DCVMN workshop QMS: Gap analysis, CAPA and environmental monitoring

(Hanoi, 23 November 2015 to 27 November 2015)
MR. STEVE WILLIAMS

Steve has over 40 years’ experience in the Biotechnology, Pharmaceutical and Medical Device industries in Quality Systems, Compliance and Manufacturing, including 25+ years consulting in GxP Quality Management and Regulatory Compliance.

Steve conducts FDA and EU/TGA/PICs compliance audits and gap analyses, assists companies with remediation programs and prepares companies for regulatory inspection. He has developed multiple training courses in PQS, GMP, GLP, Process Validation, Risk Management, Sterile Manufacture and Medical Device Quality Systems.

Steve is a registered auditor for the Australian Pesticides and Veterinary Manufacturing Authority and a past member of International Board of Directors for ISPE.

MR. PAUL FLETCHER

Paul has over 25 years’ experience in the Pharmaceutical and Life sciences industry as a Manufacturing/Operations Manager, Engineer and Consultant. From 2011 to 2014, Paul was the Manufacturing Manager for the Australian Red Cross Blood Service.

Prior to this, Paul worked in project management, qualification and validation, Production / Manufacturing and Operations Management with Sandoz, AstraZeneca, Schering-Plough, Seer Pharma and iNova. Paul has extensive industry and consulting experience in compliance, interpretation and practical application of TGA/PICs and FDA GMPs and in continuous improvement, change management and productivity improvement.

Paul is a current Director of ISPE (Australia).

MR. TREVOR EDWARDS

Trevor has the immense privilege of working as a consultant for the DCVMN in Switzerland, a Senior Sales Consultant for IPG in the UK, and as the director of Global Metanoia in South Africa. Previously he was the head of the training section at the Biovac Institute in Cape Town, South Africa; as well as a freelance professional speaker and events planner.

His passion in life is people. He loves people and loves helping people develop and grow in all areas. It just so happens that his other passion is training and public speaking, which happily results in Trevor loving the work he does and inspires him daily.