

ASEAN Enhanced Partnershp Medical Device Capacity Building Workshop July 29-31, 2007 Hanoi, Vietnam

Vincent Cheung
Director, Quality
Edwards Lifesciences Pte Ltd

Edwards Lifesciences

- Nearly 50 years of history as a global leader in products and technologies to treat advanced cardiovascular disease
- The world's number-one heart valve company with sales in more than 100 countries
- Headquarters in Irvine, California, USA
- More than 5,500 employees worldwide
- Four main product categories:
 - Heart Valve Therapy
 - Critical Care
 - Vascular Therapy
 - Cardiac Surgery Systems



Global Locations



40+ offices in 35 countries.





Why Singapore?

- Vision and commitment in the bioscience sector with a focus on helping patients
- Strategic site for Edwards' current Heart Valve Therapy manufacturing network
- Vibrant and organized business environment on issues such as intellectual property, operating costs, start-up assistance
- Favorable tax environment
- Labor availability along with strong work ethic and a commitment to quality



Edwards – Singapore Alignment

Edwards Lifesciences (EW)

- Life Sciences & Medical Devices
- IP & High Tech Commitment
- High-Skill & Value Add Manufacturing
- Talent & Skill Development
- Long-Term Player

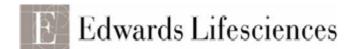
Singapore (SG)

- Fit in the Biomedical Sciences Cluster
- Strong IP Protection and Support
- High Value Add, Retrench Focus for Manufacturing Base
- Talent Focus...For the Future
- Long-Term View



Challenges

- Ensuring a Quality culture, mindset and regulatory compliance
 - Critical as Edwards' products are life-sustaining technologies
- Heart valve manufacturing is a technically complex process
- Process of transferring technology is rigorous
 - Particularly validations and qualifications
- Distance factor between U.S. and SG
 - Edwards needs to manage geographic separation
- Long learning curve to certify proficient workforce



Success Factors

- Skilled labor available in Singapore
 - 100% of workforce is Singaporean/Permanent Resident
 - High education standards has led to high English literacy standard in workforce
 - Readily available talent in Engineering, Finance, Human Resources, Quality and Supply Chain
- Strong support during start up from the Singapore Economic and Development Board (EDB)
- Good employment facilitation and training support from the Workforce Development Agency (WDA)
- Singapore's safe and pro-business environment (e.g. IP protection)



Aspirations

- FDA Registered
- ISO13485 Certified
- Heart Valve Manufacturing
- Commercial Distribution (WW)
- Potential Regional Headquarters

Future Home





Edwards

Helping Patients is Our Life's Work, and life is with