

Picture: Bayer

New Small-Scale GMP plant of Bayer Health-Care in Wuppertal/ Germany

# Pharmaceutical service providers

New business opportunities in custom development and manufacturing

The production of pharmaceutical active ingredients and their precursors were and still are an attractive option for the fine chemicals industry. Complex active ingredient structures, the frequent use of multi-stage synthesis and the need for up-to-date synthesis techniques hold out the promise of high value add. For many, this is reason enough to position themselves as custom manufacturers. However, the industry is struggling with overcapacity and is looking for new business opportunities.

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## Potential savings during drug development

IBM Business Consulting Services (BCS) forecasts growth opportunities for the pharmaceutical industry resulting from the use of new technology. The "Pharma 2010: Silicon Reality" report published in May 2004 identifies seven information technologies which can help pharmaceutical companies reduce development costs, shorten time to market for new drugs and increase shareholder value. The use of new key technologies will enable the pharmaceutical makers to develop treatment methods for patients who have specific diseases. This will make the traditional "one pill for everything" approach a thing of the past. Custom-made drugs offer better opportunities.

The authors of the IBM report assume that the cost of developing a new drug up to the market introduction stage can be reduced to an average of US\$ 200 million, which is a quarter of the current cost of introducing a drug to the market. Time to market can be reduced from an average twelve to fourteen years to three to five years. In addition, therapy can be more successful from the first human dose right up to market introduction, and the quality of the development and production processes will also improve.

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The attractiveness of the market and positive expectations (the market for prescription drugs continues to grow at up to 10 percent a year) induced companies to make significant investments in new production capacity. To qualify as producers of active ingredients, all manufacturers are careful to ensure that their systems are GMP compliant and "FDA approved". Overall, the high expectations on the part of the fine chemicals industry have not been fulfilled, and massive investment has led to overcapacity in the market (refer to the information in the box on the next page). To remedy the situation, the fine chemicals industry is now pursuing various strategies to develop new business opportunities and stand its ground in the face of competition from the Far East.

Some players in the industry have focused on core strengths and advanced

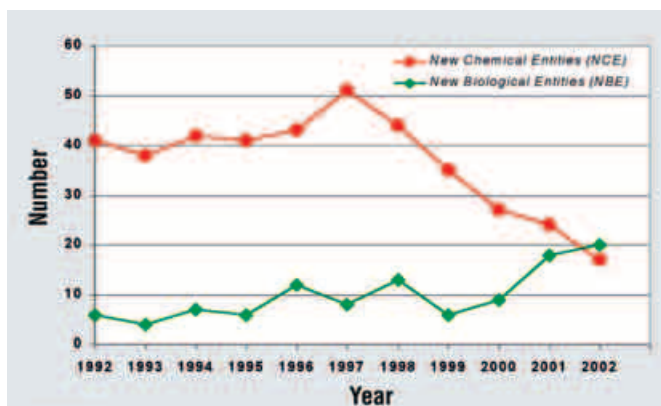
technology: specialty chemicals (e.g. fluorine chemistry), catalytic processes (e.g. for chiral active ingredients), biocatalysis, chromatography (e.g. chiral separation using simulated moving bed techniques) or hazard-prone chemistry (e.g. azide or phosgene chemistry). Others have tried to establish themselves in niche markets that offer high growth potential, for example cytostatic drugs, highly actives, or peptides and nucleosides.

Another strategy pursued by a number of companies is to transform themselves into a one stop shop through joint ventures and acquisitions. The intention is to start cooperations with customers at the clinical development stage and pursue custom development as a new business line.

The increasing number of new approvals shows that pharmaceuticals produced using biotechnology are a new growth market for the fine chemicals industry.

However, the move into biotechnology is very capital intensive and requires special know-how. Production of active ingredients using biotechnology usually requires the use of product specific systems, which means that higher investment is necessary during the high-risk development phase.

Currently, traditional business with established pharmaceutical compa-



Source: P. Pollat

FDA approvals of new active ingredients from 1992 to 2002

## Custom manufacturing: Why there is overcapacity in the market

- Contrary to the expectations of the fine chemicals industry, most pharmaceutical companies restrict their outsourcing activities to precursors or advanced intermediates and prefer to produce registered, completely processed substances in their own facilities. This ensures the supply of active ingredients, and it protects proprietary know-how.
- To an increasing extent, production of standard chemicals is moving to the Far East.
- The number of new approvals is stagnating despite enormous R&D expenditure by the pharmaceutical industry.
- Many pharmaceutical companies are currently engaged in backsourcing to utilize their own spare capacity which has become available as the result of mergers and the drop in new approvals.

nies is stagnating and only the strong players will manage to establish a foothold in the high-growth biotechnology market. However, a new business opportunity is opening up with ambitious startups and

biotechnology companies which are strongly focused on research and are introducing an increasing number of new substances (small molecules and biopharmaceutical products) into clinical development.

### New trends: service and pharmaceutical know-how

In addition to the growth of the biotechnology sector and emerging pharma, new trends are evident which will change the market for custom development and custom manufacturing. Decoding of the human genome and an understanding of the genetic origin of disease will lead to personalized medicine with many new lower volume products for specific groups of patients. This will provide a basis for more targeted clinical studies and shorter development times,

which in turn will require faster technical development. New joint ventures between service providers will be forged for activities such as joint development and production of an active ingredient and for-

**“Bayer HealthCare plans to leverage its pharmaceutical expertise to become more active in the field of contract development, both for active ingredients produced using biotechnology and for classic small molecules.”**

*Rolf Angerbauer,  
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mulation from a single partner. Systems with smaller volumes and a high degree of flexibility (small-scale GMP) will be needed for the growing number of lower volume products.

As a result, the pharmaceutical industry, service providers and ambitious biotechnology companies will have to cooperate more effectively to pool pharmaceutical know-how, technological expertise and innovative strengths. Custom development and manufacturing services, which are aimed specifically at the pharmaceutical industry, will continue to grow. Emerging pharma need expert partners for the entire active ingredient development phase and for production later on. Specific know-how in the field of pharmaceuticals and a high level of service are crucial to meet these new demands. Bayer HealthCare also plans to

leverage its pharmaceutical expertise to become more active in the field of contract development, both for active ingredients produced using biotechnology and for classic small molecules. ■

#### For further information:

[www.pharma-tec.com](http://www.pharma-tec.com)

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- Additional background information on the Pharmaceutical Division at Bayer HealthCare
- Download the IBM Pharma 2010 study
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