

- **Shawn Yang** - developed the Software for the first Total Artificial Heart and participated in the historic artificial heart HDE submission that was cleared by FDA. Following the FDA guidelines, Shawn has developed and validated software for a wide range of medical devices in cardiology, heart surgery, endo-surgery, IVDs and clinical diagnostics including the first commercial heart intra-cardiac monitor and ablation system. Shawn came to the US from China in 1979 and has worked in US medical device companies ever since. He speaks fluent Chinese.

EXPERIENCE

- 30 years experience in US and China medical device development and quality assurance.
- Independent risk based software design and code inspections for embedded medical devices.
- Developed and validated various medical devices for interventional cardiology, heart surgery, electro-physiology, endo-surgery, dialysis, imaging, IVDs and clinical diagnostics.
- Medical Device Design Control following FDA guidelines: Requirement / Design / Risk Management / Verification and Validation.
- FDA HDE and 510(k) submissions.
- Embedded and console software development and validation
- Clinical IRB and Animal studies.
- Advanced research in cardiology with the world leading Atrial-fib ablation hospitals.
- Represented software development process during technical and regulatory reviews and independent audits

CREDENTIALS

- Developed embedded control software for the first Total Artificial Heart approved by FDA.
- Led software documentation and a member of clinical / animal study data preparation for the historic Total Artificial Heart HDE submission that was cleared by FDA.
- Developed the first commercial heart intra-cardiac monitor & recording system and heart mapping system for cardiology ablation treatment.
- Developed infrared spectroscope detecting lipid rich plaques in coronary artery for interventional cardiology.
- Developed a real-time operating system kernel (RTOS) 20 years ago that is still used in medical instruments manufactured today.
- MSEE in Computer Science, Northeastern Univ. Boston, USA, 1984
- Attended AAMI/FDA Quality Systems and Software Validation courses.
- Native Chinese speaker