

Name	Job Title	Qualifications
Ms. Vanessa Hyde	Quality Assurance Director	MSc, BSc Med Hons, BSc, DipClinRes, CertQMgt, IRCA Reg

Employment History : Vanessa Hyde

Year	Company	Job Title / Description
2005	Shandon Clinical Trials Limited	Quality Assurance (QA) Director
2000 – Present	Shandon Clinic Group	Quality Assurance (QA) Director
1997 – 2000	Shandon Clinic Group	Group QA Manager
1996 – 1997	Shandon Clinic, Cork	Quality Assurance Manager
1994 – 1996	Shandon Clinic, Cork	Project Manager & QC Officer
1991 – 1994	Shandon Clinic, Cork	Clinical Research Assistant
1990 – 1991	Stowford College, UK	Biology Teacher (GCSE)
1990	Waterford Clinical Associates, Cork	Research Assistant

Higher Education : Vanessa Hyde

Year	Awarding Body	Details
2007	IRCA	Lead Auditor Certification
2006	IRCA	Internal Auditor Certification (IRCA Registered)
2002	Liverpool John Moore University	MSc in Clinical Research <i>Thesis : Defining the Healthy Clinical Trial Volunteer</i>
1998	University of Wales, Cardiff	Diploma in Clinical Research (Distinction awarded)
1996	Irish Quality Association & Cork Institute of Technology	1yr Certification in Quality Management (CertQMgt)
1995	Irish Quality Association Certificate	10 week course: Installing a Quality System
1989	University of Cape Town	BSc Med Sci Hons (Sports Medicine)
1988	University of Cape Town	BSc (Zoology & Psychology)
1984	Kaffrarian High School for Girls	Matriculation (Mathematics, Science, English, Biology, Geography, Afrikaans)

Professional Development : Vanessa Hyde

Date	Conference Attendance	Details
April 2007	BARQA Regional Meeting (As a Speaker on “Using ISO to audit non-GxP Suppliers”)	Irish Regional Meeting, Various GCP/GMP/GLP Topics
20 th April 2006	BARQA Seminar: Network Infrastructure Qualification	BARQA 1 Day Seminar on Qualifying Computer Networks
21 st October 2005	BARQA Regional Meeting (As Speaker on “Auditing Statistics”)	Irish Regional Meeting, Various GCP/GMP/GLP Topics
20 th January 2005	BARQA Seminar: Auditing Statistics	Pamela Charnley Nikols (BARQA 1 Day Seminar)
21 st – 23 rd June 2004	BARQA Computer Validation Course	3-Day Workshop @ Maddingley Hall Cambridge
10 th November 2003	Irish Regional BARQA Meeting	1 Day Meeting Legislative Updates
5 th – 7 th November 2003	BARQA Annual International Conference	Nottingham, UK “Seeing the Wood for the Trees”
11 th Feb 2003	BARQA Meeting : EU Clinical Trials Directive	One Day Seminar : Guidelines on the EU CT Directive
18 th Sep 2002	BARQA Regional Meeting	One Day Irish GCP/GLP Meeting
30 th April – 3 rd May 2001	BARQA International Conference, Prague	QA Sans Frontiers : Breaking down the barriers
11 th October 2001	BARQA Professional Development Seminar	Systems Audits in Clinical Research
22 nd March 2001	BARQA One Day Seminar	Computer Systems in Clinical Research : Are you at risk?
10 th – 12 th April 2000	DIA 11 th Annual Meeting Barcelona	Statistical Methodology in Clinical R&D
5 th – 7 th May 1999	BARQA International Conference, Dublin	
29 th – 31 st March 1999	ACRPI Annual Spring Conference, Brighton	The Millenium and Beyond
28 th November 1998	Quality & Training Solutions	Current Trends in GLP
25 th – 27 th February 1998	BARQA Short Course	GCP Auditing : A Practical Approach
17 th June 1996	Henry Stewart Conference	“The Clinical Trial Audit”
20 th – 22 nd November, 1995	BARQA Annual Meeting	Effective Quality Training, QA of Multi-site Studies, Mock Audits, Discussions

BARQA (British Association of Research Quality Assurance), DIA (Drug Information Association)

Current Job Skills, Responsibilities & Major Projects : Vanessa Hyde

Area of Responsibility	Projects / Outputs	Relevant Job Skills
Quality Assurance (QA) Systems	<ul style="list-style-type: none"> ❖ Management & development of GCP QA Systems ❖ Policy & Procedure Development ❖ Computer System Validation & Audit 	<ul style="list-style-type: none"> ❖ GCP Audits : Systems, Study Specific & Reports ❖ SOP Development, ICH GCP Compliance, Industry Updates ❖ FDA 21 CFR Part 11 Compliance
Staff Training & Development	<ul style="list-style-type: none"> ❖ Training Records Design & Upkeep ❖ Training Needs Analysis (TNA) ❖ Training Delivery 	<ul style="list-style-type: none"> ❖ Management of Staff Training Records ❖ Undertaking TNA / Supervision of ongoing GCP Staff Training ❖ Delivering training to all staff (all levels)
Study Design	<ul style="list-style-type: none"> ❖ Protocol Design ❖ Case Record Form Design 	<ul style="list-style-type: none"> ❖ QA of protocols & study documentation – in accordance with GCP, EC, IMB, SOPs & Sponsor requirements
Clinical Trial Reporting	<ul style="list-style-type: none"> ❖ Clinical Study Report 	<ul style="list-style-type: none"> ❖ All reports audited to ICH GCP and in accordance with SOPs
Standard Operating Procedures (SOPs)	<ul style="list-style-type: none"> ❖ SOP Design & Approval ❖ SOP Review, Monitoring & SOP Audits 	<ul style="list-style-type: none"> ❖ Design & Management of company SOPs ❖ Auditing procedures against written SOPs, review & update of SOPs, SOP training for all staff members
GCP Auditing	<ul style="list-style-type: none"> ❖ GcLP Auditing of Central Labs ❖ Phase I & Phase IV Clinical Trial Audits ❖ Facilities Audits ❖ Vendor Audits 	<ul style="list-style-type: none"> ❖ Clinical Trial laboratory audits to GCP and GcLP ❖ All stages of study audits ❖ Conducting audits to ICH GCP, Current EU Clinical Trial Directive , IMB Clinical Trial Act, company SOPs and appropriate FDA guidelines

GCP (Good Clinical Practice), IMB (Irish Medicines Board), EC (Ethics Committee), GcLP (Good Clinical Laboratory Practice)

Vanessa Hyde

Date