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Short Communication

2020 Regulatory Convergence Pays off

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As the global economy wrestles with the implication of the impact of the health systems on GDP, there is a move a foot to harmonize regulatory expectations. In other words there is a "Regulatory Convergence" happening whereby the regulatory requirements across countries are slowly being harmonized. The most recent example is the effort that is being undertaken by the Chinese health agency. National Medical Products Administration (NMPA) (formerly the China Food and Drug Administration, or CFDA) was founded on the basis of the former State Food and Drug Administration (SFDA). In March 2013, the former regulatory body was rebranded and restructured as the China Food and Drug Administration, elevating it to a ministerial-level agency. This move marks China's strategy to become a global supplier in trillion-dollar health care market. The rebranded NMPA replaces a large group of overlapping regulators with an entity similar to the Food and Drug Administration of the United States, streamlining regulation processes for food and drug safety, The National Medical Products Administration is directly under the State Council of the People's public of China, which is in charge of comprehensive supervision on the safety management of food, health food and cosmetics and is the competent authority of drug regulation in mainland China.

India is another great example of the regulatory convergence undertone. The regulators and the government are ratcheting their regulatory requirements aligned with practice with ICH, US FDA and EMA. This represents an important step as the india players start commercializing the expensive biologics. Intas and Biocon are examples of companies who have embraced this change and are leading the way with product launches in US and Europe.

The regulatory harmonization can be one of the most impactful movement that will change the landscape of the the global health systems. As both India and China enter in the global space of high price biologics, gene therapy and cell therapy the impact on price and access of life saving drugs is set to impact the cost of global health care. If we look deeper into the elements that are being embodied by both the India and Chinese companies who plan to compete in the global market there still remain multiple challenges that are formidable to their success.

Convergence price -global market $600 billion

The global biotech market coupled with cell therapy is exploding both on size and the individual cost of medicine. For example cell therapy products can cost in excess of $250,000 USD for one treatment and in some cases can cost upward of $1m USD. The biotech market alone for the two largest market is approximately $600 billion USD and projected to grow 15% year over year.

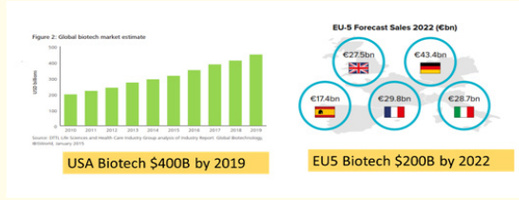

Figure 1

Thinking differently

To enter this high price game countries and companies have to think differently. There are multiple elements that require harmonization in the convergence journey. The successful companies are focusing on fixing the overall systems which in its core is anchored by Data Integrity and introspection of the old systems that have been in place in order to compete with local markets. The dynamic of the push and pull of the local regulations with global requirements are creating an interesting relationship between local and global regulators with companies and countries who are in the convergence journey. The companies who are having success see the regulators as an extension of their internal teams and often meet with them to validate internal strategies and development plans. They are also using deviation systems that were typically seen as bad news as learning tools. The corrective and preventative actions (CAPA) are transforming old processes into new allowing the convergence process to be systematized. The one quality mindset that is being embraced by successful companies are leveraging local regulatory efforts combined with the global push for right first time from the highly regulated markets like US and EU. Companies are also using consultants for short period of time to accelerate their progress in this highly price convergence strategy. The short-term consultants are being used as teachers creating internal expertise which are being placed in strategic positions in the companies.

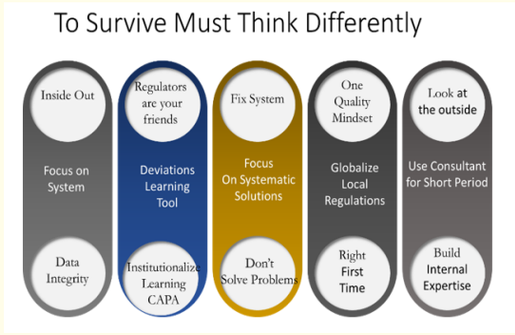

Figure 2

Leadership challenge

The companies who are embracing the harmonization and convergence are forming and creating international leadership teams and alliances. A example of this is the Mylan and Biocon biosimilar partnership which have recently achieved approvals in both US and EU markets. The company has embraced one quality mindset while leveraging external expertise to enhance their internal practices. They have adopted Mylan's right first time approach and hired short term consultants to support and accelerate their regulatory convergence. In most cases the successful companies have adopted global regulatory requirements replacing their local systems. The interlaced multinational leadership with local expertise has proven to be a successful model which allows rapid transition from local practices to global convergence.

Figure 3

Regulatory Convergence Starts with R and D

As a result of the gradual adoption of internationally recognize technical guidance documents, standards and scientific principles successful companies have found out that regulatory harmonization is required early in process development life cycle. The R and D organizations which are not used to working within a quality system framework are faced with significant organization challenge. How to innovate, develop and create in a rapid fashion, while simultaneously adopting the systems that are required to transfer product to the commercial level.

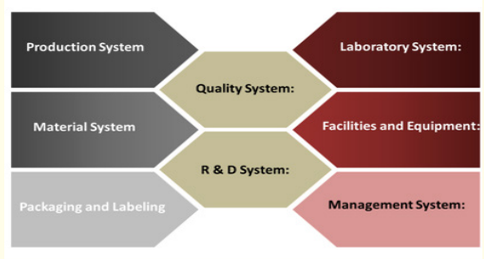

Figure 4

The R and D organization is challenged with the adoption of systems not unlike those being adopted by the GMP commercial sister organization. The management systems along with the typical systems like laboratory, material, facility, production and equipment require bolstering with a mindset that typical of full cGMP operations. The successful companies have developed a mid level organization with systems typically lead by a quality minded team that can straddle both development and the cGMP world. This organization is also leveraged in dealing with complex investigations, complaints and technical transfers to the regulated organizations.

The balancing act is achieved by looking closely at the information that will be leveraged and used in the global regulatory submission. Both experiments and data are reviewed with this lense and the balance is achieved by this intermediate organization that solely focused on meeting global expectations.

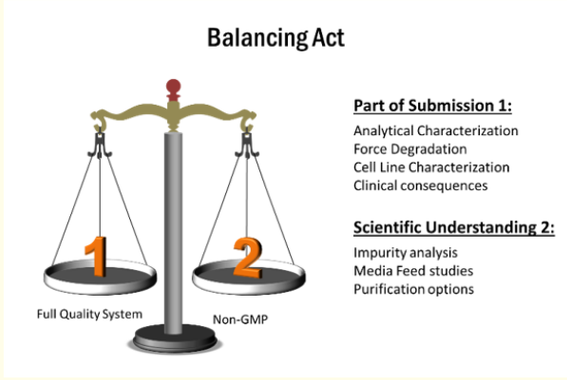

Figure 5

The regulatory harmonization and convergence will play a significant role in the global economy. As the scientific know how, coupled with the global regulatory mindset that is being adopted by the largest countries take hold in 2020 it will have a lasting impact on the global economy with the potential launches of products originating from lower cost countries in Asia and other parts of the world.

2020 transformative year and convergence benefit realized

2020 is set to be a transformative year as companies from outside US and EU are filing their products at record pace. The recent

biosimilar approvals for complex biologics are providing a lense on the impact that these countries and companies are having on the cost of health care. Europe for example has saved billions of dollars by approving biotech products that originate from other countries. Products that typically cost the health system thousands of dollars have entered the market at 50-70% discount. The approval and successes of both companies and countries who have advance on the regulatory convergence journey have shown that the effort has a significant financial benefit and lasting impact on the global economies.