

# Ho Yin (Michael) Li

Healthcare Sector Technical Manager



## General overview

- Audit and training deliver industry sector including Medical device organisations in product life cycle, including Design and development, Legal Manufacturer, Component supplier, Logistic, warehouse & distributor, HK Government and other independence authorities (HK MDCO, HK EMSD, Brazil IFBQ), etc.
- With work as Auditor and Tutor in BSI for 10+ yrs
- With work as Project team leader in a Norway based product certification body (NEMKO) for 6 yrs
- With work as QA team in an America based electronic component manufacturer (BEL) for 4 yrs

## Work experience highlights

### Health Care

- ISO13485 and ISO9001 audit for laboratory, public & private hospital, clinic, CSSD, supply chain, maintenance service provider, etc.
- Audit and training delivery for famous brand medical device organizations, e.g. Abbott, Beckman Coulter, Cook, GE, J&J, Medtronic, Philips, Stryker, etc.
- Lead auditor of HKPC Medical Device(MDGDP) pilot cases

### Laboratory

- Factory audit in China and South Asia
- Electrical household and medical product, and component test according to safety standards IEC 60601, IEC 60335, IEC61058
- Testing equipment Calibration

### Manufacturing

- Electrical and electronic product test according to safety standards UL/IEC/EN

### Energy

- ISO50001 audit for HK Government (ASD, HCAA, WSD), hotel (Cityview, Galaxy, MGM, Regal) commercial building, construction company, etc.

## Specialist subjects

- ISO13485 Medical Device
- ISO9001 Quality
- ISO14001 Environment
- ISO45001 Occupational Health & Safety
- ISO50001 Energy Management
- ISO10002 Customer satisfaction

## Career experience

- 10+ years on management systems auditing
- Conducted over 1k audit maydays
- Audits conducted in Hong Kong, China, Macau, South Asia e.g. Malaysia, Indonesia, Vietnam, etc.

## Industry knowledge

- Medical Device
- Manufacturing
- Electrical & electronic product
- Laboratory
- Mechanical engineering
- Transportation
- Retail & trading

## Qualifications

- IRCA Lead auditor