Maxim Bunimovich, MD, MRQA

Senior Quality Assurance Associate, TMQA

Maxim has been professionally engaged in GCP since 2008 when he took up a CRA position at Quintiles Russia, following graduation from occupation diseases residency of St. Petersburg Medical Academy, St. Petersburg (Russia).

After more than two years at Quintiles, Maxim was promoted to the role of a Senior CRA. In less than one year he became the Clinical Operation Quality Specialist supporting the Quality Management Department in Russia. Here he was responsible for different aspects of the clinical QMS, including conducting proactive risk identification and management activities, performing Site Quality Assessment visits, hosting and follow up of audits and inspections (EMA, FDA, local regulatory authority), management of quality issues, nonconformities and CAPAs, reviewing quality trends, development of efficient tools, procedures and processes for quality monitoring as well as acting as the subject matter expert regarding regulations and quality inquiries. In April 2013 he was promoted to Clinical Operation Quality Manager and his responsibilities were expanded to leading all activities related to the maintenance of high quality standards on country and assigned global project level and mentoring of other junior Clinical Operation Quality Management staff members.

In October 2016 Maxim took up the position of Quality Assurance Director in the CRO Gaea Clinical (UK). He was responsible for all aspects of the CRO's QMS management, including the conduct and reporting of GCP investigator site, TMF and clinical vendor (e.g. EDC, pharmacovigilance) audits, development and implementation of the electronic Learning Management System, development of different quality documents (SOPs, working instructions, project Quality Management Plans), and management of CAPAs and quality inquiries. Additionally, he acted as the subject matter expert for quality related questions. He also assisted in preparation for and hosting of sponsor audits.

In autumn 2017 he became a GCP auditor and QA consultant, delivering independent international GCP site (phases II-III), vendor and TMF audits on behalf of pharmaceutical and biotech companies. This included reviewing audit responses and associated CAPAs for suitability and their follow up. Maxim also worked as a Compliance Manager for a European CRO where his responsibilities spanned from the development of Risk-Oriented Clinical Operation Quality Control System and the delivery of Quality Control Visits across Europe to the planning and delivery of educational lessons learned sessions and workshops to CRO staff.

Maxim joins TMQA in June 2018 as a Senior QA Associate (GCP) with the key responsibilities being the independent planning, conduct and reporting of audits and providing expertise in areas of GCP and clinical trial conduct. Maxim is able to conduct audits in English and Russian and also has a limited working proficiency in Spanish.

He is a member of RQA and he actively participates in regional RQA activities in Russia, such as the development of the Russian RQA forum. In December 2017 Maxim created a social media group "Quality Management in Clinical Trials", focused on sharing of knowledge and experience amongst QA professionals in Russia. Maxim has participated in the development and delivery of various educational sessions aimed at a wide audience in Russia ("GCP advanced training" and "QMS in clinical trials" workshops).