

Make sure you are up to date with current tools and techniques needed to deal with Pharma problems in an effective, efficient and compliant way

Attend this highly interactive two-day GMP Problem Solving course and you will leave with an understanding of how to use a wide range of problem-solving tools to solve problems that occur in a pharmaceutical environment, and also learn how to take steps to avoid these problems occurring in the first place. Inadequately dealing with problems, not getting to the root-cause of a problem and not taking effective correction and corrective action are becoming THE major findings at regulatory inspections. It is therefore critical that you deal with problems in a systematic, consistent, compliant and auditable way.

### Who will the course benefit?

Our GMP Problem Solving course is aimed principally at anyone needing to be involved in problem solving within a pharmaceutical environment, including Quality Assurance, Quality Control, Engineering, Production and Process Improvement personnel.

### Course overview:

Our highly interactive Pharma Problem Solving course introduces delegates to a wide range of problem solving tools that can be used to help solve problems that occur in a pharmaceutical environment. During the course a large number of methods that can be used to deal with problems are introduced, explained and examples provided of when they may be used. The course focuses on ensuring that the correct cause of a problem is identified, that the right measures are employed to deal with the problem and that monitoring occurs to ensure that the problem has been solved for good. In addition the course looks at common reasons for problems and highlights how many systems have inadequacies within them that actually cause problems themselves.



### Expert Tutors:



#### Peter Lavis

Arguably the finest Quality Management Systems tutor in the business, Peter's enthusiasm for quality system thinking and his outstanding training abilities have gained him international praise and appeal. Peter is a leading quality management systems auditor and encourages auditors to think outside the "GMP box".

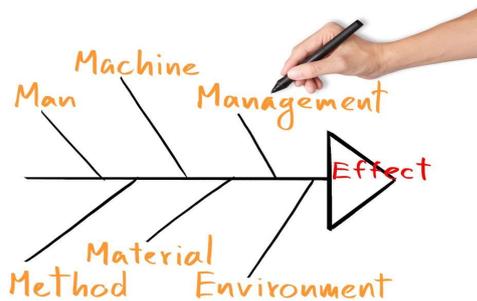


#### Dominic Parry

Dominic has worked in the pharmaceutical industry since 1992, and is a leading pharmaceutical quality management specialist. He is generally recognised as one of the leading GMP trainers in the UK and brings an enormous amount of interest, enthusiasm and fun into the training he presents.

## Course contents:

- Types of problems and deviations
- GMP requirements for dealing with and documenting problems
- The new GMP Chapter 1 and Chapter 8 requirements for Problem Solving
- Tools used to grasp the situation
- Data gathering tools:
- Charts and Graphs
- Fishbone Diagrams
- 5-Whys
- The differences between Correction, Corrective Action and Preventive Action
- Ensuring that the true cause is found
- Monitoring actions to confirm the correct steps have been taken
- Common reasons for problems
- Human error – or not?
- Problems with communication, documentation and training
- Being more proactive and less reactive
- Continual improvement mechanisms
- Managing deviations and outstanding actions
- The role of Senior Management with Problem Solving
- Risk management tools, such as HACCP and FMEA and how and when these can be used
- Documenting Deviations and Problems in a compliant manner



- Brainstorming
- Is/Is not, 5 “W”’s and a “H”
- Root-Cause Analysis tools:
- Cause and Effect
- Pareto Analysis

## Course feedback:

This **highly praised course** is presented as both a public course or for in-house presentations. **Delegate feedback is outstanding**, with a selection of feedback shown below:

***“Great tutors – engaging and fun to learn”***

Upstream Scientist, ALLERGAN

***“Very useful, relevant and addressed key issues.”***

QA Specialist, ACTAVIS BIOLOGICS

***“More fun than expected”***

Buyer, GR LANES

***“Excellent as always”***

QA Manager, PHE

***“A good introduction to the subject. Excellent – well delivered and great content”***

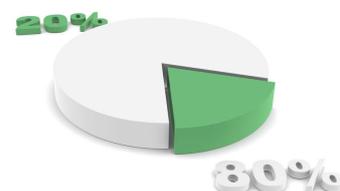
Analytical Scientist, ALLERGAN

***“Excellent materials – the time flew by”***

Senior Production Operator, ACTAVIS BIOLOGICS

***“Kept everyone captivated”***

Team Leader, GR LANES



# GMP Problem Solving course

## Course dates, venues and times:

Please see below for full details of the course venues. If required you should book accommodation yourself directly with the hotel. It is recommended that delegates stay at or close to the course venue. Please note that the cost of accommodation is not included in the course cost.

### Thursday 6<sup>th</sup> – Friday 7<sup>th</sup> June

Reading, Berkshire UK

### Tuesday 26<sup>th</sup> to Wednesday 27<sup>th</sup> November

Reading, Berkshire UK

## Times:

Day 1: 09.00 – 16.30      Day 2: 09.00 – 16.00

## Venue details: Reading , Berkshire, UK

The Holiday Inn – Reading South, 500 Basingstoke Road, Reading, Berkshire, RG2 0SL, UK. The hotel is very close to Junction 11 of the M4 – 25 miles west of London's Heathrow Airport.

Telephone: + 44 (0)871 942 9067

e-mail: [reservations@hireadingsouth.com](mailto:reservations@hireadingsouth.com)

Web: <http://www.hireadingsouthhotel.co.uk/>

A special rate of £121 (including VAT) has been agreed with the hotel (subject to availability). This is for Bed and Breakfast and includes internet access. Quote "Inspired Pharma" when making your booking.

## Costs:

The cost of attending is **£1300 plus VAT** per delegate for the 2-day course. **For group booking discounts of up to 50% for more than one delegate please visit our website for further information.**

The cost of accommodation is not included in the course cost. If required you should book accommodation yourself directly with the hotel. The cost includes:

- Refreshments and lunch during the course times.
- Course folder containing copies of slides and supplementary notes and handouts.
- Course attendance certificate.
- Full tutor support and access during course times.

The course will be charged in GB pounds. VAT (tax) will not be charged for courses held outside the UK. VAT will be charged for the courses held in the UK, however delegates from outside the UK but within the European Union (EU) will not be charged VAT if they supply their own company's national VAT number when booking. VAT will not be charged for any delegates coming from outside the EU.

## Payment and cancellations:

Full payment must be made before the course start date in order to secure a place. Payments will only be refunded in full if cancelled in writing 4 weeks before the start of the course. Delegate substitution is acceptable but please inform us.

## Contact us:

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Registered in England and Wales

Telephone: + 44 1635 866699  
Company Registration Number 7125386



Please book via  
our website  
[www.inspiredpharma.com](http://www.inspiredpharma.com)

