

Industry and Advanced Biomaterials Research

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Musculoskeletal conditions are among the most costly illnesses to treat, consuming on average three percent of total gross domestic product in developed countries. From arthritis to osteoporosis, fractures to dislocations, musculoskeletal diagnoses represent the primary non-psychological causes limiting activity in people of all ages worldwide¹. Growth drivers in the orthopaedic and trauma market are demographic developments (ageing population), population behaviour (activities), population expectations (treatment standards) and new products (new treatment methods, enhancement of clinical outcome, new technologies).

Biomaterials are part of the new technology sector and an important driving force for the growing market, valued at over \$1.4 billion in 2003, the expectations are over \$3.4 billion by 2008². The applications of biomaterials are widely spread: from hyaluronic acid injections to substitute synovial fluid in the knee to allografts used in spinal fusions and in synthetic materials used as substitutes for bone grafts in different indications. Other very important developments in classic biomaterial are porous metals, new alloys and ceramics, in particular new manufacturing technologies. Another important trend is the merging of drugs and devices.

The increasingly short product life cycles in the medical device industry implying an urgent need for fast and effective development. There is an increasing pressure for shorter time to market. – In contrast to the time to market driven trend the complexity of the products is dramatically increasing. Most of the new product developments are based on years or decades of basic and applied research, e.g. growth factors. Furthermore the industrial exploitation of results from research is very often a time and cost consuming process. There is growing concern that many of the new basic science discoveries made in recent years may not quickly yield more effective, more affordable, and safe medical products for patients. The FDA stated that the current medical product development path is becoming increasingly challenging, inefficient, and costly³.

To speed up the development time companies adopting a knowledge broker philosophy.

External knowledge sourcing, intellectual property evaluation and the attraction of bringing outside innovations instead of reinventing the wheel are becoming more important. Knowledge creation and basic research is being partially re-delegated to academic institutions and companies. The development success is found to be related positively and directly to how well informed and knowledgeable decision-makers are⁴.

A strong collaboration between industry and advanced research focused academic institutions is essential for accelerating the development process. Important steps during industrialisation are proof of principle and proof of concept, know how transfer, up scaling and regulatory issues. It is required that research results should not be single shots and should be well documented and described in every step. What is not documented does not exist. Processes, analytical procedures and resulting data must be shown to be reproducible and should be independent from on-site findings. The biological performance of the new materials as well as any influence caused by a new technology has to be investigated.

REFERENCES:

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- ¹ The Worldwide Orthopaedic Market – 2002-2003, November 2003; Knowledge Enterprise Inc. - The OrthoPeople
 - ² US Markets for Orthopedic Biomaterials 2003; Millennium Research Group
 - ³ Innovation / Stagnation – Challenge and Opportunity on the Critical Path to New Medical Products, FDA March 2004; <http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.html>
 - ⁴ O.Gassmann, B.Gaso *Increasing Creativity with Listening Posts in Decentralized Firms* (2004) 13 Creativity and Innovation Management