p.m. (GMT -4) on 15 July.

Even if you have submitted before, it is important that all potential presenters read the required information. Incomplete or incorrect submissions delay their consideration. For more information please e-mail congressspeakers@pmi.org.

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A Message from the Chair:

The Truth about Being a Volunteer Leader (or what keeps me awake past midnight on a Saturday typing this message)

Everything the PharmaSIG and the PharmaLIGs delivers is the result of the work of its volunteers (including this newsletter which is the result of Sue Fisher's volunteer's work). Leading a project team is never easy. Leading a group of volunteers is even more challenging. How do you motivate a group of remote volunteers to deliver a newsletter, a webinar or a conference by a specific deadline? Passion, I believe, is the answer.

PMI developed several years ago a Leadership Masters Class program for its volunteer leaders. I have had the privilege to be selected and recently graduated from the Leadership Masters Class of 2007. This was the first PMI Masters Class based in the EMEA region. A strength of this class was the diversity of its members, and what we learned from each others' experience and cultural perspectives.

PMI CEO Gregory Balestrero spoke to our class on the morning of 10 May. He spoke of the need for leaders to nurture their successors and to have passion about their role and work. "To take on a leadership role is to take on an obligation," he said and reminded the class that that the route from point A to point B "is not a straight line". Our class members came from 14 countries. The confidence gained from learning about yourself personally and professionally will enable me to better contribute to the PMI community as a volunteer leader.

This leadership experience was the most comprehensive I have ever participated in. Having the privilege to participate in such a class is reward enough for years of being a volunteer SIG and LIG leader. I encourage each of you to consider volunteering for your SIG, eventually become a member of the Board so you too can benefit from this opportunity to learn what kind of a leader you truly are.

Feel free to email me personally if you have specific questions on the PMI Leadership Masters Class at pmpharma@gmail.com.

Sincerely,
Eric Morfin, PMP
Pharmaceutical SIG Chair

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PMP Certification

The SIG has 2118 members, 958 of which are PMP Certified (as of Apr 2007)

Dr. Timothy M. Phelan, PMP; Whitehouse Station
Ms. Catherine G Lombardo, PMP; Lionville
Mr. Todd D Lybrook, PMP; Carmel
Steve Priebe, PMP; Ann Arbor
Mr. Peter W. Simon, PMP; London
Ms. Gaby Thonus, PMP; Mechelen
Ms. Christine Zhang, PMP; Temecula

Mr. Ka Kin Lee, PMP; N.T.
Mr. Ashish P Phatak, PMP; Pune
Dr. Iraj Daizadeh, Ph.D., PMP; Thousand Oaks
Ms. Julie B Friedman, PMP
Mr. Chris R Lague, PMP; Morris Plains
Mr. Cory R Medalen, PMP; Brooklyn Park
Ms. Christine Zhang, PMP; Temecula



Director, Project Management

Located in Costa Mesa, Ardea Biosciences is focused on the discovery, development and commercialization of novel treatments for HIV, cancer and inflammatory diseases

The Director of Project Management will apply project management skills to early stage discovery programs through the development of the candidate selection process, preclinical IND-enabling studies and the phase 1-3 clinical development process. Will act as liaison with multi-disciplinary teams in a variety of anti-viral oncology and inflammation programs and interact with development partners. Identifies and communicates critical path activities along with risks, issues or resource requirements pertaining to project plans and timelines and will work with the development team to develop appropriate solutions. Responsibilities to include setting agendas, facilitating meetings, keeping meeting minutes, documenting project team activities and deliverables, and communicating key decisions and actions during team meetings.

Ideal qualifications will include:

- Bachelors Degree with a science major.
- 10+ years experience in drug development/pharmaceutical/biotechnology; 5+ years in project management.
- Experience in small molecule development and knowledge of IND submission process .
- Proficiency in strategizing, planning, monitoring and problem solving.
- Excellent communication and interpersonal skills, team-player, and demonstrated ability to manage indirectly.
- Ability to manage multiple and diverse issues.
- Strong facilitation, organizational, analytical and time management skills.
- Excellent computer skills in: MS Word, PowerPoint, Excel and MS Project.
- Ability to "roll up your sleeves" and individually contribute results to a research and development effort.
- Experience writing technical and management documents, reports and presentations.
- Able to travel up to 20%.

We offer competitive salaries and comprehensive benefits. If this sounds like the place for you, send your resume to: careers@ardeabio.com. Visit us at www.ardeabiosciences.com.

Pharmaceutical Local Interest Group News

Do Not Miss this Opportunity to Prepare for the PMP® Exam

The California PharmaLIGs have decided to implement another PMP Exam Preparation series of sessions over the summer 2007 using Webex Sessions. With this low cost preparation approach you can achieve your PMP certification this year no matter where you are located.

SCOPE

Enable interested project managers to prepare for the PMI PMP® Exam at a relatively low cost while minimizing time involvement and maximizing PMBOK® knowledge retention. The preparation sessions will provide you with the contact hours required for the PMP application.

WORK BREAKDOWN STRUCTURE

Step 1: 1-day LIG PMP Exam Strategy Meeting (one in Northern California and one in Southern California) to prepare the PMP application, discuss exam strategies and how to benefit most from the Exam Preparation Webinars

Step 2: A series of 24 1-hour PMP Exam Preparation sessions delivered as webinars (you connect with your computer to a URL and phone a 800 number) Each participant will be expected to read a specific area of the PMBOK before each webinar. You can attend all or only some of the PMP sessions (either attend live or view each session's downloadable recording). If located outside of California, you can start at Step 2 and request a one on one session to discuss PMP® Exam application and strategy.

COST

The PharmaLIG is a non-profit organization and will deliver these sessions at cost. The cost for exam materials, software licensing for the webinars, webex webinar data access as well as teleconferencing services is \$791 dollars per person. You will not find a cheaper option to prepare for the PMI PMP® Exam. Participation will be limited to the first 100 people (limitation due to the webex service).

SCHEDULE

Start date for the webinars: July 23th week

End date for the webinars: October 8th week

Two webinars per week on Tuesdays and Thursdays at 12 noon Pacific US time (3 pm EST US, 9pm London/Paris)

Northern and Southern California face to face meeting will be scheduled in early July

WHAT YOU NEED TO DO

If interested, email pmpharma@gmail.com for additional details or send a check in US Dollars (or a US dollars bank draft) before June 29 to PharmaLIG, 1221 Woodborough road, Lafayette, CA 94549 for \$791 to confirm your attendance.

A participant will need a computer with access to the internet to join these webinars

WHO CAN JOIN

This is open to anyone, whether you are a member of the PharmaLIG, PharmaSIG or a project manager with the desire to be PMP® certified.

Want to Discuss an Idea or Opportunity with Your Pharmaceutical Local Interest Group Leader?

California- NorCal and SoCal PharmaLIGs: Eric Morfin, PMP, 510-923-5456, pmpharma@gmail.com

New Jersey LIG - Mark Taras

North Carolina (Research Triangle) LIG - Derek Ross

Potential Brazil LIG - Douglas Sato

EU Regional Organizational Efforts - Mick Brown

Dare to Innovate... (continued from page 1)

represent an even more powerful resource to amass creative improvements. With initiatives transcending individual work silos, touching all aspects of the company becomes the sought after solution in the innovation equation.

It's an Age of Knowledge. Each of us is acutely aware of the era in time in which we live and work. We know that it's no longer a matter of how much information is collected, but which information is identified, transformed and reshaped into actionable initiatives for the individual, the team and the enterprise that is significant. Back in 2002, when we were conducting some research with the University of California at the San Diego campus, a couple of managers from Hewlett Packard approached us asking what we knew about Knowledge Transfer. In essence, we were asked "is there any software or hardware out there that would allow us to hook up people at the end of the day and suck out all the good knowledge they had in their heads?... you know...just in case they don't come back the following day?" Okay, perhaps this wasn't the literal question, but it was the gist, and it was a sentiment echoed amongst many companies, not just HP. After all, with the average technology professional adopting a life cycle of about two to three years of employment within any given organization, companies have been hard-pressed to hang on to any tribal knowledge.

As part of our knowledge transfer research, we worked with more than 140 mid to senior level managers representing more than 45 different companies – with most being the "who's who" of organizations. What we discovered in the way of findings was a great deal, but what baffled us was quite plain. Simply put, people go to people. People are the only entity equipped to synthesize data, filter, adapt, attract and influence others faster than any hardware or software system. It's the people who interpret what they know in order to transcend generation, culture, geography and the customer – all the way from product concept to project execution. If you want to transfer knowledge, pay attention to Joe and Sally sitting next to you as they're the best and fastest conduits for critical information translation and application.

John Kotter, in his model of Management vs. Leadership [Force for Change](#), 1990, makes the point that individuals must build a human network with which to execute their operational plans. For those who manage, Kotter suggests that it's all about establishing structure for accomplishing the plan, staffing that structure, and then delegating responsibility while setting policies and procedures to monitor the implementation. Certainly these are needful skills and tasks. But for those keen on leading, Kotter points to alignment of those around you. In other words, the emphasis is on communicating the future direction of the team, department or organization in sufficiently compelling ways so that those who need to cooperate can "buy-in" to the vision. Leading assumes that you tap into

what is really driving someone... motivating them... rather than merely assuming the act of delegation is in and of itself inspirational.

Knowledge Can be Lost in Database Translation

In addition to the human network concept, we also discovered that most tribal knowledge (all the great stuff in someone's head) is not explicit (written down so that others can reference it). And yet while many organizations require that best practices be captured and squished into databases for record keeping purposes, few access those online archives. In effect, the knowledge can get lost in database translation unless there is a person or people affiliated with that translation.

I'm particularly reminded of a software company known for their premier security and anti-fraud technology. As we sat in round table fashion asking a cross section of their management ranks how they transferred knowledge, we were surprised at their responses. Expecting them to respond with complicated data mining algorithm examples,

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we instead got "Well, if I want to know how to deal with the ACME Customer, I go see Dan because he worked with that customer last month and has a great rapport with them. If it's the latest model for data configuration, I go see Susan because she just finished a project on Tuesday in which she discovered a new formula to heighten anti-fraud..." And so you get the point.

Build Tribal Knowledge. Create a Campfire of Innovation.

In February of 2007, a group of seven scientists and technologists showcased the impact of capturing Tribal Knowledge via a shared research data portal. This was something akin to a Yellow Pages Directory, but on steroids. As part of an internal leadership development program with Amylin Pharmaceuticals (who has adopted the Dare to Innovate Community of Practice as part of their ongoing corporate learning endeavors), the group of seven's presentation began with an early episode of Star Trek in which Captain Kirk was visiting another planet. The tribal knowledge of the village resided in the Village Chief. The dilemma for Captain Kirk was that the bear ate the chief. No tribal chief, no knowledge. Captain Kirk had his hands full.

The group attested that for their research purposes, they wanted a data base repository but with built in connection

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to the individual or group affiliated with the studies. The Amylin group went on to present that individual scientists could input on their PC desktops what they were working on – whether results of lab experiment findings or project protocol, via a Wikipedia style search engine securely housed in their organization’s intranet. Further, they proposed that while their online portal would be piloted within the research department, it could easily be transferred (in template format) to other function groups.

Capturing tribal knowledge before it walks out the door (or gets eaten by the competitive bears) is no small thing for an organization. Which is why leveraging the tribal knowledge is key.

In twelve weeks, the brain trust capability of the organization increased significantly because seven scientists from a few sectors of the organization built themselves a little campfire of innovation to keep the big bad bears away.

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Chances are you’ve Already Got a Kitchen of Innovation Down the Hall

We’ve found that the best momentum in creating an Innovation Community of Practice is to piggy back onto a company’s internal leadership development program. By innovating and therefore leveraging how you are already developing your internal staff, you’ve got all the ingredients to create a Dare to Innovate Community of Practice. Referencing your organization’s internal leadership development process works best for several reasons:

- 1. Mid-level managers representing cross functional areas of the organization have already been (or can be) selected** for the express purpose of being groomed for an increased scope in both leadership role and responsibility. This means, you’re less likely to have any village idiots in the mix.
- 2. A common language around the organization’s view and standard of leadership** has been framed so that participating managers have a shared pool of meaning as to what leadership means and should therefore walk and talk like in the context of their particular company setting.
- 3. Organizations need more than happy face evaluation sheets** to know if their mid level managers have learned leadership and this provides an ideal format. While there’s

value in learning through a classroom experience, it doesn’t come close to rolling up your sleeves and deciphering real remedies in light of actual organizational challenges. In typical classroom settings, the teaching of leadership development doesn’t link immediately to business need, so it ends up being little more than an exercise. What better way to have a first row viewing to the leadership capabilities of your “group in training” than to immerse them in an innovation challenge?

4. Project management fundamentals serve the same kind of purpose in authoring change initiatives much as the Roberts Rules of Order would in a formal meeting. We’ve been students of organizational change processes for decades and we’ve been masters of project management for even longer. What we discovered recently (yes, we’re a bit slow) is that when you overlay project management fundamentals to change endeavors, you’ve provided a way to structure, bound and direct the otherwise fuzzy and squishy nature of change. Rather than it oozing through your fingertips, you’ve provided structure giving your change initiative something to stand upon. More importantly, the innovation or change initiative is forced to move very quickly from an ethereal philosophical concept to that which is concrete and tangible.

5. You’ve got the ear of executive leadership. When you pull a cross section of people away from their everyday jobs to go through a program, you immediately have the ear of the boss, if not their entire entourage breathing down your neck to see how time is being used. If you’ve got the attention of executive leadership, chances are you can make the business case (both intellectually and emotionally compelling) as you seek their sponsorship for change initiatives. With senior or executive management in the room, you’ve got the dare for change improvement being loudly sounded. In a sense, they’re dropping the proverbial glove to an outright innovation duel.

The Power of Seven

Pairing a small group of functionally mismatched and often inexperienced people may not win poster cover appeal as an Innovation Warrior Team irrespective of their being slated for leadership development. And, chances are, they would not be viewed by senior management as those most obvious to lead the innovation charge in new product or process identification. Unlikely grouping perhaps, but this band of collaborators represents a company’s best chance at hunting down innovation and piloting it within a twelve week span. Try to find any consultant firm who can perform that kind of feat in the same amount of time.

As a small team of five to seven, the group has the capacity of organizing themselves in quick order to either self select an organizational change initiative or to do a deep dive of a problem selected for them by senior management. As one of our students from Edwards LifeSciences recently stated after working with his team

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Dare to Innovate... (continued from page 7)

on their Innovation Community of Practice project, “It’s the Power of Seven. Who would have thought that such a small group from different function lines could come together so quickly and create an innovation initiative from scratch? More than that number and I don’t think we would have been successful. Decisions were arrived at quickly. We all had our hand in what was happening and we were all accountable to one another.”

In fact, when we began running Community of Practice initiatives with a variety of organizations a few years back, we gave the assignment to large groups thinking this would provide for greater agility and resources. After all, more people means greater expertise and nimbleness to conquer the change assignment more effectively right? Wrong- as we found to our chagrin. The larger the groups, the more chaos and waning motivation ensued. People got lost in the shuffle. At the end of the working sessions, no matter how many participants started off in the group assignment, the team ended up with a relatively handful of

The larger the groups, the more chaos and waning motivation ensued. People got lost in the shuffle. At the end of the working sessions, no matter how many participants started off in the group assignment, the team ended up with a relatively handful of people (typically not more than seven) to carry the initiative through.

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We also examined the merits of small team decision making in other settings, whether in traditional project settings or within functional group configurations. In all cases, we found that decision making worked best when the number was limited to not more than five or seven individuals. The larger the participant pool, the more the dynamics became muddled. We observed how some people were more likely to play to the audience in the room when the number exceeded a certain threshold. For every one who postured for spectators, we saw an equal number abdicate from the process. The abdicators saw little point in participating since there were so many others who would tackle the initiative.

The Power of Seven goes beyond the ability to better participate or more effectively make decisions. In The Tipping Point, Malcolm Gladwell writes of the “Law of

the Few.” Gladwell puts forward the premise that most of us gravitate toward a close circle of friends comprised of those with similar temperament to ourselves. Similar seems to equate with comfort for most of us and that appears to be a great motivator when selecting whom we will spend time with. However, Gladwell implies that in our quest for comfort we intentionally bypass the opportunity to connect with those who are different. Gladwell goes on to say that some individuals possess the rare gift of connecting with many people who are not only different from themselves in outlook, temperament and geography, but also in their functionality – what they do and how they go about it. These “connectors” as Gladwell points out, are individuals who have a network in which “word of mouth” has unusual meaning. When they pass along a “word” to those in their chain, people respond, *many* people.

“When you bring a small group of people together from different functions, each individual’s circle of acquaintances is added to and complimented by those who present a different set of experiences and view points.”

It’s been our observations in the Innovation Community of Practice that when you bring a small group of people together from different functions, each individual’s circle of acquaintances is added to and complimented by those who present a different set of experiences and view points. This is a connection that wouldn’t normally have occurred in the everyday underpinnings of the work setting. And with such a small and diverse group, there is little tolerance for grandstanding and no quarter given to those who seek abdication.

It seems fitting then that when you bring an assorted collection of individuals together to work on a change initiative, you offer up a fast track to more “bigly thinking”. We believe this is the heart of innovation. The ability of a small group of people (with different thinking) to connect with one another for the express purpose of discovering a product or process which seeks remedy to a void, a need... a pain present in the organization.

The Tribe of Seven is in the Kitchen. Now What?

There are five key questions to answer before launching your Innovation Community of Practice.

What’s the Organizational Pain?

We often begin the innovation discussion with “what is it our customers want, but don’t know they want it?” Not necessarily a bad question, but is it the best? What about asking where the pain is? If we could identify a process or a product that would reduce or remove pain – either for our

(Continued on page 9)

organizations or the customers we serve, what would that be? After all, haven't people been lining up for centuries looking for the magical cure for all their aches and woes? How are our organizations any different? When you can identify a throbbing pain in need of remedy, you have identified the first part of a compelling argument- both on an intellectual, as well as emotional, level. The second portion of the question to be answered is: How does this remedy (this innovative change initiative) link immediately to business strategy and results? When the philosophical or overarching big picture can be brought down to very concrete business terms, the compelling case is made complete.

We've found the following option combo works well: 1) Allow your group to choose from a list of pre-selected initiatives approved by Senior Management sponsorship and 2) Allow for the group to identify an initiative which they consider worthy, but in which senior management approval and sponsorship must be obtained.

Where Will the Innovation be Piloted?

Most organizational change initiatives fail before they start with *committee'd to death* the prime culprit for derailment. There's a myth that exists in our organizations "If we're going to do something, we're going to do it with everyone in mind. Let's have consensus and involve all key

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stakeholders." Okay, but why all function groups and why all at once? The more departments involved on the front end, the less likely you'll ever see a back end! Why not try out the knowledge before taking on the whole organization? Pilot in a small incubator-like setting where you can test the project before rolling it out to other groups. This setting should be part of the identification process of the Innovation Community of Practice. Most of the successful Innovation teams have elected to do their projects within one of the function groups represented in their teams. This provides a familiar laboratory where the change processes can be tried out and tweaked before rolling out to other parts of the organizations.

Who's the Corporate Champion?

It's very rare for grass root change initiatives to take hold which is why support from senior management is critical. With senior level sponsorship, barriers are removed from the innovation deep dive more quickly. With only 90 days to implement a pilot initiative, access to upper management makes the pathway a little less rugged.

Who Comprises the Tribe of Seven?

Do you have a variety of representation in your team setting? What about diversity of background and experience? As mentioned previously, more *bigly thinking* takes root when the network is varied. Generation, gender, ethnic and organizational differences spark greater *what if's*.

How SMART is the process?

Give teams tools. The best and simplest would be project management fundamentals with which to direct and bound the project (see project pre-nup later in this article). The SMART model is another helpful and simple guideline to jumpstart the team. Are the action steps associated with the piloted initiative Specific? What about Measurable so there's no doubt when achieved? Who's Accountable in each action? Are the recommendations Realistic given current organizational context? What Time boundaries (project scheduling) are required?

People Can Do Anything in 90 Days

What makes strategy tactical is the ability to translate the fuzziness of the vision into tangible and concrete actions. With organizations moving at high velocity speeds, and reorganization a frequent occurrence, translating that vision into action steps on a business quarter basis offers a reasonable and realistic time period with which to achieve immediate business results. Shifting objectives still whiz by, but at least workers have a sense of direction for the short term.

We've applied the concept of business quarter focus to the Innovation Community of Practice. More than 90 days and the likelihood of internal organizational change can often derail momentum for both the project team and the individual. People can accomplish a great deal when they know there's a short time frame with which to achieve the objective. Beyond the business quarter, the wear and tear of such intensive energy and focus seems to sap even the most stalwart of innovation champions.

Team members continue to perform their regular jobs in addition to the Innovation Community of Practice, and no doubt the added burden of a hefty project can be crazy making, but by and large the team figures out how to see the task through. Team members assign roles and responsibilities to offset schedules including unforeseen events. There are periods throughout the business quarter of project execution in which some members assume greater duties to cover for those obligated elsewhere. Others return from the responsibilities which took them away to step back in allowing team mates to have their

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Dare to Innovate... (continued from page 9)

turn at business travel or regularly scheduled projects. As leaders in training, they learn to figure things out.

The Project Charter – It's Like a Prenup

The choreography of developing and applying leadership principles, confronting innovation, acquiring project management skills is first seen in the Project Charter. This is the document given to innovation teams to launch their project organization. In a sense, it's like a pre-nup... only for projects. The Project Charter includes the following elements: overarching objectives of the initiative, targeted audience, what's in scope to the project, what's out of scope, expected deliverables, senior management sponsor identification, and so on. In a few brief pages, the team answers key questions:

Project Purpose & Objectives

What specifically are we doing and why?

Who is the Sponsor?

When we need decision making intervention from on high, whom do we go see?

Deliverables

What are the expected outcomes due at the end of this project?

Measurable Success Indicators

What exit criteria is targeted?

Project Scope

What's in... what's out?

Project Issues to be Resolved with the Sponsor Prior to Project Start

What clarification, if any, is needed of any deliverables and associated timeframes?

Assumptions

What other assumptions might exist which would influence project performance?

Project Manager(s)

Who will lead the project? Who is the back up?

Timelines

What are the milestone dates? Specific delivery dates?

Communication Strategy

*How will you communicate the framework, milestone markers, and clarify expectations? When will the F2F (face-to-face) meetings occur?
How and when will status communiqués be sent?*

What do I Need from the Sponsor to Begin the Project?

What notification to managers; access to stakeholders and/or users is required? When will I obtain commitment from senior management?

Other Issues Specific to this Project

The team determines if there are any other items or issues that need to be included in the project charter.

Handing the Baton to Sponsors and Senior Management

Innovation project teams define their charters and submit to their senior management sponsors for approval. Once approval is obtained, the teams then execute their initiatives and in most cases, conduct the pilot.

It's essential that ongoing support from sponsors and advisors be given throughout the process. Approximately 90 days after charter approval, project teams formally present their findings to sponsors, advisors and other levels of management.

An interesting and risky transition point is raised. Senior management is asked to take the baton of the initiative as handed to them by the Innovation Community of Practice. Since the initiative met with sponsorship approval from the beginning of the process, there should be no dispute as to relevancy of the initiative.

The risk exists when Senior Management is handed the baton, but drops it. This isn't to suggest that Senior Management is obligated to enforce the findings from the teams, but it does imply that some action on their behalf be forthcoming. Even if there is debate over the veracity of findings, it's important to act and make known the organization's intentions. If it's to go back to the drawing board, then so be it. Make that known. The worst case is to withhold a response or ignore it altogether. Without formal recognition of efforts spent, it's safe to say that the likelihood of future initiative from the rank and file is nil. And this could be a death blow to any organization.

Metrics of Success

We've seen many different metrics from the Innovation Community of Practice initiatives conducted to date. The following are just a few of the demonstrated results:

- Product and or process innovation.
- The creation of forums for communicating, scheduling and posting pertinent information which transcends functional positions and physical locations.
- Perseverance in light of time and resource constraints (current work priorities; travel).
- Increased network and collaboration.
- Shared knowledge.
- The ability to apply the difference between authoring a project initiative vs. editing.
- Coming face to face with the real art and science of "influencing" without title.
- Shared pool and framework of meaning.

Conclusion

In 90 days, with a project charter and seven focused people, organizations have the opportunity to author continuous improvement initiatives that bring about constructive change. Tribal knowledge is captured and packaged in ways that demonstrate a high degree of allegiance to tangible business results. Attributes of leadership are seeded leading mid level managers to learn by doing.

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Dare to Innovate... (continued from page 10)

Indeed, be careful when you dare a bright group to innovate. Chances are you will get more than you thought possible.

Examples of Innovation Community of Practices

Business Partner Best Practices

October 2006; Amylin Pharmaceuticals

Innovation Incubator

September 2006; Advanced Medical Optics

Project Lighthouse: Knowledge Management Tool

September 2006; Edwards Life Sciences

Talent Management Retention Strategies

September 2006; Beckman-Coulter

Developing Info Technology as a Strategic Resource

September 2006AMC

Improving Testing of Complex RF Circuits to Enhance

Product Cycle Times

May 2005; Skyworks

The Evolution and Impact of Corporate Cultural Beliefs
May 2005; Amylin Pharmaceuticals

Measuring and Improving Performance

June 2005; FileNet

Cross Functional Communication Forum

April 2004; Elan Pharmaceutical

Balanced Score Card Biology/Chemistry

August 2004; Merck Pharmaceuticals; San Diego Lab

Knowledge Transfer

Research Department Wikipedia Style

February 2006; Amylin Pharmaceuticals

Expanded Knowledge Portal for Equipment and People

Directory

March 2007; Edwards Lifesciences

Communication Plan for Rolling Out Lean Initiative

March 2007; Amylin Pharmaceuticals

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PMI Events

CEO Gregory Balestrero highlights the PMI Educational Foundation



On May 13, PMI CEO Gregory Balestrero conducted a presentation on the current programs, benefits, and future plans of the PMI Educational Foundation (<http://www.pmi.org/pmief/>).

The PMIEF promotes project management as a life skill as stated in its vision “To champion project management knowledge and skills for educational good.” Current programs are focused on providing resources for a variety of stakeholders.

Foundation programs geared for students include university scholarships and scholastic career day materials. Organizations and government agencies engaged in relief work are served by the *Project Management Methodology for Post-Disaster*

Reconstruction (<http://www.pmi.org/pmief/learningzone/PDRM.asp>). Civic and community groups are served by the Project Management Skills for Life initiative. Mr. Balestrero described the Foundation’s plans and activities to expand services to these audiences.

Scholarships are a meaningful way to help develop the next generation of project managers. Mr. Balestrero encouraged chapters, SIGs and colleges to endow a grant or a university scholarship through the Foundation – several components do so already. The PMIEF handles the administration of the scholarship.

PMIEF has partnered with prominent foundations, corporations and educational professionals to promote project management as a life skill through academic programs for primary and secondary school students. Mr. Balestrero said, “Building life skills for children also provides fundamental life skills that serve people in the work place once they graduate from school.”

Programs are also being pursued to help promote the advancement of project management methodologies, best practices, and education for international relief and development professionals. The PMIEF is collaborating with leading relief and aid organizations to identify needs of their field-based staff and ways to improve their project management capabilities.

Attention Program Managers: PgMP leads the way as a new global credential.

As the pilot period comes to an end, PMI plans to launch the Program Management Professional (PgMPSM) as a new globally recognized, technologically advanced credential.

For other PMI credentials, candidates apply for and schedule their examinations using PMI’s web-based certification software. With the launch of PgMP, PMI will take advantage of technology improvements to introduce a new three-step evaluation process for candidates to obtain the credential. These steps include:

1. **Application Review:** As always, applicants will use the online certification system to document their education and project and program management experience. Now, the software system allows a panel of program managers from across the globe to evaluate applicants’ professional work experience. The panel is able to conduct their reviews from multiple regions.
2. **Examination:** Once an application is approved, the candidate is eligible for the multiple-choice examination that evaluates his or her ability to apply program management knowledge to both situational and scenario-based questions. The examination will be available to candidates around the world at all Prometric test centers.
3. **Multi-rater Assessment (MRA):** Candidates who pass the examination progress to the MRA. This web-based procedure is similar to a 360-degree review process in which the candidate selects a team of raters who assesses his or her performance on tasks that are pertinent to program management. PMI makes use of web technology to administer this assessment globally.

Updates to PMI’s web-based certification system not only allows for this new credential process, but also enables PMI to introduce scaled scoring for two of the three PgMP evaluations—the examination and the MRA.

This type of scoring is designed to measure candidates’ performance against a minimum proficiency level known as the passing point. It allows PMI to update assessments quickly, maintain the rigor of the assessment and ensure that all assessments are of equal difficulty.

The research and development required to launch a new credential has provided PMI with information to strengthen processes and keep them consistently fair to all project management practitioners.

Web-based software enables global access to the PgMP application directly from the PMI website, (http://www.pmi.org/info/PDC_CertificationsOverview.asp?nav=0401). For more information on scaled scoring, visit the online FAQs, (<http://www.pmi.org/scaledscoringfaq.htm>).

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Applying PMBOK Principles to Clinical Submissions Utilizing Medical Imaging (continued from page 1)

- Advances in technology along with increased acceptance and usage of automated tools to review medical images in digitized format

For early regulatory agency reviews, RadPharm provided hard copy film upon request to support sponsor's submissions. By 2005, RadPharm, as well as other Imaging Core Labs, began to provide all, or subsets of all, images utilized in a clinical study in a digitized format for use by FDA reviewers. At this time, RadPharm recognized that it faced several challenges.

Challenges

A Phase III study utilizing medical imaging and biomarkers for surrogate end points can comprise tens of thousands of medical images, even for a small to mid-sized study. Although the company's back-end processes to collect and review the images are highly automated, images are received primarily via mail in hard copy (film) or electronic media (CD or DVD containing digitized images). The nature of the work, comprising individual review of each and every image received to ensure proper de-identification, readability, and completeness of an imaging series according to protocol, coupled with the very volume of information received, require additional quality checks at submission time. Although RadPharm's statistics show extremely low error rates for raw submission materials, the company's mission is to provide the material to regulatory agencies as close to perfect as possible.

Submissions are a team activity requiring coordination of effort from clinical trial team members, Quality Assurance, Information Systems, Data Management, Medical Affairs and Digital Imaging Operations, as well as interaction with sponsors and regulatory bodies. RadPharm faced a number of upcoming sponsor submissions with no dedicated staff to drive and coordinate the efforts. Previously, submissions had been approached as "one-off" type activities shouldered by individuals who also performed their usual day-to-day job assignments. By early 2006, the growing number of planned submissions promised to place undue stress on an already busy staff.

Each submission, although similar in form, can vary in detailed requirements, depending upon the study protocol and objectives. Additionally, although RadPharm works closely with the FDA and sponsors on determining the content and format for each submission, there are no published FDA guidelines specifically addressing Imaging Submissions.

RadPharm's executive management decided to address these challenges by forming a dedicated, core team responsible for coordinating submission activities and delivering finished submission materials to sponsors and agencies. A PMP certified professional with deep pharmaceutical industry experience was identified to lead this team.

Assessment

In early 2006, RadPharm was finishing one submission

project and identified plans for four more. (Eventually, a total of six submissions were completed in 2006 and one more was finalized in January of 2007). The newly formed Clinical Submissions Team found some strong project management practices in place, some practices needing additional attention, and a need for many more to be addressed.

Practice strengths:

- A Balanced to Strong Matrix organization, with the PM given clear support from upper management
- Readily identifiable and engaged internal and external stakeholders
- An engaged sponsor possessing a good understanding of his role

Practices needing additional attention:

- Quality was recognized as a high priority throughout the project team, but there was little differentiation between high and low importance items. Additionally, there were no formal quality checklists, metrics or baselines to guide team members.
- Each submission project was comprised of competent, dedicated, conscientious and motivated team members, but teams were at risk for low morale due to poor planning, coordination and communication.
- Rough project planning had been done and a plan framework existed, but updates were made after the fact and not generally communicated.

Practices lacking:

- Poor coordination and communication among team members. For example, key documents might be duplicated and no central storage location was identified with the result that important project information could become out of synch
- There was little risk management planning and all issues were treated with the same, critical, importance.
- Lack of clear task definitions for many activities sometimes left team members confused about what specific actions needed to be taken.
- There was no scope management and some project scope changes were made and incorporated on the fly
- No critical path assessment was done, and no project slack identified, so that all tasks were treated with equal weight and sense of urgency adding undue stress for team members
- No formal post-project feedback mechanism was in place to capture lessons learned from previous projects

Approach

As several projects were becoming active at or near the same time, RadPharm's Clinical Submissions Team decided to take an incremental approach to project management improvement. Those items most critical to good project management were attacked first, followed by those that could be implemented without undue effort, the "low hanging fruit". A brainstorming exercise was planned and executed, bringing together subject matter

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Applying PMBOK Principles to Clinical Submissions Utilizing Medical Imaging (continued from page 14)

experts in all applicable disciplines, to review the entire process and identify opportunities for improvement.

One item implemented immediately was up to date project planning. This included realistic estimates of upcoming tasks based upon previous project experience and input from staff members executing the work. Overlaying task identification and work effort required was scheduling based upon resource availability, including planned vacation or out of office time.

Updated project plans were regularly communicated to team members. This resulted in better team communication and identification of tasks without clear definition. Task descriptions were added, deleted or refined to reflect the actual work to be performed. Better and more active project planning resulted in more effective team meetings, taking less time, and overall improved team member morale.

Utilizing project planning tools, critical path tasks and tasks with slack could be readily identified and prioritized appropriately.

Another factor quickly addressed was the implementation of checklists for many activities; the most important being the quality control tasks performed while reviewing images and related data-driven reports. This not only provided focus for staff members performing QC, it

allowed for categorization and, ultimately, the development of metrics useful for feedback to process improvement efforts.

A post-project "lessons learned" meeting was implemented as the final task for each completed project. The teams discussed both processes that worked well, as well as areas that could use improvement. Ideas for improving processes were formally captured and used as input to the next project planning cycle.

Results

RadPharm successfully completed six Imaging Submission projects in 2006. Each project was completed within the time frame required by the project sponsors. Four of these became parts of submissions to the FDA requesting approval for New Drug and Biologic Applications. Two were approved and two more are pending reviewing.

As formal project management disciplines continued to be applied, each project, despite it's own set of unique properties, issues and concerns, became more manageable and predictable. Staff moral has improved, executive management confidence in the process has increased, and sponsors have been satisfied. Most importantly, RadPharm has assisted in the process to bring new, innovative, treatments to market for patients who desperately need them.

Career Opportunity

Healthpoint, Ltd. and Coria Laboratories are the operating companies of DFB Pharmaceuticals, Inc., created to market branded pharmaceuticals, over-the-counter drugs and medical devices, particularly in the areas of tissue management and skin treatment. Its experienced and knowledgeable sales and marketing teams focus their efforts on the professional healthcare markets of nurses, physicians and surgeons located in hospitals, nursing homes, home health agencies and office-based practices.

Healthpoint rewards its employees with a professional working environment, a competitive salary, a contributory 401(k) plan, an outstanding benefits package that includes health, vision, dental, paid short and long term disability and life insurance, plus paid holidays and vacation.

This Senior Project Manager role will be located in **Fort Worth, Texas** and a comprehensive relocation package is available. The position reports to the Director of Project Management.

SUMMARY

Establishes, leads, supervises, or directs company sponsored projects with respect to the design, development, and registration of Branded Pharmaceutical products. This includes all aspects of formulation development, scale up, and commercialization. Employs high quality, rigorous project management methodologies and approaches within project teams to drive project delivery to the required Gateway targets. Ensures that all projects are aligned to the needs of the business and that all stakeholder needs are identified and met. Overall, is seen as the "go to" person by the team.

EDUCATION and/or EXPERIENCE

Bachelor's Degree or equivalent in either the Biomedical or Pharmaceutical Sciences, or one of its sub-disciplines, with a track record of achievement in the pharmaceutical industry. Master's Degree or MBA preferred. Experience and working knowledge of regulatory pathways employed for product development, particularly in the USA, the EU and the relevant guidelines of ICH, FDA, EMEA etc., as well as GCP and GLP. International awareness of current trends in clinical methodology and relevant regulatory activities is essential.

OTHER SKILLS

Excellent communication and interpersonal skills are required. The candidate must be a team player with a proven track record of interdepartmental conflict resolution and communication. Ability to read, analyze, and interpret common scientific and technical journals, financial reports, and legal documents. The ability to effectively present information to top management, public groups, and/or boards of directors.

CONTACT INFO

Interested candidates, please email your resume to Erik Haven, HR Manager at erik.haven@healthpoint.com.