EDWARD TOLENTINO

REGISTERED PHARMACIST

MASTER'S IN BUSINESS ADMINISTRATION- HEALTH SERVICES

CONSULTANT – REGULATORY AFFAIRS, MARKETING & DISTRIBUTION IN THE PHILIPPINE TERRITORY

Background

Edward Tolentino received a Bachelor of Science in Pharmacy from the University of the Philippines Manila in 1997 and his Master's in Business Administration Program in Health at the Ateneo Graduate School of Business in 2011.

He is a resource speaker and trainer in various conferences and training workshops by industry associations and government agency on health services.

Edward is a Consultant for Medical Device Industry with expertise in product registration, establishment registration, clinical/ product evaluation, research and distribution system. He has helped manufacturers from Japan, China, Korea to obtain product certification and penetrate market in the Philippines.

In the earlier years of his career, he spent 18 years in hospital and clinical pharmacy, lead role in establishing quality systems for JCI accreditation.

TRAINING and DEVELOPMENT

DISTRIBUTION SYSTEM

REGULATORY AFFAIRS

QUALITY SYSTEM

Bailana Mutiara

S.Farm, Apt (Registered Pharmacist)

Consultant – Regulatory Affairs & Trainer

Background

Bailana Mutiara (Muti) received a Bachelor of Science in Pharmacy from the University of Indonesia in 2007 and her Professional Pharmacist Degree from the same University in 2008.

She experienced as regulatory affairs for healthcare products, including medical devices, health supplements, traditional medicines, and cosmetics for 9 years. Her expertise is in product registration, company establishment, Good Distribution Practice, and Trademark registration. She is greatly exposed to the various multinational clients and principals in Asia, USA, Europe, and Australia.

In addition to that, she also have total 4 years experienced in managing logistics, such as supervising warehouse and importation handling. She is also actively working as a trainer for local small-medium enterprises which manufacture the healthcare products in Indonesia.

- REGULATORY AFFAIRS
- TRAINING
- GDP
- IMPORTATION HANDLING

HWEE EE TAN

PRINCIPAL CONSULTANT – QUALITY MANAGEMENT SYSTEMS AND REGULATORY AFFAIRS, MEDICAL DEVICES INDUSTRY

MASTERS OF SCIENCE IN MANAGEMENT OF HEALTH INDUSTRIES

CERTIFIED QUALITY AUDITOR (ASQ)
CERTIFIED QUALITY ENGINEER (ASQ)
CERTIFIED MEDICAL DEVICE ASSOCIATE – CLINICAL EVALUATION (CMDA)
CERTIFIED BIOMEDICAL AUDITOR (ASQ)
POST GRADUATE DIPLOMA IN QUALITY MANAGEMENT

Background

Hwee Ee has more than 30 years of experience in the medical device industry and worked in manufacturing as Engineer and also in Senior Management roles in QA / RA. She also worked as a Consultant in a Pharma/Device consultancy company.

In 2010, Hwee Ee founded DH RegSys Pte Ltd to provide advisory services to the medical device industry with focus on Regulatory Affairs and Quality Management Systems. During the past few years, the consultancy services have expanded to include providing regulatory support for medical device clinical trials in China and the region.

She is a member of Asian Harmonization Work Party (AHWP); Working Group 6 (WG6) Quality Management Systems: Audit & Assessment.

QUALITY MANAGEMENT SYSTEMS

REGULATORY AFFAIRS

AUDIT

TRAINING

Raenu Chaichanan

BSC(Nursing& Midwifery), MBA (Executive)
CONSULTANT – Market Analysis, Regulatory affairs,
Strategic Sales&Marketing, Distribution System in Thailand

MARKET ANAYLYSIS

REGELATORY AFFAIRS

STRATEGIC SALES&MARKETING

DISTRIBUTION SYSTEM

Background

Raenu Chaichanan received a Bachelor of Science(Nursing & Midwifery) from Prince of Songkla University in 1991 and MBA (Executive) from Chiang Mai University in 2008.
Her experienced management most are strategic sales& marketing for company's goal. She'd managed strategic sales for various MNC companies (Singapore, USA, UK) Thailand as well as being consultant for various medical devices to be registered import underFDA regulation –Thailand.
Raenu is a consultant for Medical Device Industry with expertise in market research, establishment registration, analysis and guiding distribution channel as well as being project consultant for various international consulting firms. She has helped manufacturers from USA, Germany, China, Korea, Taiwan to register company, launching product as well as market penetration.
In the earlier years of her clinical career, she spent 8 years in the operating theater for A to Z operations. Her experience for consulting & Management in medical device industry has more than 18 years

Siang Ying TEO

AD Consultation Services/ AD System Sdn Bhd

Bachelor Degree of Biochemical Engineering (Honours)

Senior Consultant – Regulatory Affairs, Quality Management Systems (GMP & GDP, ISO 13485)

- Regulatory Affairs
- Quality Management Systems
- Training and Development
- Local Authorized Representative

Background

TSY is one of our senior consultants and has over ten years work experience. She has an Honours degree in Biochemical engineering from the National University of Malaysia and has worked for the company on various projects in Asia.

She is a highly competent consultant and has worked as a project engineer, consulting on process, clean room and facilities validation projects for organisations such as National University Hospital in Singapore, Lu Ann Pharmaceutical in China and Flextronic in Malaysia.

For the past ten years, her work focus has been on regulatory affairs – GDPMD and medical device registration in Singapore and Malaysia. She is conversant with both the Singapore and Malaysian GDPMD guidelines, has in depth experience in implementing GDPMD, is very well versed with our template SOPs and Forms and has guided all her clients towards successful implementation thus enabling them to obtain their GDPMD certification.

On the medical device registration front, she has intimate knowledge of the regulatory requirements for both countries and has literally registered few hundreds of medical devices for clients over the past ten years – interacting with clients and their principals for product related information, assessing product risk classification and grouping, verifying that the manufacturer's documentation complies with the local regulatory requirements, managing dossiers and their subsequent submission to the regulatory authorities as well as responding to input requests from them.

Clients she has supported include MNCs as well as SMEs. Some of these are Karl Storz, Agfa Healthcare, Eye Care and Cure Asia, GCAsia Dental, Medicare Products, CooperVision, Eppendorf, Bless Care, Distrepark, The Baby Specialist, Novartis, Kavo Dental, Amway, Medi-Care Products, Pentex Medical, Shimadzu, Neopharma, VQM, Ambang Gemilang Saintifik, Nitto Denko, ULC, Oesteo Signature, Dentsply Sirona, BP Lab, Big Pharmacy etc.

Country: VietNam

David
(VO TRUNG VIET)

Lawyer Certificate

Bachelor of Law

Bachelor of Biotechnology

- Regulatory Affairs
- Quality Management Systems
- Training and Development
- Distribution

Background

David have more than 10 years experiences in Medical Devices Industry

2008 - 2012: David start to join Medical Devices market as Sales Representative since 2008

2012 - 2016: Sale Manager of Medical Devices

2016: **Medical Device Regulatory Affairs Consultant, Law Services**

- Have experience on: Law consultant, Medical regulatory affairs, Licence holder, Entrust Importer, Distribution. Ex: India (Ophthalmic instrument), Pakistan (Dental, plastic surgical), Germany (IVD instrument), Japan (Medical Manufacture Licence in VietNam)

- Product registration consultant for Import & Trading (Medical Device, Food supplement, Cosmetic)

- Help to expand customer business by connecting to the right distribution channels (B2B), right end user (B2C) or act as your in-country representative.

- Business Law Consultant Services: Investment licence, Medical manufacture licence, Labour, M & A