Interview: Fatma Taman – Chair & General Manager, ISPE Turkey & PharmaVision – Turkey



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Fatma Taman, Chair of ISPE and General Manager of PharmaVision, discusses the importance of proper education and training within the pharmaceutical industry to ensure the sector's sustainable growth and development.

Today we meet with you for the first time as the Chair of ISPE Turkey Affiliate; what have been your initiatives or priorities since assuming the position of Chair?

Considering that this year marks the 10th anniversary of ISPE Turkey Affiliate, I am very honored to have this responsibility as the organization's new chair. Under the leadership of Dr. Ünsal Hekiman, the first chair and founder of the Turkish Affiliate in 2005, and Prof. Dr. Ahmet Araman, the second chair, ISPE Turkey has grown tremendously and made significant strides in furthering the education and training of pharmaceutical professionals. This is largely on account of the high quality and good organization of the educational seminars held twice a year where the most current topics of pharmaceutical industry are presented through best available experts in a cost effective way.

Since the foundation of the affiliate, we've pursued the organization's initiatives in enhancing the industry's knowledge and the resources for the future. As a result of an active cooperation between ISPE Turkey Affiliate and the Ministry of National Education's General Directorate for Technical Vocational Education, "Pharmaceutical Manufacturing Technician" curriculum started in Turkey for the first time in 2008, at Kadırga Vocational High School, which has been chosen as a pilot school

for the implementation of this brand new project aiming to properly train qualified technical personnel needed by the pharmaceutical industry. To supplement this education on the application side, under the leadership of ISPE Turkey Affiliate again, a “Pharmaceutical Manufacturing Technician Training Laboratory” where students can prepare various pharmaceutical forms as placebo, was also built and made available to students. In the coming years, I look forward to providing and conducting more trainings at vocational high schools, combined with an increase in scholarship funds, in hopes of eventually expanding the pool of adequately trained and certified professionals available in the industry.

On the university level, ISPE Turkey had a significant input in introducing the Pharmaceutical Engineering concept and related activities to various universities in Turkey and starting the country’s first “Pharmaceutical Engineering” course at Istanbul University’s Faculty of Pharmacy. This pioneering course in Turkey initially began as elective in 2007, achieved required status in 2010 and following the approval of the related masters program by Turkish Higher Education Council, became also available in extended form as a masters program in September 2011. ISPE Board members, myself included, frequently give lectures at these universities, as we feel responsible for sharing our experiences in pharmaceutical engineering and to pass on our knowledge in this relatively new field.

Another priority focuses on building new working groups for QbD (Quality by Design) and PAT (Process Analytical Technologies), to create a forum that encourages information exchange on a quarterly basis. We believe hot topics like regulatory requirements, technical challenges, good practice examples will be easier to address with a unified voice.

Given the type and sophistication of your members, what are the key topics that ISPE Turkey is covering in your educational seminars, and in your groundbreaking pharmaceutical engineering course at Istanbul University?

Our workshops and seminars are now encompassing a broad set of areas including, but not limited to, Good Engineering Practices (GEP), Product Quality Lifecycle Implementation (PQLI), GMP Compliance, Good Distribution Practices (GDP), Containment, Good Automated Manufacturing Practices (GAMP), Biotechnology, Pharmacovigilance and Regulatory Developments. We pay close attention to all active topics regarding the current regulatory environment and changes in regulations, and consequently re-evaluate the training needs in the industry accordingly. Constantly in close collaboration with the MoH, ISPE makes extensive efforts to provide the industry with comprehensive educational resources, whether it’s through case studies, conferences, workshops, or presentations personally conducted by first-hand accounts of

regulators. Starting this year, we aim to also offer in-house trainings for pharmaceutical manufacturers and distributors based on their needs and requests in accordance with upcoming regulations.

In 2012, you shared with us several new directions that PharmaVision had the opportunity to expand in, ranging from food supplements, to niche pharmaceuticals, and exports to Europe given your late 2010 EU GMP certification. In retrospect, in what directions has PharmaVision grown over the last three years?

As a result of another inspection in 2013, our EU GMP certification for solid production has been extended for another three years. In addition, we also earned the right to receive EU GMP certification for oral cephalosporin production, which is conducted on a completely separate building. These certifications are concrete indicators of our experience and quality and constitute important milestones in the realization of our export-oriented production goals.

In light of those trends, the products manufactured at our site are exported to more than 30 countries now, summing up to ten percent of our production volume and we continue to steadily grow with production opportunities looming in the horizon. Starting 2017, several patents will start to expire, and at that point we will be able to start manufacturing products that will be exported to countries all over Europe. Molecules have already been transferred, parallel marketing authorizations already obtained, and pilot batches already produced—at this point we are ready to hit the ground running when the time arrives. Preparation before the patent expiry is extremely crucial in order to minimize inefficiencies and maximize revenue generation opportunities. With the country providing the prices near to the East with the quality of the West, we’re optimistic in the Turkish Republic’s healthcare strategies for 2023, and proud of our efforts in enhancing its progress.

Specifically, you quoted a target to double production volumes by 2015, and to begin to export products developed by PharmaVision to Europe, Canada, and Brazil. How successful have you been in achieving these goals?

We have managed to initiate technology transfers to our manufacturing facilities for more than 200 SKUs since 2012. However, in terms of production volume, that target has been inhibited by pricing challenges in Turkey. Since 2009, the exchange rate used for converting reference prices for pharmaceuticals stayed the same (1.9595 TRL/EUR, although the current exchange rate is over 2,90 TL/EUR), and this alone has been limiting our production volumes, as many companies have been downsizing order quantities—up to 50 percent at times. Thankfully, the boost in transfer

volumes have helped offset our exposure to currency risk.

Looking forward three to five years, what are your personal professional priorities and objectives, with regards to both PharmaVision and ISPE?

In terms of accomplishments, ISPE Turkey Affiliate has won three big awards in the past decade: the Affiliate of the Year Recognition in 2007, Student Chapter of the Year Award in 2009 and the Golden Mortar Award in 2011. We hope to continue this trend of excellence moving forward, as ISPE is the only institution that places unparalleled emphasis on the quality of products, as opposed to the price. With an extensive repository of experiences, perspectives, and educational resources, and a roster of nearly 200 members that collectively represent the entire Turkish pharmaceutical market, ISPE Turkey is well-positioned in becoming the preferred not-for-profit organization for educating, training, and enhancing students and pharmaceutical industry players.

For PharmaVision, we want to continue our localization efforts on the domestic front, while increasing our competitiveness globally. Ultimately, we're aspiring to become the preferred contract manufacturing partner for international companies looking to produce their products here in Turkey. We pride ourselves on operating a company that values cost-efficient solutions without compromising the quality of products. My hope is that our reputation and history of excellence will help establish a perception of trust and reliability among all PharmaVision clients and potential new partners.

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