Interview: Herny Prasetya – President, International Society of Pharmaceutical Engineering (ISPE), Indonesia



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Herny Prasetya, President of the International Society of Pharmaceutical Engineering (ISPE) in Indonesia highlights the importance of the implementation of global guidelines in Indonesia and wishes to focus on human capital, compliance and local API manufacturing for ISPE's members.

Could you please introduce to our international audience what are the main operations and activities of ISPE in Indonesia as well as the latest accomplishments?

ISPE Indonesia is an affiliate following the policy of ISPE worldwide, whose headquarters are in Tampa, Florida, in the USA. While ISPE Tampa is very close to the FDA, we are engaged in a close working partnership with the BPOM (National Agency of Food and Drug Control Indonesia). Our responsibility is to ensure knowledge sharing about the regulations for the pharmaceutical industry with all our members as well as informing good practices and new technology in pharmaceutical manufacturing.

As for our accomplishments, even though local companies were the only ones attending our workshops nine years ago, I am proud to confirm that we currently have MNCs coming as well as participating not only in the workshops but also in the seminars and conferences we organize.

Moreover, we have started to open programs for students in order to bring the industrial world closer to them and to give them the opportunity to early prepare themselves for the professional arena.

As President of ISPE, what are the main priorities on your agenda considering the high dynamism of the industry?

Our main concern is how to really help the industry to implement the regulations in their operations. We wish to bring the concept of integrity closer to the ones in charge of creating regulation and have them realize that the pharmaceutical industry is a very critical one – we are making medicine, lives depend on us. So, while we are aiming for minimal restrictions, we really stand for integrity that will ensure the highest level of quality.

ISPE is positioned as the largest non-profit association in the pharmaceutical field to support its members across the global pharmaceutical and biopharmaceutical industry in the manufacture of quality medicines. Could you expand on the added value that ISPE is bringing to its members by ensuring that the pharmaceutical industry gets the high professionals that they need for example?

It is a fact that other developing countries are already discussing beyond compliance but in Indonesia we are still struggling with compliance. If we truly wish to become the giant in the region and globally, I strongly believe that continuous improvement is crucial.

Indonesia, even though a big country, encounters the challenge of human capital. Talent pool is a theme that is certainly within our agenda and, consequently, we have added a series of aspects to address in our agenda for the year. Nonetheless, ISPE is lacking resources to speed up its operations and its board is composed of volunteers, who most of them are still active in the pharmaceutical industry.

Indonesia is one of the strongest pharmaceutical markets within the region. Indeed, it is valued at 5.5 billion USD with an incredible 12.6 percent annual growth, which is expected to be maintained in 2018 as well as to reach 12 billion USD value by 2020. As an expert in the sector, what are the steps that the international and local pharmaceutical industry should undertake, from the manufacturing standpoint, in order to encompass such growth?

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First of all, I think that being ready is not just about the hardware, building new facilities, expansion and so on. I believe that what really counts is the readiness of the professionals behind this. I foresee tighter regulations in the years to come and, in order to encompass such dynamism, the readiness of the industry is mandatory. Hence, the industry needs to increase the level of

professionalism in its organizations to successfully navigate in the short as well as the long term.

BPOM is making strong efforts to ensure that Indonesia complies with the PIC/S standards. Such intentions have increased the interest of pharmaceutical and biotechnology manufacturing companies from Europe and the Americas to establish Indonesia as a manufacturing hub for medical products. What are your conclusions on that and do you believe Indonesia offers the necessary environment for quality production?

Yes and not at the same time, it certainly depends on the way you look at it. At the moment, you can observe local companies but also MNCs competing with each other over the Indonesian market but it is also important to look beyond the local map.

As Indonesia is a member of PIC/S, industry should see PIC/S as a great way to comply with not only the national regulation but also the regional and the global standards. Complying with such a guideline since the beginning will, again, ensure the readiness of the industry as well as scale its capabilities to serve the demand outside Indonesia.

When we had the pleasure to attend CPhI Indonesia last month, the common topic was that Indonesia should reduce its dependence on imported pharmaceutical raw materials, which has now reached 95 percent, in order to reduce its manufacturing costs. What do you think that the government and the industry should do in order to increase its self-sufficiency in this regard?

There have been positive advancements during the last two years in Indonesia but there is still a long way to go. Indeed, I think that the cost of manufacturing is still quite high, especially when it comes to producing APIs from scratch. Currently, some companies have invested and taken over API manufacturers in order to produce domestically but this is far from being the rule. So of course, Indonesia should try to invite foreign as well as national investors to develop domestic APIs manufacturing capabilities because nowadays we depend so heavily on China and India.

Coming back to the foreign API manufacturers, the current situation puts the local manufacturers at incapacity to compete with the prices offered by Indian or Chinese companies.

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The government needs to create a business-friendly environment that will attract not only FDI but also NDI to develop the APIs domestic capabilities and enable local companies to integrate themselves vertically in the value chain so that they can offer more cost attractive options to the

WHO or any other national, regional, or global institution.

Thanks to its global footprint, ISPE's Indonesian affiliate acts as a catalyst of the international and regional best practices that will enhance the domestic pharmaceutical industry. What are some of the most prominent take away from the international pharmaceutical landscape that will be interesting to implement in Indonesia?

We believe that the Indonesian industry should move towards continuous production as well as enforcing data integrity. At ISPE we have speakers from all over the world coming to showcase to our members the global best practices that would be interesting to implement locally.

ISPE awarded honourable mentions during its Facility of the Year Awards (FOYA) to Kalbio Global Medika for its greenfield Biotech Facility project in Indonesia. What are some other interesting successful stories that you would like to share with our international audience?

The ISPE FOYA exists to provide local manufacturers with an encouraging outlook.

Other local company that I would like to highlight due to its great performance is Dexa Group, which stands out by its clear vision, ambition, strategy and direction. Nevertheless, there are other success stories such as Kalbe and Biofarma.

What are the three main objectives that you would like to accomplish in the upcoming years?

Firstly, we wish to strengthen the human capital within the industry, and ISPE plans to be a help to the industry in that regard, this is also the reason ISPE Indonesia is active nurturing students to be ready to enter the pharmaceutical world. Secondly, enhance regulation compliance situation in Indonesia aligning industry's operations with the national and global guidelines, ISPE has and will continuously support BPOM project in this area. Finally, we will focus our attention on data integrity since there is a lot to be done in Indonesia in this regard.

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