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#Consure Medical #Axio Biosolutions #Achira Labs #Abhinav Ramani

# How medical devices startups are taking a plunge into manufacturing

*To be world-class, the first step is to build manufacturing units that conform to global certification standards.*

It isn't easy yet to be an inventor in India. For one, the country is geared more to a culture of frugal engineering and workarounds, celebrated globally as *jugaad*, than to pure inventions.

Then, there's the uncertainty and difficult process of manufacturing in an economy that for decades has been services-led.

So it couldn't have been an easy decision for Dhananjay Dendukuri to establish a 2,000-square-foot manufacturing unit in Bengaluru, which began operations last year. His startup Achira Labs, which has about 25 patents, is a maker of microfluidics diagnostic tools, which are test kits capable of diagnosing for multiple ailments in one go.

"Our manufacturing itself has research and development components. Not a lot of people out there know to make it," said Dendukuri, a Ph.D. in chemical engineering from Massachusetts Institute of Technology. "In these cases, you want to build control and do (the manufacturing) yourselves for various reasons—one is competence, your team knows how to do it; and you may want to protect some trade secrets."

There's another reason that Dendukuri cites wearing his businessman hat: "If you need to keep iterating and going back and forth (with the supplier), it is a pain." Medical devices startups have proved to be the bright spot in India's dismal healthcare industry. Young businesses have successfully combined frugal engineering with pure innovation skills to build devices specific to the country.

Now, a growing tribe of medical device entrepreneurs is venturing into manufacturing for the improved control, IP protection and ease of making iterations it allows.

With the exception of a few like Achira Labs, nearly all medical devices startups in India began with outsourcing their manufacturing. While they do have investors backing them, these companies do not



attract the kind of capital that ecommerce companies do. Manufacturing is expensive and demands constant attention.

### **Additional burdens**

In the case of medical devices makers, it comes with the added responsibility of handholding vendors and factory workers because manufacturing for this sector is still nascent in India. There's also the apprehension of IP and design theft, high contract costs, little control over the manufacturing process, and the hassle of back-and-forth with contractors for any iterations.

"When you have your own manufacturing unit, it is under your control. For example, when volume increases, you can manage it by additional lines, shifts, whatever it takes. Delivery management becomes much easier," said K Chandrasekhar, CEO of Forus Health, whose portable eye screening devices have been deployed in 25 countries.

Forus had contracted out its manufacturing until January 2015, when it moved to its own facility in South Bengaluru. There's one more reason, says Chandrasekhar.

"By definition, when you outsource the job, you are a trader. When you are intent on working on something like government tenders, only if you have these parameters are you defined as a manufacturer. That was one thing that we always had in mind." Leo Mavelly, CEO of Bengaluru based wound care startup Axio Biosolutions, had contracted out his manufacturing to a company in Ahmedabad until deciding last year to have his company take control. "We had reached a certain volume and we knew this was worthwhile.

If we had continued with the contract, the product cost would have remained high and we would have been dependent on them. Now we can control the process. It helps us innovate and scale faster," Mavelly said. Axio is in the final stages of completing its 20,000-square foot manufacturing unit in Ahmedabad.

### **Establishing process**

To be world-class, the first step is to build manufacturing units that conform to global certification standards. For securing Conformite Europeenne certification required in the European Economic Area and approvals by the US Food and Drug Administration, "quality control is key," said RJ Venkatramanan, head of manufacturing and operations at Forus Health. "Having a world-class unit gives confidence."

To get these certifications and approvals, manufacturing units must follow strict guidelines. From factory employees to vendors supplying key components, everyone needs to comply.

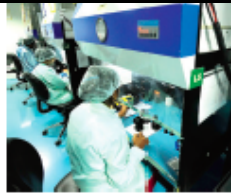
"Due to these quality systems, process structures are required. To be able to do that, (quality) has be in the blood of the organisation," said Abhinav Ramani, lead-strategy and business development at Consure Medical, a maker of stool management kits for bedridden patients that recently set up a 700-square feet manufacturing unit in its Delhi office.

Ramani added: "If you are developing novel devices that have not been in market ever before, you are creating, for the first time, machinery and manufacturing processes. You have no rule of thumb to go by."



**What goes behind building a manufacturing unit?**

- How many units are to be made in the next few years?
- Floor area required for goods, assembly lines
- Buying the required space
- Spending time on the floor plan
- Decide what kinds of rooms and devices you would want
- Setting plant processes like the equipment flow, etc
- Getting the necessary approvals



**FORUS HEALTH**

Develops ophthalmic devices. Its adult retinal imaging device '3nethra classic' is its flagship product

**MEDICAL**  
Makes stool management kit 'Qora'



**AXIO BIOSOLUTIONS**

Makes 'AxioStat', a sponge-like biomaterial dressing that stops intense bleeding within minutes



**SKANRAY TECHNOLOGIES**

High Frequency X-Ray Imaging Systems, Critical Care, Dental Care, Primary Healthcare and Telemedicine devices

**ACHIRA LABS**

Has developed a plastic, microfluidic device to perform rapid and multiple tests of blood samples

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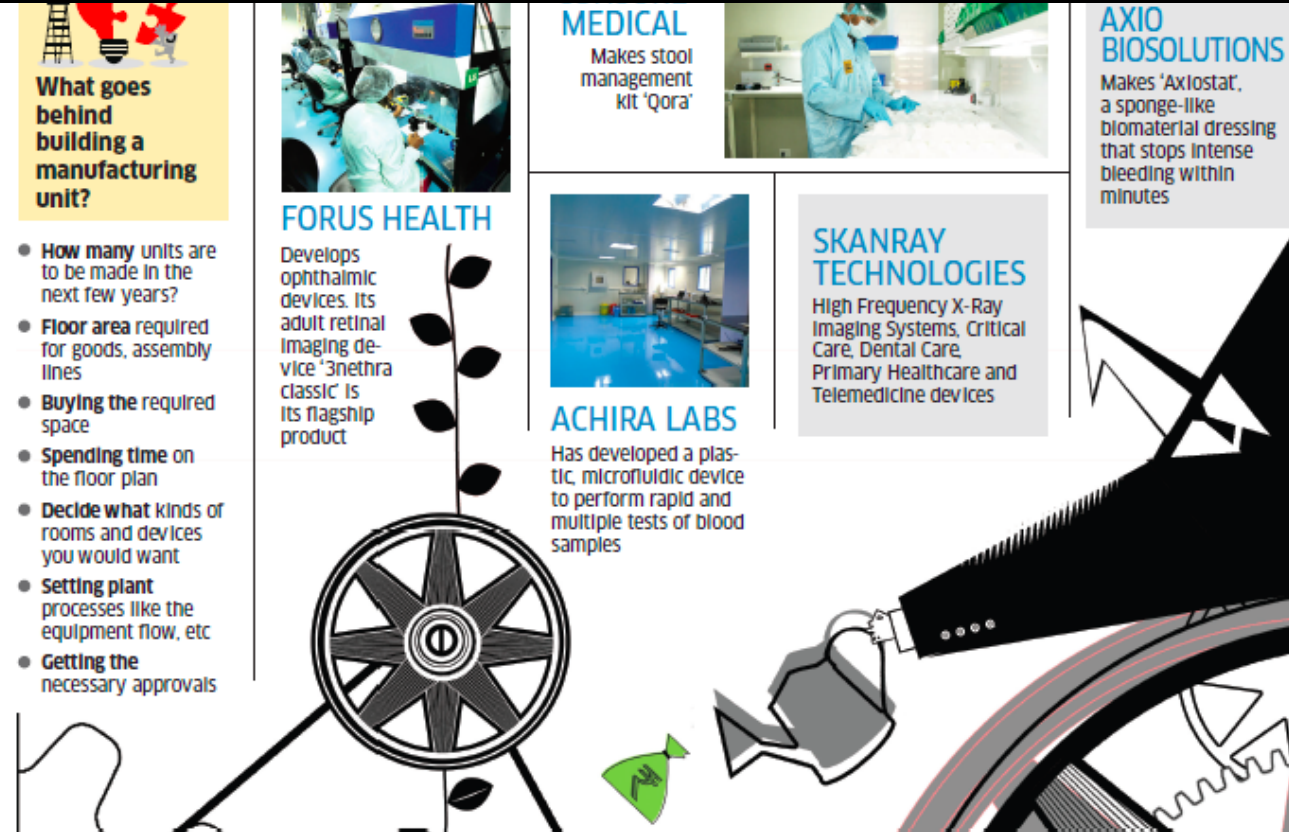
J Vignesh | ET Bureau

Aug 26, 2016, 07.39 AM IST

**Overcoming obstacles**

Sadly, the right vendors and product development talent for specialized medical devices manufacturing are in dearth.

"Apart from a shortage of product designers, India poses several challenges for med-tech design and manufacturing. India has grown as a software services and back office support hub. A lot of product development skills and hardware talent migrated to services for higher remuneration," said Vishwaprasad Alva, managing director of Mysuru-based Skanray Technologies, which manufactures a host of devices including X-ray machines, telemedicine units, dental products and patient monitoring





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"We had to create a totally new supplier base and quality mindset in small component manufacturers, which is the next big challenge after product design skill shortage," he said.

Almost all startups that have manufacturing units have had to invest time and effort in skilling their workers and handholding vendors, thereby creating processes for time to come.

Forus needed almost three years to get its vendor to understand and scale up for its processes. Deciding to have a manufacturing unit also means a large upfront cost.

This means the startups need to have supportive investors. "We cannot do it without cash. In our case, the investors understood there is no path ahead without this (unit)... It was a fairly big chunk of cash," said Dendukuri of Achira Labs.

Alva believes the government should play a role in developing the ecosystem for medical devices startups. One important factor for the new push is the Narendra Modi government's thrust on manufacturing locally with its highdecible 'Make in India' campaign.

"Access to seed funding at fair terms; fairness and transparency in government purchases and tenders; clusters and incubation centres jointly managed by the government and industry; access to test labs and government research establishments for research and core technology; working capital through simplified banking procedures will all help to create an ecosystem for new enterprises... We are seeing a lot of activity from (government) agencies," said Alva.

"There is a positive trend with new generation engineers, entrepreneurs and the new government."

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