

The Impact of Regenerative Medicine

– On the Pharmaceutical and
Medical Devices Industry



Scenario planning

Imagine that in the future insulin-producing beta cells or whole pancreas are grown in laboratories and implanted into the human body to restore glucose metabolism. What would happen to the \$13bn diabetes market? How could the companies respond to such a challenge and even use it as an opportunity? Questions such as these should be addressed early to be prepared for future innovations.

Regenerative medicine (RegMed) comprises the development and application of innovative medical therapies aiming to cure or remedy diseased or injured cells, tissues or entire organs, or support their regeneration. The vision is to avoid transplantations, pure technical solutions, or permanent pharmacotherapy. Furthermore, diseases or traumata that are beyond treatment could be successfully addressed. This will therefore lead to a complete paradigm shift in medical treatment, and not merely new technologies and products.

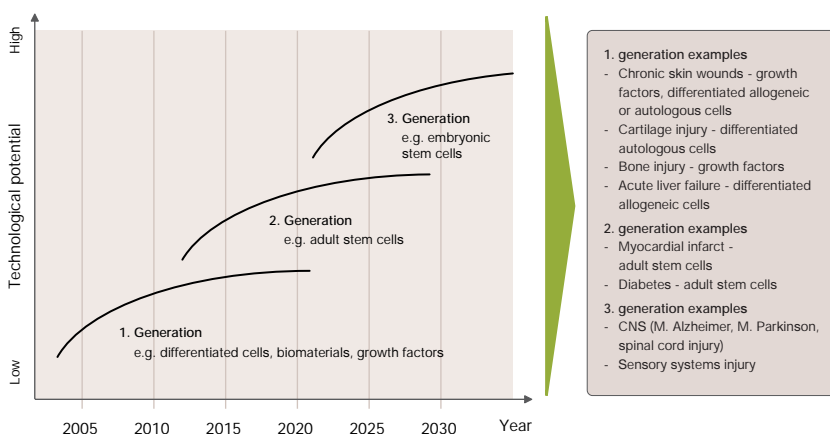
Nowadays, some first-generation products are already on the market and many are being developed. Examples for projects in development are the use of stem cells for heart muscle regeneration after a heart attack or the application of liver cells in the treatment of severe liver diseases. Products on the market, for example, are biomaterials used alone or in combination with skin cells in wound treatment or bone growth factors used in orthopedics. These products have already gained some market share, and even though a broad application is not yet in sight, they have paved the way for a new generation of products and well demonstrated the obstacles and challenges in developing products of regenerative medicine.

RegMed products are mostly developed by medical devices or biotechnology companies. Pharma companies are (yet) not very active in this field. However, Capgemini believes that in the near future, companies from all three sectors will be influenced by these new products. The challenges they are likely to meet depend on their current situation and whether they act as developers of RegMed products or if their products will be in turn challenged by existing RegMed products.

Medical devices companies will be affected in three areas: R&D and regulatory, business development, and corporate strategy. RegMed products are developed with the help of biotechnologies. Their use is quite new for most medical devices companies and implies not merely applying these technologies, but also integrating them into their existing R&D processes. This can represent quite a challenge because of new knowledge which needs to be developed in-house, and traditional differences in the way engineers and biologists work and think.

The present regulatory environment is comparatively complex and dynamic because the “classical” separation between medical devices and drugs (in Europe) and biologics (in the US) becomes blurred when dealing with combination products. To be able to decide which regulatory path will be addressed, the necessary know-how has to be assembled. The situation is complicated in some cases, especially when using cells, because precise regulatory requirements still need to be defined by the regulatory agencies.

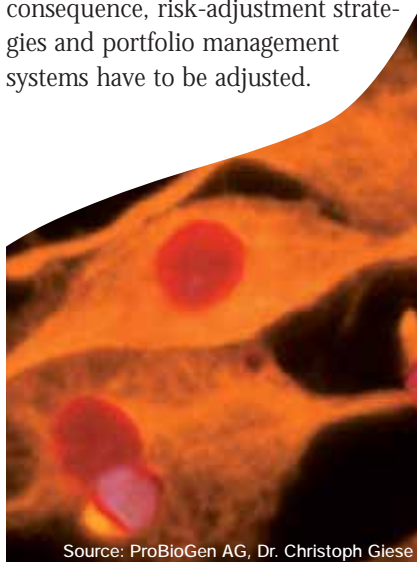
The various types of RegMed technologies are expected to have a different potential



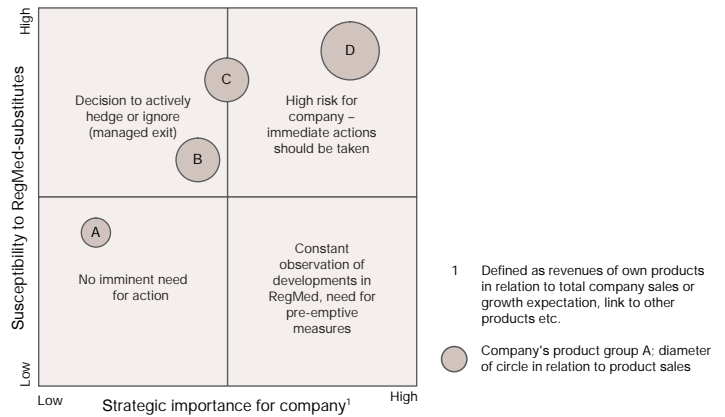
While entering the market, the newly developed products must fit the company's product portfolio, and their market launch has to be designed carefully. The products often require more explanation to the physicians than conventional products, and a decision needs to be taken on who is going to provide this information (e.g. specialized sales reps).

Instead of developing the required knowledge in-house, or acquiring it through M&A, know-how can also be "acquired" through business development by partnering with biotechnology companies. Medical devices companies have to establish a system for identifying which technologies are important and how to gain access to them. Partnering enables a stepwise, risk-adjusted approach to these technologies. However, partnering with biotechnology companies is not as common in the M&A-driven medical devices community as it is with Pharma companies; so the medical devices companies could learn from the best practices of the Pharma industry.

Corporate strategy will be affected by these challenges because overall product development times and R&D costs will increase and market launch strategies have to be adapted. As a consequence, risk-adjustment strategies and portfolio management systems have to be adjusted.



The impact of RegMed products on the product portfolio should be analyzed during scenario and portfolio planning



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Biotech companies are highly innovative in RegMed technologies and products.

However, they have to manage their growth and implement professional processes and structures while maintaining their entrepreneurial spirit. Because most small companies do not have dedicated teams responsible for clinical trials and reimbursement strategies, they either have to build up know-how internally, or partner with other companies to gain access to the relevant know-how.

Pharma companies are currently not very active in the field of regenerative medicine because today most RegMed products are in the field of wound management and orthopedics. Future products will be designed to treat cardiovascular, metabolic and CNS diseases and will provide an alternative to drugs.

Therefore, Pharma companies need to define their own position now and decide if or when they will enter the field of RegMed. They have to be aware of the different scenarios.

Hospitals as clients or competitors?

Using autologous (i.e. patient's own) cells, some clinics in Germany are already manufacturing their own products. One example is wound treatment where skin cells are taken from the patient, grown in the lab on matrices, and applied on skin wounds. Also some companies already offer these products in the market. A very new field is the treatment of heart attacks with a patient's own stem cells. Again, the cells are isolated, purified, and applied in the clinic. Hence, the clinics may at the same time be clients and competitors of the companies active in the RegMed field. The clinics will thereby gain market power. Companies have to be aware of this potential competition when developing and marketing their products.

About Capgemini's Life Sciences Practice

Capgemini's Life Sciences Practice is a leading global provider of management consulting, technology, and outsourcing services to the pharmaceutical, biotechnology, and medical devices industries. Established in 1993, we are known for the talent and dedication of our people, the value we deliver to our customers, and for working collaboratively with our clients. Our clients include the majority of the leading pharmaceuticals, biotechnology, and medical devices companies.

Capgemini has been active in the field of regenerative medicine since 1999 and worked for numerous private and public clients. Based on our in-depth knowledge of regenerative medicine, and in combination with our general consulting offerings, we provide customized solutions for our clients.

Capgemini's specialized offerings

- R&D-Portfolio analysis/ optimization (e.g. RegMed products vs. conventional products)
- R&D development process optimization (e.g. implementation of reimbursement strategies in development process, combination of clinical efficacy with clinical efficiency)
- M&A strategy, post merger integration
- Establishment of a more professional business development, and alliance management for medical devices companies with Pharma/Biotech companies
- Product launch strategy
- Competitive analysis
- Scenario planning
- Growth strategy
- Product lifecycle management
- Sales & marketing effectiveness
- Pricing and reimbursement strategies

Outsourcing Offerings

Capgemini works with leading medical device companies to take over their business processes or IT departments, or parts thereof.

- Business process outsourcing
- Application management
- Infrastructure management

Technology Offerings

Our teams collaborate with you to build and implement the right technology strategy - in national or global programs, through incremental or "turnkey" solutions, involving technology alliance partners as needed.

- ERP
- Systems architecture
- Custom development
- IT Strategy development
- Business systems validation



About Capgemini

Capgemini, one of the world's foremost providers of Consulting, Technology and Outsourcing services, enables its clients to transform and perform through technologies. Capgemini provides its clients with insights and capabilities that boost their freedom to achieve superior results through a unique way of working, which it calls the "Collaborative Business Experience".

Capgemini reported 2006 global revenues of EUR 7.7 billion and, following the acquisition of Kanbay International on Feb 8, 2007, employs approximately 75,000 people worldwide.

More information is available at www.de.capgemini.com

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