

## REGISTRATION FORM

### RISK MANAGEMENT IN PHARMACEUTICAL TECHNICAL OPERATIONS

NAME

JOB TITLE

COMPANY/ORGANISATION

ADDRESS

TELEPHONE

FAX

E-MAIL ADDRESS

#### SESSION ATTENDING

**CORK**      **13 March 2007**      ☒

**DUBLIN**      **14 March 2007**      ☐

#### COURSE FEE

(includes Lunch, breaks and course notes) €895 + vat. Group discount of 20% for three or more participants from the same company/organisation.

- ☐ Send Invoice (PO must be received in advance of course)  
☐ Cheque (Payable in EUROS to Boyd Associates Ltd.)  
☐ Bank Transfer (Account number 42545383, Sort Code 90-57-66 at Bank of Ireland, Killorglin, Co. Kerry. )

Credit Card ☐  ☐   
Card Number -----

Cardholder Name

Signature

Exp Date      \_\_ / \_\_ / \_\_

#### HOW TO REGISTER

Log on to  
[www.boydassociates.ie](http://www.boydassociates.ie)  
Fax to: 066 - 7186144  
Post to: Boyd Associates Ltd.,  
Dromavally, Ballyseedy,  
Tralee, Co. Kerry



## PHARMACEUTICAL

## BEST PRACTICE SEMINARS

in association with



### "RISK MANAGEMENT IN PHARMACEUTICAL TECHNICAL OPERATIONS"

**TUESDAY 13 MARCH 2007**  
Maryborough House Hotel  
CORK

**WEDNESDAY 14 MARCH 2007**  
Hilton Dublin Airport  
DUBLIN

**BOYD ASSOCIATES LIMITED**  
Dromavally, Ballyseedy, Tralee, Co. Kerry

Tel      066 - 7186143  
Fax      066 - 7186144

email [info@boydassociates.ie](mailto:info@boydassociates.ie)

## COURSE PRESENTERS

### Jim McKiernan, CEO, McKiernan Associates, Basel, Switzerland

Jim is an engineer who spent eight years in manufacturing and supply chain in various management roles before moving into consultancy with PwC and IBM. He established his own consulting business in January 2004.

Jim works with life science companies to improve manufacturing and supply chain operations, both from a strategic and operational perspective. He was a pioneer in addressing the critical interface between R&D and technical operations and has led projects to implement risk management approaches within pharmaceutical manufacturing and clinical operations.

Jim is a recognised speaker at international congresses and meetings on topics spanning the entire spectrum of life science supply chain management and is a Senior Visiting Lecturer at University College London.

### Gene Boyd, MD, Boyd Associates, Tralee, Co. Kerry

Gene is a chartered accountant, qualifying in 1982 with KPMG, with more than seventeen years experience in pharmaceutical manufacturing, both in Bulk and Finishing plants as well as three years managing a Pharmaceutical Sales and Distribution company.

Gene has established his own consultancy business in 2006 to provide management support to pharmaceutical companies and to expanding indigenous companies in their early / mid development stages.

## WHO SHOULD ATTEND

Executives and Managers responsible for site or functional reporting - General Management, Production, Development, Quality, Supply Chain, Engineering, HR, EH & S and Finance.

## LEARNING OBJECTIVES

### After attending this course you will be able to

- Make the link between ICH developments and your company
- Identify areas in which Risk Management should be implemented
- Understand which Risk Management methodologies and tools can be deployed
- Use FMEA (Failure Mode and Effects Analysis) to begin managing risk in your site
- Develop a Risk Management Strategy and SOP which will enhance your standing with regulators

## COURSE DESCRIPTION

This will be a day long interactive course with case study material to allow you to understand recent important developments in risk management within the pharmaceutical industry and to translate these into practical applications in your company. The regulatory agencies, such as the FDA, have embraced risk management and have started using a "risk-based" approach in deciding how they conduct site inspections. We will explore the methodologies and tools used to manage risk in a technical operations environment and focus specifically on FMEA which has been endorsed by ICH as an important approach for Pharma companies. Practical, case-study examples will be used with working sessions to allow you gain "hands-on" experience of using the tools.

Attendee numbers will be limited to facilitate participation and interactive sessions.

## COURSE OUTLINE

### ■ 9.00 Setting the Scene

- Introduction & Objectives
- What do we understand by risk?
- How has Risk Management (RM) evolved?
- The ICH initiatives
- Status of ICH Q9

### 10.30 Break

### ■ 10.45 Risk Management in Pharma

- Risk elements
- Recognising and assessing risk
- The RM toolset

### 12.45 Lunch

### ■ 14.00 FMEA

- How it works
- Putting FMEA into practice
- Case study work

### 15.45 Break

### ■ 16.00 Implementing RM

- Setting up the RM programme
- Project management and sponsorship
- Change management issues
- A successful implementation template

### 17.30 Close

## COMMENTS FROM PREVIOUS COURSES

Comments from participants at previous Pharmaceutical Best Practice Seminars on Key Performance Indicators held in October 2006.

*"Interaction, open nature of forum, thought provoking"*

*"Meets specific requirements and key personal objectives of course"*

*"Very good course. I have some good information now that I can use back at site"*

in association with

