

## Sector Conditions

Sartorius Stedim Biotech serves customers mainly in the biopharmaceutical industry, which makes its business particularly sensitive to the development of this industry.

### Strong Growth in the World’s Pharmaceutical Markets

According to several market observers, the global pharmaceutical showed a positive development once again in 2016, with growth of +4% to +5%. The availability of innovative new medications, improved access to healthcare – in part through the expansion of state healthcare systems – and the continually growing and aging population were the main drivers to this growth. These positive factors were countered by austerity measures in individual national healthcare systems and the expiration of patents.

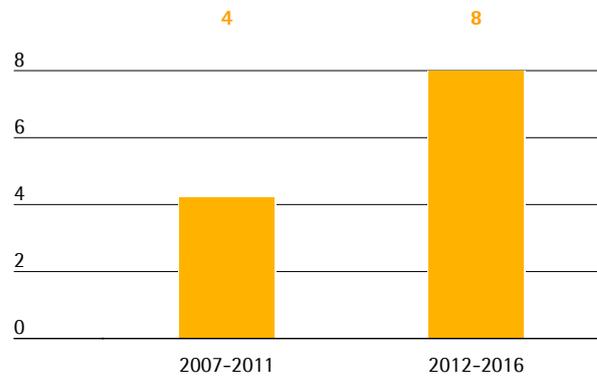
As in previous years, the strongest growth dynamic was observed in the so called “pharmerging markets”, whose development was driven by the expansion of state-funded healthcare systems and higher out-of-the pocket spending. The world’s largest pharmaceutical market, the USA, has grown significantly owing to a comparatively high number of newly approved drugs in recent years. Growth in the European pharmaceutical market, in contrast, continued to be dampened by austerity measures in individual national healthcare systems.

### Above-Average Growth in the Biotechnology Market

The market for medications manufactured using biotech methods has grown overproportionately within the world’s pharmaceutical market for many years now. It enjoyed particularly dynamic growth in 2015 that continued overall during 2016. This historically overproportionate growth is especially attributable to the launch of many new biopharmaceutical drugs as well as additional market penetration of existing medicines, in part through expanded indications.

The high R&D productivity of the biotechnology sector has led to a significant increase in the number of newly approved biopharmaceuticals in recent years: For example, the number of new approvals in the USA nearly doubled over the past five years in comparison to the period before that. Overall, the proportion of sales revenue of the world’s pharmaceutical market from medications manufactured using biotech methods grew from around 20% in 2012 to approximately 25% during the reporting year.

Average Number of New Approvals of Biotech Medications in the USA per Year



Biosimilars, which are biological copycat medications, have played only a minor role to date in the growth of the biotechnology market. However, despite being underdeveloped compared with the markets for biosimilars in Europe and Asia, the industry made significant progress in the important U.S. market during the year under review: in 2016, three biosimilars were approved by the U.S. health authority FDA following the first market authorization in 2015 on the basis of an abbreviated approval procedure.

### Single-Use Systems for Biopharmaceutical Production Continue to Gain Importance

Biotech production methods are much more complex and cost-intensive than traditional methods for producing medications. Consequently, manufacturers and suppliers are continuously looking to develop more efficient technologies. Single-use products play a decisive role in this effort: they require significantly less capital expenditure, reduce costs for cleaning and validation, and minimize downtimes. They also offer greater flexibility in production and help accelerate time to market. Thanks in particular to their cost-efficiency, single-use technologies have already become well established in a large number of process steps.

### Moderate Growth in the Global Laboratory Market

The global laboratory market grew by approximately +2.5% in the reporting year according to Frost & Sullivan. In face of moderate economic growth and uncertainty surrounding the Brexit referendum, growth in Europe came in at only +1.5%. The USA, the largest market for laboratory products, grew by +2.7%. Activity by the public research sector rose only slightly above 2015 levels, but the demand for laboratory products on the part of the biopharmaceutical industry was very strong. Significant growth was once again reported in Asian countries such as China and India, in which the laboratory market enjoyed an above-average expansion of +7.8% (China) and +8.8% (India).

### Competition

The primary means by which companies in the biotechnology market differentiate themselves from competitors are innovative process and the quality and performance of their products. The biotechnology sector is constantly discovering new areas of application and expects suppliers to be equally fast-moving and creative in developing new equipment for the manufacture of biotech products. New suppliers, in particular, seek to exploit the opportunities inherent in this environment to gain a foothold in the market with carefully targeted niche products. The more established suppliers, meanwhile, are expanding their product range continuously.

We generate around 90% of our sales revenue from validated processes in which replacing products during the production cycle is very expensive, so we receive a high proportion of follow-up and repeat business. The particular strength of Sartorius Stedim Biotech lies in its integrated process solutions: from the investigation and development of substances in the lab to the production of the end product, we offer the broadest range in the industry. Our strategic focus on single-use products gives us another edge over the competition. Sartorius Stedim Biotech occupies a strong position in the market worldwide in the fields of bioprocess filtration, fermentation, fluid management and membrane chromatography.

Most of our competitors are multinationals based in the USA. Merck KGaA, Danaher Corp., General Electric Company and Thermo Fisher Scientific Inc. are among our main rivals in the process area; Thermo Fisher and Merck are key players in the laboratory field. We also face competition from smaller companies in individual segments.

Sources: IMS: IMS Health Market Prognosis, March 2016; Global Medicines in Use in 2020, November 2015; Evaluate Pharma: World Preview 2016, Outlook to 2022, September 2016; Frost & Sullivan: 2016 Annual Report: Forecast and Analysis of the Global Market for Laboratory Products, October 2016; [www.fda.gov](http://www.fda.gov); FDA-Approves-Third-Biosimilar-in-US-First-for-Amgens-Blockbuster-Enbrel, [www.raps.org](http://www.raps.org)