

DEVELOPING EXCELLENCE IN MEDICAL TECHNOLOGIES:

Survey and Case Study Report for Massachusetts

A report prepared for
Advantage West Midlands
PLS Ramboll
E-mail: Henning.Thomsen@pls-ramboll.com



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1. Introduction

This report details a survey of medical technology companies in the state of Massachusetts and surrounding area. The report has been produced by PLS Ramboll. Information is also provided from six case studies of companies engaged in the manufacture of medical technologies.

The Benchmark Report for Massachusetts detailed the strengths of the Massachusetts area – especially along Highway 28 – in the production of medical technologies and a related group of industries.

Annex A provides details of the survey and the evident difficulties in survey companies in the USA. The results therefore should be treated as indicative of the sector/cluster in Massachusetts. But read in conjunction with the Benchmark Report and the case studies described at the end of this report, a detailed picture of the medical technology sector in Massachusetts is provided.

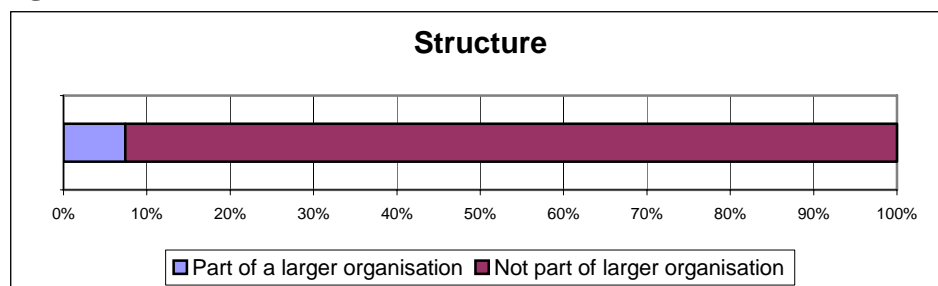
2. Characteristics of organisations

This chapter deals with the characteristics of organisations and considers the ownership of the companies; their product ranges; the value of their sales; and market trends.

2.1 Ownership of Companies

About 95 per cent of the establishments were not part of a larger organisation, as shown in Figure 1.

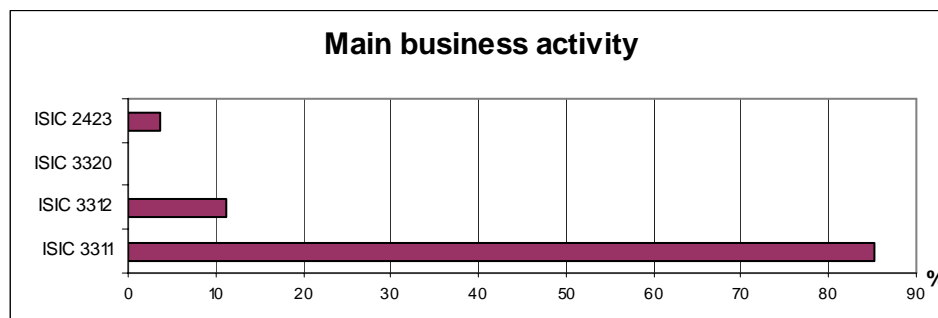
Figure 1



2.2 Product Range

Figure 2 shows that about 85 per cent of the establishments operated mainly in the ISIC3311 industry (the manufacture of medical and surgical equipment and orthopaedic appliances), and that the remaining establishments were mainly in ISIC 3312 (the manufacture of thermometers) and ISIC 2423 (surgical dressings). There was no establishment in ISIC 3320 (corrective spectacle lenses).

Figure 2



The participating establishments mainly produced medical devices, but other medical products and services were also represented (see Table 1).

Table 1

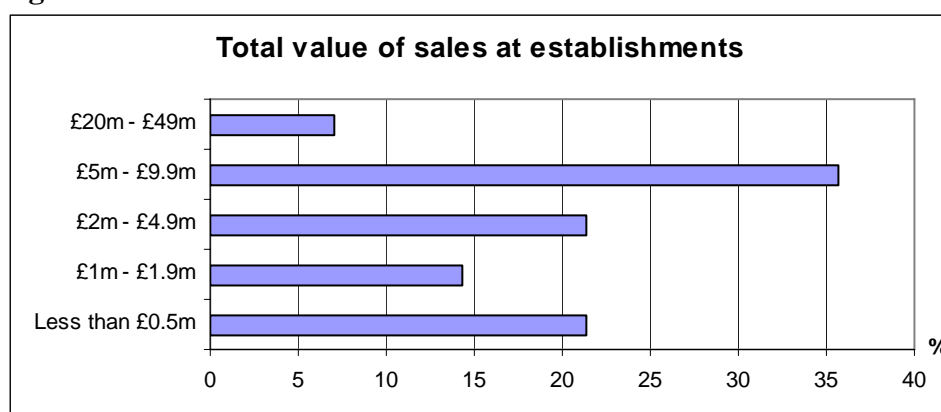
	Per cent
Medical Devices	75
Surgical Devices	21
Orthotics	4
Wound care	4
Ophthalmology	7
Genomics/ Proteomics	4
Innovation and incubation support	4
Veterinary	4
Other	7
Total	100

Note: more than one answer was not possible from each establishment

2.3 Value of Sales

About two-thirds of the establishments had annual sales of more than £2 million (see Figure 3).

Figure 3

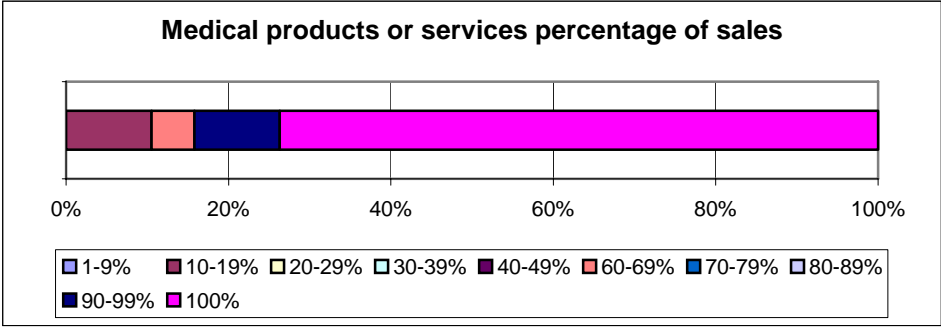


Note: 14 establishments answered the question

2.4 Share of Output related to Medical Technologies

Most of the participating establishment specialised in medical products and services. About 70 per cent of the establishments sold only medical products or services, and only two establishments sold less medical products and services than other products and services (see Figure 4).

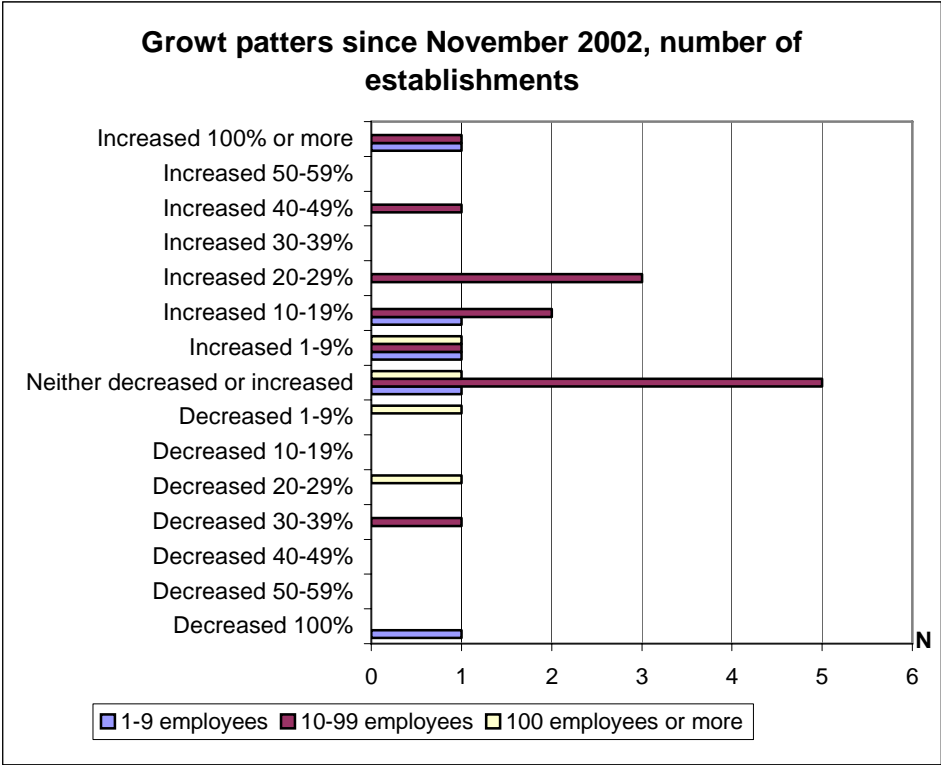
Figure 4



2.5 Trends in market/output

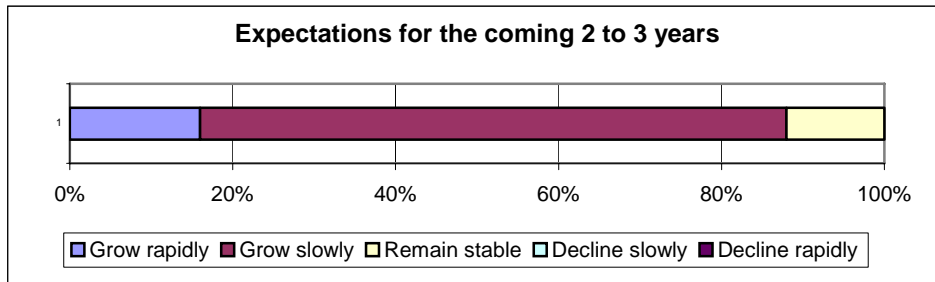
Figure 5 shows the rates of growth since November 2002 for the participating establishments. The majority of the establishments experienced positive rates of growth, and two establishments had grown by 100 per cent or more. But many remained of the same size or even decreased. This should be placed in the context of the general recession in the United States over the relevant period.

Figure 5



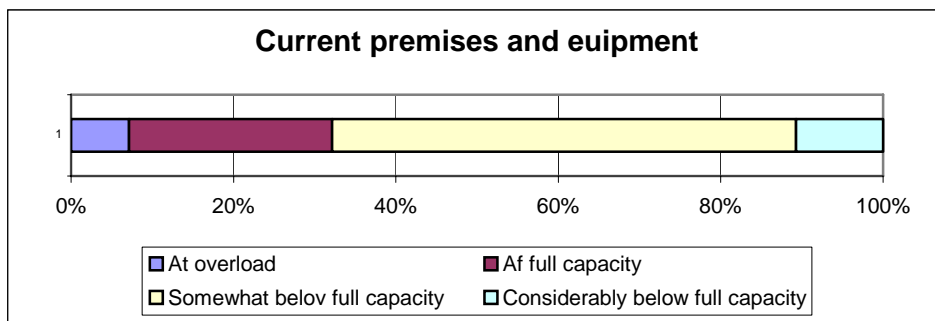
Ninety per cent of the establishments expected to grow over the coming years; three establishments expected to remain stable and no establishment expected to decline (see Figure 6).

Figure 6



About two-thirds of the establishments were working slightly or substantially below full capacity (see Figure 7).

Figure 7



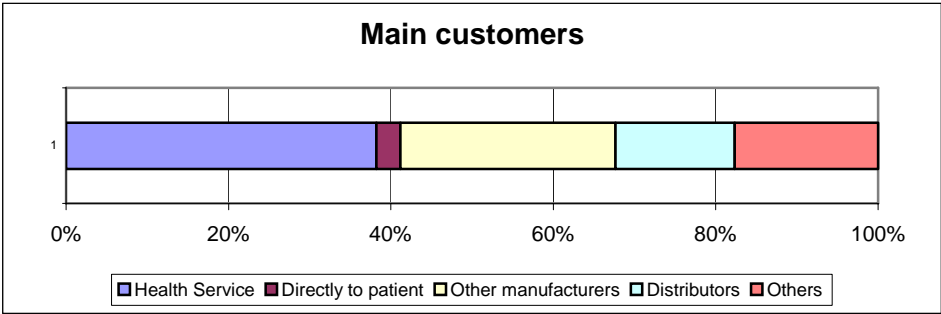
3. Product Market Position

In this chapter the product market position of establishments is considered, especially the nature of customers, the level of exports and the establishment’s product market strategy.

3.1 Customer Base

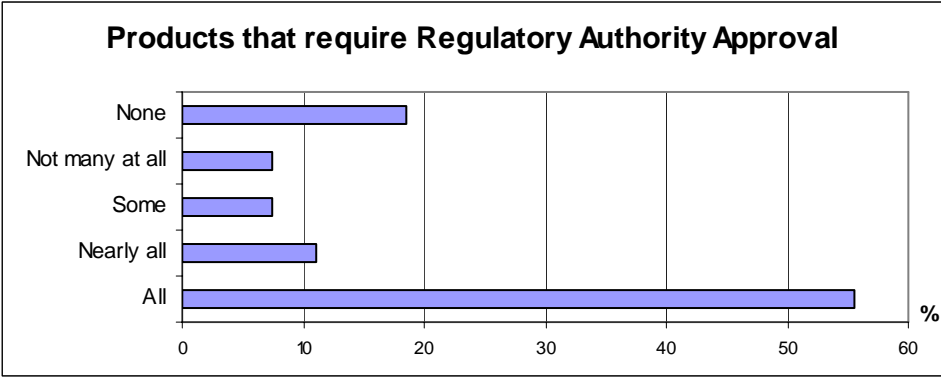
The establishments sold to a broad range of customers, as shown in Figure 8. Larger establishments, with 100 employees or more, sold exclusively to health service and other manufacturers, while smaller establishments with fewer than 100 employees had more diverse markets. The *Other* category included hospitals and health food shops.

Figure 8



About 55 per cent establishments needed approval from regulatory authority for all products, while about 19 per of establishments needed no approval at all from regulatory authorities (Figure 9).

Figure 9



3.2 Location of Customer Base

Two thirds of establishments were engaged in exports and about 15 per cent exported more than one half of their output while 25 per cent had no exports (see Figures 10 and 11).

Figure 10

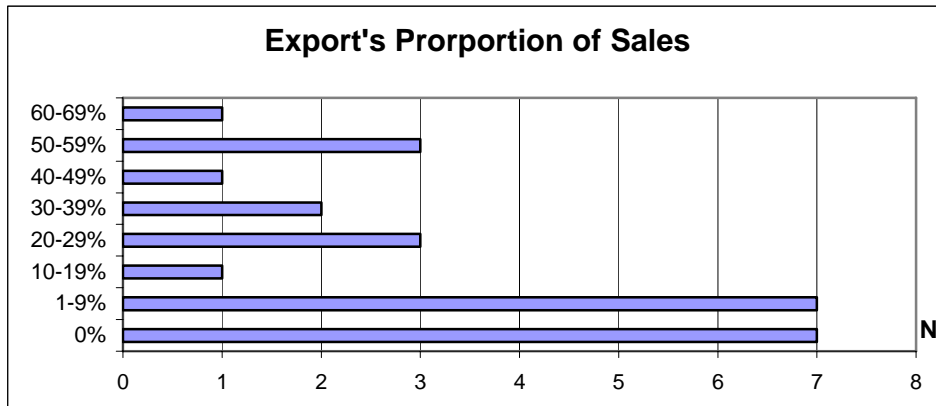
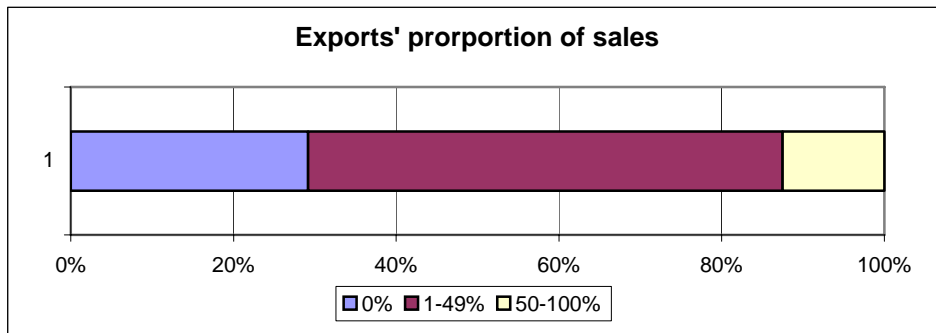


Figure 11



Almost all the establishments had always been located in the region. One establishment had relocated into the region in 1998. Most establishments had been located at their current address for more than three years (Figure 13).

Figure 12

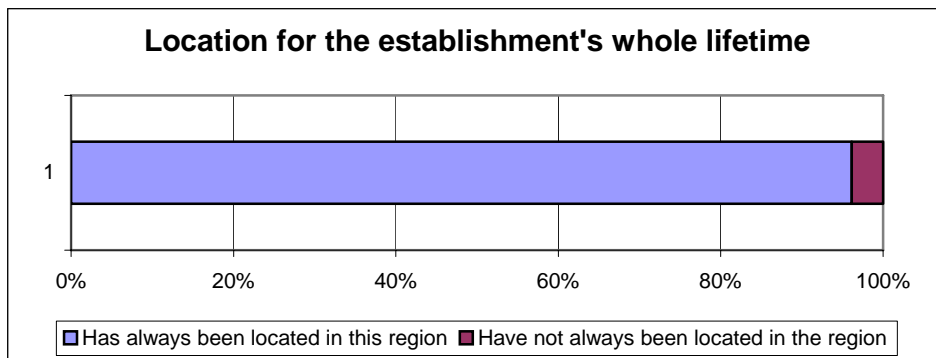
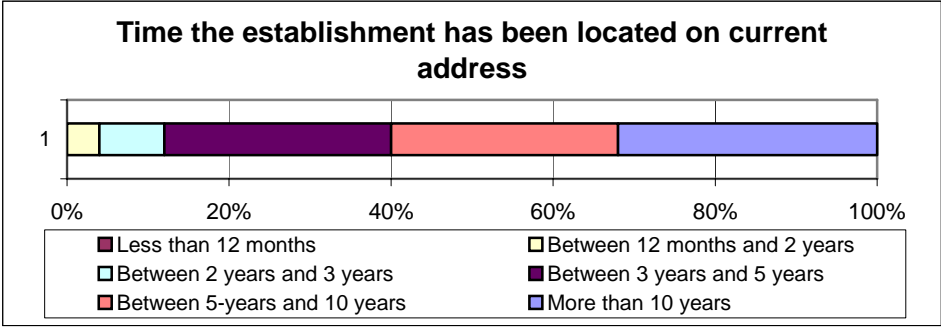


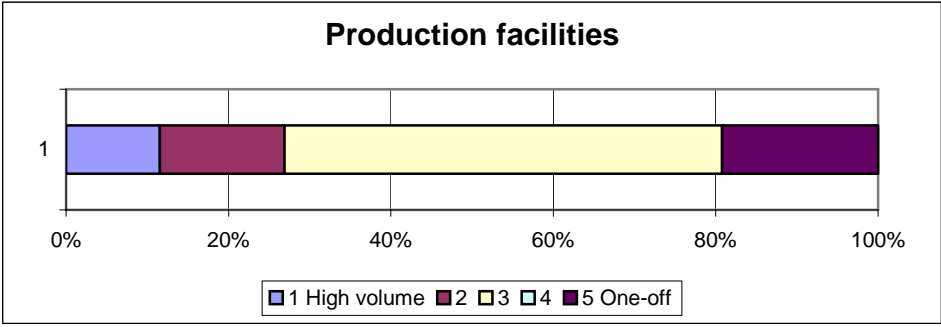
Figure 13



3.3 Product Market Position

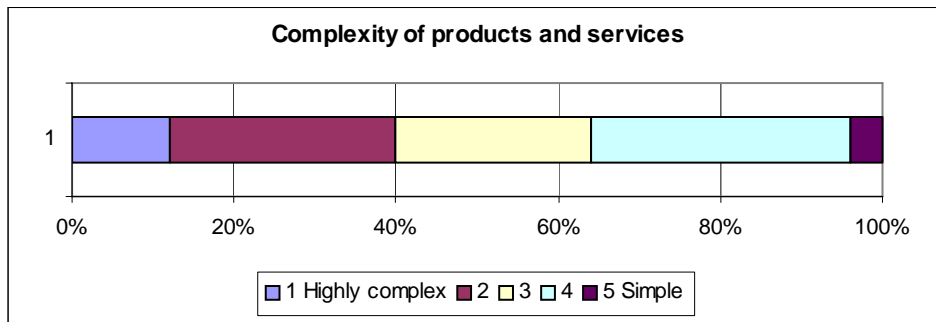
Establishments were asked to rank themselves on a scale from one to five in relation to a number of statements regarding their product market position. These included their volume of production; the complexity of their products; the extent to which competition was based on price; the level of their technological advancement; their level of automation; and the extent to which they could command a quality premium. The answers are shown in Figures 14 to 19. For instance in Figure 14 the data indicate that the establishment engaged in high volume production while 5 indicates that it engaged in single *one-off* products. The average score in answer to the question was 3.0

Figure 14



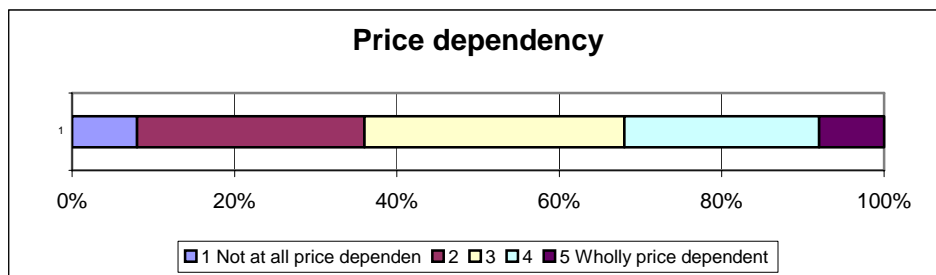
Some establishments produced highly complex products while others produced simple ones (Figure 15). The larger was the size of the establishment the greater was the complexity of its products. The average score in answer to the question was 2.88

Figure 15



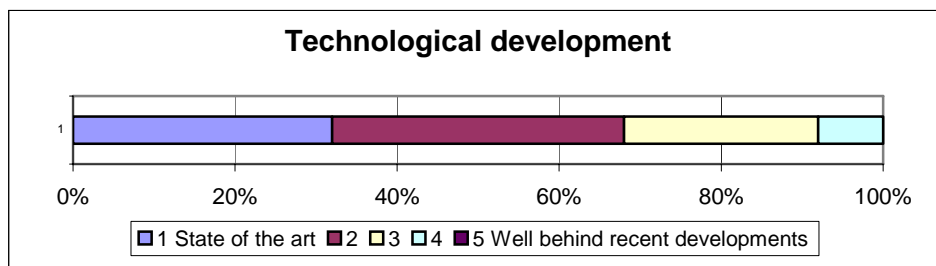
Price was not the most important consideration for competition in the American medical device industry. Fewer than one third of establishments reported that their products were *price dependent* (Figure 16). The average score in answer to the question was 2,96.

Figure 16



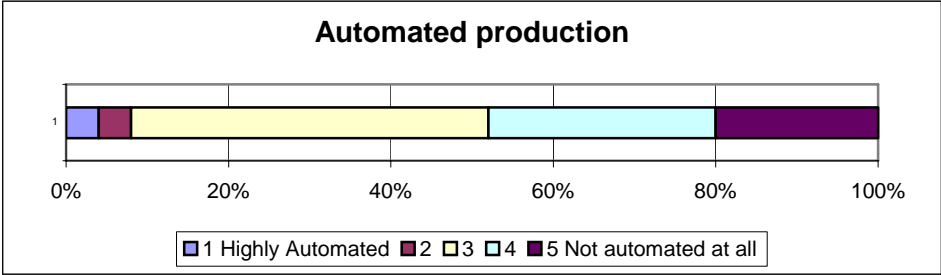
In general, establishments saw themselves as producing *state of the art* products and services. Almost 70 per cent establishments saw themselves as leaders in technological developments (Figure 17). The average score was 2,08.

Figure 17



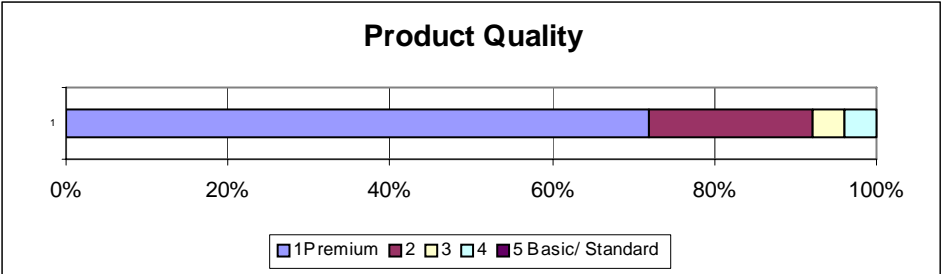
About one half of establishments did not feel that their production was automated (see Figure 18) and most placed themselves in the middle category. The average score in answer to the question was 3.56.

Figure 18



About 70 per cent of establishments felt that they were able to sell their products at a premium in the market, based on quality (Figure 19). The average score was 1.4.

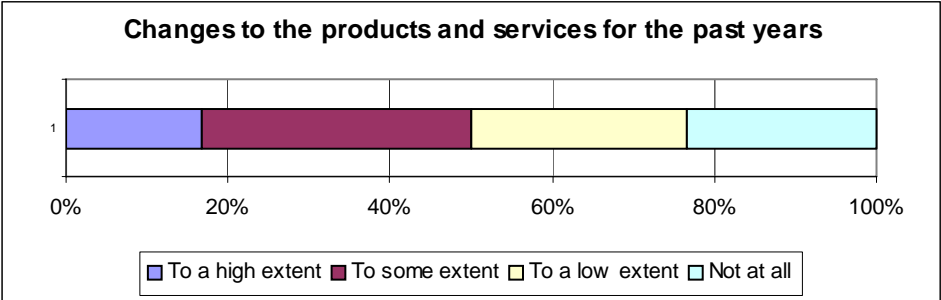
Figure 19



3.4 Changing Product Market Strategy

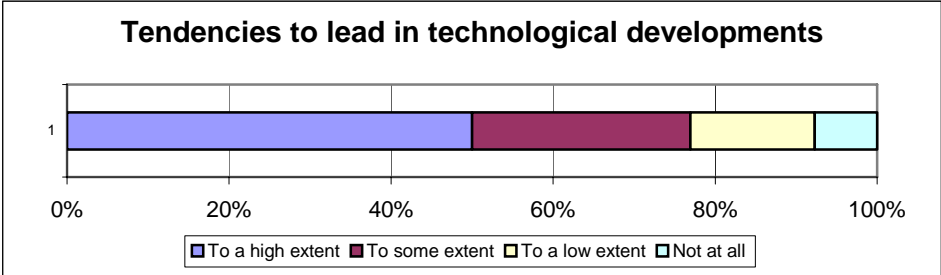
About 25 per cent of establishments made no changes to their products over the previous years (see Figure 20). But there was a marked pattern of variation in answer to the question and most had made at least some changes.

Figure 20



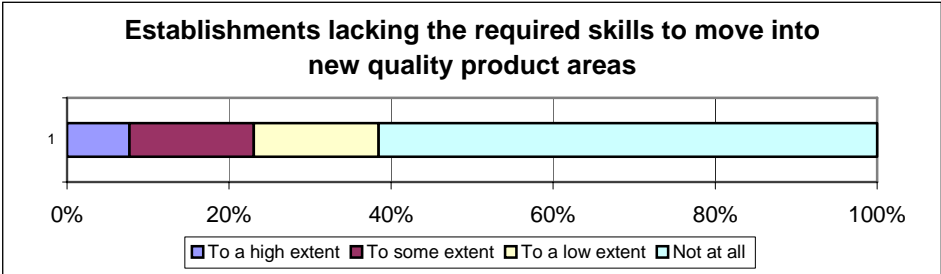
Most of the establishments saw themselves as leaders in technological development (Figure 21). Indeed, about one half felt this strongly.

Figure 21



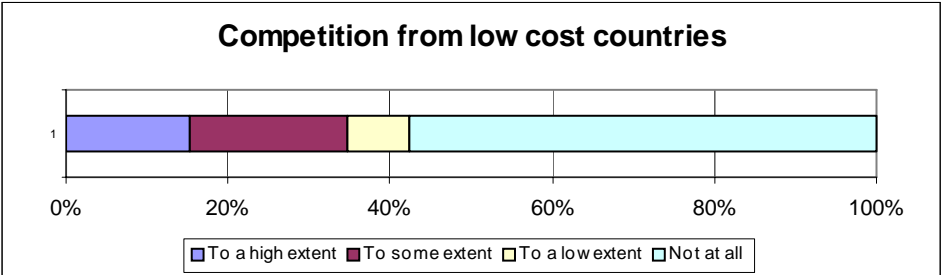
Most also felt that they had all the skills they needed to develop new quality product areas (Figure 22). Fewer than 30 per cent felt that they lacked such skills *to some extent*.

Figure 22



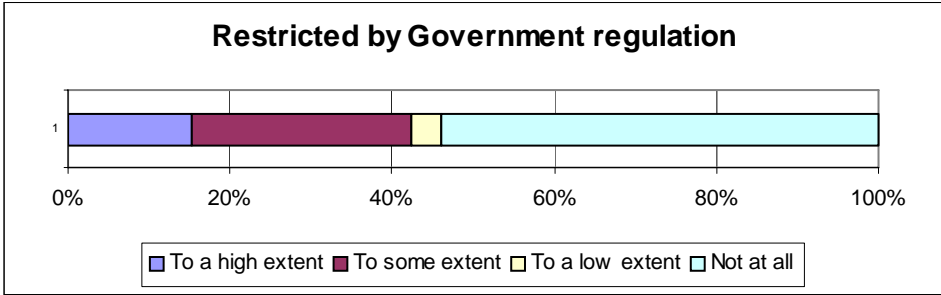
About 40 per cent of establishments reported that they faced competition from low cost countries (Figure 24), but small establishments were less likely to do so and none of those with nine employees or fewer reported such competition.

Figure 23



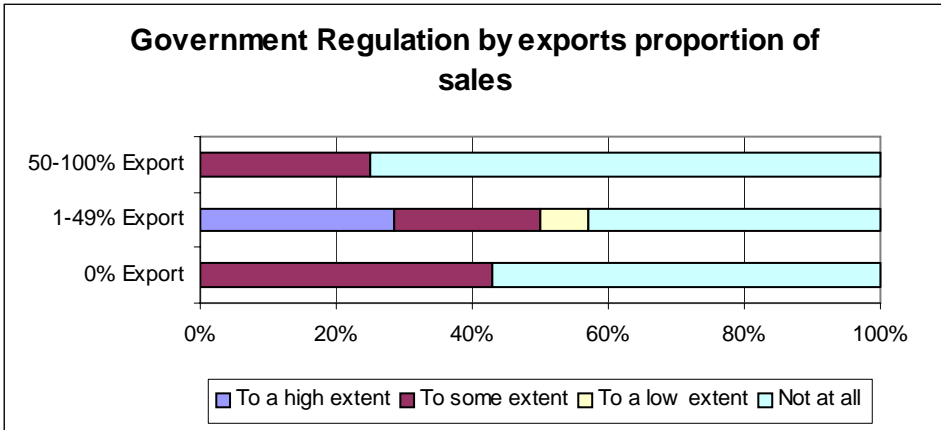
Most establishments felt that they were not at all restricted by government regulations (Figure 24) while some felt that they were restricted *to a high extent*. There was little difference in the extent to which establishments felt restricted according to whether or not they engaged in exports (Figure 25). If anything it was those who engaged in some exports but as a small proportion of their sales who were most likely to feel restricted.

Figure 24



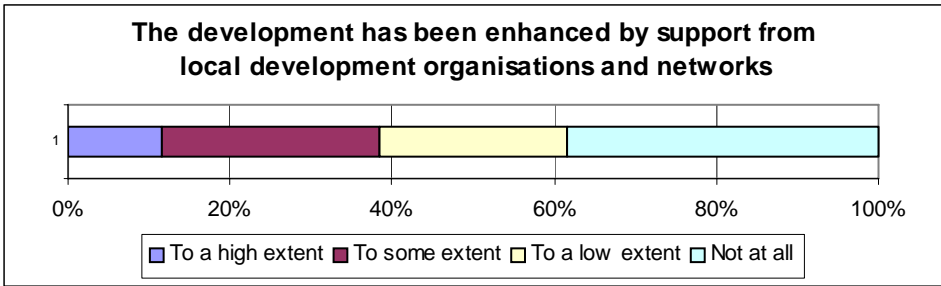
The extent to which the establishments felt themselves restricted by government regulation was about the same for companies with high and low levels of exports. Those with a smaller level (1-49 per cent) saw themselves as a little more affected by government regulations than both non-exporters and larger exporters (50-100 per cent exports).

Figure 25



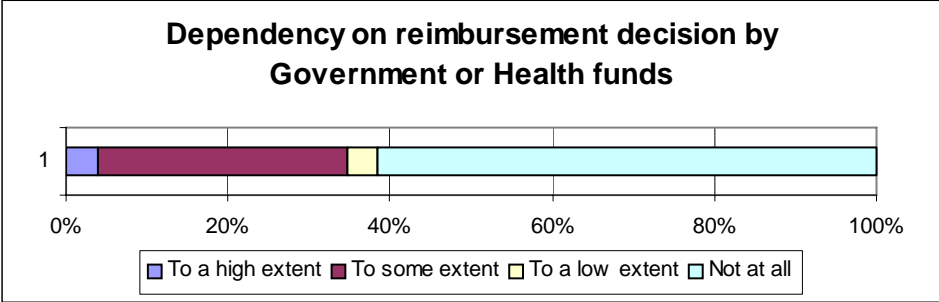
About 60 per cent establishments had received support from local development organisations and networks, but only 10 per cent felt that they had been helped by such support *to a high extent*.

Figure 26



More than 60 per cent of establishments also reported that they were not dependent on reimbursement decisions by Government or Health funds (Figure 27).

Figure 27



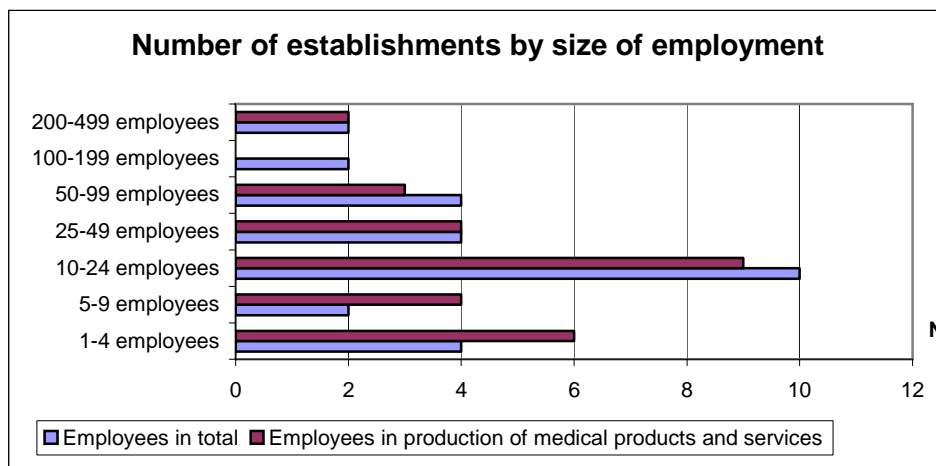
4. Employment Characteristics

This chapter considers the employment characteristics of establishments and covers the total number employed; development trends; the occupational structure of employment; and employment in Research & Development (R&D).

4.1 Total Employment

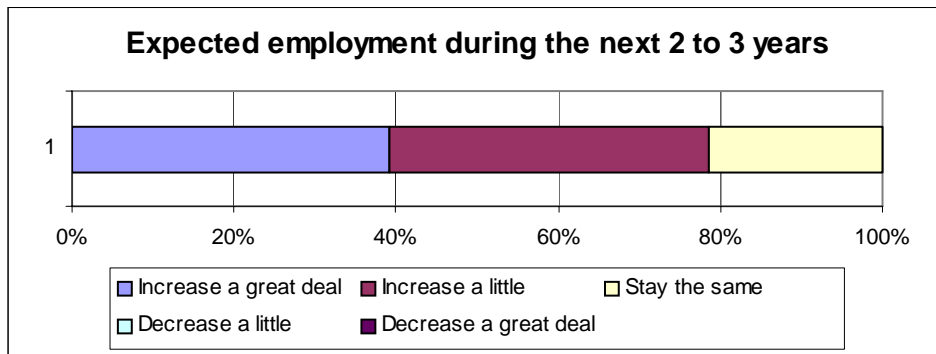
The establishments represented a broad range of sizes; six establishments employed nine people or fewer (small establishments); as shown in Figure 28.

Figure 28



No establishment expect to reduce the number employed over the coming two or three years (Figure 29), and about one half of the small establishments with nine employees or fewer expected to increase their number *a great deal*.

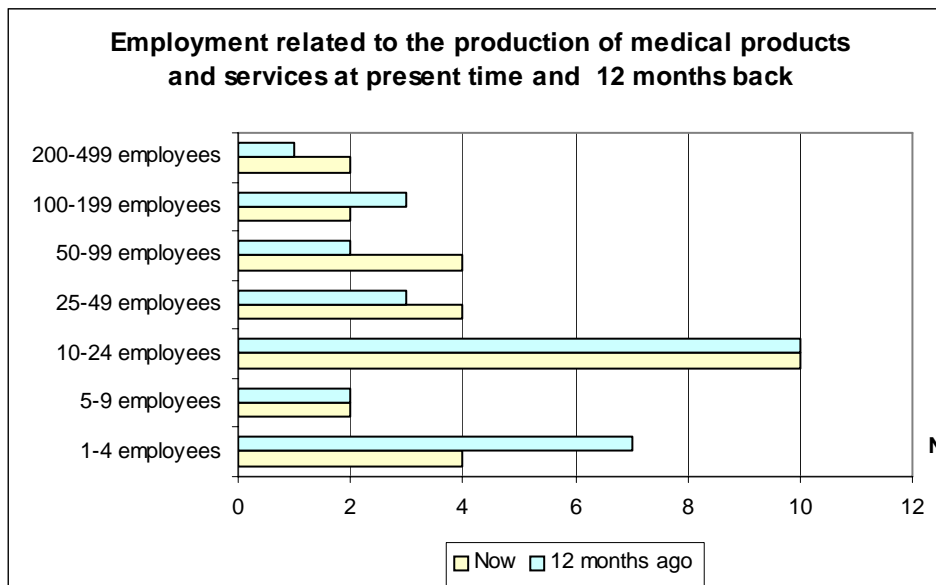
Figure 29



4.2 Trends in Employment

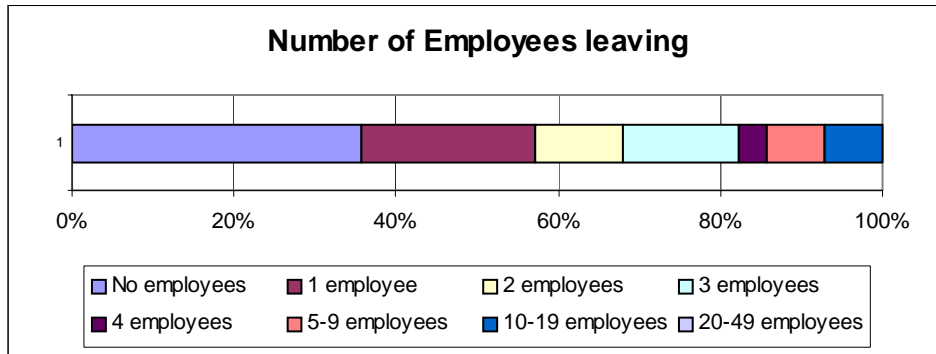
The changes in the distribution by employment categories over the last year are shown in Figure 30.

Figure 30



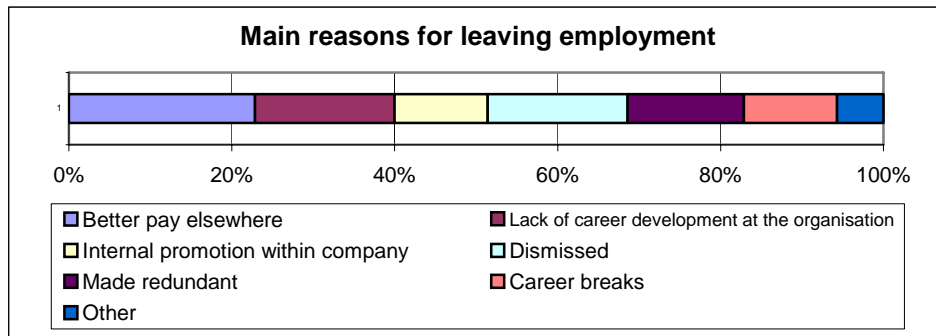
Almost half of the establishments experienced two employees or more leaving the establishment (Figure 31).

Figure 31



There were many different reasons for leaving (Figure 32). The *Other* category included retirement.

Figure 32

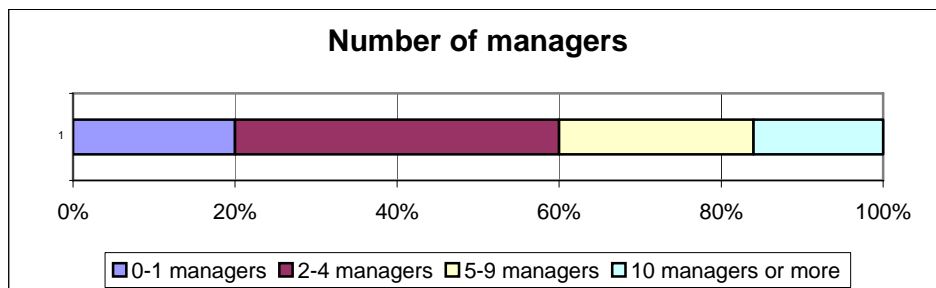


Note: more than one answer was possible from each establishment

4.3 Occupational Structure of Employment

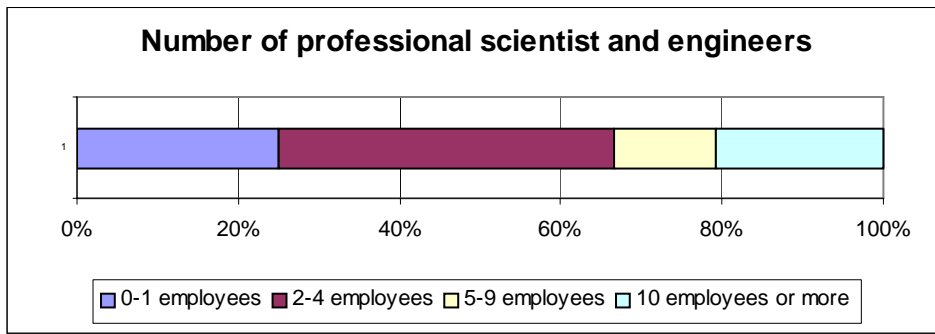
Eighty per cent of establishments had two or more managers.

Figure 33



Seventy-five per cent of establishments had two or more professional scientists or engineers.

Figure 34



Establishments generally employed more fully apprenticed manual employees than semi-skilled workers (see Figure 35 compared with Figure 36).

Figure 35

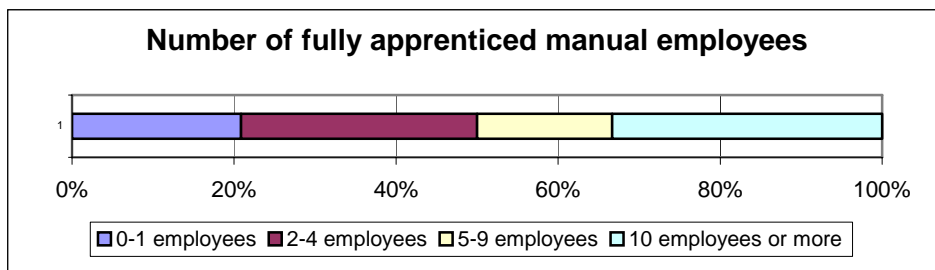
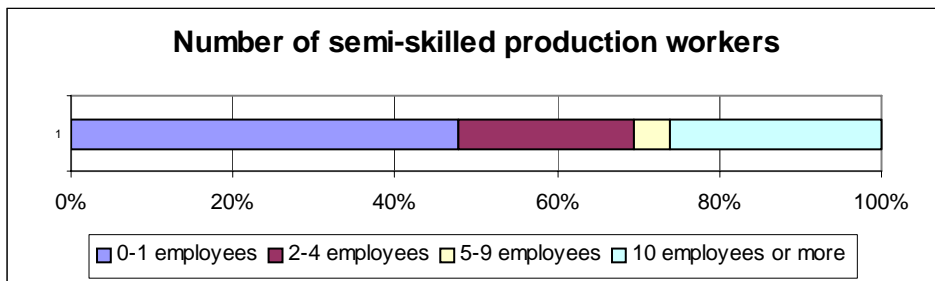


Figure 36



About one half of the establishment had no employees with a degree level qualification in a clinical or medical subject (Figure 37).

Figure 37

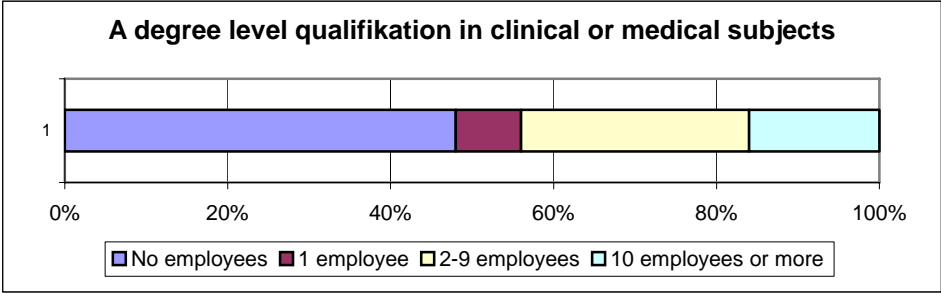
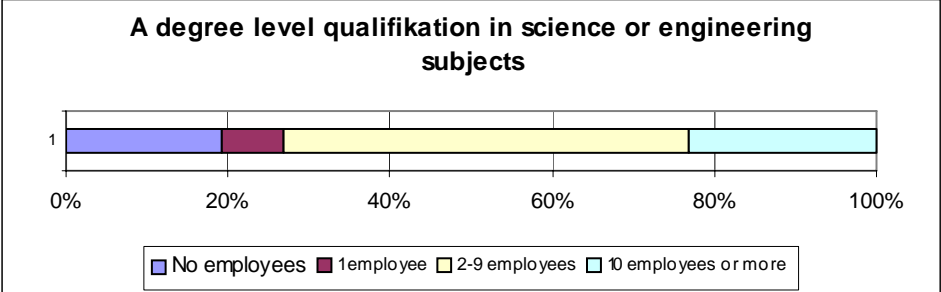


Figure 38 shows that eighty per cent of establishments had one or more members of staff with a degree in science or engineering.

Figure 38

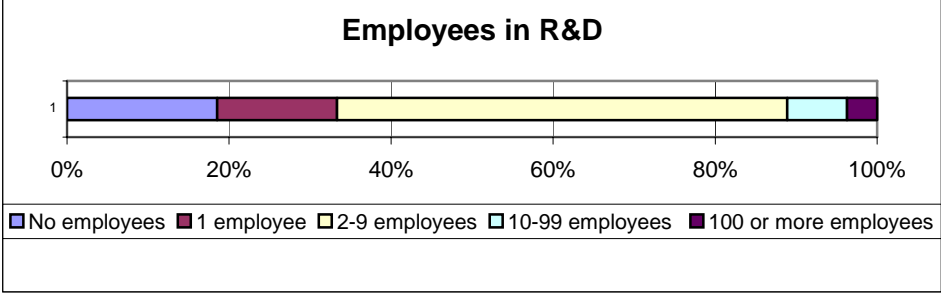


The overall pattern shows that establishments were less like to employ staff with a degree in clinical or medical subjects than persons with a degree in science or engineering.

4.4 Employment in R&D

About eighty per cent of establishments had employees engaged in research and development in medical products and services (Figure 39).

Figure 39



Two establishments had no R&D, and one establishment had no employees in research and development because research activities were carried out at another branch in the region.

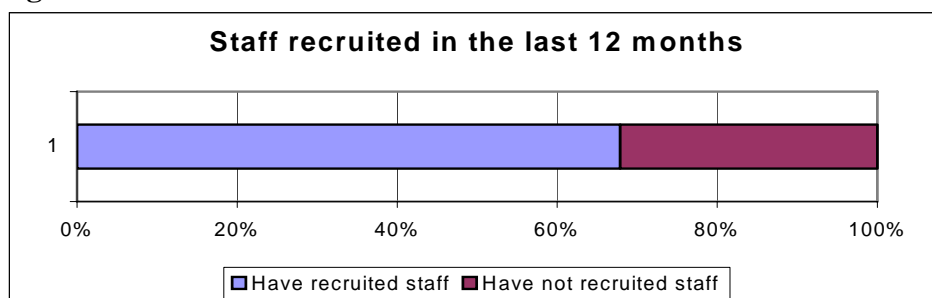
5. Recruitment

This chapter considers recruitment and covers the level of vacancies; recruitment practices and problems; skill-shortage; and the implications of recruitment problems.

5.1 Level of vacancies

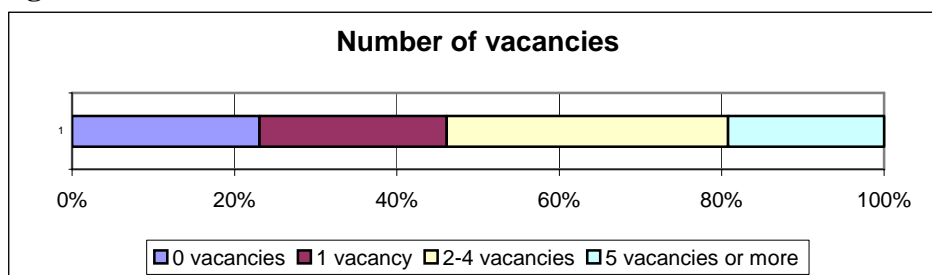
Two thirds of establishments had recruited staff during the previous twelve months (Figure 40).

Figure 40



Almost 80 per cent of establishments had one vacant position or more during the previous twelve months. Vacancies represented 7 per cent of total employment.

Figure 41



Details of the vacant jobs are shown in Table 2. The differences in numbers between the different categories may be due to either differing levels of demand or variations in rates of staff turnover.

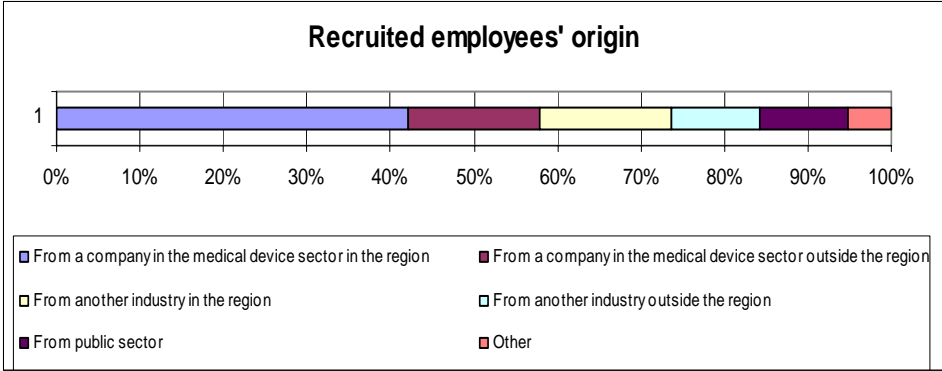
Table 2

	N
Process, plant and machine operatives (semi skilled)	3
Skilled trades occupations (fully apprenticed manual employees)	4
Professional scientists and engineers	31
Software development	44
Others	19
Total	101

5.2 Recruitment practices

Almost 60 per cent of establishments had recruited employees from another company in the medical device sector, mainly from within the region. No establishment had taken people on directly from research jobs or from unemployment (Figure 42).

Figure 42



5.3 Evidence of recruitment problems

Table 3 shows the number of hard to fill vacancies and the proportions that they represented of all vacancies in each occupational group. One half of the positions as engineers were hard to fill, while only 19 per cent the as software developers were in that category. The proportion of hard to fill vacancies represented two per cent of total employment; and hard to fill vacancies represented one third of all of vacancies.

Table 3

	Hard to fill jobs as proportion of vacancies per cent
Production workers	10
Engineers	52
Controller	100
Instrument makers	60
Quality control	100
Repair dep.	100
Director of operations	100
Software developer	19
Total	

5.4 Evidence of skill-shortages

Table 4 shows the hard to fill positions and the reasons for the vacancies being hard to fill.

Table 4

Position	Reasons for vacancies being hard to fill
Quality control	<ul style="list-style-type: none"> ▪ Not enough people interested in the job ▪ Low number of applicants with the required skills ▪ Low number of applicants with the required attitude, motivation or personality ▪ Low number of applicants generally
Production workers	<ul style="list-style-type: none"> ▪ Being flexible
Skilled machinist	<ul style="list-style-type: none"> ▪ Not enough people interested in the job ▪ Low number of applicants generally

5.5 Skills difficult to find

A list of the vacant jobs that were hard to fill owing to shortage of necessary skills is given in Table 5. In relation to each job, the specific skills that the applicants lacked for this position are indicated.

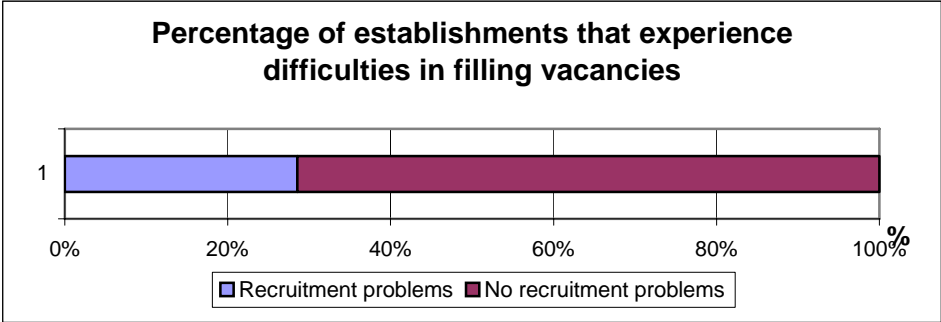
Table 2

Position	Skills lacking
Controller	<ul style="list-style-type: none"> ▪ Management skills ▪ Engineering skills ▪ Other technical and practical skills
Quality control	<ul style="list-style-type: none"> ▪ General IT user skills ▪ Management skills ▪ Scientific skills ▪ Skills related to product regulations
Engineer	<ul style="list-style-type: none"> ▪ General IT user skills ▪ IT professional skills ▪ Communication skills ▪ Customer handling skills ▪ Team working skills ▪ Foreign language skills ▪ Problem-solving skills ▪ Management skills ▪ Clinical/medical skills
Production workers	<ul style="list-style-type: none"> ▪ Multiple capabilities
Skilled machinist	<ul style="list-style-type: none"> ▪ Foreign language skills ▪ Numerical skills ▪ Literacy skills ▪ Engineering skills ▪ Clinical/medical skills

5.6 Implications of and responses to recruitment problems

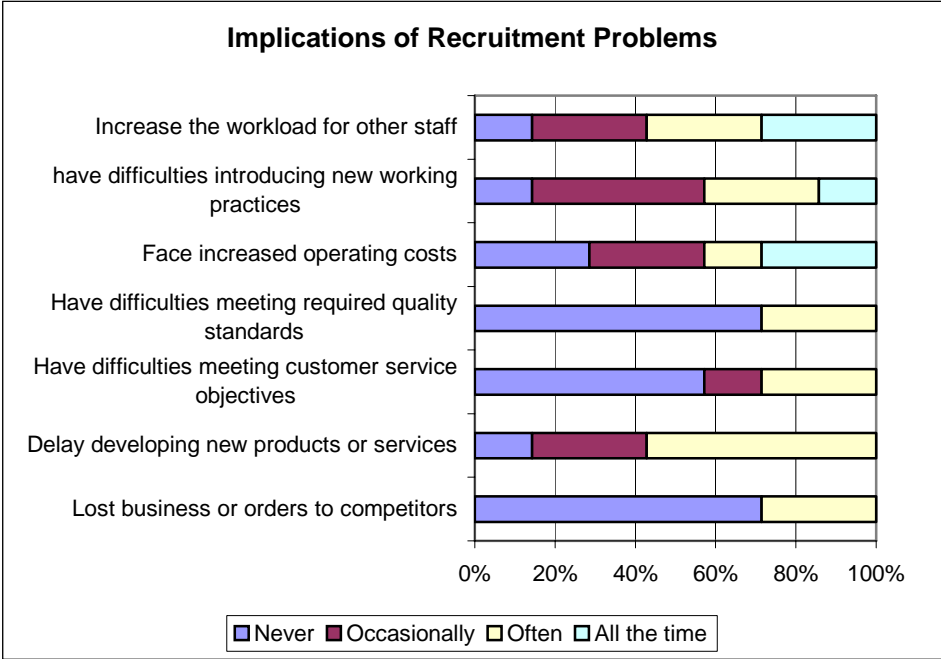
About 30 per cent of establishments experienced recruitment problems (Figure 43).

Figure 43



The establishments with recruitment problems reported a number of different consequences (Figure 44). About one half of establishments had *Increased the workload for other staff*; *Had difficulties in introducing new working practices*; or had *Delayed developing new products or services*.

Figure 44



The hard to fill positions had the implications summarised in Table 6.

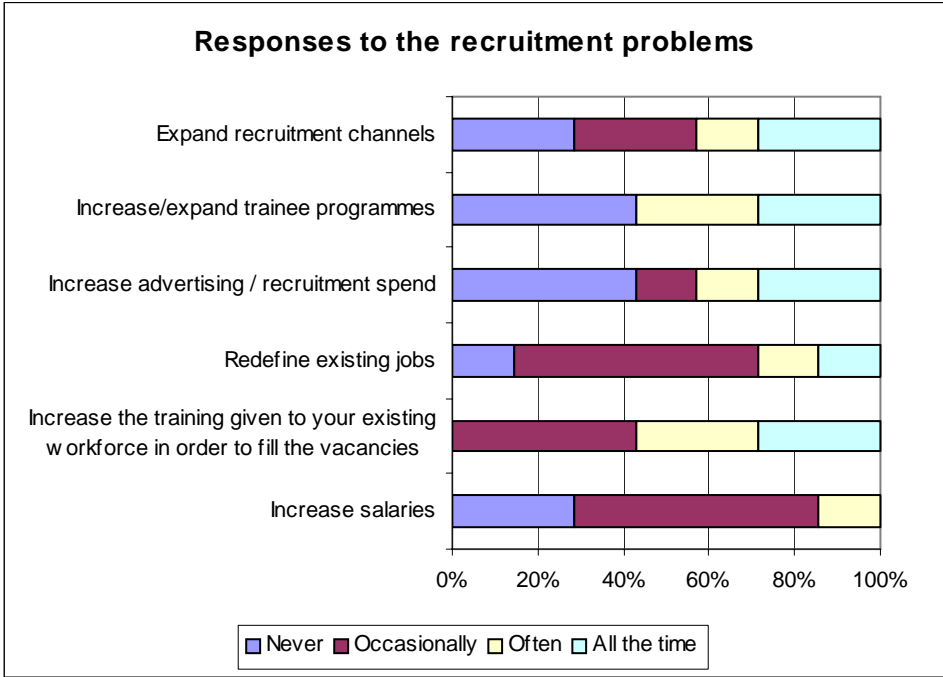
Table 3

Position	Implications
Controller	<ul style="list-style-type: none"> ▪ Increased operating costs ▪ Difficulties in introducing new working practices ▪ Increased workload for other staff
Engineer	<ul style="list-style-type: none"> ▪ Delay developing new products or services ▪ Difficulties meeting required quality standards ▪ Increased operating costs ▪ Difficulties introducing new working practices ▪ Increased workload for other staff
Production worker	<ul style="list-style-type: none"> ▪ Increase the workload for other staff ▪ Difficulties introducing new working practices
Skilled machinist	<ul style="list-style-type: none"> ▪ Delay developing new products or services ▪ Difficulties meeting customer service objectives ▪ Difficulties introducing new working practices ▪ Increased workload for other staff

5.7 The responses to the difficulties in filling vacant jobs

Figure 45 shows the actions taken by establishments in response to recruitment problems. The most common reaction was to increase the training given to existing staff or to expand training programmes. Establishment were much less likely to respond by increasing rates of pay.

Figure 45



6. Internal skill problems

This chapter considers internal skill problems and covers the proficiency of existing staff; the skills in which staff are deficient; the causes of skill gaps; the implications of and responses to skill gaps; and future prospects.

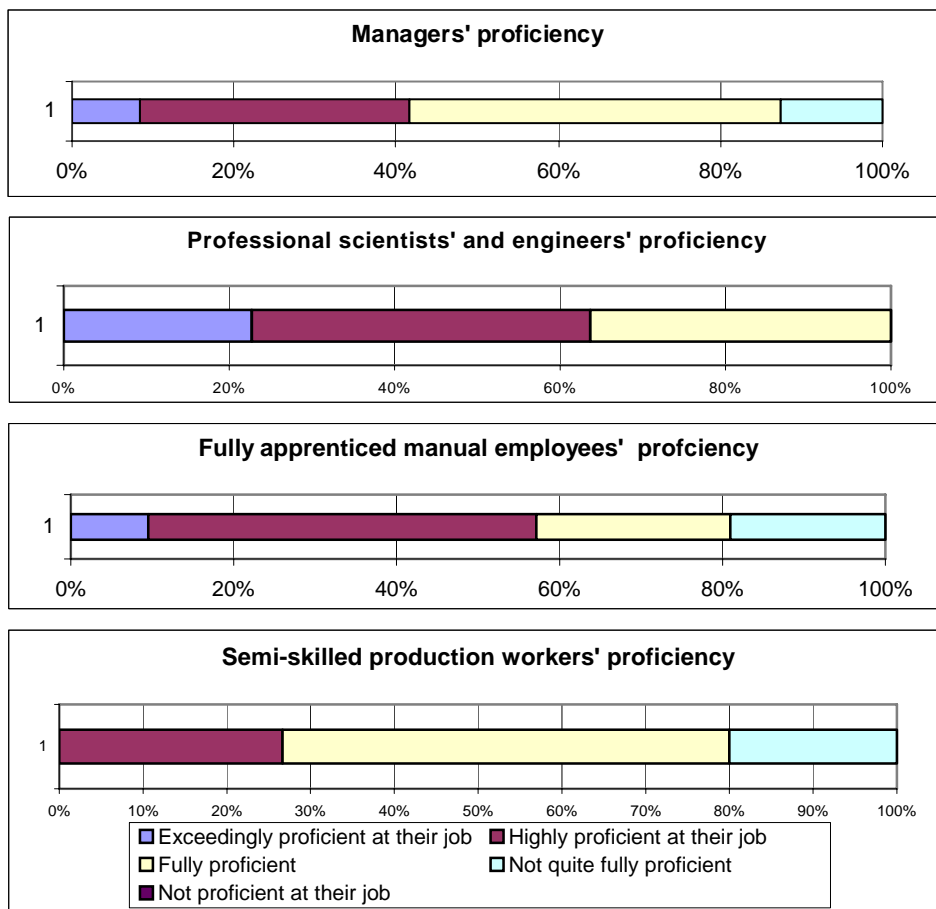
6.1 Proficiency of existing staff

Almost one half of establishments reported that their managers were *exceedingly* or *highly proficient* while about 15 per cent reported that their managers were *not quite fully proficient*, (Figure 46).

A similar pattern emerged in relation to the other main categories of employee. Only professional scientists and engineers differed from the general pattern. Establishments were inclined to rate their professional scientists and engineers more highly than any other group.

Twenty per cent of establishments felt that parts of their staff were *not quite fully proficient* at their job. Some establishments felt that this was the case for more than one job category. The nature and implications of the deficiencies are considered in paragraphs 6.2 to 6.4.

Figure 46



6.2 Skills in which staff lack proficiency

The establishments which said they had staff who were not proficient at their jobs, reported that they need improvement in the following skills:

- Team working skills
- Management skills
- Communication skills
- Customer handling skills
- Problem solving skills

6.3 Cause of skill gaps

Establishments reported the following reasons for skill gaps:

- The lack of experience among recently recruited employees
- The failure to train and develop the employees
- The rapid pace of change in industry
- Lack of staff motivation

6.4 Implications and responses to skill gaps

Establishments reported that skill gaps had the following implications:

- Increased operating costs
- Increased workload on the rest of the employees
- Delay in developing new products and services
- Difficulties in meeting required quality standards
- Difficulties introducing new working practices

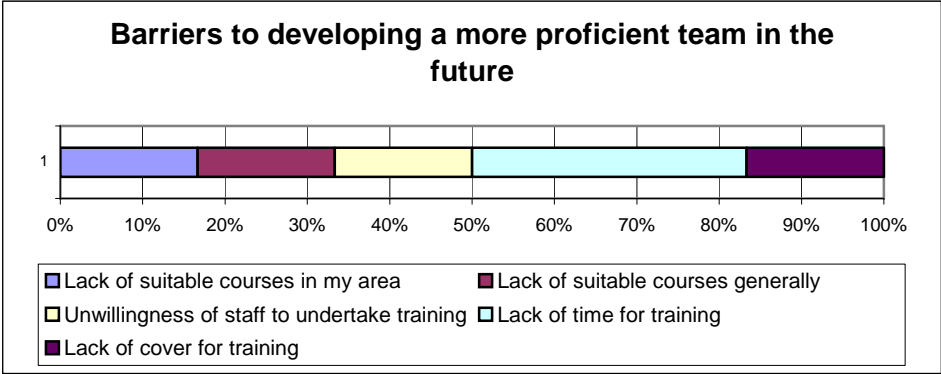
The actions being taken by establishment to overcome the skill gaps included the following:

- Provided further training
- Changed working practices
- Increased or expanded trainee programmes
- Expanded recruitment channels
- Increased recruitment
- Reallocated work within the company
- Worked closely with universities
- Sometimes took disciplinary action

6.5 Future prospects

Figure 47 shows the obstacles to developing a more proficient team, reported by establishments with skill gaps.

Figure 47



Establishments without skill gaps reported slightly different barriers to the maintenance of a proficient team in the future. Fifty-five per cent saw the lack of time or resources for training as the main barriers.

Figure 48

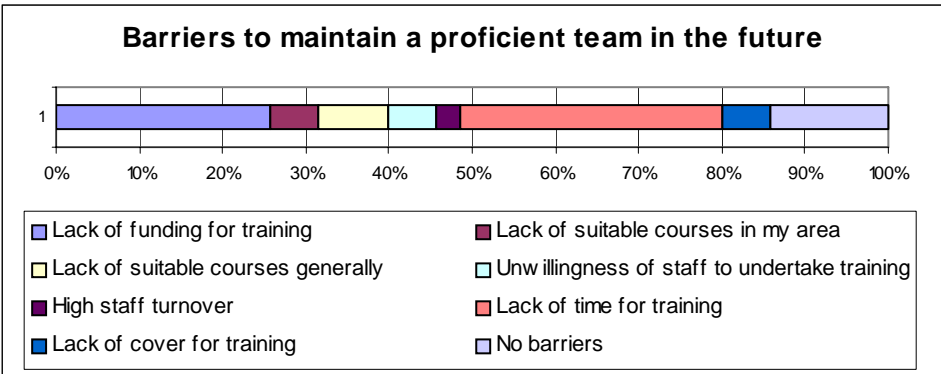
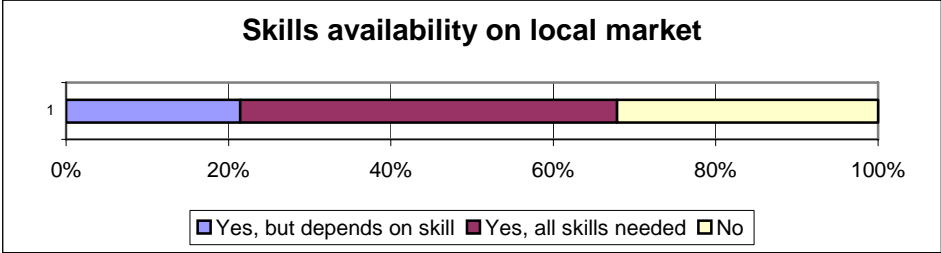


Figure 49 shows that about 30 per cent of establishments were not able to find the skills that they needed in the local labour market.

Figure 49



Establishments with difficulties in obtaining the required skills on the local labour market reported the following reasons for the problem:

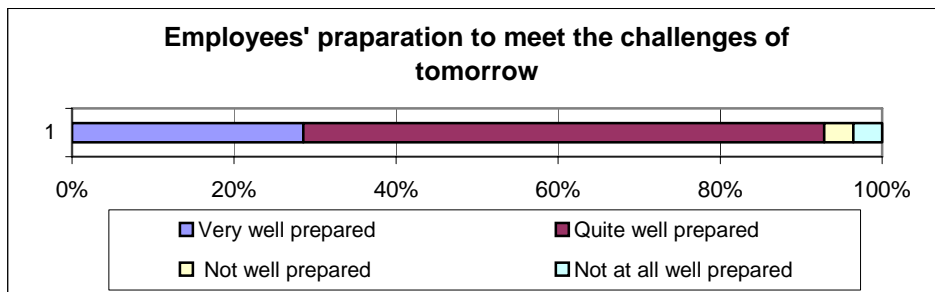
- The lack of skills and experience
- Few applicants
- The location of the establishment, outside the normal business area

The establishments without difficulties reported the following reasons:

- The establishment was located in a university area
- The high unemployment rate made it easy to get qualified people
- Limited training was needed, as their machines or technology was easy to operate

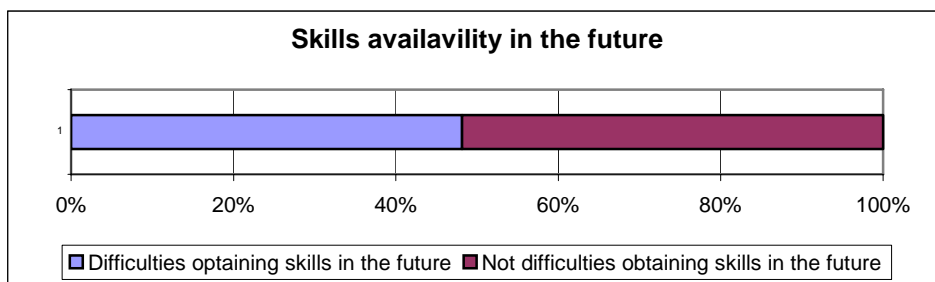
Ninety per cent of establishments considered themselves prepared to meet the product market challenges of the future (Figure 50).

Figure 50



But about one half of establishments expected to have difficulty in finding enough people with the required skills in the future.

Figure 51



Case study, Massachusetts, New England Medical Systems

The New England Medical Systems is a local distributor of *assistive technology* in the fields of mobility and support. It was established 9 years ago and has been rapidly increasing since then. The company differentiates itself from competitors by providing better services and advice, and by focusing on modern design. Therefore two third of its staff are rehabilitation specialists and technicians. This is very unusual in the area, and it is increasingly difficult for the company to get staff with the background they require.

The company

New England Medical Services started from nothing in 1995. Before that, the owner sold adjustable beds from the UK for aged people, and when he started his new business he had two beds and USD 5,000. Assistive technology was a completely new field for him, and the owner does not see any facilitating aspects in his former job. Financially, it was possible to start a business because his wife is a nurse, and she paid the bills for a period. The total sales amounted to USD 50,000 during the first year.

In the beginning, the owner started to sell different items on a trial and error basis, but he liked to work with the hospital sector, and today the firm offers 200 different assisting technology items within mobility and support.

The turnover is now at around USD 2.5 million after 9 years of operation. Revenue is now growing at an annual rate of about 10%, but they continue to grow, and the company continues to be proactive. This is done by continuing to follow the market development and by being aware of new product developments within their core field.

Product and Market

New England Medical Systems sell wheelchairs, scooters, ceiling hoists, elevators, lifts and more assistive technology in mobility and support. The main products in terms of revenue and physical space in the exhibition room are the wheel chairs.

The company mainly has its market for wheel chairs in the states of Vermont and New York, but with other products, they cover the entire New England. In two product lines that are imported from Denmark the firm covers in principle the entire USA in the sense that it has the sole rights to market these products all over the country. The introduction of these products gave the firm a sudden jump in the growth rate, and right now, the main bottleneck for the continued growth is the capacity of one of the Danish suppliers to deliver the demanded quantities. New England Medical Services also buys a number of products from Germany. European products are presently about 40% cheaper than before because of the exchange rate development.

In the beginning, the firm targeted at people above the age of 15, but today products are offered for all age groups. In fact, they have now 60% of the market for mobility and support for children. This market is monitored by the state. No registration has been made of total sales to other age groups, and therefore they cannot tell their market share, but the owner is convinced that they are now the largest in Vermont.

The customers are mostly private, and in most cases, an insurance company pays for the products. Also Medicaid pays for a number of products from New England Medical Services, but only households with asset values of less than USD 2,000 receive grants from Medicaid. New England Medical Services focuses on institutions and in particular on hospitals,

Massachusetts has a large number of hospitals, which is probably connected to the medical competencies that have developed at the famous universities in and around Boston. The main competencies in the field of medical and assistive technology is being held and developed at Harvard, but there are three very good universities in the area and in addition to this comes Yale in Connecticut. The rest is concentrated in California.

Strategies and cooperation

The firm offers 200 different assisting technology items within mobility and support. The most complicated products are wheelchairs and scooters, and the owner of the company has decided not to introduce more complicated products, such as e.g. oxygen equipment, even if this would be complementary and targeting the same group of users. The reason for not introducing such products is that they are highly regulated and would require a physician in the staff.

Potential customers are evaluated for their needs by a physical therapist. The first basic wheelchair is normally rented, and the user may buy it after ten months of use. The monthly rent is fixed at a level that pays the wheel chair over a period of 15 months. Also other items that are needed for a short period may be rented. This is the case for floor lifts, hospital beds and special mattresses for private homes.

The owner of New England Medical Services has a wide network of specialists and potential customers, and he is a member of New England Medical Equipment Dealers. 75% of companies like New England Medical Services in New England are members of this organization. They arrange quarterly meetings on billing, marketing etc. The membership fee is USD 1,000, and the fee for participation in the quarterly meeting is USD 150. The organization is quite strong and is only open for dealers. However, it has associate members among manufacturers.

Competition

The market for assistive technology is particularly increasing these years, as a result of the ongoing renovation and expansion of hospitals and because of the focus on improving cost-effectiveness. This makes it interesting to introduce labor-saving technologies like ramps and lifts. The market for assistive technology in general is rapidly increasing all over the USA. Customers are increasingly looking at the design of the products and at the services that are provided along with the products.

The main competitors are similar to the New England Medical Services, but with less focus on professional advice.

All imported items will have to be approved, but this does not create any big problem. Imports from low-cost countries like China are a problem. The products may be approved, but the quality is lower and so is the price.

Employment and competencies in the company

The company has a total staff of six. The owner takes care of management and customer relations of New England Medical Services. The remaining staff of New England Medical Services are the following:

- One orthopedic therapist
- Four rehabilitation specialists and technicians

It is unusual for a firm like New England Medical Services to employ more than one rehabilitation specialist.

Employment and competencies in the area

As mentioned, New England Medical Services contrary to its main competitors employ four rehabilitation specialists. It is very difficult to find new staff with this educational background, and presently, the company is considering recruiting mechanical or electrical engineers in stead. No schools are educating rehabilitation technicians today. Earlier, there was one in Vermont, but the leader did not do enough to recruit students, and the education has now been closed.

Relative strengths

The strength of New England Medical Services lie in the extent of professional services they offer to the clients, and their marketing in general. Another strength is the focus they have on modern design, which is increasingly important at the American market. This is the reason for the success of the products from the two Danish suppliers, Pressalit Care, who provides bathroom solutions for disabled, and Guldmann supplying ramps and lift systems. Guldmann also offers training of hospital staff on delivery of their products. Therefore, the owner will take part in the Rehab 2004 exhibition in Copenhagen in May 2004.

The weaknesses

According to the owner, the growth of the company is primarily limited by the capacity of suppliers mainly regarding the two Danish products.

Expectations for the future

The owner and manager expects the company to continue its two digit growth rates. He is convinced that the market for assistive technology will continue to grow, and he has a firm belief in the strategy of providing the best services to customers and to focus on modern design.

Case study, Massachusetts: Doran Instruments

The company, 'Doran Instruments' develops, manufactures and sells a very advanced instrument for non-invasive diagnosis and analysis of the eye. As there are no treatments related to the diagnosis, the market is still very limited. The research and development is done by the two owners of the company and the manufacturing and sales are undertaken by the 6 additional staff members.

The manufacturing process is a simple manual process and the skills that are demanded from the staff are basic technical skills, flexibility and common sense. The company has difficulties in filling a recent vacant job in the production workshop.

About the company

The firm is located at the top floor of an old industrial building from the 1880s. The workshop is integrated with office and research facilities, library and all other company activities in one room. Books, folders and notes are mixed with cables and electronic product parts on the shelves and on top of cupboards. This is a typical small enterprise, which is apparently not very well organized. The company produces electro-cardiography for diagnosis, and it employs eight people.

The company is owned by two highly skilled engineers with a strong interest in the field. Without the two engineers, the firm could not continue. A predecessor started in 1983. . Doran Instruments was the subdivision where the electronic parts are made.

The firm is based on an innovation, which was made in 1983. It made it possible to make focal electro-cardiography for diagnosis, showing response patterns in the retina of the eye on a certain light stimulus. The first product was launched in 1986.

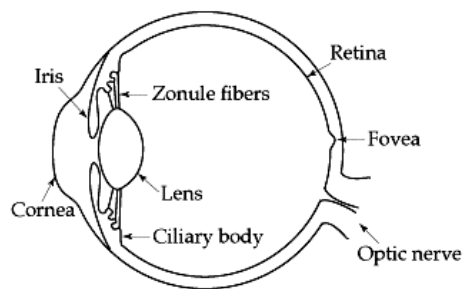
A second innovation in 1996 made it possible to measure the response with the use of an instrument, which is now produced by Doran Instruments. A more advanced system is expected to break through very soon.

Products and market

Six products of Doran Instruments have been approved by the FDA, two contact lens electrodes and four devices for focal electro-cardiography or maculoscopes. It is complicated to get an approval, but it is necessary.

The present product of Doran Instruments is the Maculoscope¹, which is a 'modified direct ophthalmoscope that projects a bright annulus onto the retina, with a rapidly flickering core that provokes a focal cone electroretinogram'

¹ An ophthalmoscope is an instrument used to examine the retina and vitreous. Ophthalmoscopy requires dilating the pupils with drops to give the doctor the best view inside the eye.



The electroretinogram (ERG) is used to investigate the origins of visual dysfunctions and acquired retinal disorders. By controlling the conditions under which stimuli are presented, the activity of the rod or cone visual pathways can be monitored independently.

Because the ERG allows retinal function to be analyzed non-invasively, the response is an ideal way to follow the progression of retinal diseases. In the research laboratory, it provides a sensitive means to evaluate experimental therapies for retinal disease, which can be repeated at different time points on the same individual. In addition, the ERG is used to characterize the effects of pharmacological manipulation or introduction of gene defects.

Although the product is advanced, state of the art, the manufacturing process is a simple and manual process.

The instruments may be used both in the human and veterinary fields. 150 systems have now been sold over 5 years. 40 percent of the sales are exported. The instruments that are sold to research institutes, hospitals, and government practices, and the demand is considered quite price sensitive by the company.

The market has grown substantially recently, but it is still a speciality and a niche. Basically, it tells you bad news, which has a value in relation to insurance companies by providing evidence that there is a problem. Right now, there is no real treatment, but if it appeared, this would really pull the product out of the research rooms.

Strategies and cooperation

After the first innovative phase, the consolidation period made greater focus on design and reduction of costs. Now, growth will depend on new innovations and market adjustments. An Internet solution has just been launched.

The future steps forward is expected to be the development of a family of products, consisting of various elements with a similar design as well as products adapted to the use of it at animals.

Competition

There are competitors, but their products are more difficult to apply, and Doran Instruments is best positioned in the market.

Employment and competences at the establishment

The total staff is presently consisting of 8 people, including the owners. The day-to-day manager is happy with the present size of the company.

The 2 founders are 100% responsible for the research and product development. In addition, the manager has a scientific technical background. Five persons are involved in the

manufacturing. Two of them are also involved in administration and another two in sales and marketing.

There is a relatively fluent situation regarding staff. The present type of staff are looking for and expecting well defined pieces of work, and the company demands a high degree of flexibility from them. Basic technical skills, common sense and a personality that suits into the firm and its staff are also important qualifications in a recruitment situation. Recruitment is a rare activity and is not in any way institutionalized. The company had a vacancy in the production department last year. It was difficult to find the right profile, because the management asked for a multitude of capabilities.

The company would avoid getting new staff from other medical device firms, as they are afraid that such staff would 'know better how things are done' and hence might be difficult to manage.

The company has no business networks of importance beyond the important and active relations to the Academy of American Ophthalmology.

Employment and competences in the area

No skills problem in local labour market.

The company has not experienced any major problems in relation to the recruitment of staff.

The strengths of the establishment

The strength of Doran Instruments is the advanced product that has been invented by its founders and the high level competency behind the company in general..

The weaknesses of the establishment

The company and its continued existence and development is hundred percent depending on the competence of its present owners. This is probably the main weakness of the company. In addition, the small size and the appearing lack of professionalism in the manufacturing and marketing activities may be seen as a weakness.

Expectations for the future

The company is presently working at full capacity, and the management expects employment to increase a little during the next 2 to 3 years. The development beyond the present limited size depends on a major breakthrough of treatment opportunities and is hard to foresee.

Case study, Massachusetts: Microline

Microline develops and manufactures an integrated responsible modular design laparoscopic instrument system and clip applier. The system provides a number of economic and performance as well as convenience related advantages to the hospitals. This makes the product series very competitive and gives the firm a strong position in the market. Microline has developed very fast since its establishment 7 years ago and has now a staff of more than 130 people.

Microline has reached a point where it has become an attractive place of work, also for staff with high education, and the company has in general no problems in recruiting staff. However, the company faces serious problems when it need technical staff with experience in the use of CNC. There are no educations in this field in the region any more. This may encourage the company – earlier than otherwise - to outsource the manufacturing to a country where such a technology is still given priority and where at the same time the salary level is lower.

About the company

Microline was started in 1987 by two persons, an engineer and an entrepreneurial type of person, who are both still active in the company. They recruited four people to start with and established the new firm. Later on they located in Cunnings Centre, a building that was the home of 'United Shoe Machines' manufacturing enterprise for many years. All other renters in this building are service firms, and Microline is the only company here, who has both production facilities and offices on location.

Microline did not receive any public support for the start-up. The new venture was financed by the starters and by good friends.

It was a surprise to all that Microline grew so much and so fast. In 2002 the firm had 60 employees. At that time they hired a quite talented salesman, and the revenue grew by 41% in one year. Right now the firm has a total staff of 133 persons.

When Microline reached the level of 75 – 100 staff a lot changed. This is partly due to the fact that Government rules and regulations are different for larger firms with more than 100 employees (record keeping, staff regulation, safety etc.) This is not related to the type of company, only to size.

Products and market

Microline developed and manufactures an integrated modular design system of resposable laparoscopic instrument system and clip applier. This system, which was developed by micro surgical engineers, allows the hospitals to reuse the instrument's durable components (i.e. hand piece) and replace just the components that are subject to rapid wear and degradation (i.e. scissors blades). Usually one instrument cost in the range of 30-50 USD, and it is obviously valuable to allow some recycling, even if the market is small.



The roots and expertise of Microline are well established in the manufacture of scissors and related instruments used in the operating room for various surgical specialties. This began with a patented idea for "intraocular" micro optical surgery scissors used in retinal surgery over a decade ago. Today, that product is still an integral part of every Ophthalmologist's arsenal for surgically preserving a patient's retina, but the product was not particularly successful and profitable for Microline.



The patented technology and manufacturing process, however, lead other companies to Microline for research, design, manufacturing ideas and assistance. In turn this inspired Microline to enter the very competitive field of

laparoscopy with its own patented

laparoscopic scissors.

All the products of Microline are approved by FDA, and Microline is also ISO certified, which requires a lot of documentation. There is some resistance to the documentation process. It slows down the speed of production, but on the other hand, holding the ISO certificate and the FDA approval provides the firm with an avenue to the market, where documentation is also needed. The documentation also has a positive value to the firm. Actually, it has happened that a planned product was changed in the process of documentation, because of the detailed planning that the process required. The manufacturing process is a high volume process.

Microline sells all products via distributors and agents who are in the local markets. The policy of Microline is to be very selective in the recruitment of agencies and distributors, who sell on behalf of the firm. Each of them has their geographical area. This model is good because it limits the number of site staff that is needed.

Sales people are still needed in the organization, as doctors and other hospital staff often contact the firm directly, and the agencies and the distributors need to be trained and serviced. In addition, the sales department troubleshoots with the customers. The firm delivers and takes full responsibility for the products. If scissors do not work, they are changed. The products are sold in 33 countries today.

Strategies and cooperation

Microline's integrated responsible laparoscopic instrument system and clip applier were developed to address a delicate balance between the surgeon's request for top performance instrumentation and the hospital administrator's quest for cost containment. The system of responsible instruments offer the customers:

- Increased cost effectiveness
- Increased efficiency

- Enhanced feel
- Improved performance.

The concept is to provide surgeons and hospitals with a superior surgical instrument that provides the durability and cost-effectiveness of reusable products, plus the convenience, quality and precision of disposables.

There is at present high capacity utilization, and right now there are plans to expand the product lines. A new director of development has just been hired. His first activity right now is to do some idea generation in the organization.

Competition

The particular nature and character of the product line of the company gives Microline a very strong position in the market. A large amount of companies make and repair surgical scissors and other equipment, but Microline is alone on the market with the particular construction that is interesting for large parts of the market at a time where cost-effectiveness is given a high priority.

Employment and competences at the establishment

Microline is 5-10 years old and employs already a staff of 133 in May 2004. However over the last year, the company has more or less stagnated.

Two thirds of the staff are semi-skilled production workers and 10 – 15% are fully apprenticed manual workers. The company also employs 5 professional scientists for the R&D department and 5 managers.

Microline was looking for an assembly supervisor last year. It was not hard to find the right person. The assembly is done 100% manually and the firm needs very skilled assemblers. This is a key to success for the firm. In particular, they ask for good eyes and good eye/hand coordination and for staff that are able to read and comprehend specific manufacturing documentation such as product drawings, bill of material, and product routings.

A background in firms producing similar products or a background from electro-mechanical enterprises is a big advantage for new Microline staff. They need not hospital background, but when they are at Microline, they must know how their products are used. This is important to be able to deliver the desired quality.

The main recruitment channels are the Unemployment services, career service facilities, Internet, a cooperation program with schools, advertisements and networking with other companies that are downsizing. The preferred sources of new staff are similar enterprises with own assembly workshop, preferably in the medical equipment field, but this is not so important.

The firm has not made much use of continued education. They have preferred on-the-job-training, and they promote the participation of staff in various school training on own initiative. Other firms give continued education a higher priority, and the HR manager expects that Microline will also some day get to that point.

Employment and competences in the area

According to Microline management, very few machine shops are left in the region, and this makes it difficult to find people with competencies in CNC. This type of specialty is not educated any more.

On the other hand, engineers are available everywhere in the region because of the high unemployment rate. When a new research and development manager was recently hired, Microline received more than 300 applications in one day, only! They were designers, developers, engineers and much more. There were no engineers with specialty in medical device, and the firm is not sure that such a specialization is available at any of the universities of the region.

The strengths of the establishment

The strength of Microline is without doubt the concept and the product that offers the hospital an increased cost-effectiveness and efficiency at the same time as it gives a better tool and a better performance. Microline also benefits from a professional management with a very targeted development strategy.

The company also seems to benefit from a position that makes it an attractive working place for staff with a higher education.

The weaknesses of the establishment

Microline still have some of the characteristics of the small company, such as insufficient training of staff, which may be considered a weakness. In addition, the product is basically a low technology product that might be more profitable for manufacturing in low cost countries.

Expectations for the future

Microline is presently at overload and is in the process of recruiting more staff. The company expects a positive development over the next 2 to 3 years.

Case study, Massachusetts: Majestic Medical

Majestic Medical was established a few years ago and employs almost 30 people. The company repairs surgery instruments and is in the process of starting up its own production. The company is very much centered around the manager and owner, who takes care of all product development, management and planning. In addition, as a result of the limited knowledge imbedded in the products, the company may be threatened by imports from low cost countries.

About the company

Majestic Medical was established in 1995. The owner worked in another similar medical device workshop before, in which he worked for 6 years, 1989 - 1996. This enterprise was strong in technology, but the weak points were the sales and marketing aspects. They produced instruments for surgery and his proposal to offer repairs as well was not accepted.

The owner started with a partner, who was later bought out in 1998. He worked full time in two jobs simultaneously during 1995-1996 until the revenue sufficient for two persons was achieved. Today the annual turnover has reached USD 2 million.

Majestic Medical could have benefited from public funding, but he never went for it. He knows that such incentive schemes aim at increasing employment, and he does not agree in this as a short term goal. In addition, the incentive packages seldom offer real money, but only payment for training.

The aim of the owner is to make a business, and he is not only doing it for profit. He complains that there is no incentive to start a business in America and mentions all the problems for entrepreneurs: The safety, health care and recruitment regulations. Today, Majestic Medical cannot fire a staff without having to pay a certain percentage of his salary expenses next year, even if the fired person was warned.

Products and market

The main (service) product of Majestic Medical is the repair of surgical instruments. This is a big business of this area because of the large number of famous hospitals with their close relations to the organ bank and the Medical Universities in and around Boston.



Ten percent of the activities are in production of surgical instruments using CNC technology. A new product is now ready for introduction. It is a kind of keyhole surgery instrument which is almost ready for release now. The production will take place in the same premises and with the same staff as today. According to the owner, there are no approval problems as long as the new product is very similar to existing ones.

The manager of Majestic Medical sees product development and improvement of products as main factors for growth. Market development is also important, and therefore, a sales company will be recruited to do the sales work. It must be a company with a good experience which may also help penetrate into the clients' organisations.

Today the sales are very much based on confidentiality and existing connections. The customers are loyal, but the manager knows that loyalty is the same as lack of a better deal. Experience taught him this!

Majestic Medical does not see the disposables as a serious competitor. They have a small niche and their market share is expected to remain unchanged.

Strategies and cooperation

Majestic Medical has tried to establish a strategic partnership with a supplier of surgical instruments. This didn't work out as the partner tried to start on his own, making use of the partnership just to build up the basis for own business activities.

The idea of the owner is to earn money from the repair activities to establish the basis for the production of a new series of instruments. The owner is the driving force in the development. He is looking at the industry and tries to figure out what is good and what is bad, and on this basis he develops ideas for new product series.

Majestic Medical cooperates now and then with hospital surgeons. He asks them to take a look at new product ideas, but there is no formalized cooperation and the surgeons cannot be made responsible. To do this they would require a high compensation.

The manager of Majestic Medical is a member of the National Federation of Independent Businessmen, but he is not a member of any medical device association. He leaves this with the big businesses. He has no time for it. "MassMedic is for the large companies who are looking to buy the small ones if they become a threat".

Competition

A number of small competing companies repairing surgery instruments exist in the area, but they are not considered strong competitors by Majestic Medical.

A major problem in introducing new products in this area is that there is a huge inflow of cheap products from Pakistan and other similar countries. A lot of cheap general instruments are imported from Pakistan. The owner doesn't know if the products are approved, but the hospitals do not always remember to ask if it is. They are interested in the best product at the best price.

Majestic Medical's type of business, on the other hand, can compete against the bigger ones, because the owner and manager can do the design of machines and the assembly himself, whereas the bigger ones would have to hire staff for this.

The owner has his own theory regarding the policy of FDA and the reason that FDA is not interested in regulation of repair activities: When the hospitals buy equipment they face a

number of regulations and requirements, but they may allow anybody to repair it. FDA has no interest in small enterprises because of their limited financial capacities. The large companies can afford to pay for the collection of information to be used as the basis for approval, but the small ones cannot. The FDA may have an interest in the fees that are paid in the process.

Employment and competences at the establishment

The owner has the key role in the firm. He is the manager and the product developer and at the same time he takes care of Human Resources and all other aspects.

The other staff consist of:

- 1 financial expert
- 1 customer relations specialist
- 2 CNC machinists
- 1 Quality control person.
- 19 experienced technicians and craftsmen without any formal education.

The main criterion when new staff is recruited is their experience from another medical device firm. Another important criteria are their initiative and their personality. The manager wants to hire people that will ‘take the broom from the manager’ to make him free to concentrate on more important activities.

The firm does not make much use of continued education. In some cases staff may be sent for training in CNC, but the training would always be very targeted and needed. According to the manager, the staff is not interested in investing in themselves, which he sees as another factor contributing to the increasing imports from Pakistan and other similar countries. The staff wants some direct pay-off in order to be interested.

Employment and competences in the area

The manager finds it difficult to get good staff in the region, because they all want to work with the big ones.

The strengths of the establishment

The main strength of Majestic Medical is, according to the owner, that he himself can do the design of machines as well as the assembly, whereas the bigger ones would have to pay for this.

The weaknesses of the establishment

The production of relatively simple surgery equipment seem to a risky business that might easily be threatened by imports from low-cost countries. The fact that all development and practically all the main competencies are concentrated on the owner is another serious weakness for the development of the company. .

Expectations for the future

The owner and manager of Majestic Medical expects the medical device market to grow slowly during the next 2 to 3 years.

Case study, Massachusetts: Aurora

Aurora Imaging Technology, Inc. is developing and marketing equipment and software for the application of magnetic resonance imaging (MRI) technology for clinical indication of breast cancer. It sells the product all over the USA but are still working for a final breakthrough. The staff of the company is around 35 people. About a third of the staff are involved in R&D and highly specialized, but the remaining staff is mainly apprenticed production workers or involved in administration and sales. The company has no problems in recruiting new staff, but expects problems in the future. A high growth is also foreseen by the management of the company.

About the company

Aurora Imaging Technology, Inc. is a privately held corporation dedicated to supporting the detection and management of breast disease through the application of magnetic resonance imaging (MRI) technology. Aurora is the only MRI system designed specifically and only to image breasts that has Food and Drug Administration (FDA) clearance and is commercially available in the United States. It is in clinical operation at a growing number of leading breast care centers.

The firm started by the scientist who developed the first version of the product 15 years ago, but the group of owners has developed and changed since then. The image quality has improved, and the product has become more user-friendly. The starter got venture capital very early, and the firm has regularly needed more capital since then.

Aurora has a product department, a sales department, and administrative department and a manufacturing department. In addition, Aurora has a clinic in Boston offering the products of the firm since 1997. This is used by physicians adjacent with X-Ray. At first they use X-ray, and if needed they also use MRI.

The products are sold or rented on a 50-50 shared revenue basis.

Product and market

Aurora is developing and marketing a system for clinical indication of breast cancer, based on magnetic resonance imaging (MRI). This is an imaging technique used primarily in medical settings to produce high quality images of the inside of the human body. It helps the surgeon to know the full extent of the problem before they start their work.

As a diagnostic imaging tool, the Aurora Breast MRI System is ideal for a wide range of indications in breast disease management including:

- Characterize Lesions
- Detect Occult Primary Breast Cancer
- Determine the Extent of Cancer
- Monitor Cancer Therapy
- Evaluate Patients with Positive Surgical Margins for Residual Cancer
- Exclude the Existence of Cancer in High-Risk Women

- Evaluate Implant Integrity and Detect Cancer in Women with Breast Augmentation

Aurora is mainly active in the local area and in the USA and the four sales people are all based in the USA. In addition the firm is interested in the Asian market, where they find a market which is more interesting than in Europe.



Strategies and cooperation

The aim is to offer physicians a package of hardware and software. The development and needed improvements and the testing are very capital-demanding. The market opened up for this product in 1999 and it is gradually increasing. The product development continues to focus on possible improvements. No additional products are planned.

Aurora is currently improving their product and developing their relations to physicians who are decisive for the future sales. The company is convinced that the more physicians know about their product, the more will be sold.

Competition

Aurora have no direct competitors. The main constraint on their sales is lack of knowledge among physicians.

Employment and competences at the establishment

Aurora employs presently 35 people, half of which are apprenticed manual employees and 12 are engineers and MRI scientists, and 4 are sales people. A total of 7 have functions as managers. The employment has been decreasing over the last year.

In addition to this staff, 5 are employed in the clinic, which is a subsidiary of Aurora.

Recruitment of new staff is mainly done on the basis of online services. It is not hard to get new staff. 150 persons applied for an MRI engineer position. They were typically unemployed that have been without a job for about a year. 8-10 candidates are invited for a team interview after which one is selected. The main criteria that are used are the job qualifications and the technical background.

After recruitment, the new staff member receives an orientation and is trained on the job by the manager of the department. Aurora does not make much use of continued education, but it encourages its staff to take an additional education by paying their tuition fees when e.g. a

person wants to take a PhD or a Master's Degree. Right now, three persons of the staff are getting a Master's degree. The firm has a budget of USD 5,000 per year per person for this type of training expenditures. In such cases the education takes place outside working hours.

If there is a particular problem in the firm, they may ask a trainer to come to train the involved persons. This type of training is done in working hours. This mostly involve the technical people, but also the HRD has received training, e.g. in State Law questions.

Employment and competences in the area

According to the HR manager, the needed skills are in good supply in the local labour market, because many are out of work. However, the company expects to find it difficult to obtain MRI trainees, scientist and developers in the future.

The strengths of the establishment

The main strength of the establishment is the capability of its product to provide valuable information to surgeons which enable them to become more effective in their work. According to the firm, there is no real alternatives to their product.

The weaknesses of the establishment

The main bottleneck for the development of the sales is the interest and attitudes of the physicians. There is a progress in the education of physicians, and the firm works with physicians to develop the market. They are thus working more closely with the physicians' community than with business organizations.

Expectations for the future

The company is presently somewhat below full capacity, but expects the employment to increase a great deal over the next 2 to 3 years.

Case study, Massachusetts: Funnell Instruments

Funnell Instruments is a one-man-enterprise operating from the home of the owner and his van. He is sharpening and repairing handheld, laparoscopic, surgical instruments, and he is importing new instruments from Poland. In addition, a few years ago, he developed a micro instrument, a 2.5 mm biopsy jar, which was patented but never prototyped or manufactured because of shortage of financial resources. The companies in this field have not shown interest for buying the patent; they prefer to develop their own products.

About the enterprise

The owner of Funnell Instrument, Mr. David Funnell, runs his business from his home and from his van, in which all his tools are installed. Nobody are employed in this one-man-enterprise, but the owner is considering to recruit the son of his neighbour for training and assistance during peak loads.

The owner was originally in the car industry, but moved into medical device as he was very good at the details. He worked many years ago for a large supplier of surgical instruments. He had direct contacts with the hospitals in parallel with the sales people who wanted to sell new products. The plan was to develop very close relationships between sales and repair departments, but this never worked out.

The supply and repair of surgical instruments is a relatively big business in the region because of the large number of hospitals and medical schools in the region. This is also the reason for a large and expanding medical device industry in the region. Six hospitals are located within walking distance in Boston, which may be seen as the surgical and medical mekka. Also gene technology is expanding in the region. People come from many other states to have surgery here, and in particular transplantations of organs are done here. Boston has one of the largest organ banks. Actually, Funnell is also working for the organ bank in Boston.

Products and market

The main activity of Funnell Instruments is the sharpening and repairing of handheld, laparoscopic, surgical instruments. 5% of the revenue, however is from the sale of Polish instruments. In addition, the founder, David Funnell had a patent issued in 1995 for a micro instrument.

The patented product is a micro instrument (2.5 mm and smaller) for capturing of biopsy samples for testing of cancer in the early stage. Back in the late 1980s he did some sharpening and repairs of such a product and saw the shortfalls of it. He developed therefore a better tool. The existing products are based on stamping, whereas his product is a 'biopsy jar'. No prototype has yet been made for the patent.

50,000 parts, similar to the patented product are sold monthly. David Funnell has tried hard to sell his product to some of the large suppliers, but until now in vain. They all prefer to develop their own technology.

The costs of FDA approvals have increased over the years as manufacturers must pay for the auditing. This makes development of new products gradually more expensive. However, the repair and sharpening activities of Funnell Instruments need no approval from FDA.

Strategies and cooperation

Before he started the enterprise, the owner of Funnell, developed good personal relationships with a salesman and they wanted to break out and start by themselves. This was prohibited, however, by an employment agreement and they were not even allowed to approach former contacts from their jobs. Therefore he started in New Hampshire, north of Massachusetts, and he repaired all types of surgical instruments, micro and the large bone cutting instruments. For tax reasons he was registered as a corporation

Funnell has tried to cooperate with two different suppliers of surgical equipment, but after a while the suppliers have both tried to take back the repair work. He has always kept the independent work with his own contacts, and this is still 90% of his total activities today, corresponding to annual revenues of USD 90,000.

A high degree of confidence is needed between the enterprise and its clients. A good synergy between sales and repairs would therefore be desirable. David Funnell's contacts in the hospitals are the following:

- The purchasing departments that want to reduce their burden by hiring private vendors and who are generally not interesting in meetings.
- Surgical Departments, who are often in a hurry
- Sterilizing Departments
- Almost never the physician

The clinical workforce is normally more educated, and the operating staff is frustrated – they know more on the practical uses of the instruments.

Networking is important for small enterprises like Funell Instruments. David Funnell therefore takes active part in medical fairs and shows.

Competition

The price for the repair of an instrument is typical in the range of USD 17 – 23, and the price of a corresponding new instrument would be USD 70. A partially replaceable instrument would cost about USD 600, and the replacement part would cost USD 100. This is not a serious competition.

The competitors are the suppliers of instruments like the ones he has worked for and a few mobile instrument services like his own. Two companies like Johnson and Johnson have each two persons in the region. In addition, Majestic Instruments are competitors.

Employment and competences at the establishment

Funnell instruments employs the owner and nobody else. The owner is considering to train and recruit a young person to assist him in periods of peak loads and to make his job while he

is busy doing other things. It is important to get a person who is good at such a piece of manual work, but no education is required.

Employment and competences in the area

This activity requires no formal education, but it is important that persons involved in the activities have the manual skills.

The strengths of the establishment

An enterprise like Funnell Instruments is very flexible and able to adjust to the needs of the customers as long as it is not operating at full capacity.

The weaknesses of the establishment

The weakness of a small enterprise as Funnell Instruments is the limited capacity to invest and in cases of full capacity to increase activities in peak load periods. The limited financial capacity is also the reason why the patented product of Funnell Instruments cannot be produced and marketed.

Expectations for the future

The owner of the enterprise does not expect it to grow beyond the stage of a one-man-enterprise and seems not to believe in a future for his patent any more. He is now a Republican candidate for the State House elections and foresees that he will have limited time for other activities than the necessary repair work as his main source of incomes.

Annex A: Survey details

Dun and Bradstreet and Yellow pages provided business registers with relevant sector and contact information for the Medical Technology Skills Study survey. A gross sample of all entries in the relevant databases covering the geographic region of New England consisted of 583 from Massachusetts, 69 from New Hampshire, 80 from Vermont, 53 from Connecticut, 35 from Maine and 60 from Rhode Island. As none of the statistical codes contain only medical device manufacturers, the lists of establishments included enterprises that were not relevant and had to be excluded from the sample. About two out of every three establishment was judged relevant on the basis of detailed desk research. In the group of establishments that were outside the scope of the survey there were 16 establishments whose Human Resources (HR) functions were centralized in headquarters outside the region.

The category *No contact possible* consisted of people who did not answer the phone or respond to messages or requests to be connected to a manager of human resources. The establishment were contacted many times (from five to 31) by telephone and, where possible, also by email, without success.

Letters with codes to answer the questionnaire on the Internet were sent to 311 establishments. The establishments were also contacted by mail in an attempt to increase the number of respondents, but still without success. After exhausting all these procedures, there were no options left for improving the response rate.

The result after having contacted all relevant establishments several times and through different means was a useable response from 29 establishments which represented a response rate of five per cent. Almost all were located in the state of Massachusetts.

The details of the sample and the response were as follows

	New England
Total sample	880
Relevant establishments	598
Did not want to respond	458
No contact possible	111
Responded	29
Response rate	5 per cent