

EMCC case studies

Biomedical healthcare sector: Q-Med AB, Sweden

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Background

Q-Med AB is a rapidly growing and profitable biotechnology/medical device company, located in Uppsala, Sweden. The company develops, produces, markets and sells implants for aesthetic and medical use. Q-Med today has just under 700 employees, with approximately 450 at the company's head office and production facility in Uppsala. Sales are mostly through the company's own subsidiaries or distributors in over 70 countries.

Q-Med was started in 1987 by Dr Bengt Ågerup with a view to commercialising the research that he had carried out into hyaluronic acid. Since the end of 1995, the company has focused purely on the new form of stabilised hyaluronic acid that Q-Med has developed and patented. In 1995, the so-called NASHA patent was filed, which is the base of all of Q-Med's products and, at the end of 1996, approval was obtained for the first Q-Med product, Restylane, for sales in Europe. Restylane is now the leading brand in the global aesthetics market.

Since 1996 the company has launched a range of products for the aesthetics market and hospital healthcare. The product portfolio today contains:

- Restylane, for filling out lips and facial wrinkles and for facial contouring.
- Durolane, for the treatment of osteoarthritis in hip and knee joints.
- Deflux, for the treatment of vesicoureteral reflux (a malformation of the urinary bladder) in children.
- Zuidex, for the treatment of stress urinary incontinence in women.

According to Q-Med's annual report of 2006, Restylane's share of Q-Med's total revenues amounts to 73%, while hospital healthcare products (Durolane, Deflux and Zuidex) account for the remaining 27% of revenues. Q-Med's first product in the field of body augmentation (e.g. body contouring, filling out wrinkles and folds and contouring lips, cheeks and the chin), Macrolane, was approved in Europe in 2006. The same year, a new product, Solesta, for treatment of faecal incontinence, also received approval for the European market.

In 2005, Q-Med received the highest points of all companies listed on the Stockholm Stock Exchange in Folksam's Sustainability List. The sustainability score is calculated as an average of each company's scores in Folksam's survey of employee health, equality and environmental work. A score was given for the status of 228 companies, and Q-Med obtained a score of 4.13, compared with an average score of 2.55 for all companies reviewed.

O-Med AB, Annual report 2006, http://investors.q-med.com/files/press/qmed/Qmed_AR_06_eng_index.pdf

Folksam is a Swedish insurance company.

³ Folksam sustainability report 2005, http://www.folksam.se/resurser/pdf/english/sustainabilityreport-2005.pdf

Uppsala-Stockholm biotechnology region

Q-Med AB is located in Uppsala, only 45 minutes' drive from the Swedish capital, Stockholm. The Uppsala cluster is today a buoyant centre of biotechnology, accounting for about one-quarter of Sweden's biotech sector in the shape of universities, industry and national agencies. The biotech industry in Uppsala is particularly strong in three segments: tools and supplies, diagnostics and pharmaceuticals. There is also a growing number of service providers that specialise in meeting the demands of these industries.

Today, Uppsala's biotechnology sector employs some 7,500 people, and 50 companies, two universities, one university hospital, the Swedish Medical Products Agency, the National Food Administration and the National Veterinary Institute are all located in the region. Academic research is mainly conducted within the two universities (the Swedish University of Agricultural Sciences and Uppsala University). The latter is a research university with a clearly expressed strategy for promoting cross-disciplinary projects in biotechnology.

In addition to the Uppsala universities, Stockholm has three more universities/institutes (Karolinska Institute, Royal Institute of Technology and Stockholm University) dedicated to biotechnological research, plus a further two university hospitals that conduct clinical research. The profile of the biotech companies and academic research in the Stockholm area is slightly different from Uppsala, with a stronger emphasis on drug discovery in central nervous system diseases and metabolic diseases, as well as a number of sales offices for international pharmaceutical companies. The majority of venture capital companies working in biotech and healthcare are also located in the city of Stockholm.

These two areas together, Uppsala and Stockholm, are home to more than half of the biotechnology companies in Sweden and provide complete coverage of competences in biotechnology.⁴

Uppsala BIO-X – cross-disciplinary research for the life science industry

Uppsala BIO-X is a cross-disciplinary research effort focused on projects based on cutting-edge science, with the potential to generate new opportunities for today's and tomorrow's life science industry.

The purpose of Uppsala BIO-X is to support ambitious, world-class research projects in the region by making available supplementary funding and resources, primarily to stimulate the formation of cross-disciplinary research teams. The aim of the effort is to create new business opportunities from collaborative research efforts between academia and industry. Projects of this nature require substantial resources; hence the strategy of Uppsala BIO-X is to give significant support to a small number of projects. The Swedish University of Agricultural Sciences and Uppsala University constitute the academic base for the effort and the Uppsala biotech industry members lend their active support by giving an industrial approach to the research effort. The Uppsala BIO-X projects are revised regularly by both industry and academia to secure a needs-motivated focus. Furthermore, a Scientific Advisory Board, comprising internationally recognised scientists from the two universities and the biotech industry, supports the management of Uppsala BIO in selecting and supervising the projects.

Source: Uppsala Bio website, http://www.uppsalabio.com/DynPage.aspx?id=4715

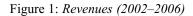
Uppsala Bio, 'Biotech hotbed' (presentation), http://www.uppsalabio.com/graphics/4746.ppt#259 and Uppsala Bio website, http://www.uppsalabio.com/DynPage.aspx?id=4706&mn1=1224

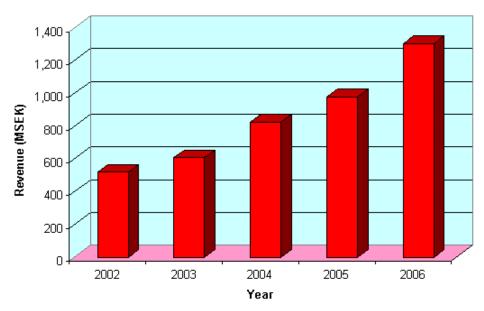
Facts about the company

Q-Med develops, manufactures, markets and sells medical implants primarily. The majority of the products are based on the company's own patented technology, for aesthetic and medical use by authorised users. Q-Med's vision is to 'create wellbeing, by offering innovative and immediate corrections of defects that are not life-threatening'.

Key figures

Q-Med has experienced constant growth in revenues. In fact, revenues have more than doubled since 2002.

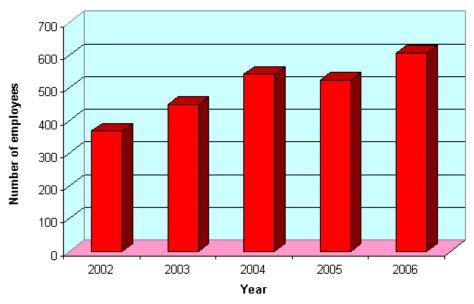




The European market is the largest in terms of revenues (43% of total revenues), followed by the US (30%) and Asia (20%).

The number of employees has also been increasing since 2002 (see Figure 2).

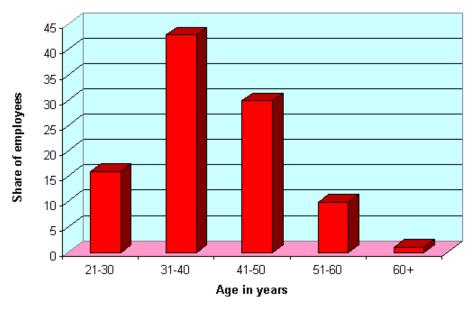
Figure 2: Number of employees



There is relatively low staff turnover in the company (3.6%). Out of the 608 employees, 62% are women and 38% are men. The share of women in senior management is 50%.

The majority of the employees are 31 - 40 years old (average age is 39 years) and more than half of the employees are either graduates or post-graduates.

Figure 3: Age profile (employees in Sweden)



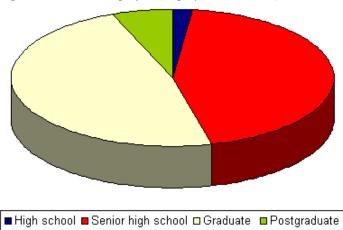


Figure 4: Educational profile (employees in Sweden)

Diversity is considered a great asset for the company. The company employs people of several different nationalities (19 countries), men and women and persons of varying ages.

Skills development and working conditions

Competence development is a priority for Q-Med as a means to promote development, growth and understanding of customers' needs, but also to ensure that employees absorb new knowledge that is necessary for the continued development of the company. Individual employee development interviews are conducted every year, laying the basis for the planning of individual training plans. Such plans can include job rotation as well as formal education, financed by the company. All employees participate in the yearly development interview.

Training is mostly focused on the employees' specific job functions, but Q-Med also considers providing or financing training or education when such training or education serves a strategic purpose. Q-Med works hard to ensure good working conditions for its employees. A pleasant and stimulating physical environment (art, modern facilities, etc.) is considered to be very important. In the words of Thomas Holmberg, HR director at Q-Med AB, a good working environment leads to better results.

The company's salary and rewards policy also makes it possible to reward outstanding individual performances. In addition, employees receive a thirteenth monthly salary if the company meets its annual objectives for sales (volume) and profit. Together, these elements ensure that Q-Med is an attractive place to work. Furthermore, the growing organisation and expansion on a global level increasingly make it possible for the company to offer new opportunities for international exchange, job rotation and international recruitment.

However, the growing organisation also presents a challenge in terms of safeguarding Q-Med's culture and values. With growing size, the closeness and day-to-day informal exchange of information between management and staff, and within the staff, gradually disappears. Q-Med addresses this challenge by regularly carrying out employee satisfaction surveys. Each survey is followed by an action plan addressing areas that need to be improved. The most recent survey highlighted communication and the spreading of information as issues that needed to be addressed. As a result, efforts are now focused on gradually replacing the current informal spreading of information with a more formal and focused system.

⁵ Q-Med AB, Annual report 2006, http://investors.q-med.com/files/press/qmed/Qmed_AR_06_eng_index.pdf

Quality assurance and sustainable development

Quality assurance and sustainable development are fundamental concepts in Q-Med's business activities. In concrete terms, this means that the company strives to ensure that the company's products are safe and effective, but also that Q-Med actively seeks to create sustainable profitability by contributing to the long-term sustainability of society. One of the key initiatives was the adoption of a new environmental policy in 2006. The same year, the company initiated a process of formalising and implementing the company's code of conduct. The code contains guidelines on how the company and its employees should act with regard to business ethics, human rights, discrimination, environmental awareness, etc.

In terms of quality assurance, Q-Med AB applies a process-oriented way of working, where the quality management system is part of the company's management system. Through this process orientation, emphasis is placed on the importance of identifying and quality-assuring the flow in the organisation – from development to sales – rather than considering separate departments or line functions. Constantly identifying and implementing new improvement activities and developing more effective measures are part of this work. It may, for example, be a question of managing critical interfaces, ensuring the employees' understanding and involvement, or securing documentation. Process performance regarding effectiveness and quality is evaluated constantly and also followed up by senior management several times per year.

The point of departure for the quality initiative is the company's own quality policy, but also selected quality objectives that are part of Q-Med's business plan. Another fundamental part is the ISO 13485:2003 quality certification, which is adapted for medical device companies. Q-Med AB also meets quality requirements, such as the US GMP/QSR (Good Manufacturing Practice/Quality System Regulation CFR820) and the European medical device Directive (MDD93/42EEG), which is necessary to obtain the CE mark.

During 2006, work on quality at Q-Med's subsidiaries has been strengthened. The objective was to assure the quality of the product in its distribution, right up to the end customer. This work focused on secure handling, storage and distribution. During the year work on risk management was also developed and made more systematic. These different initiatives are an integral part of the organisation's structural adjustment to Q-Med's rapid growth.

New environmental policy

In 2006, Q-Med adopted a new environmental policy. The policy emphasises that environmental work is an integral part of Q-Med's business activities and that it should promote both long-term sustainability and sustainable profitability.

The efficient use of raw materials, water and energy is high on the agenda, and specific work in this area has already been carried out. Heating of the company's own premises in Uppsala is largely done through geothermal means, which reduces carbon dioxide emissions. This is also the case for an additional building that was constructed in 2006/2007 on the company's premises in Uppsala. In the new building, priority has also been given to construction and materials, which have low environmental loading effects.

Transportation is another area that is mentioned in the policy. The stated aim is to eliminate detrimental environmental effects, both in company travel and transportation, as well as in cooperation with suppliers and haulage firms.

⁶ Q-Med website, http://www.q-med.com/DynPage.aspx?id=844&mn1=197&mn2=245

One specific initiative is that Q-Med's employees in Uppsala can borrow company bicycles for short errands and thus reduce the amount of travelling by car locally. Priority is also given to minimising the consumption of paper and energy.

Recently, Q-Med has decided to take its environmental policy one step further by adopting standards leading to ISO Environmental Management System approval.

Overall strategy

Q-Med's overall strategy and success factors are listed below.

Q-Med's overall strategies and success factors

- Supply high-quality aesthetic and medical products that are simple and safe to use.
- Continue to develop and document products which are primarily based on the patented NASHA technology and its applications up to proof of effect.
- Involve customers and consumers at an early stage of product development.
- Help customers to develop their ability to sell so as to attain the best possible results for both themselves and Q-Med.
- Achieve the best possible international presence in prioritised markets, with maintained or increased market share.
- Take responsibility in business and strategies for protecting the environment and surroundings and strive for sustainable development.
- Achieve strong commitment from employees by providing a good working environment, opportunities to develop and competent leadership.

Source: Q-Med AB, Annual report 2006, http://investors.q-med.com/files/press/qmed/Qmed_AR_06_eng_index.pdf

Challenges

Global expansion

Q-Med is focusing efforts on global expansion. On one hand, a global presence makes it possible for the company to offer immediate services to customers. On the other hand, it also means that the company has to be prepared to face new cultures and traditions. Global expansion does not necessarily result in more employees. Rather, the focus is on the best possible business model – not the number of employees. Expansion also means that the Swedish headquarters will focus more on managing relations than on manufacturing.

Q-Med follows a core competence strategy, developing the company's competences within research and development, rather than taking on new tasks, such as building up a sales organisation and distribution networks in new markets. The organisation is developed to adjust to markets as they expand, following analysis of the specific market. In some markets, it is profitable for the company to sell and distribute products; in other markets, these tasks are best left to other companies. For every product and market, there is a strategic choice to be made – in the opinion of the company management, no single business model fits all.

New markets

The company sees new markets emerging in Asia and Latin America. The Asian economies in particular are booming and there is a large appetite for new things and great respect for 'Western' products. This makes Asia a vital region for Q-Med.

According to Q-Med, one of the company's main strengths when entering new markets is its focus on ethics. This is especially relevant in China, where the booming economy and the growing market for aesthetics has attracted a range of unprofessional players, leading to tighter control by the authorities, with longer handling times as a consequence. In order to distance the company from such players, Q-Med is working closely with local authorities and also profiling its brand in a professional and thorough manner.

Shift in market focus

According to Thomas Holmberg, the company is experiencing a paradigm shift in the market for aesthetic products. In the future, the company will be selling directly to individual costumers in addition to the healthcare industry (doctors, etc.). Products that were previously considered to be medical products will probably become consumer goods, similar to cosmetics. This has important implications for the company, since attention needs to be directed towards marketing that is targeted directly at consumers. This paradigm shift will probably also result in less demanding approval processes.

Skills and workforce

Thomas Holmberg does not expect big changes in terms of skills needs in the coming years. However, sales staff and managers need to have a commercial focus and focus on the development of new products. The company also need skills and experience in relation to PR and marketing. Q-Med is actively addressing skills needs at the managerial level. Since 1999, Q-Med has had a leadership programme, the aim of which is to give managers the tools to develop and motivate employees and also to develop their own ability to think ahead and to grow in line with the company.

It has not been difficult for Q-Med to attract highly skilled employees. Q-Med is situated in a region with many educational institutions, it has a strong regional profile, and the company invests 20% of turnover in R&D. However, global expansion has resulted in a need for new competences (e.g. people with international experience). Q-Med seeks to fill this gap by recruiting such people, but there is also an element of 'learn as we go'.

Demographic developments

Demographic trends show that the number of Europeans is decreasing. As a result, the European market for Q-Med's products is shrinking. However, the increasing share of elderly people could increase the demand for both Q-Med's medical products and its aesthetical products. People want to look good and young, therefore the demand for Q-Med's products should increase as people get older. Also, the demographic development is primarily a European problem – markets in South America and Asia are not under pressure from demographics.

Growing competition and consolidation

The market for aesthetic products is growing and presents a big opportunity for the company and for the biomedical sector as a whole. However, competition in the sector is increasing and, as a result, the company's sales organisation needs to be strengthened and new, innovative products need to be developed.

One of Q-Med's answers to increasing competition is to increase efforts to enter into strategic alliances. One example is the signing of a licensing and supply agreement between Q-Med and Smith & Nephew in 2006. This agreement granted Smith & Nephew the global, exclusive rights to market, sell and distribute Durolane and other products intended for the management of orthopaedic conditions and diseases. Q-MED will manufacture and supply all products developed under this transaction, while Smith & Nephew will focus on and bear the costs for the clinical development, registration and commercialisation of new products worldwide.

HealthPointCapital.com, Smith & Nephew and Q-MED form hyaluronic acid treatment alliance, 28 June, 2006 http://www.healthpointcapital.com/research/2006/06/28/smith_nephew_and_qmed_form_hyaluronic_acid_treatment_alliance/

The sector is also witnessing a consolidation trend at the moment. In general, consolidation in the sector is considered to be a threat when it comes to skills. When companies merge across national borders or regions, specialised skills are often concentrated in different locations. This drains a specific region of highly specialised staff.

Regulatory field

Getting approval for products is difficult and resource-demanding. In addition, the time from idea to registered product varies from region to region due to different requirements when it comes to clinical studies and the processes of each country's authorities. FDA approval for the US market and approval for the Chinese market are particularly difficult to obtain. In Europe, it has become easier to obtain marketing approval since the establishment of the European Medicines Agency in 1995.

Location strategy

The owner of Q-Med lives in Uppsala and, for that reason, the company will probably not move anywhere. However, the company establishes presences where it makes economic sense to do so (logistics, tax benefits, etc.). All development and manufacturing take place in Uppsala, so sales and logistics are the main focus areas when it comes to activities outside Uppsala.

Conclusion

Q-Med is facing a range of challenges, including global expansion and growing competition. Among key issues for the company is the possible paradigm shift in the aesthetics domain, making it necessary for the company to change focus from healthcare personnel to end consumers in terms of marketing efforts. In terms of the company's location, Q-Med is not currently considering moving activities to other regions.

SWOT analysis

The company's main strengths, weaknesses, opportunities and threats are identified below.

Strengths	Weaknesses	Opportunities	Threats
Close relations with research environment in universities	Skills and experience in relation to PR and marketing	New markets (Asia and Latin America)	• Regulation (e.g. approval of products)
 Diversity of work force High ethical profile (entering new markets) Attractive place to work High quality of products (scientific evidence) Strong relations with customers 	Need for new competences/international experience due to global expansion	 Growth in market for aesthetic products Paradigm shift Strategic alliances 	Increasing competitionConsolidation

The EMEA is responsible for the scientific evaluation of applications for European marketing authorisation for medicinal products. All medicinal products for human and animal use derived from biotechnology and other high-technology processes must be approved by the EMEA. Source: The European Medicines Agency website, http://www.emea.europa.eu/

Sources

Interview

Thomas Holmberg, HR director

Reports

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Henrik Noes Piester, Danish Technological Institute