

Customer Success
CarboGen

CarboGen is part of Solutia Pharmaceutical Services Division (PSD). Located in Switzerland, the company has developed from a modest startup to a leading contract company in the field of active pharmaceutical ingredients (API). Building on the foundation of Microsoft Business Solutions, CarboGen has developed a molecule-tracking database that integrates the scientific perspective with project management.

This powerful approach provides a better way of meeting the time, expenditure, scientific, and quality deliverables for pharmaceutical projects. It has led to improved planning and tracking of projects, increased efficiency, and lower maintenance and per-user costs. CarboGen's technology solution was so successful that it won the 2003 BIO IT award for innovative uses of IT in the life sciences area.

"Microsoft Business Solutions has allowed us to quickly and reliably create data analyses. This enables our business leaders to quickly make fact-based decisions about our rapidly changing business environment."

Dr. Alan Fischer :: Head of IT PSD Switzerland, CarboGen

Demanding on Every Level

The life sciences industry is one of the most complex in the world. Scientific advances are revolutionizing the process of finding and developing new drugs and medical products. However, advanced medicines and medical devices require long research and development (R&D) cycles with time-consuming and expensive discovery, design, and pre-clinical and clinical development.

The time-to-market and profitability pressures are intense. Being the first company to market and patent a new product is a key indicator of potential success. Companies need to take full advantage of that position before a competing therapy emerges that is more effective or has fewer side effects.

Regulatory agencies are becoming increasingly vigilant in assuring the safety of products at all stages of the product life cycle, from manufacturing and distribution to consumption and use. 21 CFR Part 11 requires maintaining audit trails and signature records of manual or automated transactions. Beyond Part 11, companies must maintain compliance with all of the cGMPs (current Good Manufacturing Practices) applicable to the given industry.

The explosion in the need for research, development, and regulatory compliance for life sciences products is driving the need for a more flexible computing environment. Nothing is more critical than access to real-time information on production processes and business operations. Life sciences companies depend on this data to make sound business decisions, maintain compliance, and run efficiently.

Life sciences organizations of all sizes need information systems that can handle enormous amounts of data in a stable, reliable, and, above all, secure way. Companies developing pharmaceuticals, medical devices, biotechnology, and even nutraceuticals need a responsive IT infrastructure that will enable them to control compliance costs while improving business performance as they work to bring new products to market in a timely manner.

Data Management Throughout the Life Cycle

Relying on software applications to automate critical processes, companies now have greater visibility and real-time access to information to help anticipate, analyze, and respond to market demands. These systems are helping them accelerate the pace of drug discovery by efficiently managing massive data sets, identifying the products with the best market opportunities, and streamlining global R&D projects—all while meeting regulatory and validation requirements.

During the discovery process, software applications facilitate the selection of promising targets quickly and efficiently, while helping companies manage vast quantities of data and collaborate with other researchers, yet still maintain the security of their intellectual property.

During the clinical trial phase, perhaps the most complex part of the life sciences product cycle, a flexible computing environment can help track adverse events and eliminate redundancy in remote data capture. Strict regulatory requirements that require detailed records can be more efficiently met while enforcing worldwide standards to maintain consistent clinical trial data. Finally, computing solutions can expedite study closeout, reconciling clinical data with external systems such as adverse event reporting systems.

Once the product is headed to market, IT solutions can help life science companies maximize its acceptance by managing multiple sales channels to extend the reach of the sales and marketing organization. Throughout the production of the product, Part 11 audit trails can be automatically tracked and reported, including batch records, engineering changes, quality records, inventory status transactions, process instructions, and recording results.

Accelerating the Pace with Microsoft Business Solutions

Microsoft® Business Solutions understands the challenges and needs of the complex life sciences market and has developed a portfolio of solutions for this demanding industry. Technologies from Microsoft Business Solutions offer key capabilities across the range of life sciences markets—from pharmaceuticals and biotechnology to nutraceuticals and medical devices.

The Microsoft Business Solutions platform combined with our partners' deep vertical expertise enable small- and medium-size life sciences organizations to quickly deploy an integrated set of leading-edge business applications inexpensively, and without complicated customizations.

Our integrated technologies are helping life science companies adhere to the stringent data validation, security, and process integrity requirements mandated by the FDA while leveraging the power of integrated Microsoft business systems. We offer applications for all aspects of life sciences operations, including:

- Change management
- Quality control
- Quality management
- Adverse event reporting
- Traceability
- Batch and lot records management
- Verification
- Bar coding
- Restricted sales
- 21 CFR Part 11 compliance

Technologies from Microsoft Business Solutions also provide complete, enterprise-wide capabilities, including:

- Product life-cycle management
- Vendor management
- Sales management
- Financial management
- Sales order management
- Customer relationship management
- Customer service management

Competing to Win

Microsoft Business Solutions gives life sciences companies the edge they need to compete successfully. To learn more about our outstanding, cost-effective solutions, visit:

<http://www.microsoft.com/BusinessSolutions/Industry/LifeSciences/default.msp>