Catenion MedTech Series:

Executive Briefing

Managing Innovation in MedTech – How to Enable Future R&D Breakthroughs?

Catenion

Catenion is a management consulting firm devoted to helping pharmaceutical and medical products companies significantly increase the returns on their R&D and Marketing investments by creating more innovative and effective strategies and organisations.

A MedTech Success Story – At First Glance

The Medical Device and Diagnostic Industry (MedTech) has seen a modern gold rush over the past years: especially in the early 2000s, many established companies were able to generate high single-digit (or even double-digit) annual growth rates. According to EvaluateMedTech, the field was able to build a global market with annual sales of approximately $325 billion by 2011.

The mid-term prospects also look bright: driven by rapidly rising sales in emerging markets, global MedTech revenues are forecast to grow to $440 billion in 2018 at CAGR of 4.4%. (Source: EvaluateMedTech, October 2012).

A key underlying driver for this past and projected growth of the MedTech industry is innovation. However, two different types of innovation need to be distinguished in this business:

1. Incremental innovations, on the one hand, describe the development of yet another product generation. This area is one of the industry's core strengths and in nearly every established MedTech market regular re-launches of the existing products have helped to sustain revenues.

2. Breakthrough innovations, on the other hand, often occur in two forms:

   - Breakthroughs that achieve fundamental success generated purely through a technological innovation

   - Breakthroughs that are generated by a mix of a new technology in combination with either a new business model, or enabled by a significant cost benefit to the user or patient, broader access to treatment, care, or diagnostic methods (e.g. in the mid-1970s when technologies were developed that allowed self-monitoring of blood glucose levels by diabetes patients – which was previously only done in the doctors' offices)

In recent years breakthrough innovations have similarly contributed to MedTech's success and have leapfrogged several areas of the industry: sequencing technologies have started to extend the reach of molecular diagnostics; the use of sensors has revolutionised prosthetics; transcatheter aortic valve implantation (TAVI) has marked a new era for older patients suffering from severe aortic stenosis; the use of minimal invasive surgery, robotic surgery and innovative (bio-) materials has changed the landscape in many operating rooms; and renal denervation technologies are expanding the arsenal of treatment options for hypertension – a space that had previously been entirely served by pharmacologic interventions.

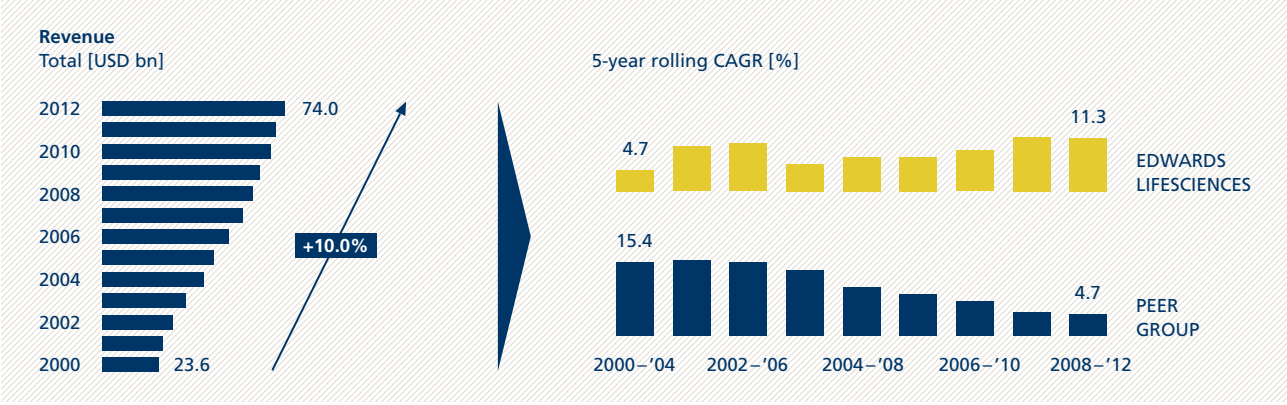
At Second Glance – Complacency and Lack of Internally Generated Breakthrough Innovation Amongst Big Players

The numbers and examples overleaf illustrate how successfully most MedTech players have performed and how prosperous the field has been over the past decade.

However, at second glance, scrutinising the financial data of a peer group of 11 major MedTech companies (with combined revenues in 2012 of approximately $74 billion) at shorter five-year rolling intervals reveals details that may be viewed as alarming – or at least show that MedTech might have now reached a mature state.

Looking in more detail at the revenue CAGR of 10.0% between 2000–2012 (Snapshot 1; upper left) and the 10.8% annual growth rate of the peer

Snapshot 1: Development of Revenue and R&D Expenditures of MedTech Peer Group vs. Edwards Lifesciences



Note: Peer group contains Medtronic, Roche Diagnostics, Stryker, Beckton Dickinson, Boston Scientific, Essilor, St. Jude, Zimmer, Biomet, Edwards Lifesciences and Sysmex; Source: Catenion based on Annual Reports of the respective companies

groups' R&D expenditures (Snapshot 1; lower left) creates a different picture:

First, five-year average revenue growth rates of the analysed players reveal that revenues have decreased from 15.4% (2000–2004) over most five-year analysis periods to a low of 4.7% (Snapshot 1; upper right – dark blue graph).

Second, R&D expenditures have followed a similar decline from 17.0% (2000–2004) to 3.4% for 2008–2012 (Snapshot 1; lower right – light blue graph).

Third, and most alarmingly, despite these significant R&D efforts (peer group companies spent 8.2% of their revenues on R&D between 2000 and 2012) the major players seem to have become complacent and have found themselves trapped in a situation in which they have become a victim of their own success. They failed to innovate and to develop the next breakthrough technologies as none of the industry's major breakthroughs over the past years (e.g. renal denervation, next generation sequencing, TAVI) originated from the established market leader's R&D hubs – despite the incumbent firms' significant investments in internal research and product development.

Instead, small venture capital funded start-up businesses often first developed innovative ideas and secured IP and then brought these technologies to the market. To not miss the next step of technological evolution, frequently the major MedTech players had to acquire these external assets or companies at high cost and high acquisition multiples.

Interestingly, the only company within this peer group that shows an opposite CAGR trend is Edwards Lifesciences: its average five-year revenue growth has changed from 4.7% to 11.3% over the period of analysis (Snapshot 1; upper right – yellow graph). After the company's spin-off from Baxter in 2000, management took the risk of re-shuffling its portfolio, divesting several of its existing businesses and acquiring Percutaneous Valve Technologies. This move advanced Edwards' position in the – at the time non-existent – market of catheter-based approaches for the replacement of aortic heart valves. In contrast to the trend of the peer group, Edwards has increased its R&D expenditures from 12.7% in 2000–2004 to over twenty percent for the latest five-year CAGR number analysed (Snapshot 1; lower right – yellow graph).

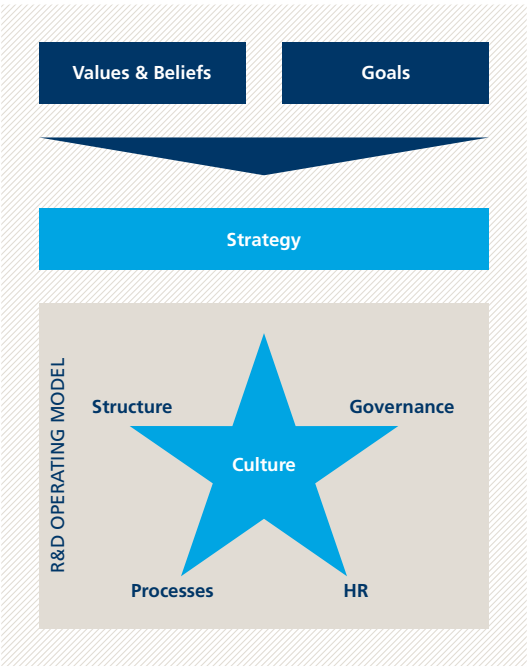
However, looking at the majority of large companies, it is legitimate to ask "Why are especially the dominant MedTech companies regularly incapable of inventing the breakthrough innovations in their fields?" Going a step further, we ask "What can be done to address this issue and how can these firms improve their R&D performance"?

Internal Reasons for Poor Breakthrough Outputs of Large MedTech Companies

The operating models of most large MedTech companies try to accomodate the renewal of existing products while simultaneously striving for technology leadership in their field(s). As a consequence, their R&D units steadily face conflicting objectives: short-term focused efforts are undertaken to incrementally improve current assets, to facilitate the launch of a next product generation, thereby creating additional revenue, while concurrently engineers and R&D staff are expected to deliver exciting breakthrough technologies.

Typically, this setting gets R&D managers into a predicament: while development times and costs for incremental improvements frequently overrun the quest for breakthrough innovation suffers to the point of deprioritisation.

Snapshot 2: Important Levers for Successful R&D Operations in MedTech



1

Explicit and Ambitious Corporate Goals
What are the long-term goals in terms of sales, profit, value generation?

2

Strategic Focus Areas within R&D
How to address the unmet needs? How to create an competitive advantage? How to mitigate risk and create log-term value? Internal vs. external growth?

3

Fit-for-purpose R&D Operating Model
How should the operating model support the strategy and goals? How to achieve operational effectiveness?

4

R&D Portfolio Management
How to best balance funding of projects across highly different dimensions (e.g. technology vs. development, life cycle management vs. novel, regional vs. global)?

Source: Catenion

Additional External Challenges and Opportunities Ahead

In light of the dynamic pace at which the field is currently moving, anticipation of and readiness for tomorrow's hurdles will be key to success. A number of changes will have significant impact on the field but will also provide a competitive advantage for those companies that are strategically prepared:

Market fragmentation

MedTech has historically been heterogeneous and is becoming even more diverse in terms of products (from gloves to cardiac pacemakers), offerings (from hardware to services), customer groups (from diabetic patients to clinical laboratories), and business models. Even today each segment requires a specific set of expert knowledge. Further innovation and new products will enhance both the heterogeneity of the field and the degree of specialisation.

Regulatory authorities

Although a reform of the 510(k) process in the US appears unlikely today, increased scrutiny and potentially other changes that may lead to tighter regulation can be expected. For instance, these may be triggered by the FDA as a reaction to the increasing number of medical device recalls in the US, or by European authorities where the CE mark does not appear to represent an up-to-date standard and recent issues have raised political and public attention (e.g. the Poly Implant Prothèse scandal).

Pricing and reimbursement

Healthcare costs have been rising considerably in most developed countries, sometimes threatening the funding capabilities of public systems. Governments and payers seek to counteract this by capping costs, often in the form of Health Technology Assessments. In the future, bringing a real value contribution rather than yet another product will be increasingly important to achieve reimbursement. Attempts to better reward improvement of value-based outcomes may shift the value equation in some segments of the healthcare market from pharmaceutical interventions towards diagnostics and medical technologies. Such a shift may be triggered by either the realisation that prevention may be cheaper than intervention or by MedTech breakthroughs that that provide alternatives to drug treatment (e.g. renal denervation). In the UK, NICE already values diagnostic tests with economic models that link results of a test to treatment outcomes and QALYs. Even if an increased cost-effectiveness of healthcare is enforced in the major markets, MedTech companies will need to prepare for a long, uphill battle for reimbursement at a time when they are still primarily concerned with an early stage of product development within R&D. One of the largest challenges for the industry remains to properly design and execute long-term studies in order to generate a solid set of data that convinces public and private payers. In the US, it has taken Genomic Health more than six years and several studies to achieve broad reimbursement for its "Oncotype Dx" test after it was launched in 2004.

Emerging markets

As markets in countries like China and India are growing at high rates, all global MedTech players are expanding their local presence and are seeking strategies to successfully address the local needs – which are often very different compared to those in the established markets. Local competition is often fierce and already requires global organisations to review their business models.

How can These Internal R&D Challenges be Successfully Addressed?

In Catenion's view, to overcome complacency and to prepare the ground for real breakthroughs, MedTech R&D organisations need to pull several levers simultaneously (Snapshot 2):

1. Explicit and ambitious corporate goals

These goals should exceed the expected revenues and growth rates that can be achieved through incremental innovation in order to stimulate R&D performance beyond the "givens". Therefore, corporate R&D budgets and resources need to be explicitly allocated to projects that have a "game-changer" potential. Technology roadmaps can be outlined to identify those areas in which a significant unmet need exists that cannot be addressed by staying in the present comfort zone. The gap between forecasts of existing products and ambitiously set goals should only be closed by the contribution of successful breakthrough projects.

2. Fit-for-purpose R&D operating model

A multitude of variables such as company size, organisational structure & governance, company culture and processes needs to be considered in order to define execution in a way that best allows achieving the corporate goals.

3. Strategic focus areas within R&D

As MedTech has been maturing over the past decade, the hurdles for successfully driving an R&D organisation have become higher and the need for a clear R&D strategy has increased. In this context, we believe that there is a lot to be learned from the pharmaceutical industry that has already gone through this maturation stage. As a consequence of these changes, most pharmaceutical companies have taken a dual approach:

- They have established R&D portfolio management as a central function
- They have established new models of scouting and external sourcing of projects in order to complement internal R&D

In MedTech, Edwards Lifesciences has demonstrated that a clear corporate focus can be an enabler for future success.

4. R&D portfolio management

Compared to the pharmaceutical drug industry where the average duration from target identification to launch can easily exceed 10 years and development

failure is the default, product development cycles for medical devices are usually much shorter and technical failure is a rare exception.

Nevertheless, the common issues in MedTech R&D are very similar:

- The portfolio lacks a clear prioritisation and deprioritisation of projects
- The pipeline lacks a sustainable output (i.e. timelines & budget are not met)
- Resource shifting is frequent as short-term objectives overrule long-term planning
- An innovation mix between breakthrough vs. incremental innovation is not visible
- The needs of emerging markets are not addressed by global R&D due to the dominating view of stakeholders with a focus on established markets

As in Pharma, all of these problems could be addressed by an effective, well-accepted portfolio management process that achieves buy-in within the organisation through its transparent decision-making.

Clearly communicated criteria for prioritisation and deprioritisation of projects are critical (dependent on e.g. future market potential, local and global unmet needs, technological advantage) and the allocation of resources should be built on these criteria. The impact of these decisions on the long-term positioning of the company in the market (does the portfolio composition fit with the overall goals and company vision?) and the importance of every product decision on other devices in the portfolio (e.g. product cannibalisation or interdependencies, role of enablers, cross-selling potential) need to be shown.

The definition of milestones, adherence to timelines and budgets, and the accountability of project managers to meet these are fundamental elements of this process. In addition, “wild card” projects that have breakthrough potential need to be advanced in parallel – as standard project prioritisation metrics often already weed these developments out during the idea stage (e.g. because a market for these break-throughs does not even exist and forecasts therefore fail to show their potential).

Moreover, the entire process needs to efficiently incorporate the lessons learnt from both successful and abandoned development projects. This applies in particular to mid-to-large R&D groups which can show a tendency to think in isolation and to repeatedly encounter the same difficulties.

External Scouting, Licensing, Collaborations and M&A to Complement Internal Activities

As in the more mature Pharma sector, the importance of supporting internal R&D activities with external opportunities is increasing in the MedTech field. Some of the prevailing objectives are to:

- Identify attractive technologies that could complement one's own set of products and offerings
- Determine opportunities that are adjacent to existing business segments (e.g. building towards an "own the disease" business model)
- Take investment decisions as early as possible and at a lower cost
- Create a greater reach into often highly diverse or fragmented target markets through collaborations with access to local market knowledge

Early scouting of small companies, evaluation of their technology and subsequent investment decision activities are crucial in support of one's own R&D efforts: "When is the right time to invest?", "Which technologies will be the next winners?", "How do we place our bets?".

Despite an environment that is getting more competitive across the board, the importance of identifying opportunities is often neglected within R&D. As a consequence, the co-operation between research units and business development & licensing or internal venture capital arms of the organisation often can be significantly enhanced – to the benefit of R&D innovation, rather than the R&D function *per se*.

Technology roadmaps can be a useful tool to identify potential drivers for the adoption of novel technologies and to define mid-/long-term growth paths. As a result, significant M&A opportunities may either not be missed or acquired at a lower price. Collaboration models are currently still in their infancy in MedTech, in stark contrast to Pharma which has been facing many of the same challenges (regulation, pricing, reimbursement) for many years.

In our view, in order to successfully manage innovation in the MedTech industry, multiple levers need to be moved in a coordinated fashion. Only those players that align their R&D efforts well with the company's goals and strategy, in addition to having mindfully built interfaces with other key internal and external functions, will generate an R&D output that secures future growth.

Catenion GmbH, Hausvogteiplatz 12, 10117 Berlin – HRB95394 b, Geschäftsführer: Dipl.-Ing. Arno Heuermann

Catenion MedTech Series:
Executive Briefing
Managing Innovation in MedTech –
How to Enable Future R&D Breakthroughs?

Berlin
Catenion
Hausvogteiplatz 12
10117 Berlin
Germany
phone: +49 30 2063 996 – 0
fax: +49 30 2063 996 – 22
email: berlin@catenion.com

New York
Catenion
405 Lexington Avenue, 26th Floor
New York, NY 10174
United States
phone: +1 212 203 7276
fax: +1 917 368 8005
email: newyork@catenion.com

London
Catenion
180 Piccadilly
London W1J 9HF
United Kingdom
phone: +44 20 7917 9511
fax: +44 20 7439 0262
email: london@catenion.com

Tokyo
Catenion
Level 20 Marunouchi Trust Tower
1-8-3 Marunouchi, Chiyoda-ku
Tokyo 100-0005 Japan
phone: +81 35288 5270
fax: +81 35288 5271
email: tokyo@catenion.com

www.catenion.com