Mastering Advanced Clinical Project Management

Employing a systematic approach to Clinical Project Management for significant cost & time savings through effective Project leadership, planning and monitoring.

Singapore

13th & 14th October 2008

"Pharmaceutical projects are like fresh fruit - they depreciate if they are not tended to, and they do poorly if sitting on the shelf with long periods of inactivity."

R. Burns

Deploying forward thinking to ensure flawless execution among project team to improve budget, timeline, performance and people management in clinical and medical devices operations

marcusevans®

Facilitated by international consultant:

Eric Morfin PMP Chair
Pharmaceutical LIG "PHARMALIG "
Partner
Critical Skills Inc
Former Senior Director, Program Management, Aradigm
Former Senior Group Director Project Management (West Coast Head), Quintiles Inc
Former Project Management Office (PMO) Director, Novartis Vaccines and Diagnostics

This masterclass is the result of a long-term partnership between marcus evans, Critical Skills Inc and the PharmaLIG. Content and materials developed by Critical Skills, reviewed and approved by PharmaLIG .

Participants who successfully complete this masterclass will receive an official Certificate of Completion from PharmaLIG as well as credits (contact hours) toward a PMI PMP certification.

For all PMP's attending this masterclass, Critical Skills Inc in Partnership with PharmaLIG will issue 16 PDU's for attending this masterclass. The Certificate of Attendance will also qualify for 16 of the required 35 hours necessary to qualify to sit for your PMP. Additional PDU's and PMP Preparation materials (CD and live sessions) are available via www.PharmaLIG.org

A Singapore PharmaLIG meeting will be hosted on **13th October 2008** by **Allergan Singapore** from **6.00 pm to 8.00 pm**. There will be a networking session and a formal presentation on Best Practices for Global Clinical Trials by Eric Morfin.

Attendance to all delegates is **complimentary** and this meeting will offer an **additional 2 PDUs**. Participants will also receive a separate Certificate of Completion. **Meeting venue:**

Allergan Singapore Pte Ltd, 460 Alexandra Road, #05-01A, PSA Building, Singapore 119963

Endorsers

PM Pharma LIG
www.pharmalig.org

PHARMACEUTICAL SOCIETY OF SINGAPORE
NOT FOR SELF BUT FOR ALL

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Benefits of attending include:

- **Promoting** thought leadership in forward thinking to ensure seamless project management execution and high quality deliveries
- **Mastering** cost, time and people issues through essential project management tools
- **Developing** effective communication skills and mastering relationship within project teams
- **Ensuring** the project vision is effectively communicated to all stakeholders and is regularly reviewed
- **Designing** a performance environment that motivates all through clear expectations and consequences
- **Mitigating** and effectively managing potential project risks
- **Applying** a systematic method to prevent potential delays and complying with governing agency regulations for Root Cause Analysis
- **Conducting** effective project review meetings
- **Determining** the appropriate reporting for protocol deviations in Product Safety
- **Highlighting** key concepts for managing outsourcing projects
- **Managing** operation challenges in patient recruitment and retention

The participants will also benefit from:

- Exchanging experience and lessons learnt to further excel in clinical trials project management
- Better learning through lively interactive sessions: brainstorming, exercises, quizzes and roundtables

marcus evans training courses are thoroughly researched and structured to provide intense and intimate practical training applicable to your organisation. Benefits includes:

- Interactive roundtable discussions, breakout sessions and opportunity for one-on-one interaction with the trainer
- In-depth tailored programme to address market concerns
- Practical local and regional case studies
- Utilisation of the skills, learning, experiences and knowledge of the participants and masterclass instructor through interactive discussions and live demonstrations
- Comprehensive course documentation
- Official certification from marcus evans and PMI PharmaLIG
- Complimentary attendance to PharmaLIG official meeting

Pre-course questionnaire

To ensure that you gain maximum benefit from this event, a detailed questionnaire will be sent to all course participants to establish exactly where your training needs lie. The completed forms will be analysed by the course trainer. As a result, we ensure deliverance at the appropriate level and issues you regard as relevant are addressed. The comprehensive course materials will enable you to digest the subject matter in your own time.

Day 1

Monday 13th October 2008

Session One
Discovering your leadership style and potential
Having all the tools to plan, execute and evaluate your trials to avoid unexpected delays and crisis in trial projects is extremely valuable. All this can be ruined by using an inappropriate leadership style. Learn to avoid that critical mistake.

- Leadership Model
- Communication Model
- Coaching Model
- Critical skills case study: Individually - Complete the Critical Skills Personality Profile and learn how to lead with the strengths and weaknesses of your style. In groups, discuss how these profiles impact your relationship with CROs or other outside partners. Eric will share with you the most likely Personality Profiles you will encounter at selected local and international companies (including CROs, Large Pharma and several Biotechs)

Session Two
Performance Management (quality and timeline tracking and monitoring) / Site Management

- Form the Project Core Team
- Identify the right sub-teams
- Roles and Responsibilities of the project leader, project manager and functional representatives
- Develop internal and external stakeholder communication plans
- Project leadership skills
- Critical thinking skills to develop a high performing project team
- Critical skills case study: Creating a strong Asian team through Quality Focus and Training
- Critical skills case study: Project Management Scenarios: Managing an Asian Project Team in charge of a Pediatric Asthma project

Session Three
Critical PM application for regional / global trials

- Understanding the value of defining a Project Operating Guideline
- Ensuring proper documentation of trial delegation decisions
- Developing a project plan and scope
- Defining project performance metrics
- Implementing GCP compliant SOPs for Project Management
- Using Singapore as a Hub for Clinical Development
- Critical skills case study: Utilising electronic data capture across Asian sites: a real life experience
- Critical skills case study: Challenges in Vaccine Trials

Session Four
Time Management/ Delays tracking & prevention

- Timeline Management Core Concepts
  - Work Breakdown Structure
  - Duration versus Effort
  - Precedence Relationships and the role of the Critical Path
  - Gantt Chart and Resource Assignments and Preventing Over-Allocations
  - Communicating project progress to senior management
  - Communicating the degree of risk of a Pharmaceutical project to senior executives
- Tracking progress against objectives and the use of Milestones
- Developing and implementing strategies for accelerating clinical trial timelines
- Identifying and overcoming obstacles
- Critical skills case study: Developing a clinical trial timeline for a Phase II Asian Trial

Session Five
Root Cause Analysis (RCA) and Preventive/Corrective Actions
Keep your projects/studies on time by applying a systematic method for preventive potential delays and complying with governing agencies regulations for root cause analysis.

- Understanding FDA and International Regulatory agencies' requirement for Corrective Actions, Preventive Actions (CAPA)
- Responding effectively to non-conformances, failures, deviations and complaints by identifying root causes and implementing corrective and preventative actions
- Applying hands-on and practical RCA tools
- Understanding the closed-loop model for success
- Gathering, organising, and managing the data required to conduct RCA
- Performing trend analysis and using effective RCA tools
- Determining whether or not a complaint should go through a CAPA
- Integrating RCA with other systems: internal auditing, CAPA, and complaint handling

About the Endorsers

The **PharmaLIG** (Local Interest Group) provides a unique opportunity for project management professionals in the pharmaceutical, bio-tech, contract research and medical device industries to network with and learn from one another. The PharmaLIG was organised in 2004.

The **Pharmaceutical Society of Singapore** (PSS) is the only professional, non-profit organisation representing pharmacists in Singapore. Originally founded in 1905 as the Straits Pharmaceutical Society, our membership comprises pharmacists practicing in the community, hospital, marketing and sales, distribution, research, regulatory, and academic sectors. Today it is steered by an elected council comprising a president and 11 council members. PSS aims to improve the public's understanding of medication and its use, promote responsible self-care and promote safe and appropriate use of medicines.

About your masterclass instructor:

Eric Morfin PMP Chair
PharmaLIG www.pharmalig.org
Partner
Critical Skills Inc

Eric Morfin, PMP, has been a project manager since 1987. A sought after speaker on the subject of Project Management, Portfolio Management and Resource Management at North American and European symposiums and conferences, Mr. Morfin has been published many times in PM Magazines and Pharmaceutical publications. Mr. Morfin is an active member of several professional societies and has developed several unique seminars on Project Management in Drug Development such as "Project Management in Discovery and Preclinical" and "Project Management for Global Clinical Trials".

Mr. Morfin has worked and consulted with companies in a variety of industry settings throughout North America, Europe and Asia such as the World Bank, Merck Frost, Hewlett Packard, GlaxoSmithKline, Aventis, Novartis, Bristol Myers-Squibb, Aradigm, Quintiles and Astrazeneca to name only a few.

Prior to partnering with Novartis in the Bay Area, Mr. Morfin managed for 10 years the project management practice of a worldwide training and consulting organisation headquartered in the USA. Previously, he worked with a leading consulting group in the strategic field. In Europe, besides managing his own computer firm, dealing in digital animation, he created and managed an entire new division for Apple Computer. More recently, Mr. Morfin has worked for several large pharmaceutical companies, a small California biotech, a CRO and is now working with a leading biopharmaceutical company in Southern California.

Mr. Morfin is bilingual in French and English, has traveled extensively in Europe and Asia, earned his M.B.A. in International Business in San Francisco. He currently lives in San Diego with his wife and daughter.

Testimonials:

"Impressive knowledge of Clinical Trials. Brought a lot of credibility. The best course I have ever taken."
Director, Clinical Development
Novartis Pharmaceuticals

"Eric Morfin has very strong and practical knowledge of the subject matter and facilitated interesting and thought provoking discussions."
Regional Director of Clinical Operations
Asia Pfizer Global Pharmaceuticals

"Eric Morfin gave very practical examples. He was motivating, energetic, responsive to questions and gave examples of past experiences."
Associate Medical Director, Global Medical Affairs Asia Pacific
Bristol Myers Squibb Company

"This training is what I needed, what I was looking for. The trainer is an excellent trainer and a great expert in clinical project management. Abundant examples and workshops make the training easy to understand and remember."
Medical Quality and Planning Manager
Eli Lilly China

"A good combination of project management and clinical research training."
Head of Clinical Research
Boehringer Ingelheim China

"Great mix of presentations, case studies and real life applications. Eric is an excellent speaker and trainer."
VP, Clinical Development Operations
Wyeth

"Course discussions and case studies positively recharged my perspective on clinical trials in Asia."
Director, Strategic Operations, Asian Markets
MedImmune

Workshop schedule

0830	Registration and coffee
0900	Workshop commences
1030	Morning refreshments and networking break
1100	Workshop re-commences
1245	Luncheon
1345	Workshop commences
1500	Afternoon refreshments
1520	Workshop re-commences
1700	Workshop concludes

marcus evans would like to thank everyone who has helped with the research and organisation of this event, particularly the trainer, who has kindly committed and supported the event.

Day 2

Tuesday 14th October 2008

Register Now

Contact Marketing at **marcus evans**

Tel: +603 2723 6604

Fax: +603 2723 6699

Email: bernardinem@marcusevanskl.com

Session One

Budget Management: Financing and forecasting / Budget control

- Negotiating and managing investigator grants/contracts
- Developing a project budget
- Developing a tracking system for investigator budgets and project budgets
- Establishing a scope change management plan
- Critical skills case study: Developing an accurate project budget

Session Two

Project Risk & Product Safety Management

- Contingency planning and emergency issues handlings
- What level of monitoring is appropriate for each clinical trials
- Monitoring and reporting systems
- Making strategic decisions when progress deviations are observed by following a rational decision making process
- Conducting effective project review meetings
- Recognising reporting requirements for adverse events
- Developing a system for managing the reporting of serious adverse events
- Ensuring proper record keeping of adverse and serious adverse events
- Determining the appropriate reporting for protocol deviations
- Critical skills case study: Strategically synchronising your Asian operations with Global project deadlines
- Critical skills case study: Ramping up capabilities in a developing country to achieve global research efficiency levels

Session Three

Optimising patient recruitment & retention / Enhancing patient recruitment & retention rates

- Establishing a recruiting and enrollment strategy for investigators and for study subjects
- Managing advertising campaigns and dollars
- Discussing the use of centralised recruiting services
- Using newsletters to keep interest alive
- Effectively tracking enrollment with spreadsheets
- Identifying what to do when enrollment is not progressing
- Critical skills case study: Mastering Asian regulatory requirements to accelerate clinical trials
- Critical skills case study: Enrollment case study for Asian population (Specific genetic patients into 3 study sites)

Session Four

Managing operational challenges and achieving significant time and money savings by applying Best Statistics Practices to your operations

- Introduction and Overview of Common Statistical Tools
- Implementing Design of Experiments
- Applying Statistical Process Control to Project Management and Operations Management
- Interacting appropriately with company statisticians
- Designing a Statistically Sound Sampling Plan
- Statistically Analysing Annual Product Review Data
- Critical skills case study: Using statistics for site management, patient recruitment and enrollment

Session Five

Improving R&D Productivity and Capitalising on Asian Unique Characteristics

- Best Practices and Lessons Learned from Conducting Clinical Trials around the Globe
- Asia: each country was not created equal: How to select the right international collaboration
- Recognising and embracing cultural challenges in international collaborations and outsourcing
- Establishing recruiting and enrollment strategy for investigators and for study subjects

Session Six

Making strategic decisions to increase your R&D productivity in a Global Context (Focus on Asia)

- Initiating and implementing Drug Development Projects in Asia - The concept of Decision Generated Risk. Systematic Rules for Solving Trial Problems.
- Selecting the ideal packaging for a Product Launch in Taiwan and China
- Critical skills case study: Selecting the ideal packaging for a product ready to be launched
- Interractive Discussion: The Tablet in China is "Out of Round, Appears Old and Worn". How to rationally separate facts from opinions to arrive at a logical resolution.

Session Seven

Best Practices for Managing Outsourced Service Providers

- Outsourcing overview
- Key concepts for managing outsourcing projects
- The Professional Services Framework
- Preparing for implementation of an outsourced relationship
- Implementing controls for your outsourcing project
- Risk Management for outsourcing projects
- Transitioning the Organisation
- The Human Side of Outsourcing Projects
- Closing the Outsourcing Project
- Managing the relationship

Session Eight

Increasing your efficiency by maximising the use of Project Management Tools

- Timeline management tools and best practices (Microsoft project and other tools) - Live demonstration
- Designing and deploying an Enterprise Project Management (EPM) solution that is scalable and efficient
- Tools, Processes and Skills: What comes first?
- Critical skills case study: Using the tool on an Asian Clinical Trial Phase 2 Timeline Development

Session Nine

Pearls of Wisdom: Critical Ideas to remember and implement (summary of both days)

- Performance Management Best Practices
- Timeline Management Best Practices
- Budget Management Best Practices
- Risk Management Best Practices
- Recruitment and Retention Best Practices

Why you cannot miss this event

According to a PhRMA (Pharmaceutical Research and Manufacturers of America) annual survey, pharmaceutical companies sink 71% of their total R&D budget into drug development. Of that, a whopping 45% of total R&D spending is devoted solely to clinical trials. In addition, half the time (7-9 years) it takes to move a drug through the development pipeline to the marketplace is spent in the clinical trial phase.

Because those figures are so high, pharmaceutical companies face significant pressure to eliminate inefficiencies that add time and complexity to development processes. With the duration of patent protection limited, every day that is saved in the development stage can translate to a significant revenue boost after a drug reaches the market.

This Masterclass offers the advanced essentials of project planning, practical problem solving skills and leadership enhancement for clinical project leaders. The customised local & international case studies and practical example sharing promotes vital think tanks and relevant deployment to improve overall clinical trials management and its quality in the most cost effective and timely manner. It includes most current issues and creative solutions to challenges faced in trials planning, implementation and assessment in both internal, outsourced and partnered projects.

Several thoughtful interactive sessions and live demonstrations have also been carefully designed for this masterclass to encourage active participation in sharing and seeking knowledge among delegates. This is also the perfect learning ground of leadership and professional skills enrichment.

Who should attend

This event will be beneficial to any project leader in clinical development and drug development, particularly:

- Directors or Heads of Research & Development
- Directors or Heads of Clinical Trials / Clinical Research / Clinical Operation
- Directors or Heads of Clinical Development & Medical Services
- Clinical Project Managers or Senior Clinical Project Managers
- Clinical Research Managers or Senior Clinical Research Managers
- Clinical Research Associates or Senior Clinical Research Associates

From industries of:

- Pharmaceuticals
- Biotechnology / Biopharmaceuticals
- Drug discovery and development
- Life Sciences
- Contract Research Organisations (CROs)
- Hospitals / Research Centers

This event will also be beneficial to those involved in Product Development, Test Studies, Market Evaluation, Project Management and Engineering from the Medical Devices industry.

In-House Training Solutions

If you have a number of delegates with similar training needs, then you may wish to consider having an In-House Training solution delivered locally on-site. Course can be tailored to specific requirements.

Please contact **Sarah Faradilla** on +603 2723 6600 or email sarahf@marcusevanskl.com to discuss further possibilities.

Mastering Advanced Clinical Project Management

SG-LST1042 Please write in BLOCK LETTERS

Sales Contract

Please complete this form immediately and fax back to

BERNARDINE MICHAEL

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Authorisation

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Fees

☐ **Professional Training fee** @ USD2,295 + GST / VAT (if applicable) per delegate

☐ **Premier Plus** - Bring 3 or more delegates to this event and benefit from a 10% SAVINGS off the regular price

All options inclusive of course papers, luncheon, refreshments & service charge.

Indemnity: Should for any reason outside the control of **marcus evans** training, the venue or speakers change, or the event be cancelled due to an act of terrorism, extreme weather conditions or industrial action, **marcus evans** training shall endeavour to reschedule but the client hereby indemnifies and holds **marcus evans** training harmless from and against any and all costs, damages and expenses, including attorneys fees, which are incurred by the client. The construction, validity and performance of this Agreement shall be governed in all respects by the laws of Singapore to the exclusive jurisdiction of whose Courts the Parties hereby agree to submit.

Business Opportunities

A limited amount of exhibition space is available at the conference. Sponsorship opportunities covering the lunch and documentation also exist. For further details contact **Raj Anand** on (65) 6720 0620 or e-mail raja@marcusevanssg.com.

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Code:E

Contact Marketing at **marcus evans**
Tel: +603 2723 6604
Fax: +603 2723 6699
Email: bernardinem@marcusevanskl.com

Date: 13th & 14th October 2008
Venue: Singapore

marcus evans
CP 21 Suite 2101, Level 21 Central Plaza
34 Jalan Sultan Ismail, 50250 Kuala Lumpur
Malaysia
www.marcusevans.com

Payment Method

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Confirmation Details: After receiving payment a receipt will be issued. If you do not receive a letter outlining joining details two weeks prior to the event, please contact the training coordinator at **marcus evans** training.

Terms & Conditions

1.Fees are inclusive of programme materials and refreshments.

2.Payment Terms: Following completion and return of the registration form, full payment is required within 5 days from receipt of invoice. PLEASE NOTE: payment must be received prior to the conference date. A receipt will be issued on payment. Due to limited conference space, we advise early registration to avoid disappointment. A 50% cancellation fee will be charged under the terms outlined below. We reserve the right to refuse admission if payment is not received on time. Unless otherwise stated on the booking form, payment must be made in pounds sterling.

3.Cancellation/Substitution: Provided the total fee has been paid, substitutions at no extra charge up to 14 days before the event are allowed. Substitutions between 14 days and the date of the event will be allowed subject to an administration fee of equal to 10% of the total fee that is to be transferred. Otherwise all bookings carry a 50% cancellation liability immediately after a signed sales contract has been received by **marcus evans** (as defined above). Cancellations must be received in writing by mail or fax six (6) weeks before the conference is to be held in order to obtain a full credit for any future **marcus evans** conference. Thereafter, the full conference fee is payable and is nonrefundable. The service charge is completely non-refundable and non-creditable. Payment terms are five days and payment must be made prior to the start of the conference. Non-payment or non-attendance does not constitute cancellation. By signing this contract, the client agrees that in case of dispute or cancellation of this contract that **marcus evans** will not be able to mitigate its losses for any less than 50% of the total contract value. If, for any reason, **marcus evans** decides to cancel or postpone this conference, **marcus evans** is not responsible for covering airfare, hotel, or other travel costs incurred by clients. The conference fee will not be refunded, but can be credited to a future conference. Event programme content is subject to change without notice.

4.Copyright etc: All intellectual property rights in all materials produced or distributed by **marcus evans** in connection with this event is expressly reserved and any unauthorized duplication, publication or distribution is prohibited.

5.Client information is kept on **marcus evans** group companies database and used by **marcus evans** group companies to assist in providing selected products and services which maybe of interest to the Client and which will be communicated by letter, phone, fax, (inc. automatic dialling) email or other electronic means. If you do not want **marcus evans** to do this please tick this box [ ]. For training and security purposes telephone calls maybe recorded.

6.Important note: While every reasonable effort will be made to adhere to the advertised package, **marcus evans** reserves the right to change event dates, sites or location or omit event features, or merge the event with another event, as it deems necessary without penalty and in such situations no refunds, part refunds or alternative offers shall be made. In the event that **marcus evans** permanently cancels the event for any reason whatsoever, (including, but not limited to any force majeure occurrence) and provided that the event is not postponed to a later date nor is merged with another event, the Client shall receive a credit note for the amount that the Client has paid to such permanently cancelled event, valid for up to one year to be used at another **marcus evans** event. No refunds, part refunds or alternative offers shall be made.

7.Governing law: This Agreement shall be governed and construed in accordance with the law of Singapore and the parties submit to the exclusive jurisdiction of the Singaporean Courts in Singapore. However **marcus evans** only is entitled to waive this right and submit to the jurisdiction of the courts in which the Client's office is located.