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‘Regulatorism': A New Terminology For Medtech And Pharmaceutical Leadership Mindsets

Thoughts From Jack Wong, Secretary And Founder Of The Asia Regulatory Professional Association

by

The new regulatory professionalism drive sweeping over the global medtech and pharmaceutical sectors will lead to better value for all health care stakeholders. This is of particular relevance in regions such as Asia, where regulatory manpower is often at low levels.

Regulatory affairs roles are the means by which companies ensure that they comply with the regulations and laws pertaining to their business. These roles are vital in making safe and effective health care products available worldwide.

The responsibilities of an RA executive often begin right at the start of a product’s R&D phase, and continue through clinical trials and into premarket approval activities, manufacturing, labeling and advertising, then finally into post-market surveillance, on a continual basis.

Increased success in this field is being achieved by a heightened awareness of what is being called 'regulatorism,' which involves medtech companies’ regulatory professionals – and indeed the wider company – complying with and even getting ahead of regulatory needs and demands in a consistent, professional way.

RA Competence Is A Necessity

Sound regulatory competence is vital. It is not an option, it is a necessity. Regulatory competence is required for several reasons, and is critical to:

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- Patient care and business success: Innovative technology delivers better health care to patients. The effort and investments that go into inventions are immense. And sound regulatory knowledge and skills can pave the way for *faster product launches*, for example, by pointing to the right test at the right time, selecting the right product classification and registration pathway, and in addressing regulators' questions efficiently.

- Compliance: The medical devices and pharmaceutical industries are very highly-regulated, compared to many other business sectors. Regulatory oversight is needed in such diverse areas as research, clinical trials, testing, product registration, promotion, importing, and adverse event reporting – *indeed, every aspect is regulated*. Companies and service providers must therefore have a good understanding of regulation.

- Efficiency: Even when regulatory manpower is low. Securing adequate regulatory manpower to guarantee RA competence can be a challenge in Asia, for example. Local regulators often speak of a high percentage of product registration *documents not meeting requirements*. This is partly due to there being insufficient regulatory manpower in the region. Many SMEs and start-ups do not have dedicated regulatory functions; and in multinational companies, the regulatory teams often suffer high staff turnover in what is a small talent pool.

Regulatorism Defined

What is regulatorism? It is both a state-of-mind and also a belief – a dream or faith if you wish – that all medical device companies, pharmaceutical companies and related service providers integrate strong RA competence across their activities.

It requires a recognition among industry executives that companies and service providers – including SMEs and start-ups which may not have in-house resources—should drive for the highest standards in regulatory affairs.

The Path To Regulatorism

There are several vital steps on the path to regulatorism:

- Securing management buy-in and support. The industry needs to ensure that company

management teams are agreed on the importance and impact of regulatory affairs. The management should commit to understanding regulatory systems, and allocate resource to execute regulatory tasks according to both external regulatory and internal business needs. They should also regularly review their regulatory awareness and the quality of their internal regulatory operation system.

- Ensuring resource allocation. Resources required could include manpower, training, tools, access to regulatory intelligence and networking with peers, among other things. Training should include training on the products, regulatory requirements, and clinical and commercial planning. Companies should also source relevant publications and identify the industry associations that can be useful as they strive to improve their regulatory skills and knowledge. They should also research conferences, forums and networking events to hear experts deliver thoughts and updates on regulatory issues.

- Execution. This important phase comprises performing the regulatory tasks, for example preparing supporting documents, performing testing, and addressing regulators' queries and follow-up requirements.

- Measurement. Many companies measure the time taken on regulatory filings projects as a simplistic addition of the registration submission time and the approval time. But we should also factor into launch timings other elements that can sometimes delay product launches e.g. wrong labels or claims being approved. To avoid engaging in low quality and time-expensive regulatory activity, RA internal audits are recommended. ARPA has developed a regulatory audit scheme, and is happy to share details about it with the industry.

A Company-Wide Need

Crucially, the whole management team must be involved in RA to some degree. Regardless of their department—RA, QA, supply chain, medical affairs, market access and even the HR department—there is a legal requirement to know the regulations and be compliant in the medtech industry.

In addition, companies can add much value to themselves by being compliant, for instance, supply chain executives become increasingly knowledgeable of regulatory timings and are able to predict approval times. That enables them to manage production processes and, say, produce labels in a timely fashion in a competitive market.

Please share this article with your management teams and non-RA departments, for their awareness of regulatorism. Asia Regulatory Professional Association (ARPA) is an organization that promotes professionalism and recognition of regulatory professionals, and provides training, regulatory intelligence updates and project management tools in Asia: www.asiaregulatory.com.