INNOVATION COUNCIL

Q&A with Techinvention

Innovation Council brings together diverse innovators to share their experiences with policymakers and other stakeholders. TechInvention Lifecare PvT Ltd, was founded in 2016 with the objective of increasing the supply of Vaccines and Bio-Therapeutics for low and middle-income countries (LMICs), is an Innovation Council member based in India. Here, in his own words, Syed Ahmed, the company's CEO, shares insights about his company's activities, challenges, and successes in recent years.

In order to ensure success in this endeavor, TechInvention operates using a three-pronged strategy:

a. **A Technical + Strategic Advisory Team**, which conducts comprehensive feasibility studies for vaccine and biotherapeutic manufacturing projects, and is responsible for managing all stages of these projects.

b. **A Licensing Team,** supported by 4 sub-teams: IP, Regulatory, Clinical, and Medical, which successfully license in products and technologies appropriate to LMICs and register them in countries and regions of interest. Access to these products and technologies has often proven vital to the success of local manufacturing projects, especially those that involve a backward integration strategy.

c. **An R & D team**, focused on developing Vaccines and Bio Therapeutics for infectious diseases endemic to LMICs. The R&D team is also involved in those manufacturing projects in which a forward integration strategy is followed by full-cycle manufacturing

d. In most instances in LMICs, a hybrid model works best, in which all three of the above-mentioned teams work cohesively to enable a successful project outcome.

1. How did your companies get started?

a. During the last Swine Flu (H1N1) pandemic, there was a scramble for vaccines, and many LMICs contemplated getting into vaccine manufacturing in order to reduce import dependence.

b. When those countries began looking for companies that could make vaccines on their soil, however, they found that there wasn't a single organization that could carry out the process from start to finish, and also bring into the country the expertise necessary to overcome a lack of preexisting local knowledge and experience in biomanufacturing. Rather, the only entities that they could find to do this were consortia of different companies, making the process complex and challenging.

c. The need for such an organization, which could carry out all parts of the manufacturing process while also training local scientists and factory workers during the process of scaling up manufacturing (in other words, which could carry out every part of the process "from concept to commercialization," was widely acknowledged, and provided the impetus for us to start TechInvention. It took us a few years to get off the ground, but now we are meeting this need.

2. When was the moment when you knew that your business was on track for a successful future?

When the scope of our engagement with a state-owned company in Russia started expanding from just technology transfer to strategic and technical advisoring for vaccine manufacturing.

3. Name some factors behind your company's success to date?

a. The specific focus on a "niche" in the market - Vaccines & novel Biotherapeutics as a core competence.

b. The adoption of the above-mentioned 3-pillar company structure, providing 360-degree support to enable successful project outcomes.

c. Being sensitive, acting with a huge degree of empathy for the needs of LMICs when it comes manufacturing projects of the highest complexity in Pharma, namely vaccines and biotherapeutics.

4. What is the role of innovation at your business?

Vital. This is because:

a. With the IP frameworks that are evolving in many LMICs, we need to ensure that we don't infringe upon the IP of others. Rather, we have to innovate on our own.

b. In LMICs, innovation largely revolves around the so-called "two C's:" Cost Effective and Compliant. Meeting both of these requirements, being both economical and in line with regulatory requirements, poses special challenges, and requires quite a bit of out-of-the-box thinking and innovation.

5. How much does collaboration matter for your work?

It is of paramount importance, especially given that most LMICs do not have structures in place to manage local vaccine and biotherapeutic manufacturing projects. For this reason, collaboration across borders, and between governments and private organizations, are absolutely crucial. There are several important success stories of collaboration between governments and private entities.

6. What can governments do to foster innovation and entrepreneurship?

In the arena of vaccines and biotherapeutics in LMICs, this is mostly a matter of making projects viable. Particularly important is the fact that governments are the primary buyers of locally-manufactured vaccines and biotherapeutics. Hence, governments wishing to foster entrepreneurship can:

a. Support companies by using buy-back arrangements

b. Use incentives and standard operating procedures (SOPs) to incentivize the use of local manufacturing over imports

c. Be more open to the concept of public-private partnerships (PPPs) and similar structures.

7. How has your company interacted with the intellectual property rights system?

For starters, we have categories of products for which we undertake R&D: vaccines and biotherapeutics.

a. For both categories, we use incremental innovation, which may, under some circumstances, be considered disruptive.

b. Also in both cases, after a freedom to operate analysis (FTO), we have been filing patents in India. We have also started filing in some other overseas jurisdictions.

8. What are the most important lessons that your team has learned so far?

a. The need to have comprehensive & all-encompassing legal documents in place prior to the commencement of any project.

b. Not to let out too many concepts at a pitch stage. (start-ups are vulnerable to exploitation by established companies, and are normally not in a position to take legal action given their limited resources)

c. A thorough and in-depth profiling of the target product is required to ensure its commercial success in a particular country

9. New technologies and approaches sometimes face a lag in customer and government regulators' acceptance. What can be done to accelerate uptake of novel products and services?

a. Initiate communication with regulators early on in the development process.
b. Gain the support of key thought leaders and subject-matter experts in the field
c. Promote the concept through global forums, networks, and scientific symposia.

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