

Katarina Eghan, BSc (Hons), MSc, MRQA

Head of Clinical QA Services, TMQA Managing Director, TMQA Central Europe

Katarina has been professionally engaged in GCP and GMP (IMPs) since 2005 when she took up the position of Pharmacy Technician/Production Manager at Quintiles' Phase I Unit in London (UK), following Pharmacy positions in St Georges' Hospital NHS Trust, London (UK).

After more than three years at Quintiles, where her responsibilities also included Health & Safety and Radiological Protection, Katarina was appointed as the QA Manager at Richmond Pharmacology in London (UK), a Phase I Unit. Here she was responsible for all aspects of the QMS, including assurance of GCP/GMP compliance, management of procedural documents and CAPA processes and hosting external client and regulatory audits. She also provided guidance and training to staff on GCP, GMP, SOPs and inspection readiness.

In November 2010 Katarina took up the position of Specialist, Therapeutic Area Clinical QA with Janssen, Pharmaceutical Companies of Johnson & Johnson. Her duties included all aspects of the preparation, conduct and reporting of audits of phase I-III clinical trials, as well as response/CAPA review and follow-up. Additionally, she provided QA support for compounds in clinical development, including but not limited to, audit planning for global clinical trials and the management of the information derived from audits in order to track trends and achieve improvements. She also assisted in the preparation for and hosting of regulatory inspections.

Katarina joined TMQA in November 2013 as Principal Associate (GCP). In January 2014 she became responsible for TMQA's Central European operation in the Slovak Republic which enhances the 'GxP' support offered to clients, particularly for audits in Central and Eastern Europe. She became the Head of TMQA Clinical QA Services in May 2018.

In 2013, Katarina was awarded the degree of Master of Science in Quality Management in Scientific Research and Development from Cranfield University (UK). Her thesis was entitled 'The Clinical Quality Audit Function in Drug Development: a Study of Internal Stakeholders' Perceptions'. She also holds a Bachelor of Science (Honours) degree from the Open University (UK) in the subject area of mathematics and statistics. Katarina speaks Slovak (mother tongue), English (professional level proficiency), and Czech (professional level proficiency).

She is a member of the Research Quality Association (RQA) where she actively participates in the QUASAR Group. She was previously member of the Education & Training Committee between 2013 and 2016 and the Publications Committee between 2013 and 2017. Katarina has co-authored RQA's booklet 'Management of the training and competency of personnel in GxP and research environments Part 1: An introduction to training systems' and has written articles for RQA's magazine QUASAR.