DEVELOPING EXCELLENCE IN MEDICAL TECHNOLOGIES

Benchmark Report for USA

A report prepared for
Advantage West Midlands

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1. Introduction

The purpose of the benchmarking report is to provide a commentary on how the medical technologies industry has developed in the Boston area, Massachusetts, USA. The report seeks to identify the stimulants and catalysts to growth; and the extent to which the existing industrial development and skills supply infrastructures, at national and local levels, contributed to or inhibited the growth of the industry

The benchmarking report will provide:

- The size and characteristics of the medical technologies sector in each country;
- An account of national institutional arrangements for the development of the medical technologies sector;
- The supply of skills to the medical technologies sector;
- An account of a region where the medical technologies sector is concentrated and the factors behind the location of the industry in that locality;
- The characteristics of the medical technologies industry in that locality.

In this study, the medical device industry is defined within the International Standard Industrial Classification of All Economic Activities (ISIC, Rev. 3), as follows:

Applied definition of medical device industry
Section D: Manufacturing
Division 33: Manufacture of medical, precision and optical instruments
Group 331: Manufacture of medical appliances and instruments and instruments for measuring, checking, testing, and navigating and other purposes...
Class 3311: Manufacture of medical and surgical equipment and orthopaedic appliances

The definition excludes the manufacture of surgical dressings (2423), the manufacture of thermometers (3312), and the manufacture of corrective spectacle lenses (3320). There are a number of linkages that will be addressed, such as the link to human health activities (851).

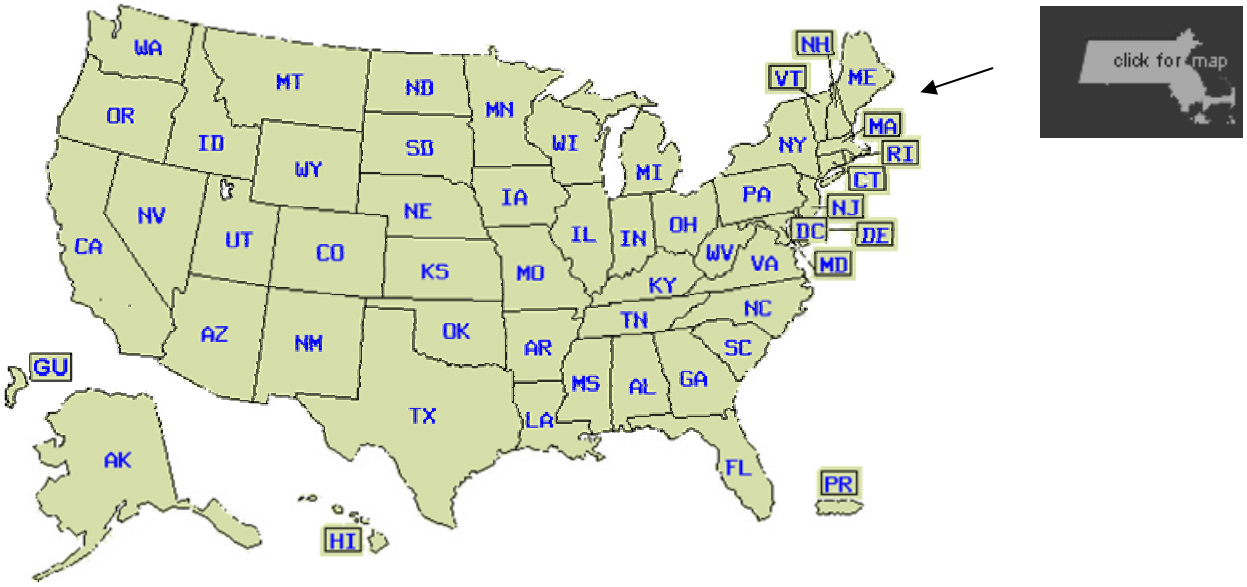
The definition of the sector may vary between countries depending upon the extent of linkages between the various parts of the industrial cluster. The purpose of the study is to address the industry concerned with the manufacture of medical devices this will lead to overlaps with:

- The health service (i.e. hospitals, medical teaching centres/universities);
- Pharmaceuticals (where they are concerned with devices for the administration of medicines);
- Bio-technology;
- Information and communication technologies (ICT) where the development of products or services is concerned with the provision of medical treatments (e.g. telemedicine).

The benchmark study for Massachusetts is thus to a large extent based on the broader definitions that are used in the various sources applied.

In chapter 2, the economy and industrial policy are briefly described at the national (that is to say, the federal level) and in chapter 3, the national medical device sector is described. In chapter 4, the local region (that is to say, the state of Massachusetts) and the importance and characteristics of the medical device sector in the state are described.

United States of America **Massachusetts**



2. National Overview

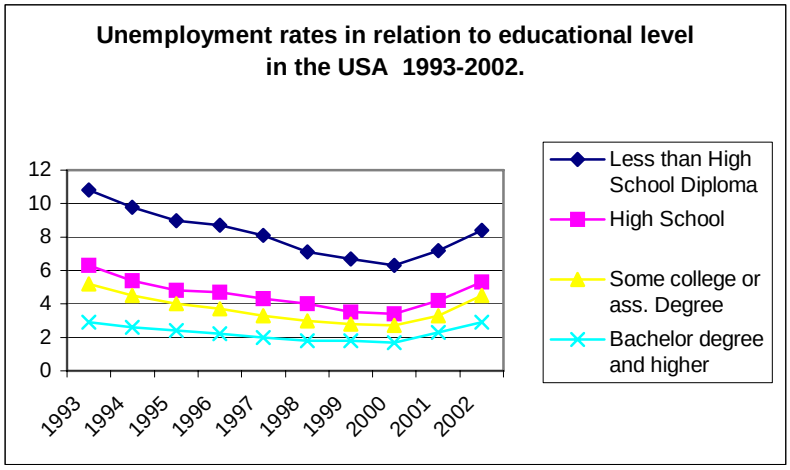
2.1 Overview of the National Economy

2.1.1. Overall Macroeconomic Performance In The United States

The United States has a powerful, diverse and technologically advanced economy that is by far the largest in the world, with a per capita GDP of US$36.300 (2001). The economy is very market-oriented and dominated by the private sector. Most economic decisions are left to private individuals and business firms. The federal and state governments predominantly buy the goods and services they need in the private market place, and US businesses enjoy substantially greater flexibility than their counterparts in Western Europe and Japan. There are relatively few regulations restricting decisions to expand capital plant; lay off surplus workers; or develop new products.

The rapid development in the technology sector combined with a relatively free market largely explain the gradual development of a *two-tier labour market* in which those at the lower level lack the education and the professional and technical skills of those at higher and increasingly fail to get comparable rates of pay; private health insurance; and other benefits. US firms are in many fields among the leading in technological advances, especially in computers and medical, aerospace and military equipment. Its financial services, media and entertainment sectors are fully global in their coverage. Of great significance to the global economy, the United States has, over the past five years, been running huge current account deficits in relation to the world's exporting economies which sold record amounts in the U.S.[1] The period 1994 to 2000 witnessed solid increases in real output; low rates of inflation rates, and a drop in unemployment to below five per cent.

Figure 1



US Department of Labor (www.dol.gov.us)

As figure 1 demonstrates, there exists a consistent association between unemployment and level of education; the higher the level of education, the less likely people were to be unemployed. The group with the lowest educational level clearly have the weakest position at the labour market. At the same time the relative position of the different groups remained similar over the period and their levels of unemployment moved in parallel.

[1] IFC website and Travel Document Systems website.

The country's longest period of economic expansion ended in early 2001, when exports increased by only 0.3 per cent. The US economy slipped into recession, as industrial production dropped sharply; investments and exports declined; and employment and weekly hours fell. The downturn was triggered in part by the collapse of the Information Technology (IT) boom in March 2000 and the associated collapse of stock market prices; but recession was further exacerbated by the September 11th terrorist attacks, which contributed to a further loss of confidence and job losses. As a result, following a period of real GDP growth in excess of four per cent during the previous four years, the economy slowed sharply in 2001. At the same time, and perhaps led by deceleration in the US, the world economy also began to slow dramatically, making 2001 the first year of global recession since the middle 1970s[2].

However, a modest economic recovery became apparent in the third quarter of 2001, resulting from a variety of influences, including the lagged effects of monetary policy (set by the Federal Reserve) and multiple interest rate reductions during 2001; combined with an expansionary fiscal policy (set by the President and the Congress), which added substantial increases in government spending to the Bush Administration's programme of tax reduction. These provided strong stimuli to demand. Lower energy prices and increased spending on consumer durables added further stimulus.

In spite of the stagnation of the global economy; falling exports and continued weak fixed investments, as the business sector (manufacturing in particular) struggled with excess capacity and inventory, and falling prices and profits, the economy actually grew a little in the fourth quarter of 2001, and the unemployment rate even turned around in December 2001. But the stock market experienced a sharp fall in the first part of 2002, thereby continuing the substantial decline of stock markets since 2000.

The annual growth forecast for manufacturing in the US was less than three per cent for 2003 and many sectors showed signs of weakness. The FED expected stagnation in the retail sector; in automobile sales; and in commercial real estate. But production related to defence; construction; and energy-related manufacturing remained among the bright spots in the manufacturing sector.

Apart from the short term economic problems, the main long term challenges to the American economy include inadequate investment in economic infrastructure; rapidly rising medical and pension costs in an ageing population; sizable trade deficits; and the stagnation of family incomes in the lower economic groups[3].

2.1.2. Overview in relation to Broad Industrial Group

In the United States, 80 per cent of GDP currently comes from services; 18 per cent from manufacturing industry, and two per cent from the primary sector. The share of manufacturing industry has been decreasing in the US for almost three decades, which has reflected a long period of contraction worldwide[4].

In the last two decades of the 20th century the US economy was transformed in a way and at a speed that few could have anticipated. The 19th century's long-term transition from an agrarian economy to an industrial economy was replicated in an accelerated transition from a manufacturing economy to a technology based economy. While traditional agriculture and manufacturing will always be important economic sectors, today's new economic growth is being driven far more by

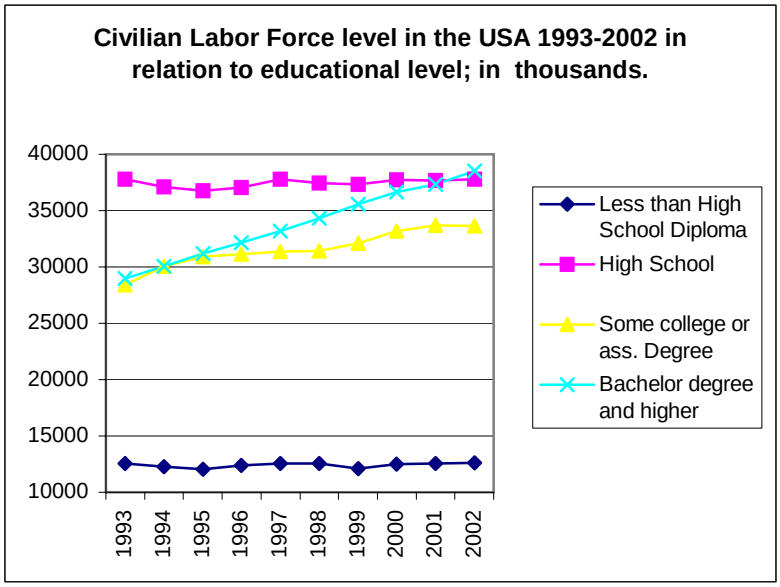
[2] IFC website, Travel Document Systems website and IMF, 2002.

[3] IFC website, Travel Document Systems website, IMF, 2002 and Economic Report of the President, 2002..

[4] IFC website, Economic Report of the President, 2002, and Annual Report, 2002.

technology and its influence on traditional economic sectors than ever could have been foreseen[5]. Not surprisingly this development into a technology based economy has also changed the composition of the labour force. The section of the work force with the highest educational level has increased rapidly over the period 1993 to 2002 (see Figure 2).

Figure 2



US Department of Labor (www.dol.gov.us)

2.1.3. Forecasts for the Medium-Term

A plan proposed by the President in January 2003 promised to enhance the long-term growth of the economy while supporting the emerging recovery. Perhaps most important in ensuring recovery has been the underlying flexibility and dynamism of the U.S. economy. At the start of 2003, the consensus of private forecasters predicted accelerating growth in real GDP over the course of the year (from 2.5 per cent in 2002 to about 3.25 per cent in 2003), which would raise investment, reduce unemployment, and increase job growth. Forecasters saw an economic up-turn beginning in the second half of 2003 and continuing through 2004. In the forecasts, the unemployment rate was expected to fall from 6.1 per cent in June 2003 to 5.9 per cent in December 2003 and to continue to fall to 5.7 per cent the following June. But the recovery in investment could be delayed by weaker than expected growth in profit; and higher required rates of return arising from geopolitical and other risks. More general risks to recovery in 2003 included an increased sense of caution, which could lead households to pull back on their spending plans, and the threat of further terrorist attacks. The forecasters' views of long-term output growth and inflation were as follows: real GDP would grow by 3.2 per cent annually and inflation would average 2. per cent over the coming ten years[6].

[5] Dick Thornburg, 2002

[6] IMF 2002, Economic Report of the President, 2002, and June 2003.

2.1.4. Long-term labour market Forecast

Labour force
The civilian labour force is projected to increase by 17 million over the period 2000 to 2010, reaching 158 million in 2010. This increase of 12 per cent is only slightly greater than the increase of 11.9 per cent over the previous decade, 1990 to 2000, when the labour force grew by 15 million. The demographic composition of the labour force is expected to change because of changes in the demographic composition of the population and because of differential rates of participation across demographic groups.

Industry Employment
The service sector is expected to continue to be the dominant source of jobs in the economy, adding 20.5 million jobs by 2010. Within the goods producing sector, construction and durable manufacturing will contribute relatively modest employment gains. While employment in the service sector is expected to increase by 19 percent, manufacturing employment is expected to increase by only three per cent over the period. Manufacturing will return to its 1990 employment level of 19.1 million, but its share of total jobs is expected to decline from 13 per cent in 2000 to 11 per cent in 2010.

Service-employment
Health services, business services, social services, and engineering, management, and related services are expected to account for almost one of every two non-farm wage and salary jobs added to the economy during the period 2000-2010. The sectors listed account for a large share of the fastest growing industries.

Occupational employment
Professional and related occupations and service occupations are projected to increase the fastest and to add the most jobs; 7.0 million and 5.1 million, respectively. These two groups, at the opposite ends of both the educational attainment and the earnings spectrums, are expected to provide more than half of total job growth over the 2000 to 2010 period. Transportation and material moving occupations are projected to grow by 15 per cent, about the same as the average for all occupations. Office and administrative support occupations are projected to grow more slowly than average, reflecting long term trends in office automation. Production occupations should grow much more slowly than employment on average because of manufacturing technology advances. Eight of the ten fastest growing occupations are computer-related, commonly referred to as *information technology occupations*.

Education and training categories
Employment in all seven education or training categories that generally require a college degree or other post secondary award is projected to grow faster than the average across all occupations. These categories accounted for 29 per cent of all jobs in 2000 but will account for 42 per cent of projected new job growth over the period 2000-2010.

2.2. Overview Of Industry Policy

2.2.1. National industrial policy

The overall industrial policy has been described by the President of the United States, George W. Bush, as follows*, The role of government is to create conditions in which jobs are created, in which*

people can find work. The President further made it clear that competition, not Washington's selection of winners and losers, should shape the economy[7].

In the Department of Commerce, efforts have been made to transform the Economic Development Administration (EDA) into a key actor in domestic economic development. In order to generate a high economic impact per dollar of input, EDA will pursue an economic development strategy aimed at enhancing regional competitiveness; fostering innovation; increasing productivity; and developing industry clusters.

According to President Bush, Federal Government does have a role to play in economic development, *Notwithstanding the demands placed on our budget by national and homeland security efforts, we believe there continues to be a significant federal role in economic development activities*. The Bush administration further underlines the importance of ethics in corporate governance. The President has signed the corporate accountability bill and asked for an additional US$20 million in 2002 for SEC to be able to hire more enforcement personnel[8].

2.2.2. Approaches to industrial development

Dick Thornburg, former Governor of Pennsylvania and current chairman of the State Science and Technology Institute, recently expressed a general attitude regarding approaches to industrial policy. Commenting on economic development over the last two decades of the 20th century, he argued that no master plan or industrial policy directed out of Washington, DC could effectively stimulate the new opportunities for economic growth and future-oriented jobs. *Nor should it attempt to do so*, he said, and he went on to conclude, *The challenge for today's state and local officials and policy makers is to fashion strategies for each state to ensure they are positioned not to just compete, but to thrive in the new economy*. While it is not possible to predict what the next *hot ndustry* will be, it is possible to be confident that innovation and the imbedding of technology in core industries and manufacturing processes will drive the next regional economic engines of growth.

The economic development strategy at the Department of Commerce and Economic Development Administration (DOC/EDA), however, is based on enhancing regional competitiveness and the development of industry clusters. The strategy is based on the research of Professor Michael Porter. It is considered appropriate because it is based on a good understanding of how regions can build long-term economic success and because it is market driven.

According to a 1996 study by the National Academy of Public Administration, annual federal government support for economic development totalled over six billion dollars each year, including outlays; tax subsidies; and the cost of loans and loan guarantees. The level of support has grown. A reassessment of the role of federal government and its investment of resources seems to be underway. The appropriate role of the federal government in promoting economic development has been questioned and a number of think tanks, including the National Academy of Public Administration, have looked at the question over the years, partly sponsored by the DOC/EDA.

One policy goal is to increase the productivity and wealth of the American economy. After more than a decade of efforts to compete in the global economy it is still important that public policies encourage and strengthen firms to become more productive and profitable. A second policy goal is to ensure that all communities receive a share of economic development.

[7] Department of Commerce website.

[8] EDA website

The importance of linking economic development and work force development is stressed by EDA. The US Assistant Secretary of Commerce at a Workforce Innovation Conference in July 2002 recommended the following prescription, *to invest in human resource development; create a favourable environment for entrepreneurship; and let the markets do their work - the rest will follow*[9].

More specifically in relation to medical technologies, The President of AdvaMed[10] has criticized the US regulatory framework for being particularly inhospitable to small medical device companies, who must negotiate the same FDA requirements as the largest medical device companies, but without the benefit of the big regulatory affairs staffs that large companies can afford[11]. The FDA, as the regulatory authority is accused of disregarding the needs of patients by a regulatory process that is unpredictable and prone to delay, *After all, it is the patients, not the medical device companies, who suffer most when the development of an important new technology is stifled or delayed*'. A revitalizing of innovation and easing the path of product development is therefore demanded by the industry. But the FDA, as the regulatory body, with the responsibility for the consequences of an inadequate documentation of the quality of new technologies, will have to continue to exercise care, even if this hurts potential clients.

2.3. National overview of approaches to local economic development

2.3.1. Institutions responsible for industrial development at a national level

The main national institutions involved in industrial development at national level are the Economic Development Administration (EDA) under the US Department of Commerce and the Small Business Administration (SBA). At state level, the Department of Economic Development (DED) plays an important role together with its five agencies.

The Economic Development Administration
The Economic Development Administration (EDA) was established under the Public Works and Economic Development Act of 1965 (42 U.S.C. 3121), as amended, to generate jobs, help retain existing jobs, and stimulate industrial and commercial growth in economically distressed areas of the United States. EDA assistance is available to rural and urban areas which experience high unemployment; low income; or other severe economic distress. In fulfilling its mission, EDA is guided by the basic principle that distressed communities must be empowered to develop and implement their own economic development and revitalisation strategies. Based on these locally and regionally developed priorities, EDA works in partnership with state and local governments; regional economic development districts; public and private non profit organisations; and Indian tribes. EDA helps distressed communities address problems associated with long term economic distress, as well as sudden and severe economic dislocations including recovering from the economic impacts of natural disasters; the closure of military installations and other Federal facilities; changing trade patterns; and the depletion of natural resources.

[9] Economic Development Administration, EDA, 2002.

[10] The Advanced Medical Technology Association, AdvaMed, (formerly HIMA) is the largest medical technology association in the world. It represents more than 1,100 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Members manufacture 90 percent of the $71 billion of health care technology purchased annually in the United States and more than 50 percent of the $169 billion purchased around the world annually

[11] Jain, G.L., 2001.

EDA has six regional offices, each covering from five to 15 states. Each center has Office Contacts in a number of local communities in their area such as the Philadelphia Office, which has a contact point in New Hampshire, Massachusetts.

Small Business Administration (SBA)
The US Small Business Administration (SBA), established in 1953, provides financial, technical and management assistance to help Americans start, run, and grow their businesses. With a portfolio of business loans, loan guarantees and disaster loans worth more than US$45 billion, in addition to a venture capital portfolio of US$13 billion, SBA is the nation's largest single financial backer of small businesses. Last year, the SBA offered management and technical assistance to more than one million small business owners. America's 25 million small businesses employ more than 50 per cent of the private work force, generate more than one half of the nation's gross domestic product, and are the principal source of new jobs in the U.S. economy.

2.3.2. National industrial policy at local level

Some communities have high unemployment and low incomes, and economic development does receive some federal attention, especially in distressed communities. Need, or economic distress, qualifies a community for consideration for EDA investment assistance. Owing to limited financial resources, EDA has established clear funding priorities and investment policy guidelines to enable investment decisions that will generate lasting, long term economic growth.

The impacts of federal investment in economic development is to some extent limited by the effects of other federal policies and programmes that focus on national economic conditions and on providing the legal and regulatory frameworks within which private sector activities take place. Federal policies and programmes in transportation, technology and other fields that are not primarily directed towards economic goals may still have implications for state and local economies. Expenditure on such programmes are far larger than federal investment in economic development.

A second limiting factor that reduces the impact of federal economic development programmes is the market, which is the primary force driving both the overall rate of economic growth and the geographic location of economic activities. Economic development programmes cannot counteract these powerful forces but they can work in tandem with them. Programmes are developed to help private businesses build links with public institutions, like schools, universities, community colleges and research institutions. They are intended to ensure that the public infrastructure is available to support economic development and that public services are provided to attract economic growth. They can help emerging businesses find their way through complex regulatory systems.

Economic development activities are aimed at influencing both the rate and location of economic change. When particular geographical areas are missed out by economic development, or when regional economies are experiencing structural economic change, programmes are used to build a more favourable business climate to attract private capital investment by encouraging new partnerships and new institutions to respond to market opportunities.

Communities are able to attain real economic improvement in their own area by mobilizing a broadly based and well conceived effort to increase economic opportunity. Helping distressed communities get started and contributing to their momentum are among the goals of federal government. Federal economic development programs are designed to help states and localities learn through better information, to enable them to gain access to all available resources, and to link scattered initiatives to serve local needs.

Higher levels of private capital investment drive the creation of more highly skilled and better paid jobs and, hence, an enhanced tax-base. To this end, the mission of EDA is to help foster a positive business environment among distressed communities, both rural and urban; to attract private capital investment to produce goods and services and increase productivity, thereby improving employment opportunities.

In regions or communities experiencing chronic economic distress or structural economic change caused by changes in trade and industry patterns or the closure of government facilities, EDA has its role among government agencies facilitating and accelerating economic development. In many of these areas, existing market conditions will not justify a sufficient rate of return to the private sector without public sector participation to enhance the business environment. In such cases the state and local officials and policy makers see their roles as developing strategies for their area to position themselves better to compete and develop[12].

2.3.3. Approaches to local industrial development

The main institution responsible for development of industry in Massachusetts is the Department of Economic Development (DED). The Department's mission is to help grow and sustain the economy of Massachusetts and to ensure that this is done with regional equity. The Department is responsible for attracting, retaining, and spreading economic prosperity throughout the state. The mission is pursued through web based services and through five agencies that are charged with stimulating economic development in the Commonwealth. The agencies include the following:

- Massachusetts Office of Business Development (MOBD) whose mission is *to assist in the creation and preservation of jobs in Massachusetts* through industry sector specialists and five regional offices through which, MOBD helps companies to obtain the human, financial, and technological resources necessary to grow and prosper.
- Massachusetts Office of Travel and Tourism (MOTT) which is responsible for overseeing an annual advertising and promotions program that stimulates travel to the state, as well as supporting the state's travel business and tourism markets.
- State Office of Minority and Women Business Assistance (SOMWBA) which is dedicated to the development of certified minority, women-owned business ventures and non-profit activities. SOMWBA offers a variety of business assistance and advocacy programs.
- Massachusetts Trade Office (Mass Trade) which assists state businesses with international interests in connecting to global market opportunities to generate new revenues, create jobs, and encourage increased foreign investments in Massachusetts.

The Department of Business and Technology (DBT) provides access to a wide range of business assistance and industry information *to help you gain the competitive advantage you need to help your business not only compete, but succeed in the Commonwealth*[13].

In addition, there exists a wide range of private and public agencies to promote economic development; job creation and retention; and facilitate growth in the business sector[14]. They include the following:

- The Donahue Institute is *the public service, outreach and economic development unit of the University of Massachusetts President's Office*. The institute aims at bridging theory and innovation with real world public and private sector applications through providing contacts

[12] EDA, 2003, and Dick Thornburg, 2002

[13] Department of Economic Development website

[14] Massbedrock Business Information, website

and information about the services, business units and publications that are generated by the Institute.

- The *Doing Business* channel of the *Mass. Gov portal* provides information to help businesses to succeed; to comply with relevant laws and regulations; and to sell the state.
- The Office of Economic Development of the University of Massachusetts works to raise awareness of its resources to regional and community economic development initiatives and Massachusetts firms.

After recommendations from the Governor's Council on Economic Growth and Technology, a consortium of the state's utility and telecommunications companies, real estate associations, and the MOBD, founded the Massachusetts Alliance for Economic Development (MAED). The main purpose of the Alliance was to encourage the expansion and retention of business within the State and to provide property information for expanding and relocating companies. To this end, MAED's *Site Finder Service* was founded to assist companies find appropriate properties. Later, a research and information service and an *ambassadors program* were established to provide support to companies considering Massachusetts as a location for their business.[15]

EDA funded research from 1998 identified four basic rules for economic development in 21st century America that focus strongly on the development and utilization of clusters in economic development, as follows:

- Think regionally to compete globally - Industry does not care about political boundaries;
- Industry clusters drive regional performance;
- Economic input-advantage fuels cluster competition;
- Collaboration achieves economic advantage.

With this background the need for collaboration is underlined. Long-term development strategies and investments in regional assets; education; research; and physical infrastructure have to be agreed upon. With such a strategy in place, the state is in a position to attract private investment and employment, and thus build a *platform for economic growth*. Communities that fail to realise this, and fail to come up with a long-term development strategy will either decline, or they will stagnate.[16]

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2.4. The National Educational and Training System

2.4.1. Institutions responsible for education and training

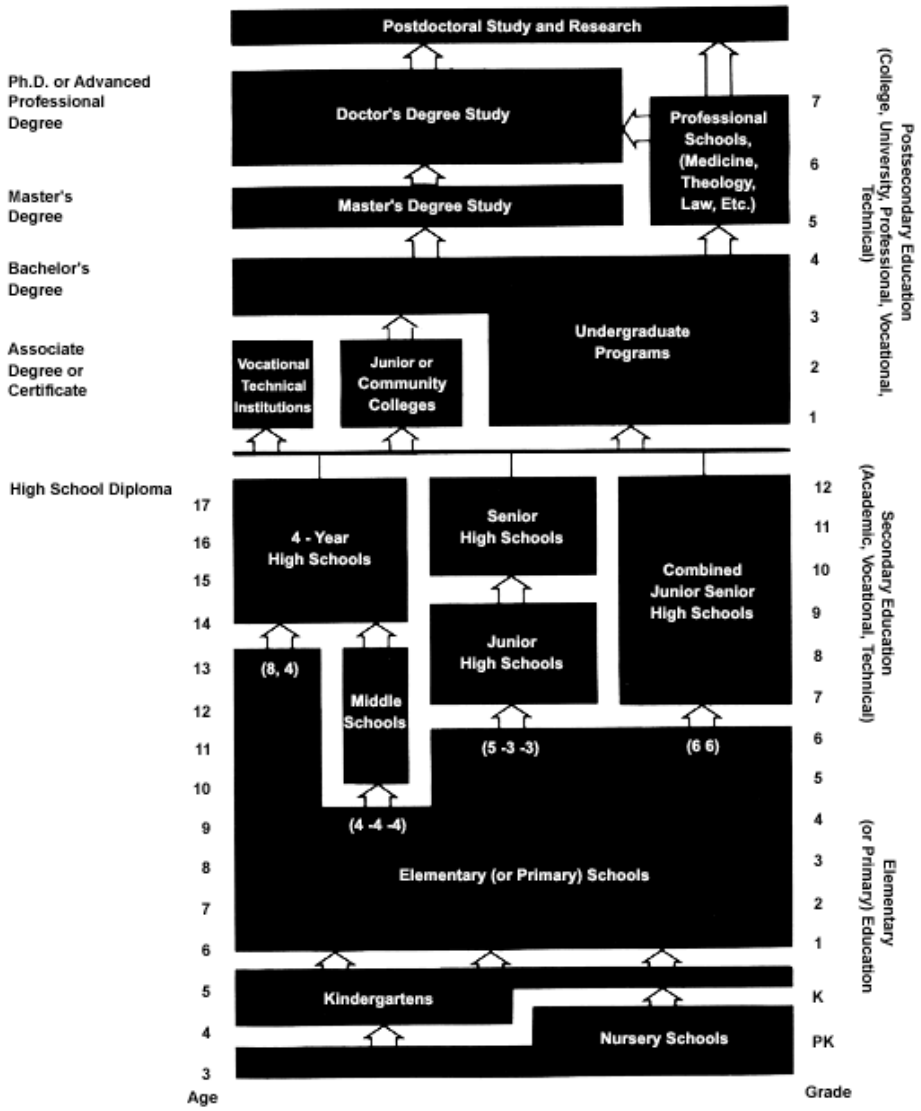
The main institutions, responsible for education and training in the US include the US Department of Education; the universities and community colleges; and a large number of private providers of training and education.

The large number of universities in the United States covers a wide range of private and public universities with varying degrees of specialization and with different levels priority attached to research; education; and external links with other institutions and with industrial sectors. The structure of education is shown in the diagram below.

[15] Massachusetts Alliance for Economic Development

[16] EDA Denver Regional Forum, 2002

Figure 3 The general structure of the American education system



The diagram shows the structure of education in the United States. It presents the three levels of education (elementary; secondary; and post-secondary) and gives the normal age range of young people. Pupils ordinarily spend from six to eight years in the elementary grades, which may be preceded by one or two years in nursery school and kindergarten. A four to six year programme in secondary school follows elementary school. Pupils normally complete the entire programme by the age of 18.

High school graduates who continue their education may enter a technical or vocational institution; a two year college; or a four year college or university. A two year college normally offers the first two years of a standard four year college curriculum and a selection of terminal vocational programmes. Academic courses completed at a two year college are usually transferable for credit at a four year college or university. A technical or vocational institution offers post-secondary technical training leading to a specific career. An associate degree requires at least two years of college level work, and a bachelor's degree is normally completed in four years. At least one year beyond the bachelor's is necessary for a master's degree, while a doctorate usually requires a minimum of three or four beyond the bachelor's degree. Professional schools differ widely in admission requirements and length of programme. Medical students, for example, generally

complete a four year programme of pre-medical studies at a college or university before they enter the further four year programme at a medical school. Law programmes normally require three years of coursework after the completion of a bachelor's degree.

Massachusetts hosts more than 120 accredited colleges and universities, and Boston, in particular, benefits from a high level of activity in the fields of education, innovation and knowledge. The city is unique in having the campuses of eight major research universities within a 15 kilometres of its state capital. The eight research universities with a community of more than 500,000 people constitute the following:

- Boston College
- Boston University
- Brandeis University
- Harvard University
- Massachusetts Institute of Technology
- Northeastern University
- Tufts Universtity
- University of Massachusetts

The universities produce innovations and discoveries and act as engines for growth and development. A recent study concluded that these eight major universities directly and indirectly created jobs for 85,000 people that are largely funded by federal budgets. In addition, the universities create jobs through companies that have been founded by university graduates; through the licensing of innovations; and through the attraction of major companies to locate their operations nearby.

The Bush Administration is committed to reforming education in the United States so that all adults are able to face the contemporary challenges of a high skilled economy. To this end, the Office of Vocational and Adult Education (OVAE) provides information on adult education and literacy; career and technical education; high schools; and community colleges. Community colleges serve over 11 million students in the US annually, offering a wide range of programmes and services, including two year associate degrees; transfer programs with four year institutions; and job training and retraining.

2.4.2. Description of education and qualifications system

A number of national and state organisations have identified *Level 3 proficiency* as a minimum standard for success in today's labour market. Findings from the International Adult Literacy Survey show that only one half of the US adult population aged 16 to 65 have reached this level.

The United States lack a strong national framework for recognising qualifications. Employers generally place a low value on training received from previous employers which may reflect the uncertain quality of the training.

A system of measuring continuing education has been developed by IACET, who created *the Continuing Education Unit* (CEU). One CEU is equal to ten contact hours of participation in an organised continuing education experience under responsible sponsorship, capable direction, and qualified instruction. Under IACET's auspices the CEU has evolved from a quantitative measure to a hallmark of quality training and instruction.

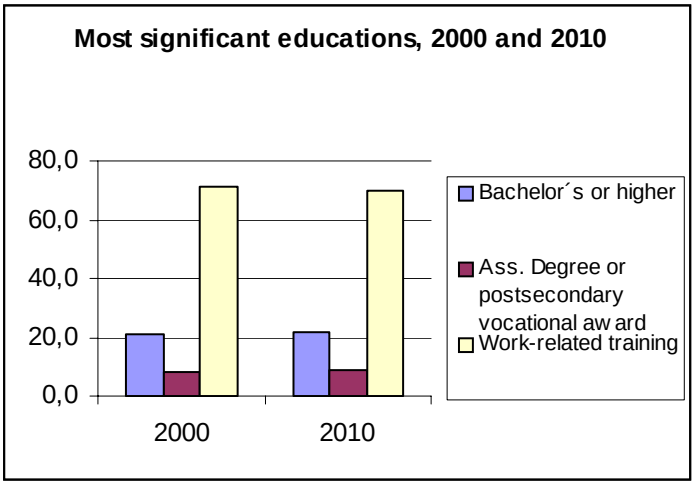
IACET was created as a non-profit association of education and training organisations and individuals to provide a forum for discussion of education standards and an organisational body to promote quality standards and to improve the effectiveness of continuing education, training and human resource development. IACET authorises educational providers to award the CEU. Authorised Providers undergo a strict evaluation of their educational processes according to the IACET Criteria and Guidelines, including two reviews by IACET's Commission and a site visit by an IACET Commissioner.[17]

2.4.3. The provision of initial education and training

Educational attainment has risen in the adult population. By the year 2000, 84 per cent of the population aged 25 years and over had completed high school compared with 78 per cent in 1990; and 26 percent had completed four or more years of college compared with 21 per cent in 1990. By 2000, about six per cent of people aged 25 or older held a master's degree as their highest qualification; more than one percent held a professional degree such as medicine or law and one per cent held a doctorate[18].

But two thirds of America's young people still do not obtain a four year college degree and at least 25 per cent go straight into work directly after high school. Most young people therefore must draw on skills learned outside of four year colleges to succeed in the workforce. A forecast from the bureau of labour statistics shows the importance of the continuation of this work related training up to the year 2010, although these critical education activities are in marginal decline.

Figure 4

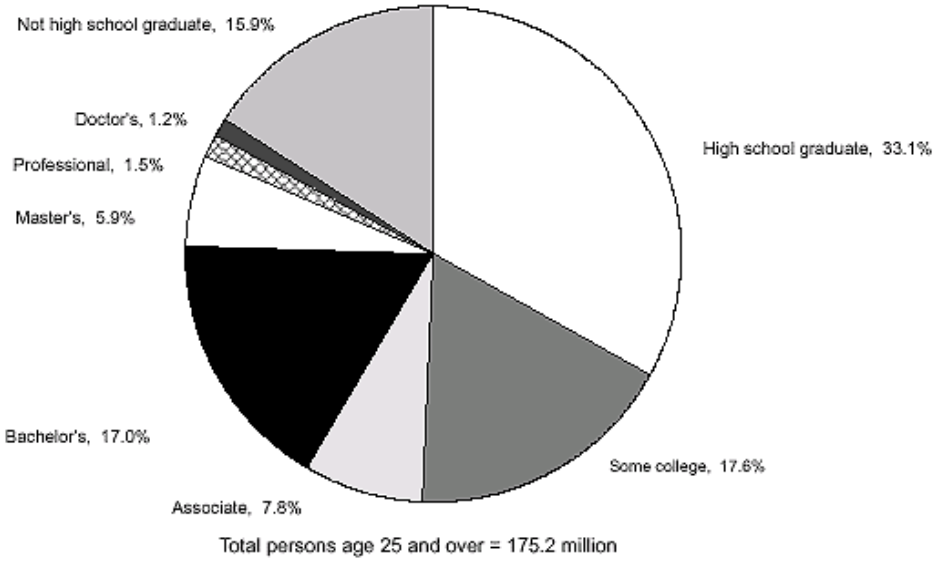


Good career and technical education at secondary schools and community and technical colleges is therefore of crucial importance. The educational level of American citizens aged of 25 and above is shown in Figure 5.

[17] IACET, http://www.iacet.org/awarding/APprocess.htm

[18] Marsha Silverberg, Elizabeth Warner, David Goodwin, Michael Fong, U.S. Department of Education, Office of the Under Secretary: National assessment of vocational education. Interim report to congress, Executive Summary, 2002.

Figure 5 Educational level of American citizens, 2001.



Source: U.S. Department of Commerce, Bureau of the Census, Current Population Survey, unpublished data.

Elementary and secondary schools and colleges and universities spent an estimated 7.1 per cent of the gross domestic product in 2000-01.

Many jobs require technical skills, as well as strong academic skills, that can be learned in secondary and post secondary vocational courses but do not require a bachelor's degree. Therefore, many Americans with bachelor's degrees are also turning to career and technical courses in community colleges.

Vocational education occupies a significant place in American education to help ensure that young people get the skills necessary to succeed in a changing world of work. The mix of skills is constantly evolving. Vocational education is an important part of the high school curriculum. Many students take vocational courses to prepare themselves both for the world of work and further educational programs.

2.4.4. The provision of continuing education and training

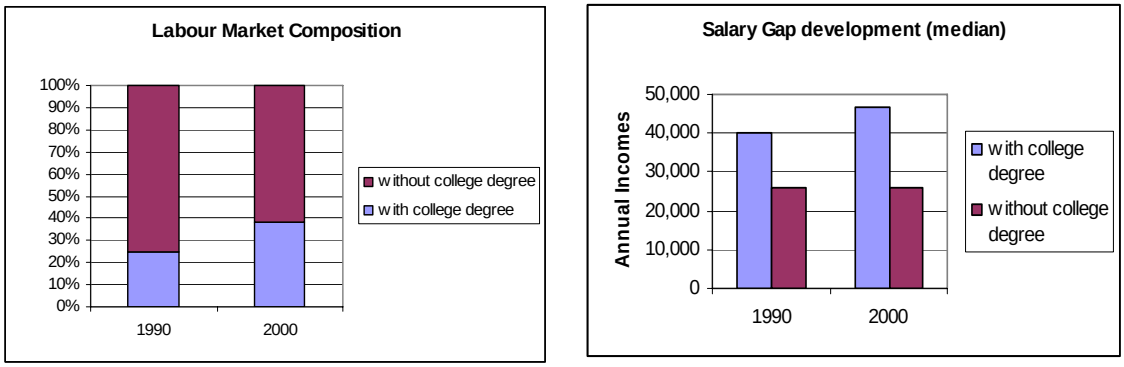
In 1999, 44.5 per cent of adults aged 17 years and older participated in some type of adult education programme: 1.1 per cent participated in a basic education programme; 0.9 per cent in English as a second language programmes; 9.3 per cent in part-time post secondary education; and 22.2 per cent in career or job related courses. In the same year, however, only 14.7 per cent of adults aged 17 and older with eighth grade or less education participated in some type of adult education programme while 25.6 of those educated to between the ninth and twelfth grades (without a diploma) did so; and 34.8 per cent of those with a diploma did so[19]. Thus, it is those who already have the best education who are most likely also to benefit from further adult education.

[19] Digest of Education Statistics, 2001

2.4.5. Industry and education links

According to EDA, American businesses often face a workforce *skills gap* that limits their ability to introduce new technologies. Skills and education are seen as a most important requirement in order to compete in the global economy. Having suitably skilled workers is as crucial to economic growth as the technology itself. EDA is therefore committed to developing closer linkages between workforce development and economic development. A measure of the skills gap is apparent in the trend in levels of earnings for different categories. Over the ten years from 1990 to 2000, the gap between workers with and those without a college degree in Massachsetts increased from 14,100 to 20,500 US$. At the same time the proportion of the labour force with a college degree increased from 25 per cent to 38 per cent[20].

Figure 6 Labour Market Indicators, Massachusetts, 1990 - 2000



Source: Ralph Whitehead, Jr. and Robert J. Lacey, 2002.

According to the bureau of labour statistics those with a college degree will account for 42 per cent of all projected new jobs up to the year 2010, compared with 29 per cent in 2000[21].

Improved adult education based on close co-operation between industry and the education sector, or encouraged by financial support to training activities, might help to reduce the gap between those with and those without college degrees, to the benefit of both employers and employees.

It is the general experience in all parts of the United States that universities support innovation and economic development, but it is less clear under what conditions a university plays this role most effectively. The best examples are apparent in *Silicon* Valley, California, and in the *Route 128* region around Boston, Massachusetts. These are two of the principal concentrations of technological innovation and development, not only in the United States, but also in the world. In both cases the existence of world-class academic institutions have played an essential role in the developments[22].

[20] www.bls.gov

[21] www.bls.gov

[22] Paul Mackun, 1998.

2.4.6. Main strengths and weaknesses of the education and training system

The main strength of the American education and training system lies in the high level world class academic institutions that help to generate innovation. This has been of great importance for economic development in some regions of the United States. The high priority given to vocational training also contributes to the high average quality of the labour force.

A weakness of the system is the relatively low priority that seems to be given to continuing education and training, which tends to reduce both economic growth and social equity. One of the main challenges to the American education system lies in demographic developments that make it increasingly difficult to ensure that the labour force, including large numbers of immigrants have the skills, training and qualifications needed for the jobs available.

2.5. Organisation of Health Care System

2.5.1. Regulation of the health care system

There is no organised public health care system in the United States. The field is covered by *Managed Care*, which is a combination of insurance company functions, health care delivery systems, and health outreach programmes. This has gradually replaced the former *fee for services* system, which was a free market for health services[23].

Health Maintenance Organisations (HMOs) are one form of managed care. For a prepaid monthly premium, members have access to the physicians, clinics and hospitals affiliated with the plan. There are several types of HMO. In a group or staff model HMO, physicians practice in the same medical centre at a central location. A member may choose or be assigned to a primary care physician. In another HMO model, physicians practice under contract to an Individual Practice Association, which is under contract to the HMO. Members choose a primary care physician from the list of those participating in the plan.

Preferred Provider Organisations (PPOs) are a type of health plan that features elements of *fee for service* and *managed care*. The PPO contracts with networks of providers who agree to provide services and be paid negotiated rates. Those enrolled make lower payments or have improved benefits, or both, if they see physicians and hospitals on the preferred list, which is created by insurance companies or employers.

Provider Sponsored Organisations (PSOs) is a managed care plan similar to an HMO, except that it is owned and operated by a network of independent physicians and hospitals rather than by an insurance organisation. A new health care option called *Medicare+Choice* designed to make Medicare managed care plans more widely available was introduced in 1997. *Medicare+Choice* adds such options as *preferred provider organisations* and *provider sponsored organisations*. The law phases in some restrictions on the ability to switch from plan to plan or to return to traditional Medicare *fee for service* coverage.

The independent, not-for-profit National Committee for Quality Assurance (NCQA) conducts accreditation reviews of managed care organisations to help citizens in their choice. The NCQA has performed reviews on about one half of the managed care plans.

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[23] *AARP website and PLS Consult 1996*

The Centres for Medicare and Medicaid Services (CMS) administer Medicare, the nation's largest health insurance programme, which covers nearly 40 million Americans. Medicare is a Health Insurance Programme for people aged 65 and older, some disabled people under 65 years of age, and a few other groups. When reaching the age of 65, people may select among different Medicare models. Most people receive Part A automatically when they reach the age of 65. If they or a spouse have paid Medicare taxes while they were working, they do not have to pay the monthly premium. If not, it is possible to buy the same service from the age of 65.

Medicaid is a programme, jointly funded by federal and state authorities, that provides health insurance to approximately 40.6 million low income women with children and disabled persons, including low income people over 65 years of age. Most of those enrolled are children and their mothers. While the elderly and disabled make up only 10 per cent and 17 per cent, respectively, of the Medicaid population, they consume almost 72 per cent of all Medicaid spending. A large proportion of expenditure goes to nursing homes. Seventeen per cent is spent on children and 11 per cent on parents[24].

Medicaid programmes are administered separately in each state, subject to federal guidelines. Each state Medicaid agency establishes its own eligibility standards and the type, amount, duration, and scope of services; and sets reimbursement rates for services.

2.5.2. Extent of public and private provision

There is no public support to the managed care plans, but support is given to the Medicare and Medicaid programs, that address people aged over 65 and groups of low income persons and families.

The health portion of gross domestic product from 1993 to 2000 was slightly more than 13 per cent. This was forecasted to grow to 14.8 per cent in 2002 and then to 17.7 per cent in 2012. The principal impetus behind the growth in health care spending overall is a continued increase in hospital expenditure that is expected to grow at a rate faster than that of other segments. Spending on prescription drugs, however, is expected to grow even faster at an average annual rate of 11.1 per cent between 2002 and 2012. By 2012, prescription drug spending is expected to account for 14.5 per cent of total health care expenditure, up from 9.9 per cent in 2001[25].

National expenditure on health care is US$1.55 trillion in 2002 but is expected to double to US$3.1 trillion by 2012 (according to a Centres for Medicare and Medicaid Services (CMS) study published on the web site of the journal *Health Affairs*). Expenditure on health care increased at an average annual rate of 6.5 per cent in 1991-2001 and had a growth of 8.6 per cent in 2002. The study forecasts that growth will fall to an average 6.9 per cent from 2009 to 2012, primarily due to a slowdown in Medicare spending. For the period 2002–2012, expenditure on health care is expected to grow by an average of 7.3 per cent..

2.5.3. Main challenges facing the provision of health care

The present system of health care in the United States has been subject to many discussions since its introduction. The central question concerns a possible medicare reform that might bring the United States closer to other developed countries in providing a system of health service that was free at the point of delivery and financed from taxation. The fear is that the costs of the health

[24] Kaiser Commission, 1999.

[25] MedMarkets March, 2003

care system would again start to increase beyond the former peak of 12.2 per cent of Gross Domestic Product.

A second important question concerns the incentives generated by the existing system. It is questioned whether the system actually achieves a high degree of free market cost control and, hence, more cost efficient services. It is suggested that, as a result of the widespread use of the capitation system, the present arrangements encourage health care staff to minimize efforts rather than to increase efficiency.

There is a strong pressure to reduce health care expenditure, especially spending on salaries and wages. The pressure has resulted in an out flow of physicians from Medicare. Medicare law required a reduction of payments to physicians of 4.4 per cent in 2003 after a similar reduction in 2002. But, at the start of the year, Congress authorized CMS to revise the 2003 rates, and payments were instead increased at an average rate of 1.6 per cent. CMS is hoping that this step will slow the loss of physicians and persuade those who remain to continue serving Medicare patients.

3. The Medical Technologies Sector

3.1. Broad description of sector nationally

Worldwide expenditures on medical devices are forecast to surpass the US$150 billion mark in 2003. Some estimates are higher, and the demand for new products and services is continuously increasing, fuelled by the combination of an ageing population, new technologies, refined surgical procedures, and products that make possible faster, less invasive diagnosis and treatment and make it easier to deliver care in the home and other low cost settings. Global demand for medical devices is therefore growing rapidly and US device manufacturers, with their strength in R&D and their advanced technologies, are in a good position to exploit international markets. As the demand for health care products and services continues to grow both in the US and worldwide, the outlook for the medical devices industry remains favourable[26].

The US medical device industry has been a bright spot in an otherwise gloomy economy. It has blossomed into a lucrative international business and is poised for sustained long term growth. The industry's substantial recent growth has taken the spotlight away from the pharmaceutical industry, which is struggling with the implications of the expiry of patents; disappointing debuts; and concerns about liabilities.

The costs involved in the process of innovation in the medical technology sector are high, but in spite of this, the industry is experiencing an increasing demand for new products and services. Spending on R&D as a proportion of sales therefore increased steadily through the 1990s. Currently, the figure is about 13 per cent[27].

The medical device industry, however, faces great difficulties as soon as it seeks to launch a new product. Increased regulation and controls over new products provide great protection to users and patients but inhibit the introduction of new developments. The field therefore is not progressing as quickly as it should. A number of US manufacturers of medical devices are relocating research and development and manufacturing operations overseas. Places like Mexico and Eire are providing alternative, lower cost and less restrictive alternatives. Medtronics, a giant in the field, had all 15 of its major new products or ventures developed, tested, and produced in Europe during the period 1993-1995 and made all of them available to patients overseas long before they were introduced in the United States. Another noticeable change is an increasing use of contract manufacturing facilities in United States. Presently, the ratio of manufacture under to finished device manufacturer is 1:3 and this ratio is decreasing rapidly.

3.2. Performance of sector

Estimates of the worldwide market for medical devices varies from US$150 to 175 billion. The market in the United States alone is about 42 per cent of the total world market. The total number of industries registered with USFDA (16,170, if not more), is equal to the total number of industries in the rest of the world. Nationally, there were 335,800 employees in 1997, or 1.26 per thousand residents. This implies an annual turnover of US$188,000 per employee.

[26] Jain, G.L. 2001, Larta University web site and Jeffrey L. Gren, 2003.

[27] Jain, G.L. 2001.

A Frost and Sullivan team expected steady overall growth in the medical device market. It predicted that the US medical market would grow by 7.7 per cent, to US$59.8 billion in the current year, and, thereafter to climb to US$70.3 billion in 2005.

3.3. Performance of the industry by sub-sector

The largest industry in the American medical device sector is *surgical and medical instruments* which accounts for 31 per cent of employment in the sector. The next largest, with 16 per cent of employment, is *electromedical and electrotherapeutic apparatuses*. Other product groups including *irradiation apparatuses*, *ophthalmic goods*, *in vitro diagnostic substances*, and *laboratory apparatuses and furniture* account for the remaining 53 per cent.

Important new product launches were expected in 2003 with the *cardiology area* being most promising. A large number of devices were approaching commercialisation in areas such as *orthopedics*, *plastic surgery*, and *urology,* among others. Also, *polymer development* and *medical plastics* are expected to show high growth rates over the coming years.

- A report titled *Plastics for Medical Devices from Business Communications Co. (BCC)* predicted *styrenics, engineering resins*, and *thermosets* would grow by six per cent to 6.5 per cent annually in the US during 2004.
- The US market for disposable medical supplies, then at US$48.6 billion, was expected to grow by six per cent annually up to and during the year 2005, according to research from the *Freedonia Group*.

Rapid growth was also expected for *pre-filled inhalers* and *pre-filled syringes*; *trans-dermal patches*; and *hematology, nucleic*, and *immunochemistry diagnostics*.

Home health care is likely to be the fastest growing market as consumers broaden self-treatment and preventative medicine activities.

Among other main development trends in the medical devices sector, the following are in highlighted in the American medical device sector publications:

- Medical devices are becoming lighter, more portable and user-friendy, with improved functionality, thereby having performance advantages over much larger and more expensive equipment.

- The use of plastics in medical applications is expected to continue its steady growth as new polymers edge out metals, ceramics, and other traditional materials. Innovative materials are replacing the conventional ones such as PVC.

3.4. Intellectual Property Generation

Universities attribute a rapid growth in the licensing of sponsored research to the Bayh-Dole Act, passed in the 1980s. The legislation made it possible for universities to own the intellectual property created by faculty and research personnel. Other countries are beginning to follow this model, an indication of the policy's success in increasing the volume of university sponsored research

The University of Massachusetts receives approximately US$ 200 million in research money each year. More than half of this goes to the Umass Medical Centre. License revenues to the

university's Office of Commercial Ventures and Intellectual Property amounted to US$ 4 - 5 million in 2000, and increased at annual rates of more than ten per cent since the office was started in 1995. About 75 per cent of the revenues are related to the medical field, and more than ten per cent directly concerns medical devices.

Massachusetts General Hospital carries out research to the value of about US$ 250 million annually, and a substantial proportion relates to medical device research in *lasers*, *imaging devices* and *other radiology applications*. Licensing related to medical device generates income of about US$ 2 million each year.

3.5. Linkages to other Industries

The medical device industry has clear links to a number of other key industries; in particular the other parts of the medical technologies sector, namely the biotechnological and the pharmaceutical industries. Large parts of the products in these three groups are related and in some instances integrated in their use by hospitals or patients.

In addition, a number of key industries, well represented in American manufacturing industry, act as main suppliers to the medical industry. This is, in particular, the case for the polymer industry which has an increasingly central role in the supply of material to the industry. But suppliers of electronics and metal parts are also important for the industry. Finally, a number of medical device firms supply parts and products to other firms in the industry which creates internal linkages between companies within the medical device sector.

3.6. Final consumer of products and services

In the medical device sector, a company which develops a new concept or product has to think long and hard before it launches the innovation commercially. After a long development phase, the device may or may not get the approval of the regulatory agency and. even if it gets approval, it may be too late to make it commercially viable. In other fields, like computers, where the customer is the regulator and not the regulatory agencies, the rate of innovation tends to be much faster.

Managed health care is transforming the market place for medical technology. The focus in the market place is on cost effectiveness and demonstrable patient outcomes. This makes it increasingly complicated to market a piece of new technology once it has been approved. In addition, the market for medical technology is becoming increasingly global as barriers to international trade continue to fall.

The increase in managed care will have a substantial impact on the industry. HMOs, PPOs, large hospital consortiums, and government agencies account for over 60 per cent of all purchases of medical devices. The rate is expected to increase to between 80 and 90 per cent by 2005. Managed care may also reduce the industry's income and profits through increased bulk purchasing; therapeutic substitution for treatment (using treatment methods in which devices are not used); and strict screening of incoming patients, which often results in services that do not require the use of devices[28].

[28] Larta University web site

3.7. Ownership and key players in industry

The ownership of the American medical device industry is similar to that of other modern industrial enterprises. A number of major enterprises in the industry are large international companies with subsidiaries in various countries and states. Many are owned by institutional investors and a large number of new enterprises are still owned by the innovator. Such enterprises typically have a relatively short life time. They either do not survive or are bought by large international corporations, able to provide the large investments on a scale and at a rate required to exploit opportunities in a rapidly developing market.

3.8. Characteristics of employment

The occupational distribution of medical device workers in the United States is compared with that of manufacturing industry and total employment in Table 1.

Table 1 Occupational levels in medical device compared with other industries (percentages)

Occupation categories	Medical device	Manufacturing industry	All jobs
Machine operators, assemblers, inspectors, transport	42.6	49.9	-
Executive, administrative, managerial, professional experts and technical	37.6	25.6	27.5
Sales	5.3	3.9	14.3
Clerical jobs	10.8	10.0	13.1
Service and others	3.7	10.6	-

Sources: Allan Clayton Matthews, 2001

The medical device industry employs a smaller proportion of its workers in the first category (in machine operation; assembly; inspection; and transport) while a higher proportion is employed in executive, administrative, managerial, professional specialities and technical occupations. This indicates a concentration of employment in occupations requiring higher levels of education.

The proportion of medical device workers engaged in sales occupations is slightly higher than in the rest of manufacturing; 5.3 per cent compared with 3.9 per cent. This difference reflects the more intense marketing effort required in comparison with other manufacturing industries, because medical device products need to be marketed to individual physicians. Sales jobs make up a total of 14.3 per cent of all jobs, but this also includes the retail sector. The proportion of staff in clerical occupations is about the same as in manufacturing overall but less than in the overall economy. Not surprisingly, the medical device industry, like manufacturing generally, employs few workers classified in service occupations.

3.9. Skill profile of employment

A relatively high educational level characterises the staff of medical device industry in the United States. This is the case for medical devices, biotechnological and pharmaceutical enterprises

where the proportion of staff with higher education is higher than in other manufacturing enterprises as well as among the entire labour force.

Figures for the state of Massachusetts, in particular, are provided in chapter 4.

3.10. Extent of unmet skill needs

Shortage of skilled labour is a general problem in IT, biotechnological, medical device and other emerging, knowledge based, technology industries. Well educated immigrants are therefore in demand among the universities and companies in the sector.

3.11. The future of employment in the industry

Employment in medical devices sector is expected to continue its high growth for some years. In particular, both the home market and the European markets are growing and, in the longer term, the products will also be demanded on a large scale by the health sectors in other parts of the world.

4. Localities In Which the Sector Is Concentrated

4.1. Overall Macroeconomic Performance In Massachusetts

The economy of the State of Massachusetts has largely followed developments at the national level. The economy presently seems to be trapped in recession. Nearly all of the indicators for the Massachusetts economy show downward trends. The state's economy is even weaker than that of the nation as a whole. The level of recovery in the US economy is slight and there remains a risk of continued and growing recession. The Massachusetts Leading Economic Index was predicting that gross state product would continue to contract at an annual rate of one per cent over the first half of 2003. The war in Iraq, impending state and municipal lay-offs, and the prospect of continued negative trends in the stocks market were weighing the economy down[29].

Population growth in Massachusetts is low. With a population of 6.35 million, the state experienced an average annual population growth rate of 0.5 per cent from 1990 to 2000, while the nation grew at 1.2 per cent in 2000. According to Bureau of Labour Statistics, Massachusetts had an unemployment rate of 2.6 per cent in 2000, while the US unemployment rate was 4.0 per cent. However, from 2001 the unemployment rate has been rising for both Massachusetts and the US. In October 2001, the Massachusetts unemployment rate had jumped to 4.2 per cent and the U.S. rate had increased to 5.4 per cent. In 2002, rates of unemployment rates increased still further[30].

4.1.1. Employment growth, skill levels

Since 1993, medical device employment in Massachusetts has experienced an upward trend, especially after 1996. In 1993 and 1994, there were about 16,000 jobs in the medical device industry. In 1997, employment rose sharply to around 17,000. The strength of the industry is especially marked when compared with overall trends in Massachusetts manufacturing employment. While employment in manufacturing industry has fallen since June 1999, the fall in medical device employment was less severe. The latest estimates of employment in medical devices are close to 23,000 in Massachusetts.

The proportion of medical device workers who have college educations is substantially higher than that for other manufacturing workers and for all other workers. The proportion of staff in medical devices with a professional or higher degree is almost double that in the work force generally (see Table 2).

Table 2 Labour Force Educational level, Massachusetts 1997 (Percentages)

	Medical device industry	All employment
College education	57.1	50.7
Associate's degrees	9.2	7.8
Bachelor degrees	18.4	15.8
Prof. or graduate degrees	12.0	6.3

Source: A. Clayton-Matthews, 2001

Medical device workers are more highly skilled, better educated, and better paid than workers in manufacturing as a whole, and in the economy overall.

[29] A. Clayton-Matthews, 2003

[30] Mitchell Adams, 2001

Low population growth looks likely to create the danger of a tight labour market in Massachusetts. This could limit economic growth in the state, put pressure on wages, and may make the state less competitive[31].

4.1.2. Institutions responsible for regional and local development of industry

There is a wide variety of institutions working for economic development through information services, networking and linking university resources with private business in Massachusetts. The state of Massachusetts itself plays an important role in offering tax credits for enterprises that establish new facilities, and in administering funds for enterprises expanding in the fields of emerging technologies. Finally the state offers grants of up to 50 per cent for major programmes of continuing education and training at enterprises in Massachusetts.

According to the Massachusetts Industries of the Future web site[32], the key industries in Massachusetts are the following:

- Metal Processing Industry
- Chemicals and Plastics
- Information Technology and Electronics
- Printing and Publishing Industries

In addition the industrial sectors that are categorised as the *life science sector* or the medical technologies sector, including the medical device industry, are seen as a spearhead for development in the state.

In the following paragraphs the key industries and the resource organisations that provide relevant assistance to existing or potential business owners planning to start, relocate, or grow their enterprise are briefly described.

Metal Processing Industry
The primary metals industries include Metal Casting, which manufacture products using sand and die casting techniques. These industries employ over 2500 workers and generate more than 300 million dollars in gross sales. The MAIOF Metal Processing Initiative also includes related industries to Metal Casting including metal forging, powder metallurgy, finishers, platers, heat treaters and fabricators. These ancillary industries raise the labour and gross revenues of the whole sector by a factor of five. The main challenges of the industry include: products and market, materials technology, manufacturing technology and environmental technologies.

The Office of Industrial Technologies utilised nearly six million dollars in the sector, in the year 2000 to fund technology partnerships, educational programs, showcases, and technology outreach and technology transfer.

Chemicals and Plastics
The Chemical and Plastics Industries in Massachusetts can be identified as chemical input manufacturers and chemical products manufacturers. The former provides the latter with raw materials for production. Chemical and Plastics inputs include: industrial inorganic chemicals; plastics and resins; organic chemicals; agricultural chemicals; and miscellaneous plastics.

[31] Massachusetts Technology Collaborative website

[32] : Industry of the Future, http://www.maiof.org/mainpage.htm

Chemical product industries manufacture: pharmaceuticals; cleaners; paints; varnishes; lacquers; enamels; and solvents. Plastic products include: plastic films; plastic sheets; plastic profiles; plastic bottles; and foam. These industries employ over 36,000 workers and generate more than 3,5 billion dollars in gross sales. Employee compensation from the Chemicals and Plastics Industries is more than 2 billion dollars. The Chemical and Plastics industries make direct purchases from the National IF industries at a rate of roughly one quarter their gross output.

The industry National Roadmap identified the following key areas for investment.

- New chemical science and engineering technology
- Supply chain management
- Information systems
- Manufacturing and operations.

The Office of Industrial Technologies invests nearly 12 million dollars in the sector each year to fund technology partnerships; educational programs; showcases; and technology outreach and technology transfer.

Information Technology and Electronics

The Information Technology and Electronics Industry includes important manufacturing in electronic computers; semi-conductors and related devices; and electronic components. These industries generate more than 7,9 billion dollars in value added product and represent as much as five per cent of the US market. There are 72,000 workers employed in these industries with employee compensation totalling 4,8 billion dollars.

Printing and Publishing Industries

The Printing and Publishing Industries include periodicals; newspapers; commercial priorities; book publishing; and miscellaneous publishing. These industries employ over 54,000 workers in the Commonwealth and generate more than 3,3 billion dollars in gross sales. Although Printing and Publishing is not a National IOF, this manufacturing base is important in the region. The particular needs of the industry follow a combination of needs identified by the chemicals and paper industry.

Medical devices and biotechnology

Three organisations are active in promoting the biotechnology and medical device industry in Massachusetts. These non-profit organisations promote the interests and provide services for specific sectors of industry. They are the Medical Device Industry Council (*MassMEDIC)* with more than 225 manufacturers; The Massachusetts Biotechnology Council (MBC), representing over 400 companies and institutions, and Massachusetts Biomedical Initiatives (MBI).

- The Massachusetts Biotechnology Council (MBC), founded in 1985, and representing over 400 companies, academic institutions and service organizations, is a not for profit organisation that provides services and support for the Massachusetts biotechnology industry. The MBC aims at advancing the development of critical new science, technology and medicines and is involved in biotechnology and health care. The MBC provides member services and works with public leaders to influence policy and promote education.
- The Massachusetts Medical Device Industry Council, (MassMEDIC) is a membership organisation which aims to create a positive environment and united voice for the Massachusetts Medical Device Industry. Its purpose is further to promote the growth of the

medical device industry in Massachusetts and make Massachusetts the international centre for medical device research, development and manufacturing. The objectives are pursued by supporting collaborative initiatives among industry partners; world-class research institutions; and the 14 academic health centres located in the state. MassMedic also provides services and undertakes awareness and collaboration programs and initiatives for individual member companies and for the industry as a whole. MassMEDIC receives limited amounts of public, state funds as payment for development programmes undertaken in the field of business networking.

- MBI is an independent, tax-exempt corporation created to support the growth and expansion of biotechnology and medical device companies throughout the region, enhancing the status of Massachusetts as a world leader in the medical industry[33].

4.2. The Massachusetts Medical Technology Sector Performance

4.2.1. Sector Size and Composition

According to the U.S. Department of Commerce data, the Boston area has nearly 600 medical technology enterprises with annual sales of more than US$8.3 billion. These employ more than 35,000 people and contribute an increasingly important share of the regional economy, particularly as a source of high wage jobs. These figures, however, are based on a broad definition of medical technologies which includes medical devices; pharmaceuticals; and biotechnology. In 1997 the medical technologies sector in Massachesetts had the composition shown in Table 3.

[33] Massachusetts Biomedical initiatives - http://www.massbiomed.org/about/

Table 3 Overall structure of the medical technologies sector

	Manufacturing establishments	Employees	Payroll (million US$)	Annual shipments (bill. US$)
Medical devices	264	20,756	989	4.0
Pharmaceuticals	57	5,612	270	1.8
Biotechnology	282	9,311	589	1.5
Total med-tech	603	35,679	1,848	7.3

Source: A. Clayton-Matthews, 2001

Salary levels in the medical device industry are high compared with other industries, but they are the lowest among the broad medical technologies industry groups.

Table 4 Characteristics of the medical technologies industrial groups

	Average number of employees	Average salary (1000 US$)	Annual shipments per employee (1000 US$)
Medical devices	78.6	47.6	192.7
Pharmaceuticals	98.5	48.1	320.7
Biotechnology	33.0	63.3	161.1

The medical device industry is defined by Alan Clayton-Matthews as comprising the following industries, shown in Table 5.

Table 5 Medical Device in Massachusetts, Employment by industrial sector (percentages)

	Employment shares
Surgical and medical instruments	37
Electro medical and electrotherapeutic apparatuses	23
Surgical appliances and supplies	11
Irradiation apparatuses	9
Ophthalmic goods	9
In-vitro diagnostics substances	7
Laboratory apparatuses and furniture	4

Source: 1997 Economic Census and A. Clayton-Matthews, 2001.

Adopting these definitions there were, according to the 1997 Economic Census, 264 manufacturing establishments in the Massachusetts' medical device industry. The companies employed 20,756 workers, or 3.39 of every thousand residents. Nationally, there were 335,800 employees, or 1.26 of every thousand residents. The industry was thus 2.7 times as concentrated in Massachusetts as in the nation overall. The value of shipments from the state's manufacturing facilities totalled US$ 4.0 billion, with a payroll in 1997 of US$ 1.0 billion.

Boston has been considered a national leader in medical technology development for many years. That leadership is expected to continue, as a result of the region's critical mass of existing medical technology companies and growing pool of qualified staff supplied by world-class academic institutions. Continuing levels of investment and provision of technological resources reinforce the trend. The medical device industry is an important part of the overall sector, of which it represents about 48 per cent of total employment[34].

Production in Massachusetts is concentrated in surgical and medical instruments, and electromedical and electrotherapeutic instruments which account, respectively, for 37 per cent and 23 per cent of medical device employment. By contrast, in the national economy generally, these two industries comprise 31 per cent and 16 per cent of employment in medical devices. The relative concentration of the two industries in Massachusetts reflects the state's comparative specialization in precision specialty production and electronics

Aggregate sales are dominated by a handful of large companies. In a Compustat list of largest medical device companies in Massachusetts in 2002, sales ranged from US$2.9 billion for Boston Scientific Corp., the largest company, to US$ 105 million for number eight, Lifeline Systems and 39.8 million for Aspect Medical Systems, the company ranked tenth in terms of sales.

Table 6 Companies ranked by revenue.

Rank	Company	2002 revenue (millions)	Per cent change from 2001
1	Boston Scientific Corp.	2,919.0	9.2
2	Haemonetics Corp.	335.1	5.6
3	PolyMedica Corp.	334.6	26.9
4	Cytyc Corp.	236.5	7.0
5	Inverness Medical Innovations	207.9	339.8
6	Hologic	191.6	4.8
7	Zoll Medical Corp.	160.0	29.1
8	Lifeline Systems	105.0	8.7
9	Candela Corp.	69.4	12.8
10	Aspect Medical Systems	39.8	11.0

Data: Compustat, 2003

In 1998, there were just over two dozen publicly held medical companies with head quarters in Massachusetts and they accounted for US$3.2 billion in sales. Although the large majority of companies are privately held and relatively small (about half of the manufacturing establishments employed fewer than 20 employees), they are considered of critically importance to the vitality and technological progress of the industry.

According to a Price Waterhouse Coopers' survey in 2000, venture capital funding received by medical device firms in Massachusetts totaled US$314 million over the four quarters ending in the third quarter of 2000. This investment was roughly equal to the total research and development spending of the 26 Massachusetts based, publicly held medical device companies in 1997 and was nearly twice the amount spent in 1997 on capital expenditures for all medical device manufacturing establishments in the state[35].

[34] Hot Spots, Medical Devicelink

[35] A. Clayton-Matthews, 2001, and 1997 Economic Census

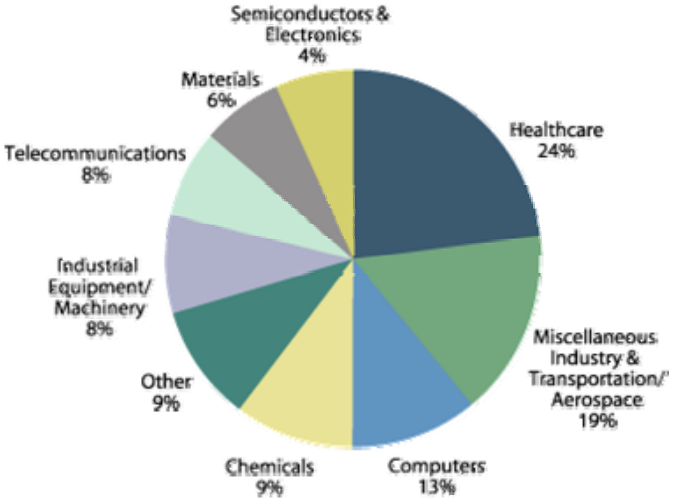
4.2.2. Patenting

The number of patents per capita issued in Massachusetts is relatively high but, recently, the rate of growth as slowed compared with that of similar state economies throughout the United States. These states are referred to as the Leading Technology States (LTS) and in addition to Massachusetts, they include California; Colorado; Connecticut; Minnesota; New Jersey; and New York.

Over the period 1996 to 2000, the absolute number of patents in Massachusetts increased by 41.6 per cent from 2,713 to 3,841. But that represented one of the smallest increases in the LTS group, although most of the group experienced a slow down in the level of patent activity over the previous year. Massachusetts, Connecticut, and Minnesota all had 61 patents per 100,000 people.

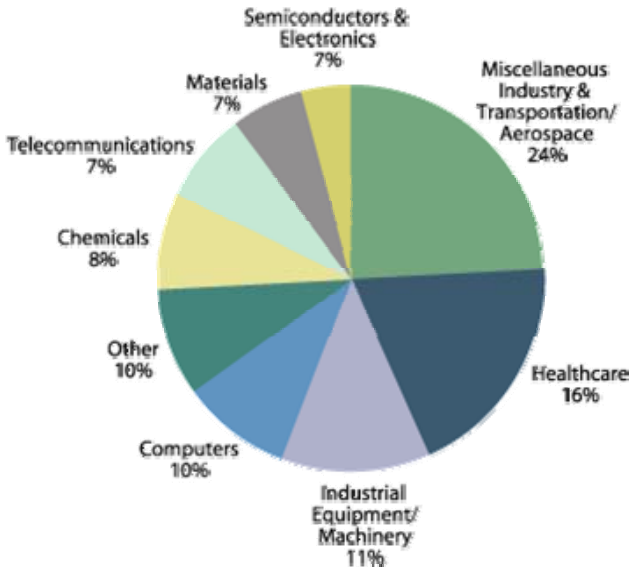
Health care was the most active area for patenting in Massachusetts and accounted for 24 per cent of all patents (see Figure 7) compared with 16 per cent between 1991 and 1995 (see Figure 8). About one half of the patents in the sector related to medical devices. *Miscellaneous Industry & Transportation/Aerospace* was the second most active in the 1996-2000 period and accounted for 19 per cent of all patents, followed by Computers (13 per cent), and Chemicals (nine per cent).

Figure 7: Distribution of patents issued, Massachusetts, 1996-2000



Source: Massachusetts Technology Collaborative:

Figure 8: Distribution of patents issued, Massachusetts, 1991-1995



Source: Massachusetts Technology Collaborative

4.3. Main characteristics of employment in medical technology sector

4.3.1. Employment in medical device

According to the economic survey of 1997, the number of people employed in the Massachusetts medical devices industry was 17,500; and in 2001 the Massachusetts Technology Collaborative estimated the total employment in medical devices in Boston at almost 23,000. This figure is compared with other top ranking *Life Sciences Regions* Table 7.

Table 7 Employment in Medical Devices according to region, 2001

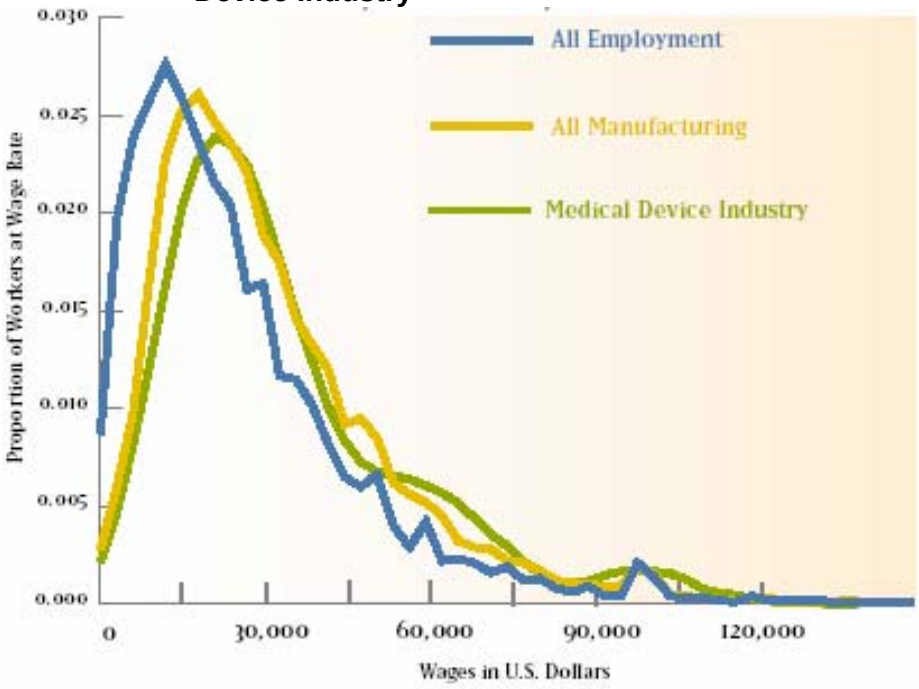
Region	Number of employees
Boston, MA	22738
Los Angeles, Riverside Orange County	28752
New York, Northern New Jerey, Long Island, NY, NJ, CT, PA	24577
Raleigh, Durham, Chapel Hill, NC	427
San Diego, CA	7428
San Fransisco, Oakland, San Jose, CA	26344

Source: Mitchell Adams, 2001/Massachusetts Technology Collaborative

4.3.2. Wages, Salaries, and Benefits

Wages and salaries in the medical devices industry are higher than in both the economy as a whole and in manufacturing as a whole. Median annual wages of medical devices workers were US$ 30,000 during 1994–1998, according to the Census of Population Surveys, compared with US$ 28,000 in manufacturing and US$ 21,243 for all workers.

Figure 9 US Annual Wage Distribution for All Employment, Manufacturing and Medical Device Industry



Sources: A. Clayton-Matthews, 2001, and US Bureau of the Census

Even though manufacturing workers on the whole have a lower level of educational attainment than workers in the economy as a whole, they are generally paid better. For medical device workers educated to college level, the premium is even greater (see Table 8).

Table 8 Average Annual Salary, 1994–1998

	Medical device industry	All manufacturing	All employment
Associate's degrees	US$41,145	US$36,916	US$30,470
Bachelor's degrees	US$66,292	US$54,012	US$44,307
Prof. or graduate degrees	US$85,101	US$77,477	US$70,704

Source: A. Clayton-Matthews, 2001

In addition, many medical device workers are among the high salary earners. Five per cent earned more than US$100,000 per year in the 1994–1998 period.

Medical devices employers also provided better benefits than employers in manufacturing as a whole. In the 1994–1998 period, 75 per cent of medical device workers had health insurance provided by their employers or unions, compared with 71.3 per cent of all workers in manufacturing and 50.1 per cent of all workers, generally. Pension and retirement benefits were also more

common in medical device firms, with 62.8 percent of employees participating in employer or union plans compared with 57.3 percent of all manufacturing employees and 36.7 percent of all employees

The median age of medical devices workers was 39, and one half of workers were aged between 32 and 48. This median is the same as in manufacturing as a whole and is slightly older than for all workers, where the median age is 37, and where one half of all workers are between 27 and 47 years of age.

The gender distribution in medical devices is more equal than in the rest of manufacturing and is much like that of overall employment. In medical devices, 46.5 per cent of workers were women, compared with 33.0 per cent in all manufacturing and 45.5 per cent for all workers.

4.3.3. Value added and productivity

Value added per production worker is higher in the medical device industry in Massachusetts (US$129 per worker hour) than in the United States as a whole (US$115 per worker hour). This partly reflects a relative concentration in higher productivity industries such as electromedical and electrotherapeutic apparatuses with a value added of US$178 per worker hour.

The state's workers are more productive that the US average in four of the sector's seven industries, and are less productive in the other three.

The four industries where they are more productive account for three-quarters of employment and are as follows:

- Electromedical and electrotherapeutic apparatuses
- Laboratory apparatuses and furniture
- Surgical and medical instruments
- Surgical appliances and supplies

The three industries where they are less productive account for less than one quarter of employment in the sector and are as follows::

- vitro diagnostics substances,
- irradiation apparatuses, and
- ophthalmic goods

The differences in productivity between Massachusetts and the nation as a whole may reflect a different mix of products within each of the seven industries as well as different production technologies. Whatever the reason, higher productivity in Massachusetts is a common theme across all manufacturing. The state has a general comparative advantage in producing products that require higher skills or more intensive use of engineering, and the area of medical devices is no exception

Capital expenditure per worker is also higher in Massachusetts relative to the United States as a whole in those medical device industries that have higher value added. Less intense use of production workers is probably associated with a more intense use of scientists and engineers (including computer related engineers)[36].

[36] A. Clayton-Matthews, 2001

4.4. Main influences on the development of the industry

Given the concentration in higher education; teaching hospitals; precision production; and electronics, and the fact that research, development, and improvements in technology are supported in large part by the state's hospitals and by suppliers of venture capital, it is not surprising that Massachusetts ranks high in volumes of production of medical devices[37].

Silicon Valley, California, and *Route 128*, the 100 kilometer highway around Boston and Cambridge in Massachusetts, are two of the principal concentrations of new technology, not only in the United States, but also in the world. These are regions that since the second World War have been devoted to the creation of new information technology. Both regions have developed on the basis of active collaboration between high level research universities; companies that intensively make use of the knowledge developed at the universities; and a public sector which both provided active support to the development of the university resources and expertise and also fuelled the development through large scale and demanding military and airspace programmes[38].

The cluster faces many challenges and the manner in which the public and private sectors handle these challenges will determine the cluster's future economic growth. In order to remain competitive with other states, Massachusetts must continuously ensure the existence of an environment that supports research and entrepreneurship so the region can continue to pioneer biological, medical, and scientific innovations to the benefit of the region, the nation and the world[39].

4.5. Linkages to other industries locally, nationally, internationally

The medical device industry is part of the so called medical technologies sector or medical science sector, which is composed of the three main industry groups: medical devices; pharmaceuticals and biotechnology. These three groups are interrelated in many ways and the existence of all parts of the medical technolgies sector, like the co-existence with research universities and teaching hospitals, doubtless creates strong synergies between different organisations in the region. Important linkages also exist between medical device manufacturers and manufacturers of electronics; producers of precision metal components; and plastics manufacturers that are all important sectors of manufacturing industry in Massachusetts.

4.5.1. Demand linkages

Local demand is important for the medical devices sector. In 1998, 48 per cent of total sales in the market in Massachusetts was purchased by local customers. A. Clayton-Matthews has established the relationship between medical expenditure in Massachusetts and the demand for medical devices. The main results are given in the following Table 9.

[37] A. Clayton-Matthews, 2001

[38] Paul Mackun, 1998

[39] Mitchell Adams, 2003

Table 9 Purchases of Medical Device for every US$ 100 of services

Health sectors	Purchases per US$100 of services
Hospitals,	US$ 2.81
Health practitioners purchase	US$ 2.51
Nursing and personal care facilities,	US$ 1.11
Ophthalmic goods producers,;	US$ 1.92
Health services not elsewhere classified,.	US$ 4.61
Other sectors	Small purchasers

Source: A. Clayton-Matthews, 2001

4.5.2. Supply linkages

According to analyses undertaken by A. Clayton-Matthews, US$100 of medical device output in Massachusetts requires the purchases shown in Table 10., both from within and outside the state.

Table 10 Demand Generated by a US$100 Purchase of Medical Devices in Massachusetts

Industrial sector	Total supplies	Out-of-state supplies	Massachusetts supplies
All purchases	US$ 45.08	US$ 23.20	US$ 21.88
Electronic components and accessories	US$ 8.89	US$ 6.63	US$ 2.4
Other medical device firms	US$ 4.78	US$ 4.35	US$ 0.43

Source: A. Clayton-Matthews, 2001.

In addition a one dollar purchase of medical device generates the demand for 21 cents labour costs and overheads of 34.2 cents. The economic effects of the medical device industry go beyond the initial purchases of the industry itself through the multiplier effect. The economic impact multiplier is the ratio of initial, direct, and induced effects to the initial purchases. The output and employment multipliers for medical devices in Massachusetts are 1.45 and 1.79, respectively, which means that one dollar of additional purchases will generate a total of US$ 1.45 demand in the state and that 100 jobs generated in the medical device sector will generate another 79 jobs in other sectors of the Massachusetts economy. As the multipliers are calculated as average relations in an existing situation, they may not be fully valid as forecast multipliers in relation to marginal changes in demand. The marginal multiplication effect tends to be lower because of the limited capacity of the economy in the short term. But applying these multipliers to the 1997 value of shipments of US$ 4.0 billion and employment of 20,756 from the 1997 Economic Census, the total effect of the medical device industry on the state's 1997 economy was approximately US$ 5.8 billion and 37,000 jobs.'[40].

[40] A. Clayton-Matthews, 2001

4.6. Importance of local skills supply in the development of the industry

Like other parts of the United States, Massachusetts expects to suffer from a shortage of skilled labour in the near future. The increasing demand for highly qualified and skilled people combined with the low rate of population growth and the ageing population will all contribute to this development.

There are two main ways in which the state can reduce the problem. The first is to attract more skilled people into the state; and the second upgrade the existing labour force through further education and training. In Massachusetts, both solutions are being are pursued. A relatively high inflow of immigrants consists of 60 per cent highly educated people who are attracted by the world famous universities, and 40 per cent of unskilled people. At the same time, efforts are being made to educate the existing labour force. The state of Massachusetts offers financial support to those enterprises that undertake major training schemes among their staff. Short-term training that does not provide academic credits is eligible for support. The training courses may have durations of up to one year.

Teaching hospitals and research universities play an important role in the growth of the medical device sector. More research is done in these institutions than in private industry, often resulting in the licensing of technology to medical device firms and occasionally in the formation of start-up companies or joint ventures with existing companies. Massachusetts's hospitals and universities enter license agreements and form ventures with companies around the world. About 30 to 40 percent of the deals are made with partners within the state[41].

There is therefore no doubt that the supply of university level skills together with networking among university researchers, health sector specialists and private enterprise research and executive staff is of the utmost importance for the development of the medical device industry in a region like the Greater Boston area. The relatively large share of the population who have a college education further helps industries like the medical technology industries to get the educated staff they need.

4.7. Skills supply as a barrier to growth

With low population growth and a low unemployment rate combined with an ageing population, which creates a tight labour market for Massachusetts, the supply of staff at all levels is bound to remain a main challenge. This could inhibit economic growth in the state, put pressure on wages, and make the state less competitive.

Stagnation in other sectors and, in the case of Massachusetts, the attractions of existing industry and the world-class universities have until now helped mitigate the problems.

A further obstacle to an increased immigration of educated staff is the level of real estate prices in Massachusetts. The relatively high price of private houses makes the state less competitive than many others.

[41] Mitchell Adams, 2001

5. Conclusion

5.1. Identification of the main needs for the development of the industry

In order to foster continued growth in medical devices and to keep Massachusetts in the forefront of the industry, state public policy needs to focus on[42]:

- Providing high quality public education,
- Take steps to reduce the high cost of living in Massachusetts,
- Promote Massachusetts as a place to do business, and
- Develop strong linkages with the industry

In addition, a continuous and increased effort to promote training and further education would reduce the danger of a future, major skills gap.

5.2. Importance of inter-industry linkages

The inter industry links, like the linkages between the industry and universities have played an important part in the historical development of the industry and will be critical to the future development of the medical devices industry. Experience from regional competence clusters show that such agglomerations create synergies which generate higher levels of innovation; improved competitiveness; increased sales and exports; and, thereby, rising profits and growth.

5.3. Major obstacles to the future development of the industry

There is no reason why the medical devices sector should not continue to grow in Massachusetts. So long as a high level of innovation is maintained and competitiveness remains high as the industry keeps pace with the growth of the market, then the development of the sector is likely to continue.

The main possible obstacles to the future development of the industry in Massachusetts are the following:

- Skills shortage arising from insufficient numbers going through college and higher education and also inadequate vocational training and further education
- Lack of population growth and an ageing population
- High cost of living especially in relation to housing

5.4. Dependence of one or two major players

The medical devices cluster in Massachusetts has the advantage of the continuous development through the new enterprises that are generated through the local universities. This creates mass, diversity and renewal. Most of the manufacturers in the Massachusetts medical device sector are either subsidiaries or very small. Two main forces are currently influencing the development of the industrial structure; one is the development of new small ventures based on university research some of which are rapidly expanding; and the other is takeovers of the small growing companies

[42] A. Clayton-Matthews, 2001

by the large international companies when they judged to be of particular value to future developments.

5.5. Development of intellectual property at local level

There is a widespread use of contract manufacturing and licensing, and as a result of regulative and legislation encouragement, universities and their staff are actively involved in the commercialization of the knowledge innovations that they generate.

5.6. Future opportunities for the industry

This sector seems to be set fair for a long period of growth. There is a continuous flow of new knowledge and of innovations to provide improved medical devices and markets are likely to grow at home and abroad.

5.7. How important is the role of skills supply

The industry is heavily dependent on a continued supply of skilled and highly qualified people. If firms experience serious and sustained shortages in the supply of skilled staff, they may be tempted to move out of the state and to relocate.

5.8. Importance of links with local education institutions

The triangular cooperation and communications between universities and research; private businesses; and the public education system are critically important for the success of the industry.
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5.9. Future skill needs of industry

The Commonwealth’s medical device industry is growing rapidly. Employment, wages, productivity, and foreign exports in the industry have been growing faster than manufacturing as a whole in Massachusetts. Wages and salaries and exports in the medical devices sector have been growing faster recently in Massachusetts than in the rest of the country.

Many companies in the Boston area are involved in leading edge collaborative research projects with Silicon Valley companies. Researchers of the Whitehead Institute at the Massachusetts Institute of Technology, for example, have collaborated with the San Francisco firms Hyseq and Affymetrix, two manufacturers of microarray chips, in genomics research[43]. Such collaboration is considered important for the continued development of new knowledge and its applications, in both regions.

No one can predict the exact type of skills that will needed in future, and the best possible strategy is to stay in front in the relevant areas within the sector in order to be able to take immediate steps to exploit new opportunities and developments as they emerge.

[43] Medical Devicelink, Hot Spots, website.

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