Medtech Report India

A handbook for Swiss startups
In this report, medical technology (medtech) is defined to include medical devices, surgical and medical instruments, surgical appliances, dental equipment, medical equipment and wearables. Healthcare sector includes medtech as well.

**Million** ($10^6$) is denoted by m and **Billion** ($10^9$) by bn.

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The Medtech Market Potential in India

Growing population, rising income levels and changing disease profiles call for high quality medtech to bridge the gap between demand and supply of healthcare, making India an extremely attractive market.

**CHF* 50 billion**

market opportunity by 2025.

Medtech sector growth
(in CHF*)
12% **CAGR**

Healthcare status
Low doctor population ratio 1:1428
(Switzerland - 1:250)

Infectious diseases:
Tuberculosis kills more than 1000 people a day
95% of India resides in Malaria endemic regions

Non-communicable diseases:
Largest number of diabetics in the world
Heart disease occurs 10-15 years earlier than in the west

Rapidly growing healthcare sector
Revenue by disease (80 billion CHF* in 2013)

- Infectious Diseases: 21.35%
- Cardiovascular/ Hypertension/ Diabetes: 17.85%
- Oncology: 7.74%
- Trauma Care: 7.37%
- Gastrology: 6.99%
- Orthopedics: 4.99%
- Others: 33.71%

Medtech sector segmentation:

- **TS**: TotalSales CHF* (m)
- **I**: Imports CHF* (m)

**Electronics and equipment, surgical instruments**

- TS: 2459.26
- I: 2150.48
- % Imports: 87.44

**Implants**

- TS: 325.93
- I: 259.35
- % Imports: 79.57

**In-vitro diagnostic reagents**

- TS: 362.96
- I: 280.53
- % Imports: 77.29

**Disposables and consumables**

- TS: 1429.63
- I: 468.76
- % Imports: 32.79

**Sectors by revenue**

- Manufacturing (Domestic sales and exports, finished and raw materials): 40%
- Sales: 40%
- New market creation (products, investments): 20%

Fast growing segments

- **Patient aids**: 19%
- **Connected medical devices**: 30%
- **Self and home care devices**: 18%
- **Hospital and laboratory equipment**: 15%

Read the full CTI Startup report on the Indian Medtech industry at www.swissnexindia.org/forstartups
innovation@swissnexindia.org
EXECUTIVE SUMMARY

India’s medtech market was valued at USD 10 bn in 2014 and is expected to touch USD 50 bn mark by 2025. This is in part due to India’s rising income levels, swelling private sector investment in healthcare, ageing population, growing medical tourism industry, and government incentives in the medtech space. All these factors make India an extremely attractive market for international firms.

There is a need to use medtech effectively to address the huge gap between demand and supply of healthcare services in India. The medtech sector in India is at a nascent stage with most of the indigenous manufacturing restricted to medical consumables. In fact, imports still constitute over 75% of the current medtech market. India is looking to improve self-sufficiency in medtech as a part of the “Make in India” initiative. The rapidly expanding sector presents immense opportunities to global players.

India is on the cusp of epidemiological transition. There is a big shift in health burden from communicable to include non-communicable diseases, which in turn is driving key medtech segments. There is a demand for both cutting-edge precision technologies and for affordable low technology.

The Indian medtech innovation ecosystem is fast evolving and vibrant with academic research, venture capital firms, government funding and promising startups developing products specifically for the Indian market. In many ways, the ecosystem is very reflective of the Swiss medtech innovation ecosystem.

This report aims to outline the Indian medtech and healthcare scenario. It intends to provide the reader with a specific overview of the market opportunities, challenges, the innovation ecosystem and strategies for success with illustrative case studies.
Medtech industry in India is growing rapidly, and provides plenty of opportunities for innovative Swiss medtech startups to contribute. There is a strong disparity between supply and demand. Demand factors such as a growing population, increasing purchase power and a changing health profile are driving the need for high quality innovative solutions.

1.1 Medtech Market Analysis

The Indian market is among top 20 markets globally in terms of market size. In Asia, it is 4th after China, Japan and South Korea. The medtech sector in India was worth USD 10 bn in 2014 and is growing at 12% compound annual growth rate (CAGR). In contrast, the global medtech market is growing annually at the rate of 4.1% (1). The Swiss medtech market, which has the highest density of medtech related activities, is currently valued at USD 14 bn and growing at a single digit rate. The world’s largest medtech market, the US market, enjoyed a rapid double-digit growth rate in the last decade, but will see a sluggish 5% growth rate post 2020 (2). These numbers have sparked immense interest in India from international medtech firms. A snapshot of the sector is shown in the exhibit below.
1.2 An Import Driven Market

At present, the medtech sector is dominated by imported products both as finished goods and raw material. This is primarily due to lack of a strong regulatory environment coupled with an inverted duty structure favouring imports. Basic customs duty ranges from 5-7.5% with up to 4% special additional duty for finished goods and 2.5% basic customs duty on raw materials and accessories used to manufacture medical devices. High-tech equipment like MRI, CT Scanners etc constitute a big bulk of the medical devices imported into the country (3).

Unlike China or USA, India also does not have a preferential purchase policy for domestically manufactured goods for use in public health infrastructure.

<table>
<thead>
<tr>
<th>Vertical</th>
<th>Total Sales USD* (m)</th>
<th>Imports USD* (m)</th>
<th>% Import</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disposables and consumables</td>
<td>1429.63</td>
<td>468.76</td>
<td>32.79</td>
</tr>
<tr>
<td>Electronics and equipment, surgical instruments</td>
<td>2459.26</td>
<td>2150.48</td>
<td>87.44</td>
</tr>
<tr>
<td>Implants</td>
<td>325.93</td>
<td>259.35</td>
<td>79.57</td>
</tr>
<tr>
<td>In-vitro diagnostic reagents</td>
<td>362.96</td>
<td>280.53</td>
<td>77.29</td>
</tr>
<tr>
<td>Total</td>
<td>4577.78</td>
<td>3159.12</td>
<td></td>
</tr>
</tbody>
</table>

Table 1 * USD 1 = INR 67.5

Domestic companies largely manufacture low-end products, which serve both the domestic and international markets. Products manufactured in India are mainly syringes, needles, catheters, blood collection tubes, medical equipment and medical electronics. Consumables and disposable segment is the only sector of the Indian medtech industry where the sale of indigenous products overshoots the sale of imported products. More than 60% of domestically manufactured goods are exported.
Some key domestic players include:

- Trivitron Diagnostics (www.trivitron.com)
- Forus Health (www.forushealth.com)
- Nidhi Meditech Systems (www.nidhimeditech.com)
- Hindustan Syringes & Medical Devices (www.hmdhealthcare.com)
- Opto Circuits (www.optoindia.com)
- BPL Healthcare (www.bplmedicaltechnologies.com)
- TTK Healthcare (ttkhealthcare.com)
- Appasamy Associates (www.appasamy.com)
- Wipro GE Healthcare (www3.gehealthcare.in; wipro.com/industries/medical-devices)
- Siemens AG (w3.siemens.co.in)
- Philips India (www.philips.co.in/healthcare/solutions/)

Figure 3. Industry profile of medical devices manufacturing in India (4)

<table>
<thead>
<tr>
<th>Turnover (USD* m)</th>
<th>% Distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;2</td>
<td>65%</td>
</tr>
<tr>
<td>2-10</td>
<td>25%</td>
</tr>
<tr>
<td>10-20</td>
<td>5%</td>
</tr>
<tr>
<td>20-100</td>
<td>3%</td>
</tr>
<tr>
<td>&gt;100</td>
<td>2%</td>
</tr>
</tbody>
</table>

* USD 1 = INR 67.5
2. Setting the Context: Healthcare in India

Medtech sector and the healthcare sector are interdependent. Hence, it becomes imperative to understand the health status and healthcare delivery status in India. These inform the need of medtech solutions and product development.

In 2014, India was the 6th largest global market in terms of size and is expected to rank in the top 3 by 2025. India accounts for 20% of world’s population and is forecasted to cross 1.4 bn by 2025, of which 50% will be over or below 30 years. India’s average expenditure on healthcare over the last decade has been around 4% GDP. India’s per capita expenditure on healthcare was USD 75 in 2015, as against USD 420 in China, USD 9403 in the USA and USD 9674 in Switzerland (5).

In India, 58% of all healthcare expenditure is out-of-pocket. India has a wide socio-economic index consisting of people who are able to afford world-class treatment and those who are pushed deeper into poverty due to healthcare expenditure. In comparison, Swiss only pay 25% of their health expenditures out of their pocket, a result of higher state expenditures on public health, advanced social security coverage and more widespread insurance penetration (5).

Despite advances, health infrastructure is not equitably distributed and overall the infrastructure is well below WHO guidelines. To drive equitable healthcare, the role and market opportunity of every segment in healthcare delivery systems is paramount; given the large unmet needs of the growing population to provide high quality and affordable healthcare.

2.1 Health Infrastructure in India is Below WHO Guidelines

- **Death at Childbirth**: India has the highest number of maternal deaths in the world, accounting for 17% of all the women who died during or after birth (6).
- **Infant Mortality**: Even though India achieved impressive growth in child survival, 38 out of 1000 children still do not reach the age of one. This is significantly higher than Brazil, with an infant mortality rate of 15 out of 1000 children and neighbouring countries such as Bangladesh, with 31 out of 1000 children (7). These numbers underline the enormous demand in affordable basic healthcare solutions that strengthen mothers and newborns.
- **Shortage of Healthcare Professionals**: According to the World Bank, India has only 0.7 physicians per 1000 people, which is half of the global average at 1.5 physicians per 1000 people (5). With this number, India also has a much lower doctor density than China and Brazil, which are both around 1.9. Switzerland currently has 4 doctors per 1000 inhabitants. Solutions that allow healthcare staff to extend their reach to remote places (virtual doctors) as well as time efficient medtech solutions are needed.
• **Shortage of Healthcare Infrastructure:** The World Bank estimates that the Indian government currently spends about 1% of its GDP on public health care. The hospital resources fall short on the number of people they are expected to serve: India has only 0.7 hospital beds per 1000 people, while other BRIC countries like Brazil and China have 2.3 and 3.8 respectively. Switzerland has 6 beds per 1000 people. **Medtech costs 30-40% of the total investment required to set up a tertiary care hospital and contributes to 20-25% in total healthcare cost to a patient.** Given this, affordable medtech is a key determinant in improving the health infrastructure.

<table>
<thead>
<tr>
<th>India’s current health infrastructure (5)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>per 1000</td>
<td>India</td>
</tr>
<tr>
<td>Infant mortality rate</td>
<td>38</td>
</tr>
<tr>
<td>Maternal mortality rate</td>
<td>1.74</td>
</tr>
<tr>
<td>Penetration of sanitation</td>
<td>400</td>
</tr>
<tr>
<td>Doctors</td>
<td>0.7</td>
</tr>
<tr>
<td>Bed density</td>
<td>1.3</td>
</tr>
</tbody>
</table>

Table 2

However, these numbers average out the healthcare scenario in India. For e.g. Goa and Manipur have the lowest infant mortality rate at 11/1000 live births, while Madhya Pradesh has the highest at 59/1000 live births. Similarly, there are >1.5 doctors in Tamil Nadu and Karnataka while <0.5 doctors in Bihar, Uttar Pradesh. **Target regions are distinct depending on the kind of problem the medtech product addresses.**

### 2.2 The Stark Urban-Rural Divide

The contrasts are stark and there is a large urban-rural divide in the supply and demand of healthcare. While 70% of the Indian population resides in rural areas, majority of the doctors, pharmacies and hospitals are in cities. The poor infrastructure coupled with a lack of well-trained medical staff is a huge challenge for rural healthcare delivery. This is in stark contrast to the cities in the country, where due to the dominance of private healthcare players and the spending power of the urban middle class, access to the best medical equipment is a given. **There is a huge opportunity for innovative solutions that increase accessibility to good healthcare.**
Healthcare is offered through several delivery channels right from grassroots level physicians including those practicing traditional or indigenous forms of medicine, independent practitioners with clinics of varying sizes, hospitals and specialty hospitals. Availability is driven by purchasing power and demographic profile. Apart from special government initiatives on healthcare (HIV/AIDS, TB, Malaria, vaccinations, etc.), private sector dominates the market. 80% of all out-patient and 60% of all in-patient services are provided by the private sector (10).

Out of the total healthcare spend, the government spend was only one-third (WHO Global Healthcare Expenditure Database). Government spending continues to be low, resulting in an increased private sector presence. Recent estimates indicate that around 95% of the new hospital beds will be added by the private sector (12).

Figure 4 **Infrastructure is skewed to favour urban areas** (11)
Region/ Approx. % of total in 2012

<table>
<thead>
<tr>
<th>Region</th>
<th>Approx. % of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>70% 30%</td>
</tr>
<tr>
<td>Hospital beds</td>
<td>25% 75%</td>
</tr>
<tr>
<td>Doctors</td>
<td>27.5% 72.5%</td>
</tr>
</tbody>
</table>

Rural Urban

Figure 5 **Private sector is dominant in providing healthcare** (10,13)

<table>
<thead>
<tr>
<th>Service</th>
<th>% Out-patient</th>
<th>% In-patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of Spending</td>
<td>32.2</td>
<td>67.8</td>
</tr>
<tr>
<td>Government</td>
<td>20</td>
<td>40</td>
</tr>
<tr>
<td>Private</td>
<td>80</td>
<td>60</td>
</tr>
</tbody>
</table>

2.3 **Healthcare Market Analysis**

Apart from rise in income, change in social and age demographics, increased awareness, epidemiological transition, penetration of health insurance, increasing mobile usage and emergence as a key destination for medical tourism have propelled the demand for healthcare in India. The industry has growth rate of 10-12%, and with a 12% CAGR, the sector will grow to USD 250-300 bn by 2025.
Figure 6  Healthcare market is pegged at USD 250-300 bn for 2025 (1)

<table>
<thead>
<tr>
<th>Disease</th>
<th>% Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infectious Diseases</td>
<td>21.35</td>
</tr>
<tr>
<td>Cardiovascular/ Hypertension/ Diabetes</td>
<td>17.85</td>
</tr>
<tr>
<td>Others</td>
<td>12.61</td>
</tr>
<tr>
<td>Oncology</td>
<td>7.74</td>
</tr>
<tr>
<td>Trauma Care</td>
<td>7.37</td>
</tr>
<tr>
<td>Gastrology</td>
<td>6.99</td>
</tr>
<tr>
<td>Orthopedics</td>
<td>4.99</td>
</tr>
<tr>
<td>Maternity and Infant Care</td>
<td>3.75</td>
</tr>
<tr>
<td>Neurology</td>
<td>3.50</td>
</tr>
<tr>
<td>Dermatology</td>
<td>3.50</td>
</tr>
<tr>
<td>Opthal/ Dental/ Renal</td>
<td>3.25</td>
</tr>
<tr>
<td>Respiratory</td>
<td>3.00</td>
</tr>
<tr>
<td>Gynaecology</td>
<td>2.75</td>
</tr>
<tr>
<td>Urology</td>
<td>1.37</td>
</tr>
</tbody>
</table>

Table 3  Healthcare market revenue by disease in 2013 (1,14)

<table>
<thead>
<tr>
<th>Year</th>
<th>Market size USD (bn)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>59.5 bn</td>
</tr>
<tr>
<td>2013</td>
<td>80 bn</td>
</tr>
<tr>
<td>2025</td>
<td>250-300 bn</td>
</tr>
</tbody>
</table>

Healthcare market is pegged at USD 250-300 bn for 2025 (1)
3. Key Drivers for Healthcare and in turn, the Medtech Market

Epidemiological transition and changes in demographic profile in parallel are causing a swift transition in health status. Aside from changes in disease profile and age demographics, rising incomes, increased health awareness, penetration of health insurance and increasing demands from medical tourism will push the demand for better healthcare and medtech. Factors expected to drive growth of the industry are described below:

3.1 Epidemiological Transition

The health burden of India has shifted from communicable to include non-communicable diseases. India’s current health status is characterised by high morbidity (incidence of disease), low mortality (incidence of death) and dual burden of communicable and non-communicable diseases (NCDs). NCDs include asthma, acute bronchitis, problems of joints/ bones, hypertension, cardiovascular diseases (CVDs), diabetes, cancer, etc. There is a pattern of increasing morbidity with age. Chronic NCDs have increased over five-fold in prevalence in ageing populations especially those over 60 years. Rise in NCDs has not replaced communicable diseases either (15).

### The national health profile for 2015 attributes over 50% death to NCDs (16)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Death %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communicable, maternal, nutritional diseases</td>
<td>28</td>
</tr>
<tr>
<td>Cardiovascular diseases</td>
<td>26</td>
</tr>
<tr>
<td>Chronic respiratory diseases</td>
<td>13</td>
</tr>
<tr>
<td>Cancer</td>
<td>7</td>
</tr>
<tr>
<td>Diabetes</td>
<td>2</td>
</tr>
<tr>
<td>Injuries</td>
<td>12</td>
</tr>
</tbody>
</table>

Table 4

### Non-Communicable Diseases: A Snapshot

The rise in non-communicable diseases like diabetes, stroke, cancer and cardiovascular diseases have reached alarming rates within the Indian population. According to the World Health Organization, one in four Indians will die from a non-communicable disease before the age of 70 (17). There is an increased life expectancy (age > 60 years). However, older people are experiencing poorer health due to chronic diseases. Demographically, urban females are the most vulnerable (18). Cardiovascular diseases and accompanying risk factors like obesity, diabetes, hypertension and elevated lipids are more prevalent in high socioeconomic groups (19).
Cardiovascular Diseases: Cardiovascular diseases (CVDs) will be the largest cause of death and disability by 2020 in India. The World Congress of Cardiology estimates that 40% of deaths in India will be from heart disease. By the year 2020, 2.6 m Indians are predicted to die due to coronary heart disease which constitutes 54.1% of all CVD deaths. Nearly half of these deaths are likely to occur in young and middle-aged individuals (30-69 years). Currently Indians experience CVD deaths at least a decade earlier than their counterparts in countries with established market economies (20). Heart disease has reached epidemic proportions with 30 m patients and 200,000 surgeries being performed (21). One of the key reasons for the grim statistics is late diagnosis of cardiovascular issues. This is more often than not due to limited access to diagnostic equipment, qualified cardiologists and preventive care especially in the rural areas of the country.

Diabetes: India has the dubious distinction of being both the cardiovascular disease and the diabetes capital of the world. There were 69.1 m reported cases of diabetes in 2015 (22). Studies have also shown that the disease sets in at a younger age in the Indian population. The average age of a diabetic is 40 in India, 10 years younger than in developed countries (23). In the rural areas where there is limited access to monitoring equipment, affordable care and trained medical personnel, the disease takes a toll on entire families. The alarming number of diabetics in the country has led to a scurry of activity in the local medtech market to manufacture cost effective, easy to use diabetes monitoring devices and service delivery innovations for early diagnosis.

Chronic Respiratory Diseases: 30 m patients in India are estimated to have chronic respiratory disease. Smoking behaviour, the most important risk factor, contributes to maximum cases. Unconventional forms of smoking (e.g. bidi and chillum) are more common but increase the incidence of respiratory disease by 6 times. Biomass fuel, used in 90% of rural and 32% of urban households for cooking in poorly ventilated kitchens is yet another major risk factor (24). Rising incidence has put nebulizers on a fast growth track at 25.8% CAGR (25). Technologies are required to generate awareness of the disease for patient monitoring and communication.

Communicable Diseases: A Snapshot

Within communicable diseases, Tuberculosis, Diarrhoea, acute respiratory infections, Malaria, HIV/AIDS, maternal and child conditions account for about 50% of India’s disease burden.
• **Bacterial Diseases:** Tuberculosis causes around 1000 deaths each day and accounts for a loss of over 11 m disability adjusted life years (DALYs). Bacterial resistance is a growing threat due to indiscriminate use of broad spectrum antibiotics (26). It is estimated that 40% of the Indian population has active or latent tuberculosis (27). Emergence of immune compromising HIV/AIDS and diabetes could increase the prevalence. **Newer diagnostic methods to ascertain for antibiotic resistance at the onset and equipment to improve biosafety laboratory infrastructure are required.**

Outbreak of typhoid, an acute condition caused by poor sanitation is a reason for high mortality. The central ministry of health indicates a morbidity rate from 1 to 22 per 1000 people due to typhoid in different parts of India (28). **Equipment to improve cold-chain to improve immunisation are needed. Cold chain is also a requirement for polio, diphtheria pertussis tetanus vaccines and diluents among others.**

• **Diarrhoeal Diseases:** 1 out of 242 children in India dies from diarrhoea before turning 5 years of age. The incidence is highest in children below 1 year. 15% of pediatric beds in India treat gastroenteritis (29). **Ways to improve vitamin supplementation, safe water and improved sanitation are unmet needs.**

• **Parasitic Diseases:** Endemic diseases like Kala-azar and Malaria are major public health problems in the states of Bihar, West Bengal and Uttar Pradesh. The diseases affect the poorest people and is linked with a weak immune system, poor sanitation and living conditions. In 2013, 882,000 cases of malaria were reported. Though malarial cases have almost been halved from 2 m in 2000, emergence of chloroquine resistance and vector resistance to insecticides has hampered malaria control. **India's National Vector Borne Disease Control aims to eradicate malaria by 2030 by expanding community based diagnostic testing and treatment (28, 30).**

• **Viral Diseases:** India accounts for over 2.1 m HIV/AIDS cases with 75,948 new cases in 2015. Though HIV/AIDS rates have dropped from 24% to 0.26% between 2007-2015, incidences have been increasing in several states in north and north-east India - Assam, Tripura, Sikkim. **There is a need for quick diagnosis and interventions in medicine delivery across hostile terrain (31).**

### 3.2 Increasing Population and Life Expectancy

From 1.2 bn in 2011, India’s population is set to grow to 1.4 bn by 2025. Declining infant mortality and increasing life expectancy will augment the demand for healthcare. Even though the Indian population is currently young – with a median of 26 years – the population distribution is slowly changing. Indian population over 60 years will contribute to 12.5% of total population by 2025, which means, a whopping 175 m will be elderly. Estimates by the UN Population Fund show that 66% or **115 m of the elderly are likely to suffer from at least one NCD ailment** (32).
3.3 Rising Income Levels Increases Affordability

Access to affordable healthcare is a major constraint for 59% of households with an annual income of <USD 3000 per year. Households in the income bracket of USD 3000-7500 is expected to increase to 37.5% by 2018 (10). This increasing population group, who are willing to pay for better healthcare services, will be favourable for the industry.

3.4 Increasing Health Awareness Drives People To Seek Healthcare

In January 2016, India crossed 1 bn mobile phone subscribers mark. The ubiquitous reach of mobile phones has made it the most effective way for last mile connect. Of these 302 m had internet connections (33). Cheapest calling rates in the world and increasing internet penetration are of consequence for tele, e- and mhealth. This translates to an increased market opportunity for medtech in this segment. Connected devices are currently one of the top 5 fast-growing segments in medtech in India.

3.5 Health Insurance Coverage

In 2014 only 17% of the Indian population had a health insurance (34). So the ability of lower income groups to access quality healthcare still remains an impediment. Government sponsored schemes account for around 80% of the health insurance coverage provided. The low penetration is set to change as the commercial health insurance policies have been increasing at 10% CAGR (35). Health checkups which are mandatory for health insurance will also rise requiring quality medtech to service the demand.

3.6 Rising Medical Tourism

India is currently one of the top three destinations for medical tourism in the world. The medical tourism industry in India is expected to grow to USD 10.3 bn by the year 2020 from USD 2.8 bn in 2015. Investments in luxury healthcare are growing because of the strong demand for high quality below-international prices of healthcare. For e.g. ABV is investing USD 78 m for a luxury hospital in Mumbai, Aster Medcity has built a 575-bed hospital in Kolkata, Fortis has built a 450-bed hospital in Delhi (36). India hosted 240,000 medical tourists in 2013 (37). Highly sought-after treatments in India include bone marrow transplants, cardiac bypass surgery, eye surgery and hip replacements, all of which require sophisticated and state-of-the-art medical technology.
4. Opportunities for Medtech Industry across the Healthcare Spectrum

Technological advancements have expanded the role of medical technologies to play a key role at all stages of healthcare chain – increasing access, screening, diagnosis, treatment, reparation and monitoring.

4.1 Case Studies of Innovations Made for India

at each stage of the healthcare chain are given below. These case studies illustrate that to succeed in India, the focus must be on improving affordability, accessibility, availability and quality.

**Screening: UE LifeScience - Intelligent Breast Examination iBE**

iBE is a low-cost portable, non-invasive, radiation-free FDA approved handheld scanner. iBE pairs with smartphones through Bluetooth and scanning results appear on the screen. The emphasis is on affordability with each screening costing just USD 1.5. Operating requirements are very low so the device can be operated at home, temporary health camp or in a clinic. UE Lifesciences is backed by Unitus Seed Fund.

**Diagnosis: Remedio - Fundus on Phone**

Fundus on phone connects to a mobile phone camera to take pictures of the retina to diagnose diabetic neuropathy. It is priced at USD 2,700 while comparable wide-field imaging camera to obtain a complete picture of the retina costs about USD 90,000. The device is battery operated and can be installed even in remote area outposts increasing accessibility. The images can be transferred in almost real time to physician’s phone to enable diagnosis. Remedio was incubated by IKP Knowledge Park, a Department of Science and Technology supported incubator and got USD 750,000 from Wellcome Trust for development. Most recently, Remedio has successfully raised an undisclosed amount in series B funding from Cipher-Plexus capital advisors and individual investors.
**Treatment: Perfint – Maxio**

Maxio is a minimally invasive, image-guided robotic system for interventional oncology procedures like ablation, drug delivery, biopsy, drainage, fine-needle aspiration, etc. It is an integrated **precision** device combining tumour visualization, treatment planning, robotic navigation and image verification. In 2015, it was used in 1,500 procedures across US, Germany, Russia and India. Perfint raised USD 11.04 m in series D from Norwest Venture Partners in 2013.

**Reparation and Rehabilitation: IIT Delhi, Phoenix Medical Systems, Saksham Trust - Smart Cane**

12 m people in India are visually impaired, the largest in the world. Smart cane uses ultrasonic technology to identify obstacles within a detection range of 1.8 m indoors and 3 m outdoors. The sensor is detachable, which means it can be removed and used with another cane. Comparable navigational devices cost USD 950, while Smart Cane only costs around USD 50 (**affordability**). Smart Cane is distributed through Saksham trust, an NGO focused on the blind and Snapdeal, one of India’s largest online marketplaces. The product was developed with USD 650,000 grant from Wellcome Trust, UK.

**Patient Monitoring: Cardiac Design Labs - Mobile Intelligent Remote Cardiac Monitor (MIRCaM)**

MIRCaM is an ambulatory cardiac monitoring and diagnosing system capable of real-time monitoring, analysis and diagnosis of a range of cardiac conditions like arrhythmia, myocardial ischemia and infarction. MIRCaM continuously analyses the ECG of the patient in real time, uploads data onto the server periodically and allows the physician to monitor live/ browse stored ECG remotely. It assists in alerting the doctor in case of any emergency or potential risk of cardiac condition. By decentralizing cardiac care MIRCaM extends **availability** of cardiac healthcare to suburban and rural parts of India. Product development support of USD 24,000 came from the Department of Scientific and Industrial Research.

**Increasing Access: BPL Medical Technologies - LifePhone Plus**

Online doctor consultation segment in India is booming. DocsApp, MeraDoctor, HealthEnablr, iClinic, JustDoc are some startups in this space. They allow patients to chat with doctors, share pictures and reports of the ailment through dedicated apps or website so people can get expert consultation on demand. This has in turn increased the demand for home health monitoring/ mhealth devices to record and share data with doctors. One such medtech is LifePhone plus which can record ECG, measure blood glucose, blood pressure and physical activity to check and store measurement. It includes specialist consultation through mobile phone apps. BPL Medical Technologies raised USD 20.18 m from Goldman Sachs.
Key takeaways for product development

- Tailoring the product to India, specifically to the market (private or public)/region (urban or rural, specific state or city) one intends to sell
- Cost differentiation
- High quality at lower prices
- Portable products that can be used at lower levels of health infrastructure
- Products requiring less training (low operational requirement)
- Saleability at early stages of development
- Innovative business models
5.

Business Considerations

To an outsider, India may seem like a single market with huge volumes, but the reality is India is not one market, but many. There is a market for high quality, cutting-edge high precision medical equipment at the upper end of the value chain and for low-technology high volume products at the lower end of the value chain. Healthcare is evolving dramatically with advances in IT, data analytics, precision engineering, and genetics. Hence, innovations in business models, regulation and technology adoption have to be generated to encourage industry growth.

5.1 Innovative Business Models

To succeed in India, innovation cannot be confined to product level technology but supported by two other pillars of innovation – service delivery and operating models. Companies have adopted interesting ways to capture, consolidate positions in existing markets and for new market creation. The following case studies of Thyrocare, GE, Philips and Lybrate illustrate new, innovative business model ideas:

Thyrocare - Service Delivery Business Model

Diagnostic services including radiology is an unorganised USD 3.5 bn market with a 20% growth rate. Only 10% is captured by organised players (38). Rather than sell medtech directly, companies in India are now setting up medtech to offer diagnostic services. Investor interest in diagnostics segment is underlined by recent oversubscribed initial public offerings (IPO) in this segment. Most recently, Thyrocare Technologies IPO on 29 April, 2016 was oversubscribed 72.26 times.

Thyrocare is an automated diagnostic laboratory with a focus on affordable, high quality clinical chemistry and preventive care diagnosis. Thyrocare has a hub and spoke business model, where franchisees collect samples from individual doctor clinics, laboratories, home collection, hospitals and walk-in customers. The company operates with a few centralised processing laboratories and have used total laboratory automation, bar coded sample sorting, air cargo driven logistics for incoming specimens ensuring samples reach processing labs before midnight. Thyrocare processes over 40,000 samples and runs 2,00,000 clinical chemistry investigations every day. Fair rates and high quality have helped Thyrocare gain market traction. This case study illustrates a business model for using medical technologies to offer services in diagnostics and radiology.

GE and Philips - Public-Private Partnership (PPP)

GE Healthcare in partnership with the state government of Maharashtra and Ensocare, a part of the USD 7 bn Enso group has equipped and is running advanced diagnostic tests at 22 hospitals in Maharashtra. Services are offered at government rates (39).

Sawai Man Singh hospital in Rajasthan is one of Government’s few multispeciality hospitals serving multitudinous people. Philips India worked with the radiology department of the hospital to set up three Tesla MRI scanners and two 128-slice CT scanners costing USD 4.5 m in a PPP model where a private player was roped in for funding. The funder gets paid on a per use basis. The hospital handles 150 cases per day and a high-volume, low margin business model has been set successfully (40).
Lybrate – mHealth

In a country with over 1 bn mobile phone connections and 300 m mobile internet connections, using mHealth to offer healthcare is a good proposition. Lybrate describes itself as the ‘Facebook of healthcare’. Lybrate is an app which enables users to get credible solutions or second opinions for their health issues from a pool of trusted doctors on an open-ended platform. It also provides private consultation with a doctor of their choice. Users can share their medical reports, pictures, prior medications, or any other record in a one-on-one discussion with the doctor. Lybrate has over 80,000 doctors from different specialties on its platform. Patients seek multiple opinions from doctors for free on the open platform, or start a one-on-one dialogue privately for a fee with doctors. On the open platform, doctors’ replies are endorsed by other doctors increasing their reputation in the client base.

5.2 Adoption

mHealth platforms like Lybrate present a market opportunity for sensors, devices for remote monitoring, artificial intelligence and mobile applications that can improve healthcare delivery. Outlook of healthcare practitioners is key for adoption of new technologies.

In Himachal Pradesh (an Indian state), 90% of healthcare services are provided by the government. 70% of the region is difficult to access, with mountainous terrain and sub-zero temperatures most of the time. Healthcare provision is sub-optimal with individuals having to travel 10-15 km on foot to the nearest healthcare centre. The state has the highest tele-density of all states in India. Therefore the idea of using mHealth instead of in-person doctor visits for clinical diagnosis, providing health advice, monitoring compliance for treatment and exchanging clinical information with patients is appealing.

A study on 592 doctors showed that mHealth tools were accepted as an additional tool but not as a replacement for interaction with patients. There was a perception that patients would not readily accept mHealth services. Only 58.8% of participants were open to easily adopting mHealth services. Concerns ranged from competency of handling personal information, how mHealth would affect customer base, and whether it would really enhance the effectiveness of healthcare activities (41).

With increasing mobile penetration, information technology literate population, and awareness, addressing concerns of stakeholders is key for new technology adoption.

Medtech companies worldwide are facing increasing competition in the same segment making product differentiation difficult. Customer experience is a key differentiation factor and especially influences adoption in India. At Sawai Man Singh hospital, Philips did not only sell and set-up the instruments but worked with the radiology department to train technicians and optimized the workflow to increase throughput.
5.3 Distribution

A medical device has to pass from the manufacturer through unorganised distributors to reach hospitals, clinics and laboratories. Challenges in this multi-tier distribution system include a supplier driven market and lack of information leading to pricing issues for manufacturers. From the buyer perspective, equipment is expensive, training is an issue and access to cheaper medical devices comes with “no service” which decreases confidence in buying the medtech product itself.

Instead, refurbished equipment which come at 60% of the cost of a new one are often preferred. MRIs, X-Rays, ventilators, cath labs are most commonly purchased refurbished equipment. Approximately, 20% of the overall equipment sold and almost 30% of the sales in the private sector is refurbished (42). 20% new beds are being added in tier 2/3 cities (cities with population between 20,000 – 1,00,000) every year. Hence, it becomes important to provide services across these regions efficiently.

This is now changing with players like Collateral Medical, acting as a pan-India agent to directly sell to end customers online at transparent prices.

Collateral Medical –
IT-enabled Pan-India Distribution Company

Collateral Medical is a medical device marketing and distribution company headquartered in Mumbai. They have partnered with global and domestic original equipment manufacturers (OEMs) leveraging technology – e-commerce portal, internet and mobile technologies to serve pan-India customers ranging from corporates, NGOs to individual doctor’s clinics. Colmed mainly targets small hospitals and clinics where demand is very high. By acting as procurement agents for these smaller customers, Colmed is able to manage inventories and negotiate a fair price by aggregating small orders. From the medtech manufacturer perspective, products are quickly brought online as customer offerings and technology dissemination done through videos, features, etc. The company is growing over 100% each year and has serviced orders from all of 29 states in India.

5.4 Regulation

Till 2016, everything other than the 15 categories of devices were regulated as drugs. The Ministry of Health and Family Welfare of India has notified Medical Devices Rules, 2017 that will come into effect from 1 January 2018. The newly formed medical devices rules have separated devices from drugs. The new rules include risk-based classification, identification requirements and quality audits through Notified Bodies. The new rules conform to the international global harmonisation taskforce framework. Exact information can be found at http://www.mohfw.nic.in/showfile.php?lid=4168 (43, 44)
Salient features of the Medical Devices Rules, 2017 (43) include:

**Classification:** The medical devices will be classified based on the risks associated with them as Class A (low risk), Class B (low moderate risk), Class C (high moderate risk) and Class D (high risk). In-vitro diagnostics follow a similar classification. This is similar to CE system of classification into Class I, Class II and Class III. The rules envisage a system of ‘Third Party Conformity Assessment and Certification’ through professional accredited Notified Bodies. Accreditation of Notified Bodies will be through National Accreditation Board for Certification Bodies.

**Product standards:** Medical devices are required to adhere to the Bureau of Indian Standards. If no standards for the said medical device are specified, it is required to conform to ISO or IEC standards. The new rules also provide for detailed guidelines on quality management systems for design, development, servicing and packaging. Periodic assessment by Notified Bodies to verify and assess quality management systems is envisaged. Quality management systems are required to adhere to ISO 13485. New laboratories are being established by the National Accreditation Board for Testing and Calibration Laboratories (NABL) for testing of medical devices.

**Licensing and compliance:** For manufacturing of Class A devices, self-certification of compliance by the manufacturer is sufficient to obtain manufacturing licence. Post approval audit will be carried by Notified Bodies to check conformance with quality management system. Class B, C and D device manufacturing licences will be granted post quality management audit by Notified Body.

Class A and Class B devices will be regulated by the State Licensing Authority; Class C and Class D medical devices will be regulated by the Central Licensing Authority. Import of all medical devices will continue to be regulated by the Central Drugs Standard Control Organisation (CDSCO).

**There will be no requirement for periodic renewal of licences and the manufacturing or import licences issued will remain valid until these are suspended, cancelled or surrendered.** The entire process from submission of application to grant of licence will be through an online platform. Costs and timelines have been set in the medical devices rules for activities from the regulators’ side. These two initiatives will create a conducive environment and eliminate uncertainty for Indian manufacturing.

**Clinical Investigations:** Medical devices will no longer require 4 phase clinical trials. Instead, the clinical investigations will be split into two parts - Pilot clinical investigations on small population to test the device performance and safety followed by a larger pivotal study to evaluate effectiveness and adverse effects. Clinical investigations can be initiated only after approval from registered Ethics Committees and after permission from Central Licensing Authority has been obtained. In case of adverse effects during the trial, it is mandated for the sponsor or the representative of the sponsor to provide financial compensation and pay for medical management to the subjects of clinical investigation.
**Shelf life:** The new rules have capped the shelf life of medical devices at 60 months. Imports are allowed only with a certain percent of shelf life still remaining. The shelf life could be extended provided sufficient evidence is provided by the manufacturer to the Central Licensing Authority.

**Labelling:** The rules require medical devices to have their device identifier and production identifier number. Device identifier being the global trader identifier number and production identifier being serial/ batch/ lot number, manufacturing and expiry date. For sterile devices, its sterile state and method of sterilization also need to be mentioned. For medical devices raw material like titanium, expiry date is not necessary.

**Import:** The rules have eliminated the need to obtain a registration certificate at the time of registering as a foreign manufacturer. Now the foreign manufacturer needs to only appoint an authorised agent in India and apply directly for an import licence. On receipt of application, there may be an inspection of the overseas manufacturing site at a cost.

Where a free sale certificate has been issued in respect of any medical device by the national regulatory authority or other competent authority of any of the countries namely, Australia, Canada, Japan, European Union Countries, or the United States of America, a licence shall be granted to the applicant without carrying out clinical investigation. Where a medical device is imported outside of these countries, licence will be furnished after clinical investigations in India.

In case of investigational medical device or new in-vitro diagnostic medical device, the applicant has to obtain prior permission from the Central Licensing Authority. Without prior permission, no licence to import any medical device would be granted. The sponsor or organisation are needed to maintain data, records and registers for a period of 7 years after completion of clinical investigation and make the data available to the licensing authority upon request.

**Price control:** The National Pharmaceutical Pricing Authority (NPPA) and the National Medical Device Authority will function as authorised bodies to enforce control policy, safety standards and pricing as well. Most recently in February 2017, the NPPA capped the price of drug eluting stents at approx. CHF 460 and bare stents at CHF 112 (45). With about 475,000 stent implants in India annually, patients now stand protected from profiteering on overpriced stents. Currently, pricing of other implants – orthopaedic, heart valves and intra-ocular lenses are being scrutinised.

The new rules position India competitively in medical device manufacturing with quality standards at par with international standards. The regulations also simplify importing latest technologies. Thus, the rules provide for a conducive environment for fostering innovation, investment, market entry, quality and range of medical device products and services.
5.5 Good Manufacturing Practice (GMP)

GMP guidelines are prescribed for companies manufacturing in India. Foreign manufacturers also need to submit their GMP certificate. Non-compliance leads to cancellation of manufacturing license. To curb below-par standards of devices, the government has a “whistle blower” policy and incentivises citizens who bring to attention spurious cases (44).

5.6 Intellectual Property Policy

India complies with the World Trade Organization regulations and, specifically, the Trade Related Aspects of Intellectual Property Rights Agreement (‘TRIPS’). India has a well-established statutory, administrative, and judicial frameworks to safeguard IPRs. Patented inventions (including products) are given 20 years of protection in India. Computer databases and software programs, which are widely used by the medical devices industry, have been protected under copyright. Computer programs having technical application to the industry and computer programs in combination with hardware can now be patented in India. Though trade secrets and know-how are not protected by any legislation, they are protected under the common law and through contractual obligations (44).
5.7 Where does the Indian Market Stand – a Comparison with China

As a result of China’s economic growth and government’s health reform investments, the healthcare industry in China has been continuously growing in the past years and this trend will continue in the coming years. In the table below, some of the significant differentiators between the Indian and Chinese medtech markets are given.

<table>
<thead>
<tr>
<th>Market Size</th>
<th>India</th>
<th>China</th>
</tr>
</thead>
<tbody>
<tr>
<td>Currently the market size is significantly smaller than China and valued at USD 10 bn in 2014 and expected to grow at 12% CAGR.</td>
<td>The sales volume for medical devices reached total revenues of USD 21.2 bn in 2011. With double-digit annual growth rates of the medical device industry, China is expected to become the second largest market before 2020 (46).</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Local Competition</th>
<th>India</th>
<th>China</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is little to no interference from the government in the medtech industry and the competition among the players is stiff and on a level playing field.</td>
<td>A large number of enterprises are state owned and insulated from competition. These enterprises not only enjoy financial support from the government but also monopolies within the country (47).</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regulatory Environment</th>
<th>India</th>
<th>China</th>
</tr>
</thead>
<tbody>
<tr>
<td>Although a framework to establish a regulatory authority is in the works, currently medical devices with a CE mark or FDA approval are allowed to enter the Indian market. Local clinical data is not required, making market access easier in India.</td>
<td>In China, clinical evaluation is more robust than clinical evaluation reports submitted in Europe and USA for Class II/III devices. Pre-existing CER is not sufficient for approvals in China, necessitating local clinical data (48).</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Government Interference</th>
<th>India</th>
<th>China</th>
</tr>
</thead>
<tbody>
<tr>
<td>The government is involved in setting the framework but does not interfere in the market.</td>
<td>Government interventions in the healthcare sector are common and can occur on short notice.</td>
<td></td>
</tr>
</tbody>
</table>

Table 5
6. Medtech Ecosystem in India

India is one of the hotbeds for startups offering huge opportunities. This is reflected in the Global Startup Ecosystem Ranking where Bangalore was placed #15 on the list. Delhi and Mumbai, two other India cities, were also featured in the top 20. In comparison, Switzerland did not make it to the top 20 list. Exit values, VC investment from Bangalore have grown 4 times each (49). The state of entrepreneurial ecosystem specifically for medtech is described below.

6.1 Investor Interest

Medtech sector is witnessing lot of Foreign Direct Investments (FDI). Between 2000 and 2011, inflows were around USD 36.7 m each year. It has increased to USD 134 m in 2014. Presently, even the Swiss financial centre and SIX Swiss Exchange are reaching out to 200-250 pharmaceutical, biotech, healthcare and medtech companies in India for listing on their platform (50).

Recent deals in the Indian medtech sector:

<table>
<thead>
<tr>
<th>Medtech Company</th>
<th>Investors</th>
<th>Investment (USD m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trivitron Healthcare</td>
<td>Fidelity Growth Partners</td>
<td>74.11</td>
</tr>
<tr>
<td>BPL Medical Technologies</td>
<td>Goldman Sachs</td>
<td>20.18</td>
</tr>
<tr>
<td>Forus Health</td>
<td>IDG Ventures India, Accel Partners, Asian Healthcare Fund</td>
<td>13.5</td>
</tr>
<tr>
<td>Perfint Healthcare</td>
<td>Norwest Venture Partners, Accel Partners, IDG Ventures</td>
<td>43</td>
</tr>
<tr>
<td>MedGenome</td>
<td>Sequoia Capital</td>
<td>20</td>
</tr>
</tbody>
</table>

Table 6

India’s FDI Policy

In January 2015, the Indian government clarified its FDI Policy specifically for the medical devices sector. Upto 100% FDI is permitted without government approval in new as well as existing companies that manufacture medical devices including in those companies that are engaged in the manufacture of medical devices that are regulated as drugs under Drugs & Cosmetics Act (51).
6.2 Academic Research and Technology Transfer

Academic research in the medtech sector in India is looking at finding solutions for the local market needs which are low-cost, less time consuming, point-of-care and easy to transport given the fragmented nature of healthcare delivery in India. Examples of translational projects originating from academia supported by Government of India for commercialization of research discoveries is given below:

<table>
<thead>
<tr>
<th>Academic Institute (Location)</th>
<th>Example of work in the medtech space</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indian Institute of Science (Bangalore)</td>
<td>Hand-held imaging flow cytometer for quantitative diagnosis of Malaria</td>
</tr>
<tr>
<td>National Chemical Laboratory (Pune)</td>
<td>Bio-absorbable implants based on polylactic acid</td>
</tr>
<tr>
<td>Indian Institute of Technology (IIT Delhi)</td>
<td>Rapid diagnosis of bacterial gastroenteritis in resource poor settings</td>
</tr>
<tr>
<td>Indian Institute of Technology (IIT Mumbai)</td>
<td>Development of a point-of-care device for prenatal diagnosis of congenital anomalies</td>
</tr>
<tr>
<td>LV Prasad Eye Institute (Hyderabad)</td>
<td>Tear dipstick immunoassay for diagnosis of adult primary glaucoma</td>
</tr>
<tr>
<td>BITS Pilani (Pilani, Goa, Hyderabad)</td>
<td>3D printing technologies to produce innovative limbs at affordable costs for the disabled</td>
</tr>
</tbody>
</table>

Technology transfer and academia-industry links are strengthening with applied research being transferred over to the industry. Below are two case studies of successful academia-industry collaborations with products innovated for India, but impacting patients all over the world:

**Technology Transfer of an Indigenous Heart Valve from Sree Chitra Tirunal Institute For Medical Sciences And Technology to TTK Healthcare**

The heart valve was innovated in response to a public health need - rheumatic heart disease. An estimated 2-2.5 m patients suffer from rheumatic heart disease in India (53). A result of 12 years of meticulous research, the TTK Chitra valve provides a high quality affordable replacement to expensive imported heart valves costing upwards of USD 1,500 at a price point of USD 350, making it the most price friendly heart valves in the world. The mechanical implant is extremely durable with projected lifespans exceeding that of human lifetimes. The
valve has been implanted in over 100,000 patients and is used in Thailand, Nepal, South Africa and Kenya. Sri Chitra institute has over 130 patents out of which 50 have been commercialised or are in the process of being converted to technology.

**Technology Transfer of a Computing Technology for Eye Disease Screening from IIT Madras to Forus Health**

A recent example, Healthcare Technology Innovation Centre at IIT Madras transferred an eye image computing solution to screen for eye diseases intelligently in low resource settings. Eye-Pac technology is now used in over 10 countries - India, China, France, Thailand, Guatemala, Sri Lanka, Nepal, Oman, Mauritius and Somalia.

### 6.3 Incubators and Accelerators

Developing medical technology requires a lot of machines that startups can’t really afford to buy. Co-creating, co-working spaces, makerspaces, incubators and accelerators provide key resources for product development, interactions and office infrastructure. India has around 60 Ministry of Science and Technology supported incubators (full list at www.nstedb.com) and 100+ independent incubators. Relevant examples for medtech are given below:

<table>
<thead>
<tr>
<th>Incubator/ Accelerator</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>InnAccel, Bangalore</td>
<td>A medtech specific acceleration platform driving innovation for critical unmet healthcare needs in India and emerging markets.</td>
</tr>
<tr>
<td>IKP-EDEN, Bangalore</td>
<td>India’s biggest hardware product incubator with state-of-the-art makerspace and prototyping center.</td>
</tr>
<tr>
<td>HealthStart, Noida</td>
<td>An accelerator dedicated to support startups in healthcare industry through funding and mentorship.</td>
</tr>
<tr>
<td>Venture Center, Pune</td>
<td>A technology business incubator specializing in technology startups in the fields of materials, chemicals and biological sciences &amp; engineering.</td>
</tr>
<tr>
<td>TIMed, Trivandrum</td>
<td>Technology Business Incubator focusing exclusively on medical devices and biomaterials sector.</td>
</tr>
<tr>
<td>Healthcare Innovation Technology Centre, Chennai</td>
<td>Collaborates with medical institutions and industry players to develop and deploy healthcare technologies specifically for the Indian market in ophthalmology, ultrasonography, orthopedics, neonatal care, patient monitoring, etc.</td>
</tr>
<tr>
<td>CEPT Fablab, Ahmedabad</td>
<td>Co-run by CEPT University and The Motwani Jadeja Family Foundation. Fablab doesn’t charge a membership fee and supports product innovators with mentorship.</td>
</tr>
</tbody>
</table>

Table 8
Medtech industry in India is nascent and growing fast. Lessons from other industries are key to figure out successful formulae to sell in India. More than the best management systems, big financial resources or big brands, strategies and execution are what matter.

Establishing a Local Presence
India is the only country in top 5 automobile markets where one company has over 50% market share. Automobile giants like Ford, General Motors, Volkswagon, Toyota are way behind Maruti-Suzuki. Automobile experts opine that this is due to disconnect of the board members located in Detroit, Wolfsburg, Tokyo (54). Local presence is invaluable to build relationships, deeply understand customers and Indian conditions either directly or through a local partner as exemplified by Maruti-Suzuki.

Pivoting in Response to Market
Uber Technologies, the world leader in online transportation network recognized dual barriers to Uber’s business model of cashless transactions - customers’ preference to pay cash and banking regulations that allows credit card payments only with an authentication process. In response, Uber built entire logistics to manage cash operations. To further consolidate its position, Uber is looking at factors effecting business like signal strength, state of roads and traffic jams. With impressive market gains, the company predicts that India will soon surpass its US market (55).

The cash payment system developed specifically for India is being used in other countries like Indonesia and Singapore. Safety features that allow one to track journey, SOS button, etc. which are now standard features were originally developed for India.

Tailoring Products with Local R&D
When Gillette, the razor company first launched its products in India, it was marketing a US-developed razor. Response to the product was lukewarm and it managed to capture a small premium segment. To become market leaders, Gillette had to focus on the next segment of 400 m men. This segment is cost conscious and has different requirements - usage of less to no running water and ability to shave longer facial hair. More than the quality of shave, safety was the prime concern. Understanding the customer segment and tailoring products helped the company gain 47% market share (56). The Gillette story illustrates the importance of tailoring products so it is relevant for India.
A good strategy for Swiss entrepreneurs is to visit India to understand the size and nature of the Indian market, positioning for their product and assessing their value proposition.

swissnex India offers a structured market validation plan for startups visiting India. The 1-3 weeks plan includes meetings with potential customers, collaboration partners, key opinion leaders (KOLs), regulatory and legal experts. swissnex India also promotes technology showcase through conferences, forums, trade shows and big ticket events. In this period, the startup can hope to

- Understand cost structures of setting operations
- Meet experts and validate the product/service offering for the Indian market
- Network with potential customers and collaborators
- Understand IP/legal issues surrounding the company

swissnex India regularly conducts market validation tours specifically for medtech and healthcare startups, mentors, investors and other interested Swiss stakeholders. The tailored program exposes participants to two top startup ecosystems in the world – Bangalore and Delhi. The tour includes networking with hospitals, experts, startups in India and KOLs. For our next tour, check www.swissnexindia.org.

Startups ready for India can use swissnex India as a base while they set up their own offices within India. Support includes a short-term office infrastructure, access to networks and help with hiring.

Contact: innovation@swissnexindia.org

8.1 A Personal Account of Two Swiss Medtech Startup CxOs

Marc Spaltenstein (CEO & Founder of Sterilux Sàrl)

Sterilux is developing a sterilization medical device for hospitals in developing countries. Their solution consumes less water and electricity for an overall cost reduction of a factor 100 compared to today’s solution. It is easy to use, low maintenance and transportable. With these advantages, this solution is a perfect fit for areas where natural resources are a problem.

Why did you consider coming to India?

“India is a huge market which shows multiple advantages. Firstly, a lot of people speak English. Secondly, it is only one border to cross, meaning one regulation. Lastly, natural resources are not always available in rural areas, where our product will have a big impact.”
Alberto Schena (COO of Lucentix SA)

Lucentix produces handheld medical devices to instantly measure the concentration of substances or biomarkers in a single drop of blood or saliva. Similarly to glucose blood monitoring devices, with a test strip and a simple device of the size of a smartphone, the patient will be allowed to perform the medical test at home or while traveling, without the need to go to the hospital. The data will be stored and plotted on demand and securely made available to the patient’s physician, allowing patient empowerment, personalized treatment and lower costs for the healthcare system. Their technology, developed at the Swiss Federal Institute of Technology in Lausanne (EPFL), allows measuring the most diverse types of substances, from vitamins to drugs, and constitutes a platform for monitoring the patient state in a multitude of medical conditions.

Why did you consider coming to India?
“India is an ideal market for Lucentix’s medical device, as many people do not have access to hospitals and the healthcare system does not allow everyone access to specific treatments.”

What milestones have you already achieved (in India)?
“We validated our technology on human samples from the local hospital in Lausanne and on samples from a multinational pharma company and we are currently finalizing our prototype of test-strips that can already be stored safely at room temperature for several months and of our handheld test-strip reader.

Thanks to swissnex India, we have access to the startup network in Bangalore. We have now many essential contacts, ranging from the healthcare sector in India to manufacturing and software development. Last month, we filed a patent in India to protect our technology in prevision of marketing in the future.”

What advice would you give to other startups that are planning to come to India?
“I would advise them to go there and feel the atmosphere. India is not a place where you can just meet people on the internet to put a collaboration together. You need to be present on the spot and meet and talk directly to the people, to create mutual trust. In this, swissnex India can really be of help. Moreover, it is indispensable to have a local Indian contact who is able to communicate with different players on behalf of the startup.”
The Indian market is very unique. In India, consumers shop for healthcare. This means there’s a market for every segment of medtech to enable healthcare delivery. Ideas for the medtech and healthcare segment are plenty – innovative business models, working directly with clinical research and hospitals to provide customized solutions, using the population as a base to inform big data and analytics, developing new products and manufacturing in India.

By 2020, Asia-Pacific will surpass the European Union in terms of size of medtech market, with majority of the customers beyond the premium segment. Further, individual markets that make Asia-Pacific are a complicated collection with different political systems, culture and disease profiles. Doing business in India gives a heady mix of the same extraordinary challenges and big opportunities, mimicking that of Asia-Pacific market as a whole. Worldwide, healthcare systems are in great economic stress and are increasingly demanding greater returns on investment. Innovating for India automatically focuses on maximum value. This learning translates to helping healthcare systems worldwide with their cost curve, a global opportunity.

India is characterized by complexity, ambiguity, uncertainty. However, a country with over a billion people cannot be ignored. To succeed, come with the right mindset, establish local leadership, create innovative business models, pay attention to the customer and make medtech for India.
References

34. Mehra, P. (2014). Only 17% have health insurance cover. http://www.thehindu.com/news/national/only-17-have-health-insurance-cover/article6713952.ece