

## ÅKRN IS NOW ISO 9001 QUALITY CERTIFIED

We are pleased to announce that AKRN, Now part of NAMSA, is now ISO 9001:2015 quality certified by EQA, a recognized Spanish accredited certification body.



Maria Nyåkern, Founder and Executive Director, commented:

"This certification is a testament to AKRN's commitment to providing high-quality medical device services tailored to our client's needs. Since the company's inception, we have always adhered to industry standards, including ISO 14155 GCP for medical devices. The 9001 certification is a milestone for us as a team, and I believe that our operating procedures can guarantee client satisfaction and results that our entire organization can benefit from."

The ISO 9001 standard, established by the International Organization for Standardization (ISO), is the quality standard par excellence, and its structure forms the basis for other quality standards such as the medical device quality standard ISO 13485. Implementing ISO 9001:2015 aims to support organizations in enhancing their overall performance and client satisfaction.

As a client, you can expect:

- European Medical Device and IVD expertise
- Accountability & ownership
- Optimized services & high responsiveness
- High compliance with industry standards
- Businesses continuity
- Reliable and controlled budgets

AKRN offers clinical, regulatory and quality consulting services for medical devices and in vitro diagnostic medical devices in the European market. Our experience covers a wide range of medical device therapeutic areas, including cardiovascular devices.



Maria Nyåkern, PhD. Founder and Executive Director at ÅKRN



Ariadna Navarro, PhD. Associate Director Quality & Regulatory Affairs at ÅKRN



José Velazquez, M.Sc. Quality Assurance Manager at ÅKRN