APACMed ASIA PACIFIC MEDICAL TECHNOLOGY ASSOCIATION

Building Regulatory Professional Capacity for Medical Devices in Asia Pacific

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About APACMed

Founded in 2014, the Asia Pacific Medical Technology Association (APACMed) is the first and only regional association to provide a unified voice for the medical technology industry in Asia Pacific. APACMed works proactively with bilateral, regional and local government bodies to shape policies, demonstrate the value of innovation and promote regulatory harmonization. APACMed engages with medical device associations and companies in Asia Pacific to jointly advance regional issues such as access, innovation and collaboration to improve standards of care for patients.

The report was initiated by the APACMed Regulatory Affairs Committee.

Authors

Miang Tanakasemsub, APACMed RA Co-Chair
Regional Regulatory Affairs Head, Asia Pacific & Russia
Alcon

Carol Yan, APACMed RA Co-Chair
Vice President Regulatory Affairs, Asia Pacific
Johnson & Johnson

Jason Guo, APACMed RA Vice Chair
Director, Regulatory Affairs & Quality Compliance, Asia Pacific
Abbott Vascular

Sherry Keramidas (independent consultant)
Chief Executive Officer
Mindfuleadership

Tran Quan
Vice President Regulatory Affairs
Asia Pacific Medical Technology Association (APACMed)

Fredrik Nyberg,
Chief Executive Officer
Asia Pacific Medical Technology Association (APACMed)

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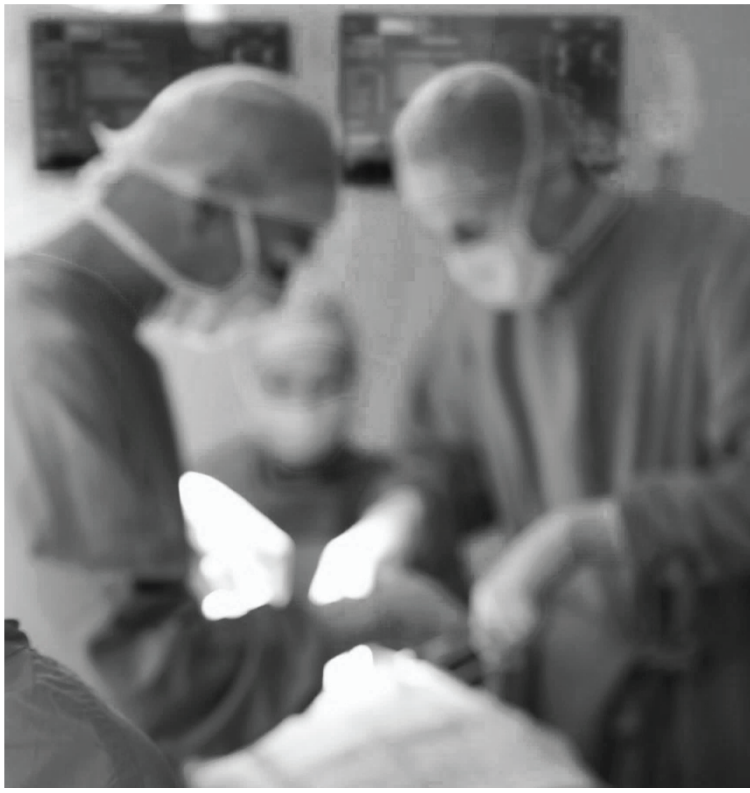
Building Regulatory Professional Capacity for Medical Devices in Asia Pacific

In November 2016 APACMed hosted a summit on building regulatory professional capacity for medical devices in the Asia Pacific region. Immediately following and built upon the Asia Pacific MedTech Forum 2016, the summit included over 60 senior professionals from regulatory agencies, industry and academia in the region and focused particularly on approaches to building a key element in capacity building - a regulatory professional workforce. Additional information collected through APACMed surveys of executives and regulatory professionals in the region is also presented.

This report summarizes the presentations and discussions during the summit and suggests steps to progress along the path of regulatory capacity building.



01 Background

MedTech-medical devices and in vitro diagnostics (IVDs) offer essential life-saving and life changing products, from the simplest to the most complex imaging and implantable devices. The need for medical devices in the Asia Pacific region is immediate. Addressing the need and demand in the region will be a challenging and complex undertaking. However, many stakeholders, including industry, regulators, ministries of health, professional and patient groups appear ready to accept the challenge.

In December 2015, McKinsey & Co., in collaboration with APACMed, released a report on the opportunities and challenges for the medical device sector in Asia[1]. The report notes that by 2020, Asia Pacific is expected to rank as the second largest market for MedTech, surpassing Europe. This growth will reflect regional economic development and urbanization, growth in the aging population and in births, and growing and changing health needs. The report also articulated the realities and challenges in the region, including regulatory complexity.

1. *MedTech in Asia : Committing at scale to raise standards of care for patients*, December 2015.

Regulatory issues are among the leading hurdles and key areas of focus for the medical device sector in Asia Pacific

The regulatory landscape in the region varies from little or no structure to highly evolved regulatory systems, seen in Japan and China. Several markets face the added challenge of a lack of regulatory professional talent, especially among regulators. Combined with a challenging pricing and reimbursement issues, this creates a pressing need for regulatory capacity building.

FRAGMENTED REGULATORY AND MARKET ACCESS LANDSCAPE

- Complex and varied regulatory approval timelines
- Diverse clinical trial requirements
- Fragmented market access

REGULATORS AND INDUSTRY ENGAGEMENTS

- High profile regulatory lapses across markets & industries (beyond pharma & medical devices)
- Limited opportunities for interaction and discussion between regulators & industry

SUPPORT FOR LOCALIZED INDUSTRY

- More favorable regulatory and market access for local MedTech players
- Local R&D or manufacturing requirement

TALENT SHORTAGE

- Lack of capacity & market access across and within countries
- Pharma-oriented mindset in device regulatory bodies

Figure 1. Regulatory & Market Access Challenges in Asia Pacific

In 2016, McKinsey & Co. and APACMed conducted follow-on survey to the 2015 report, receiving input from 130 senior executives from 18 multinational medical device companies actively involved in the Asia Pacific region. Regulatory and related issues remained a top concern.

Intensified regulatory challenges were noted by 90% of respondents. However, only 35% of respondents believe they have strong capabilities to address regulatory issues. Further, respondents reported a decline in "regulatory preparedness" and insufficient investments in building regulatory capacity (Figure 2).

Q. We are well prepared to cope with regulatory change

Companies are less ready for regulatory changes

Q. We are making sufficient investment in building regulatory capabilities

.... yet insufficient investment in regulatory affairs

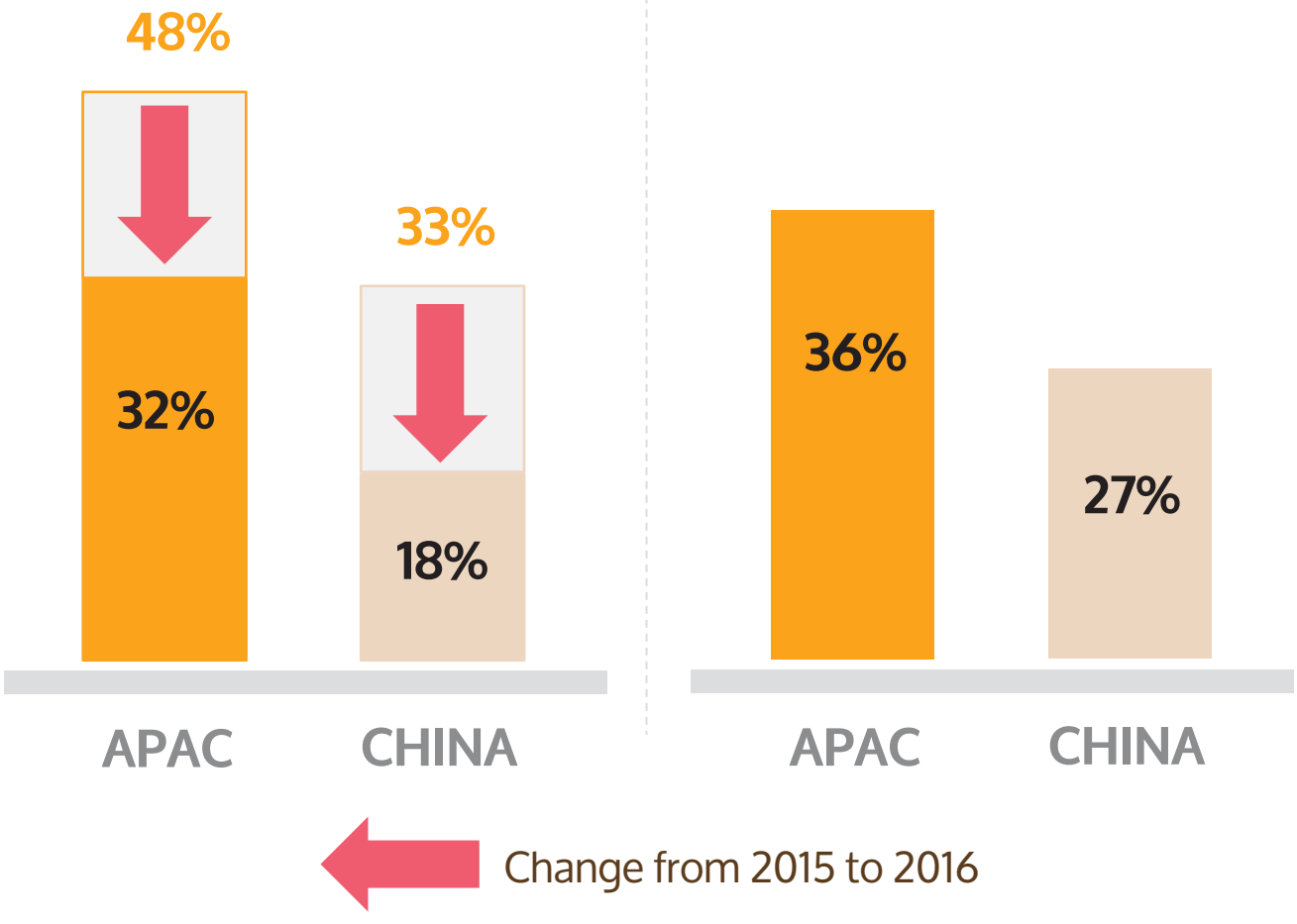


Figure 2. APACMed 2016 Business Sentiment Survey: Changes in Regulatory Capacity 2015 - 2016

"A major question is how can industry and regulators build regulatory capacity and move closer to a shared goal of enhanced, value-driven products and innovation that meet the needs of individuals and the societies and nations in the region?"

02 What is Regulatory Capacity Building?

Regulatory capacity building is based on factors, including:

- A clear legal/legislative foundation
- A regulatory authority with the ability to establish a regulatory framework and the authority and capacity to exercise independent decisions within the framework
- The ability of industry to address regulatory requirements and effectively interact with the regulatory authority.
- Capable professional staff in regulatory agencies and industry.

Engaging capable professionals with appropriate expertise in regulatory agencies and in industry is critical to capacity building. Without capable staff involved throughout the product lifecycle there cannot be effective regulation.

While the capacity to regulate medicines exists at varying level in the Asia Pacific region, some countries have not had the legislative authority, resources or technical expertise to specifically regulate medical devices. However, because of the mode of action in the human body, the diversity of products, the nature of the product life cycle and the nature of the industry itself, it is important for the region to build regulatory capacity (both systems and professional talent) specific to medical devices.

Several organizations and agencies have engaged in building regulatory capacity for medical devices, beginning with the Global Harmonization Task Force (GHTF) in the 1990s.

GHTF efforts were followed by the International Medical Device Regulators Forum (IMDRF), the Asian Harmonization Working Party (AHWP), and the World Health Organization (WHO). Industry and professional groups were important partners in these groups. All of these efforts were vital to recognizing the need for regulatory systems specific to medical devices and for developing relevant models and guidances.

Recent frameworks developed by the AHWP[3] and the WHO[4] incorporate the models, definitions and guidances into approaches that can be adapted for countries with no or limited medical device regulation and to countries with full capabilities. These models require staff with specific understanding of medical devices and regulation.

Today, regulatory affairs is recognized as a profession, serving a vital role in the health product sector. There also is growing awareness of the need to educate and train regulatory professionals who are prepared to work with the unique dimensions of the medical device area and the needs, requirements and culture of their country and region.

Efforts to train regulatory agency staff in new and developing regulatory agencies have spanned more than two decades but were of limited success. This finding was reinforced by the 2012 report of the National Academy of Sciences, Ensuring Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad.

3. Playbook for Implementation of a Medical Device Regulatory Framework, AHWP, 2015

4. WHO Model Regulatory Framework for Medical Devices Including IVDs , WHO 2016 draft

Several factors may contribute to the limitations of previous regulatory training programs for new and developing regulatory agencies.

These include:

- The perception of the regulatory role as a lower level administrative role with limited prospects for career advancement
- The focus on training to specific regulations or guidances rather than a more comprehensive professional training approach
- The lack of continuing learning and mentoring opportunities in - country to support advancing knowledge and skills.

However, recent examples of regulatory training programs point to opportunities to establish effective partnerships among academic organizations, professional and trade non-profit organizations, regulators and industry in the region These programs include: PMDA - sponsored training for Asian regulators; the US-Japan Harmonization by Doing Initiative; the Medical Device Graduate Certificate Program in the Biomedical Engineering Department at National University of Singapore; and seminars offered by the Center of Regulatory Excellence (CoRE) at Duke-NUS in Singapore. Experiences of these programs also demonstrate the critical importance of collaboration among academic institutions, industry and regulators to create courses and to engage experienced faculty while integrating the scientific and clinical expertise and innovative teaching resources available through academia.

03 Building Regulatory Professional Capacity

Effectively building regulatory professional capacity for the medical device area in Asia requires a process.

The process begins with examining the scope of practice - the essential work being done by individuals working in regulatory bodies and industry. This provides a foundation for defining essential competencies, which, in turn, guide development of curricula for education, training and for continuing professional development. (Figure 3).

Figure 3. Process for building regulatory professional capacity

Existing regulatory frameworks and models such as the WHO, AHWP and IMDRF tools offer a starting point for defining scope of practice of regulatory professionals.

The resources developed initially by the GHTF (see Appendix A) followed by refinements made by the IMDRF, AHWP and the WHO (see Appendix B) offer progressive frameworks and guidances regulating medical devices for agencies just embarking on device regulation to those with established, comprehensive programs. Each country in the Asia Pacific region will adapt and use these models as appropriate for their own use. These models also help to define the scope of practice of regulatory professionals, from the basic to the more advanced levels.

Key aspects of these models to be considered in the professional capacity building process include:

- The models reflect the unique "lifecycle" of medical devices, from product conception, product development, clinical trials, registration/review, to post market.
- The models include definitions and classification of products based on risk.
- The models place strong emphasis on quality systems and safety monitoring.
- The models reflect the importance of international standards and awareness of the regulatory approaches implemented by advanced regulators.
- The WHO model also includes new terms of good regulatory practice and reliance.

04 Essential Competencies of Medical Device Regulatory Professionals

The November 2016 Summit hosted by APACMed was a starting point for defining essential competencies of regulatory professionals working with medical devices in the Asia Pacific region.

Participants reviewed the regulatory models and frameworks used in the region and considered their application to the scope of practice and essential competencies of regulatory professionals.

Two essential threads woven into the competencies of regulatory professionals working in the medical device sector are:

- Critical thinking
- Understanding societal and personal tolerance for risk combined with the personal awareness of the benefit of products[5] .

KEY DEFINITIONS

COMPETENCY: cluster of related knowledge, skills, abilities, and characteristics that affect a major part of one's performance and are significant to the practice of a profession. A competency may be specific to the profession (*functional*) or reflect knowledge and skills that apply to regulatory and other professions (***foundational***).

Competencies are broken down into *domains* (major areas) and subareas that encompass the major roles, responsibilities and tasks undertaken

5. This critical, overarching competency is also cited in Strengthening a Workforce for Innovative Regulatory Sciences in Therapeutics Development*: A Workshop Summary*, National Academies Of Science, 2012.

Regulatory professional competencies must embody the scientific, technical and business aspects of the work as well as the inherently collaborative nature of regulatory practice, including working with regulatory professionals in other settings, and with scientists, engineers, clinicians, statisticians, business and policy staff.

The competency domains identified by summit participants are shown in Figure 5.

While these domains are relevant to professionals working in regulatory agencies and in industry, responsibilities vary by employment setting. These variations should be identified in the defining the subareas within in each domain, the next step in developing a competency framework. The subareas will also reflect the level of development and complexity of the regulations in the country in parallel with the progressive development model of the GHTF, AHWP and WHO. Finally, the subareas within each domain will also change with professional level.

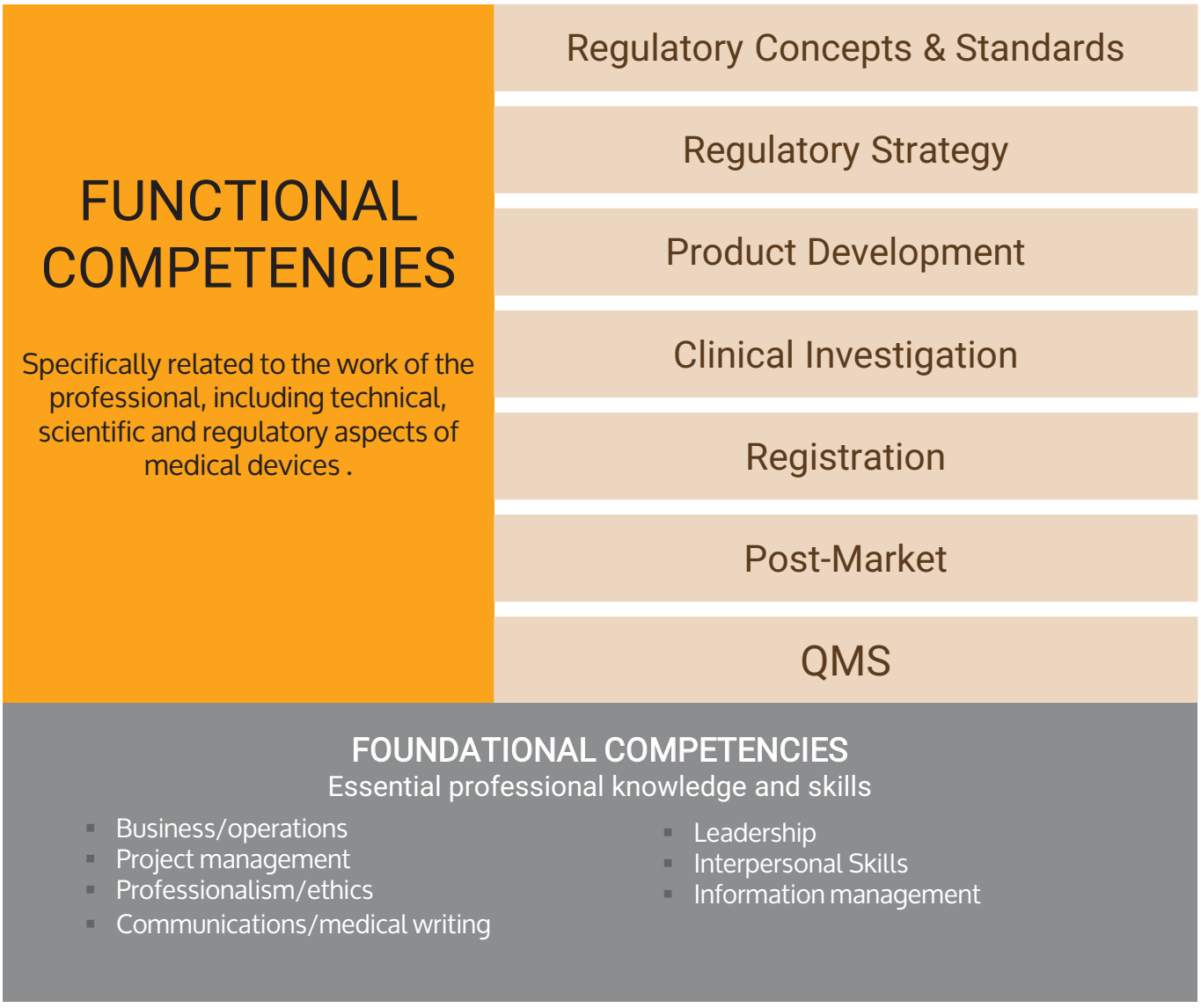


Figure 5. Regulatory Professional Competencies

05 Moving Forward

Discussions during the summit and throughout the 2016 APACMed MedTech Forum reinforced the need to continue the systematic process of professional capacity building for medical device regulatory professionals in Asia Pacific. To be successful, the path forward must include effective partnerships among stakeholders from industry, regulators, academic groups and relevant NGOs.

Recommended next steps in this process include:

- ***BUILD A FULL COMPETENCY FRAMEWORK FOR MEDICAL DEVICE REGULATORY PROFESSIONALS IN ASIA PACIFIC.*** This can be undertaken by an expert group of regulatory professionals from industry and regulatory agencies. Work by this expert group can be validated with input from a broader audience of regulatory professionals in the region.

- ***TRANSLATE COMPETENCIES INTO CURRICULA.*** Education experts from academia and other organizations can work closely with the expert group to effectively translate competencies into modular curricula that can be adapted to different countries.

- ***DETERMINE TRAINING PRIORITIES.*** What professional level(s) are most critical to regulatory capacity building today and in the next three to five years. This will be important for assuring adequate resources are available to develop a well trained and highly competent regulatory workforce.

- ***DEVELOP TRAINING PROGRAMS AND TRAINING MATERIALS.*** Based on training priorities and the location and special needs of the target audiences, training programs can be designed and implemented. Ideally, these programs will be developed as collaborative efforts among multiple academic and other organizations and will include methods for educating and training students in different countries in the region.

Education and training programs for regulatory professionals must reinforce the importance of critical inquiry and create professionals who are thinkers and problem solvers. Programs should utilize learning formats and approaches that combine self-paced and distance learning with seminars and other interactive forums that build the cross-cutting competencies of the profession and the skills and knowledge essential to work in industry and in regulatory agencies. Training for regulatory professionals, no matter where they work, is most effective when offered by experts with real experience and able to provide case-based learning. Finally, programs must develop outcomes measures linking training to on-the-job effectiveness and improvements in the regulatory process. These recommendations were also supported by the training survey of regulatory professionals undertaken by APACMed in January 2017 (Figure 6).

Priorities for training	■ Topics range throughout device lifecycle ■ Similar priorities for industry, regulator-based professionals
Training for industry professionals	■ Value training offered by regulators ■ Value training offered by experts with high-level experience ■ On-the-job training reported by less than 25%
Training regulators	■ Opportunities for training by industry professionals cited by 31% of respondents ■ Involvement with harmonization groups offers learning opportunities ■ Regulator-regulator recommended by 20% of respondents
Approaches to training	■ Training by highly experienced professionals is critically important ■ Case-based learning seen as important approach ■ Combined on-line and in-person viewed as useful

Figure 6. APACMed post- RA Summit Survey on Regulatory Training
[Sample: 41 Professionals working for 13 MNCs across 12 countries in Asia Pacific]

Developing regulatory professional capacity for the medical device area in the Asia Pacific region will not be a quick or simple endeavor. To be effective, it must be a collaborative effort among diverse partners. However, it will be important for an organization like APACMed to lead and facilitate the process, to identify stakeholders, forge partnerships and drive the path forward. Without a systematic and thoughtful process it may not be possible to achieve success. Ultimately, the outcomes of this undertaking will benefit the people government agencies and the industry that serve the vital health needs of the region.

Appendix A

GHTF Lifecycle Model and Related Guidelines

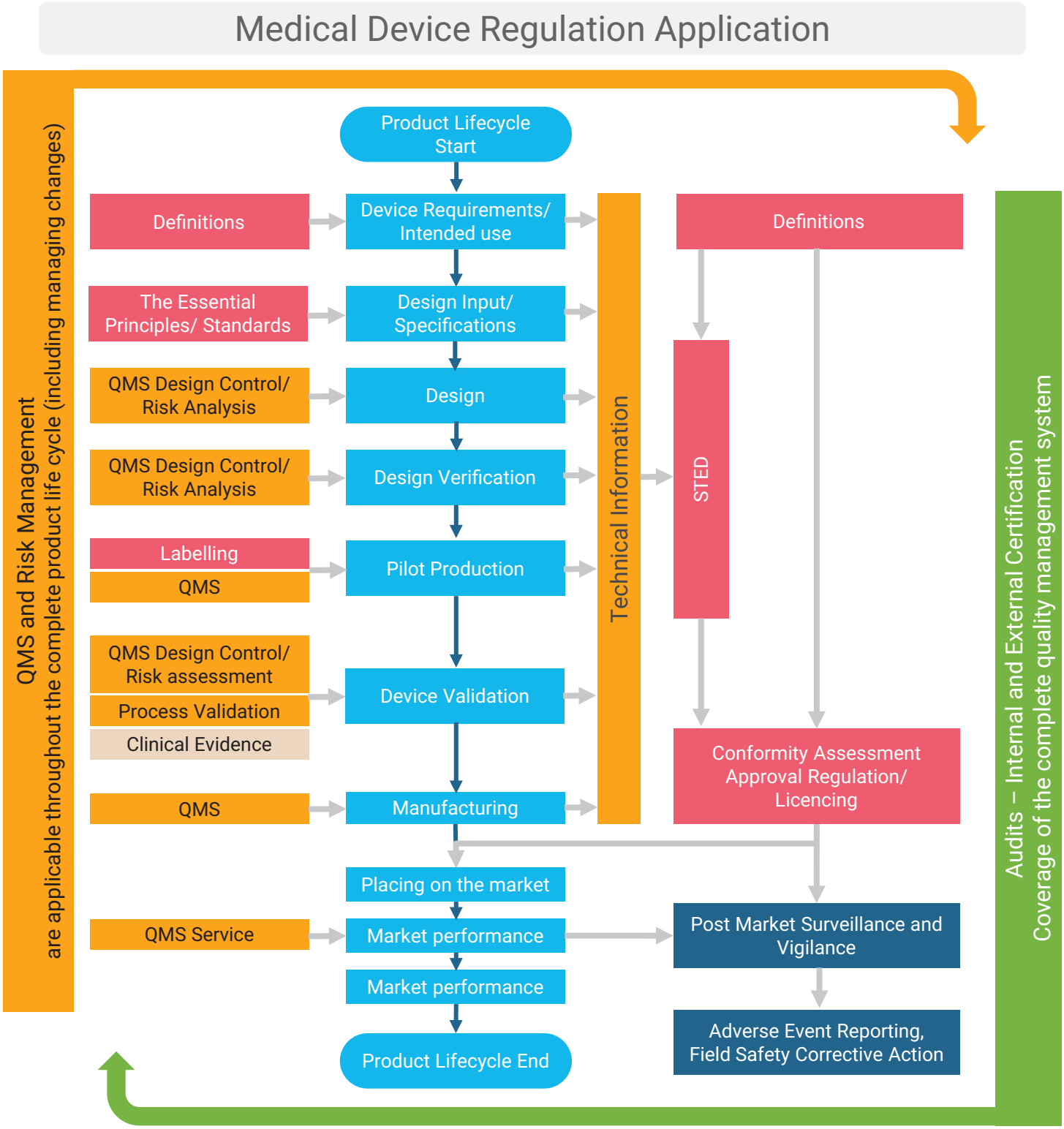


Figure 7: Global Harmonization Task Force Regulatory Model, 2011

Appendix B

2016 Draft WHO Model for Medical Devices

LEGAL FRAMEWORK

Expanded Level Controls and Enforcement

Pre-market	Placing on the market	Post-market
Create oversight of clinical investigations	Perform in-country quality management systems audits	Establish within the regulatory authority a post-market surveillance and vigilance reporting system
Appoint and have oversight of conformity assessment bodies (CAB)	Perform review of submissions for compliance with Essential Principles	Require mandatory reporting by manufacturers of adverse events
Recognise standards		Inspections of registered establishments
Adopt a medical device nomenclature system		Provide for testing laboratories
Control advertising and promotion		

Basic Level Controls and Enforcement

Pre-market	Placing on the market	Post-market
▪ Publish law, including definition, and regulations with transition period ▪ Establish medical device classification for regulatory purposes ▪ Establish Essential Principles of safety and performance ▪ Establish basis for reliance and recognition ▪ Establish requirements for Declaration of Conformity ▪ Establish requirement for manufacturers for a Quality Management System ▪ Establish requirements for labels and labelling ▪ Prohibit deceptive, misleading and false advertising ▪ Establish provisions for exceptional pre-market situations	▪ Registration of establishments ▪ Listing of medical devices ▪ Import controls	▪ Establish a system for vigilance reporting ▪ Require mandatory notification by the manufacturer of field safety corrective actions ▪ Establish a procedure to withdraw unsafe medical devices from the market ▪ Establish procedure to issue safety alerts to users ▪ Undertake market surveillance

Figure 8: World Health Organization, 2016

APACMed ASIA PACIFIC MEDICAL TECHNOLOGY ASSOCIATION

ASIA PACIFIC MEDICAL TECHNOLOGY ASSOCIATION LTD

2 Science Park Drive, Ascent Tower A, #02-03, Science Park 1, Singapore 118222

+65 6816 3180 www.apacmed.org