

a report by
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Modern medical technologies are indispensable for saving and improving quality of life. In fact, the European industry has contributed significantly to the increase in life expectancy by eight years, over the last 30 years.

Exciting breakthroughs in medical technology mean that medical practitioners are able to win the fight against many of the harmful diseases being faced, with products that blur the traditional distinctions between biologics, drugs and devices and force them to think about 'treatment regimes' and 'combination products'.

A number of factors have accelerated the growth in the medical device industry. The advancements in the available technology and materials, an ageing population and an increased understanding in the pathology of disease have all contributed to this growth. The world market for medical devices is now worth an estimated US\$100 billion and is predicted to grow further. This large ageing baby-boomer generation has ensured that there will be a double-digit growth in the industry for years to come.

The US market generated US\$43 billion and remains the largest medical device market, while Western Europe is the second largest market and accounts for nearly 25% of the global medical device industry.

The medical device industry is fast evolving into a medical technology industry as it adds bio-materials and pharmaceuticals to enhance its established products in diverse applications such as surgical implants and diagnostic equipment.

The challenges of ethical concerns and complex regulations associated with the new technologies in medical devices are great, yet progress is transforming many fields of medicine – cardiovascular, orthopaedic, respiratory, ophthalmic, neurological, urinary and infection medicine.

Business Briefing: Medical Device Manufacturing and Technology 2005 looks at the use of cardiovascular

devices. Approximately 12 million Americans have a history of myocardial infarction (MI) or angina pectoris related to coronary heart disease (CHD). In addition, CHD is responsible for 1.5 million deaths in the US annually, accounting for approximately one in five of all deaths. The industry has already developed interventional devices to treat CHD.

Device companies are now investigating how best to predict and potentially prevent heart attacks and acute coronary syndromes with new interventional cardiology device-based strategies.

The large number of new medical technologies emerging is accelerating the growth of the industry. Tissue engineering, the development of new 'intelligent' materials, the integration of telemedicine, minimally invasive surgical technologies and nanotechnology will result in the development of more sophisticated therapies for treating disease.

These advances demonstrate that the brink of a medical technological revolution is now being reached, yet much regulation relies on an antiquated and underfunded standards system. There are now more standards in preparation than have been published, yet product and technology-specific standards are lagging far behind innovation. Regulators now face a challenge as great as the technological challenge facing industry.

Standards are a better alternative to regulations, but they are not free of charge – governments need to invest in and support the standards development process to make it more responsive, consistent and professional.

This edition of *Business Briefing: Medical Device Manufacturing and Technology 2005* once again examines these key issues and highlights the latest developments in the expanding medical device industry, covering a full spectrum of device technology from cardiovascular and wireless devices to materials and testing. I trust that you will find all these articles interesting and informative. ■