Interview: Carol Cheng – COO, Taiwan Research-Based Biopharmaceutical Manufacturers Association (TRPMA)



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Carol Cheng, COO of the Taiwan Research-based Biopharmaceutical Manufacturers Association (TRPMA), provides insights into the recent development of the country's innovative biopharmaceutical industry, while she also highlights TRPMA's eye-catching initiative to promote international collaboration between Taiwan's academia and the global industry, thanks to the recent set up of the association's BioIPSeeds

® platform, which proudly stands as the first application of the blockchain technology into the biopharmaceutical field.

You have been heading TRPMA since it was founded in November 2012. What are the association's main mandates?

Taiwan Research-based Biopharmaceutical Manufacturers Association (TRPMA) comprises 28 Taiwan-based, R&D-driven biopharmaceutical companies. As the association representing local innovators, we hold a central role in bolstering strategic alliances including the R&D-driven biopharmaceutical industry, academia, and Taiwan's government. Regarding our relationship with the government, we jointly strive to make Taiwan an evermore competitive and attractive biopharmaceutical hub, which will in turn boost our country's economy – especially as President Tsai recently established our industry as a strategic sector for Taiwan's new economic model.

In the meantime, TRPMA also plays a crucial role in nurturing knowledge transfer among its members. In this regard, we organize more than 150 training sessions and regulatory reviews per year, which involve all these companies' operational departments, from drug discovery to international marketing and pricing.

Finally, TRPMA aims to operate as a window to the world for its members, by providing them with a comprehensive monitoring of key target markets. To help our members adapting their strategies to the recent reforms implemented by China FDA, we provided them with comprehensive regulatory and market reviews beforehand, while overall we cover the policy changes and market trends occurring in a vast array of countries, including Japan and China, and also the US, the EU, and the ASEAN region – in line with the global strategy favored by most of TRPMA companies. Actually, this international approach goes far beyond the regulatory side, as we also handle international promotion activities and reach out to TRPMA's counterparts all over the world and showcase the achievements of our country's biotech industry.

What are the main aspects that you are currently discussing with Taiwan's government to propel the growth of the local, innovation-driven industry over the upcoming years?

Even before President Tsai was elected in January 2016, TRPMA was already liaising with her campaign team to discuss crucial reforms that could be implemented under her tenure, especially with regards to labor and corporate regulations. Since she took office in May 2016, this privileged flow of communication has been preserved, and it now stands as a great asset towards our common objective to boost Taiwan's biotech capacity.

Furthermore, TRPMA is particularly focused on further streamlining and shortening all kind of approval processes that still slow down the development of innovative biopharmaceutical companies in Taiwan, be it related to clinical trials, market approval or pricing policies for locally developed treatments. In this endeavor, it is crucial to ensure Taiwan stands as the first country in the world to approve locally developed treatments, as this approach would in turn accelerate the triggering of local companies' export strategies.

[Featured_in]

Regulatory support should also be provided at the very early stage of the drug development process, by following the way of the US FDA and its "breakthrough therapy" designation.

Overall, it means our healthcare ecosystem should embrace a three-fold reform: first, a true mindset change regarding the role to be played by regulatory organizations in the development of

our local industry. This should be combined with a structural reform of our market access regulations, while – finally- we need to continuously strengthen our country's scientific capacity when it comes to market access evaluation of new biopharmaceutical products.

In the grand scheme of things, our overall objective from a patient-centric point of view would be to ensure Taiwan's patients are among the first in the world to access life-changing treatments, whether they were locally developed or not.

What are the tangible signs that make you believe Taiwan's innovative, biopharmaceutical industry has truly been gaining in maturity over the past few years?

First, the growth of Taiwan's biopharmaceutical, R&D-driven industry has been constant over the past three years while our companies have been steadily accumulating overseas success and recognition, especially in the US.

Second, our members are increasingly keen to share expertise and collectively find solutions to ensure our companies become stronger year after year– and TRPMA plays a central role in fostering this crucial aspect. Although our members are operating throughout a great variety of fields and therapeutic areas, we are now clearly focused on finding synergies and benefiting from each other's experience.

From an R&D perspective, our progresses are also eye-catching. TRPMA members' combined pipeline has not only been maturing over the past years, but also continuously expanding to now count 173 compounds under development. As part of these 173 molecules, 82 investigational new drug (IND) applications were submitted to the US FDA. In the meantime, we see that TRPMA's members have also been gaining in precision in the drug discovery process, especially with regards to the drug design and selection process, as well as for the development of strategic and international alliances. Overall, this enriched experience contributes to reduce the risk exposure of our companies.

Finally, we also see that the international R&D dynamic has been evolving in a very promising direction. A few years ago, the innovation flow between Japan and Taiwan would mostly relate to the in-licensing of Japan-developed innovative projects by ambitious Taiwanese companies. We now see Japanese companies increasingly licensing-in innovative projects developed and matured by Taiwanese companies.

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Further bolstering Taiwan's collaboration culture is particularly high in the agenda of many public and private stakeholders. What is the contribution of TRPMA to the fulfillment of this important objective?

There is a crucial need to develop Taiwan's Open Innovation culture, as such collaborative approach encompassing both academia and the industry hasn't yet been embedded deep enough in the roots of our healthcare sector. Taiwan undeniably holds world-class research and cutting-edge innovation capacities, while our biopharmaceutical ecosystem has also accumulated a considerable amount of expertise over the past decade. Nevertheless, the impact of these twenty years of intensive R&D efforts could be even further enhanced if local research institutions and international companies were partnering more comprehensively and at an earlier stage of the drug development process.

Our strategy was to build a completely safe, user-friendly digital platform that would gather together all discoveries and innovation coming from Taiwan's research centers and universities. This vision became a reality with the set up of BioIPSeeds in February 2017, a groundbreaking platform that aims to foster the collaboration between Taiwan's individual researchers and research institutes (universities, industry-academia collaboration centers, and technology transfer offices) and the global industry (biopharmaceutical, medical devices, and all healthcare-related companies as well as venture capital companies).

Given that BioIPSeeds aims to gather all the most recent discoveries coming out of Taiwan's research centers and connect them to the global industry, building the safest digital environment possible must stand as one of your main priorities. **Is it the reason why you opted for the blockchain technology, rather than a traditional database?**

Exactly! As a matter of fact, our BioIPSeeds platform proudly stands out as the first application of the blockchain technology into the biopharmaceutical field.

Conceptually, blockchain stands as a distributed database that maintains a continuously growing list of ordered records, which means that, by design, blockchains are inherently resistant to modification of the data. Once recorded, the data in a block cannot be altered retroactively and becomes part of a permanent record.

Furthermore, thanks to its inherent peer-to-peer network, a blockchain database is managed autonomously; hence, no middleman is needed. These specificities stand as particularly crucial assets when it comes to gathering early phase projects and world-class discoveries on the same platform. It also explains why we chose to invest in such a cutting-edge technology, which was

described in 2015 by the Economist as *“a machine for creating trust”.*

With our BioIPSeeds platform, both the IP summary (non-confidential data) and the IP Notary (confidential data, including a proof of ownership) are safely anchored on both Bitcoin and Ethereum public blockchains with timestamp. When a given IP draws the attention of a company, the latter can request more information about it from the researcher directly through BioIPSeeds. If interested, the IP’s owner can then issue an online Non-Disclosure Agreements (NDAs) that is also anchored on blockchains, rendering rendering this usually time-consuming part of the co-development process tremendously easy and convenient.

Once the NDA is safely signed by the two parties, the researcher can then send and transfer the encrypted data to the designated receiver, who would be the only holding the personal key needed to decrypt the data file.

It is very rare to see an industry association developing such an innovative platform to link local researchers and universities to the healthcare industry. Which companies will be able to benefit from BioIPSeeds ?

More than a simple tool, with BioIPSeeds we aim to create a new model of cooperation between academia and the global industry, triggering the launch of an increasing number of successful projects and facilitating technology transfer, authorization, and commercialization process globally.

In terms of tangible, expected benefits, BioIPSeeds and decentralized peer-to-peer marketplaces will contribute to tremendously reduce the time and the cost invested by companies in innovation screening, while online NDA and IP exchange will bring more efficiency to the global co-development and commercialization process.

As a result, BioIPSeed’s target goes beyond Taiwanese companies and TRPMA’s members, which have naturally been the first ones to benefit from this innovative platform. Our overarching ambition is to narrow the gap between Taiwanese researchers and international companies, encompassing their executives, R&D-decision makers, as well as their regional and global business development leaders. As a matter of fact, we have already been rather successful in this regard, as – only a few weeks after we launched our BioIPSeeds platform – we are particularly glad to announce that a first international company has already joined the platform.

In the meantime, we already cover more than 15 universities and research centers in Taiwan, including some of the country’s most prestigious institutions involved in the pharmaceutical and healthcare fields, and this number keeps on increasing rapidly.

What is your final message to our international readers?

For the last fifteen years, Taiwan’s biopharmaceutical ecosystem has been tirelessly nurturing its continuous improvement, and we have already reached some critical milestones on the international stage, with locally- developed innovative products receiving FDA and EMA approval and international licensing partnerships formed by some of our most advanced companies.

Taiwan also holds world-class research centers and experts in crucial therapeutic areas and pioneering drug development fields, while local research and development costs remain substantially lower than in Europe, North America or Japan.

If we combine these structural elements with the experience gained by our innovative companies and the new collaborative approach TRPMA strives to bolster with BioIPSeeds, I am confident Taiwan’s innovation-driven ecosystem will soon be widely recognized as a biopharmaceutical hub of reference in the world.

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