QUNIQUE & Evnia Partner To Expand MDR & IVDR Services

QUNIQUE and Evnia are announcing their strategic partnership to bring innovative solutions. The two companies are joining forces to better assist their clients in the areas of regulatory affairs, quality management and pre-clinical/clinical documentation, with an in-depth focus on the new EU Medical Device Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR). The partnership also brings clients the opportunity to access additional exclusive services, unavailable anywhere else.

Joining forces to provide the right answers
As the due dates for the MDR and IVDR applications draw near, an increasing number of industry professionals are seeking help from subject matter experts in order to ensure their compliance with the upcoming regulatory expectations. Where certification is concerned, it is critical for manufacturers to choose the right consulting partner to guide them through the complex documentation process. This served as the launch pad for the collaboration between QUNIQUE and Evnia, aiming to innovate the industry through combined expertise within these fields and involve experts from various backgrounds to provide mutual customers with optimal solutions.

This cooperation will give clients access to a wide range of services, such as assistance with:

- quality management systems;
- pre-clinical and clinical documentation (CER) requirements of the MDR;
- performance evaluation requirements of the IVDR;
- adequate training and industry events.

These exclusive services will provide manufacturers with a competitive advantage by keeping them best informed in the sphere of quality management and regulatory affairs.

Regulatory Strategy premium Service
"An important aspect of this strategic partnership is that we will be able to offer an additional joined service to manufacturers," said Dr. Bassil Akra, CEO of QUNIQUE. "Within this premium service, the Technical documentation including either the Clinical Evaluation or Performance Evaluation Reports, prepared by Evnia, will be reviewed independently by us at QUNIQUE, weighing in regulatory and notified body experience in the content and output. This premium service will reduce the risk of manufacturers by getting pre-challenged documentation before submission."

"We at Evnia are very excited about this partnership," said Dr. Efstathios Vassiliadis, CEO of Evnia. "Both of our companies understand that the IVDR and MDR compliance can only be achieved through a holistic approach towards quality management systems and pre-clinical and clinical documentation requirements. It is exactly this focus that

makes this strategic partnership unique and provides unparalleled value to manufacturers."

Additional Resources
Follow QUNIQUE on Twitter, Facebook, LinkedIn and YouTube
Follow Evnia on Twitter, LinkedIn

About QUNIQUE
QUNIQUE is a quality management and regulatory affairs consultancy, specialized in developing tailored concepts and solutions to support, maintain, and improve the compliance of companies in the medical, in-vitro diagnostic and combination device sectors. QUNIQUE is the only consultancy organization with key subject matter experts who were involved in the designation/notification process of MDR and IVDR notified bodies and can deliver insights in the preparation of the EU Regulatory strategy. For more information, visit www.QUNIQUEgroup.com

About Evnia
Evnia is a specialist consultancy firm that prepares compliant clinical evaluation reports, technical documentation, and IVDR performance evaluation reports for manufacturers. Evnia has deep cross-functional experience and know-how, involving a wide range of professionals, such as medical doctors, biostatisticians, medical and clinical writers, and engineers, who work collaboratively to ensure a holistic approach towards compliance. For more information, visit www.evnia.dk