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'Medical device regulatory is complex'

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Singapore: Medical device industry is a complex one and even more complex is the regulatory landscape of the sector, echoed the stake holders gathered at MedDevice Asia, hosted in Singapore on October 29-30, 2014.

"Medical device is a big and diversified sector with an even complex and often partially defined regulatory process", commented Mr Seth Goldenberg, director, global regulatory strategy, NAMSA, USA.

Mentioning the challenges of regulatory structure of medical device industry, Mr Alok Mishra, Vice president, Strategic Business Systems-Johnson and Johnson, Medical Asia Pacific commented that first the regulatory in medical devices are not clearly defined and secondly, policy makers often implement the same parameters as included in more defined pharmaceutical industry that often leads to a complex structure. Besides, the number of products being added to medical device sector every year is much higher as compared to pharmaceutical industry, hence the regulatory requirements do not often match the trends of the sector.

One of the industry wish list is to have a unified regulatory procedure for different countries that would hopefully makes the process less complicated. ASEAN countries are in the process to harmonize its regulatory structure and even countries including US, Brazil, Canada and Australia have initiated medical device single audit pilot (MDSAP) as a common platform for regulatory approvals. The process is still at an infancy stage and it may be a possibility of the future but currently it has its own formulating and implementation challenges.

Highlighting the innovations in medical device sector, the panel of speakers mentioned that the industry is definitely going through innovations but most of them are coming from start-up firms and early starters instead of the big multinational firms. Mr Seth suggested that that if a start-up wants to achieve success for its innovative medical devices, understanding and complying with regulatory structure, the most complicated phase, is the key.

Sharing the opportunities of medical device industry in Asia, Mr Mishra added that in Asia Pacific, 100 million old population will be added in the next six years and by 2030, 61 percent of the old age population will be in APAC. Added to this, there

would be 23 million new patients in Asia in diseases including diabetes, cancer, arthritis and obesity by 2020 and 80 percent of the patients will be from India and China.

With the growth in demand of patient care, hospitals in Asia are integrating their infrastructure with electronic health and medical records, but shortage of physicians would be a major challenge for these countries.

Mentioning the initiatives by Singapore to enhance regulatory structure in medical device sector, A/Prof Tan Sze Wee, deputy executive director, Biomedical Research Council, Agency for Science, Technology and Research, mentioned that Singapore has partnered with global organization, Regulatory Affairs Professionals Society (RAPS), to develop and implement new medical device regulatory affairs (MDRA) training program to build knowledge, critical thinking and application skills required of regulatory professionals. Besides covering the regulatory systems of the US, Europe and Asia Pacific markets, the training program is designed to offer instructions focused on the medical device regulatory requirements across Southeast Asian markets. The curriculum is delivered through a combination of online training, interactive seminars, peer interaction and case-based learning.

Some of the panellists and speakers included Ms Sasikala Devi Thangevelu, senior principal assistant director, Medical Device Authority, Malaysia; Mr Salman Bokhari, managing director, Sidrapex, Singapore: Mr Hareesh Nair, partner, Quadria Capital, Singapore; Mr Viren Mahurkar, managing partner Hitchinrock Advisors, Singapore; Dr Kevin Koh, partner and vice president, MZ Advisory, Singapore