

Biography

Bob McDowall is an analytical chemist with over 45 years of experience. After graduating from the University of Newcastle-upon-Tyne in 1972 he completed his PhD at the Department of Forensic Medicine, London Hospital Medical College, University of London in 1977. Then, he worked for two major international pharmaceutical companies working in bioanalysis for 15 years. In 1990 he was a co-chair of the first Bioanalytical Methods Validation meeting that was co-organised by the American Association of Pharmaceutical Scientists and the Food and Drug Administration. He was a co-author of the subsequent publication that was a major input into the FDA's Guidance for Industry on the subject issued a few years later.

In 1993 he set up his consultancy practice. Initially, this was McDowall Consulting but this entity was replaced by R. D. McDowall Limited, founded in 1998.

Bob's interests are process improvement, laboratory informatics, computerised system validation including Part 11 and data integrity, quality software development, interpretation of GXP regulations and laboratory automation. He is also a trained auditor working in the GLP, GMP and GCP areas.

He has published widely for over 40 years including editing the first book on LIMS in 1987 and for his work in training and advancement of the subject he was presented with the 1997 LIMS Award by the LIMS Institute. Bob has written the Questions on Quality column in LC-GC Europe since 1993 and the Focus on Quality column in Spectroscopy since 2000. He is also a presenter and trainer giving many presentations and short courses in his subject areas.

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He has been a contributor to the GAMP Good Practice Guides for IT Compliance (2005) and Control and Risk Based Validation of Laboratory Computerised Systems second edition (2012). Bob was a co-author of a stimulus to the revision process of United States Pharmacopoeia general chapter <1058> in January 2012 and the final version will be published in USP XXXX 1st Supplement in 2017.