

# Quality Management Systems Consulting Until ISO Certification

**Case Study:** QMS establishment for nephrology device company in Singapore until ISO13845 certification

## Needs



X months?

The company had QA resources, but the team is just established, and the management needed assistance to have the right establishment of the quality management system to ensure it is appropriate for their organization



4 months

**Connected with Access-2-Healthcare via a referral**

## Action!



8 months

Assessed organization planned size, supply plan, technology roadmap

Design quality management system according to the company situation, guided company to develop SOPs and instructions

Systematically assessed the various aspects of the quality systems against various quality system standards and regulations



Provide workshop for entire company for audit readiness, tips and guidance

## Results



**Receive ISO13845 quality systems certification with minimal findings**

**Other examples:** Quality Systems established and certified, post process setup for cardiovascular device manufacturing line