

Programme			
Dates: 9th - 10th March 2010		Day One Tuesday 9th March	
Venue: Madingley Hall, Cambridge		Day Two Wednesday 10th March	
<p>This new, highly interactive course will provide state of the art guidance on how to implement quality systems into the research environment. The programme is delivered by leaders in the field who quite simply, "Have Done It". Whether you are at senior management level seeking strategic direction, a new lab head wishing to deliver science that will stand the test of time or a quality professional thrown in at the deep end, this course will provide key insight and practical guidance to underpin your future success. Based on phase appropriate systems, tried and tested over many years in the field, the programme will help you define, train, implement and monitor the quality of your research, irrespective of field or discipline. Position your organisation for the future success it deserves.</p> <p>The benefits of the course are multiple. You get immediate access to highly experienced workers in this challenging field, who will share their experience and insight in an area where few others have been successful. Accordingly, you will be guided thoughtfully through each key component of the initiative in a stimulating learning environment crafted to deliver clarity from the onset. The course probes all avenues of the research quality arena, from an initial understanding of the cultural aspects of the scientific discovery environment, to how to manage quality in outsourced research programmes. Computer systems and e-data security in the research environment will be discussed in detail and pragmatic solutions described to help manage the ballooning cloud of e-data. In addition, the ever blurring boundary between the regulated and non regulated research environments will be discussed and delegates given perspective of future developments in the field.</p> <p>The course is designed for all those involved in the research quality arena and has been tailored to meet the needs of scientific management, bench scientists and quality professionals alike. With this knowledge, you will get it 'Right First Time'.</p>		<p>8.50 Registration</p> <p>9.00 <b>Welcome and Introductions</b></p> <p>9.30 <b>History and Overview of the Field, Examples of Business and Regulatory Risks, Consequences of Low Quality in Research</b></p> <p>10.30 Break</p> <p>10. 50 <b>The Culture, the Politics, the Scientist's Perspective</b></p> <p>11. 50 <b>What's out there already – Standards and Guidelines</b></p> <p>12.30 Lunch</p> <p>13. 15 <b>Group Breakout – What do you think are the Critical Success Factors for the Implementation of a Successful Quality System?</b></p> <p>13. 45 <b>Debrief and Summary</b></p> <p>14.15 <b>Training – Get it Right First Time</b></p> <p>14. 45 Break</p> <p>15. 00 <b>Implementation and its Challenges "If I have to do this I will have to stop my Science!"</b></p> <p>16. 00 <b>End of day wrap up and debrief</b></p> <p>16.30 Close of day</p> <p>19.00 for 19.30 Course dinner</p>	
		<p>9.00 <b>This highly interactive session will go through a compliance assessment programme in detail and will cover key topics including:</b></p> <ul style="list-style-type: none"><li>▪ Strategy Definition</li><li>▪ Management Buy In</li><li>▪ Preliminary Communications</li><li>▪ Opening Meeting</li><li>▪ Audit Scope and Requirements</li><li>▪ Data Ownership Reviews and Data Selection</li><li>▪ Archives and IT Infrastructure</li><li>▪ Data Reconstruction Interviews</li><li>▪ Updates</li><li>▪ Escalation</li><li>▪ Closing Meeting</li><li>▪ Report Writing</li><li>▪ Report Communication</li><li>▪ Programme Iteration &amp; Continual Improvement</li></ul> <p>Q&amp;A</p> <p>12. 30 Lunch</p> <p>13. 30 <b>Computer Systems in the Non-regulated Research Environment</b></p> <p>14. 30 <b>Research Outsourcing &amp; Quality – What Can Be Done</b></p> <p>15. 15 <b>The Future</b></p> <p>15. 45 <b>Conclusions and Wrap Up</b></p> <p>16.00 Close of course</p>	

Course Tutors		Course Fees		Accommodation	
				(not included in course fees)	
<b>Stephen Volsen</b> QA Auditor, Novartis Pharma AG (Course Principal)		<b>Association Members</b>	<b>£750</b>	<b>A. Dinner and accommodation on 8th March</b>	<b>£110</b>
<b>Louise Handy</b> Head of Regulatory and Quality Affairs, OI Sciences Limited		<b>Non Members</b>	<b>£910</b>	<b>B. Course dinner and accommodation on 9th March</b>	<b>£110</b>
<b>Marc Masson</b> Eli Lilly and Company		(all prices are in GB Pounds and include VAT at the standard rate).		<b>C. Day Delegate including course dinner on 9th March</b>	<b>£45</b>
<b>Peter Esch</b> Senior Auditor IT Systems, Novartis Pharma AG		The member rate is available as a concession to those working in relevant charities and academic institutions or for the NHS. Concessions cannot be booked online. Please see the Terms and Conditions for more information.		<b>D. Day Delegate (no course dinner or accommodation)</b>	<b>£0</b>
				All bedrooms have ensuite facilities	

The Research  
Quality Association

Date \_\_\_\_\_