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Dr Ingolf Stückerath joined sanofi aventis in 2000 as an assistant plant manager. After becoming a Six Sigma Black Belt in 2002, he was responsible for the implementation of Six Sigma at the Frankfurt Biotechnology site. As a member of the site's management committee, he is now a Six Sigma Master Black Belt.

The West's pharmaceutical industry is facing strong challenges. Countries such as India and China are showing rapid development in the pharma field, which is particularly problematic for the West as it cannot compete with Asia's low labour costs and minimal environmental requirements. In addition, the FDA has changed its process and analytical technology initiative from just three validation runs to a complete process understanding, a design to quality approach and continuous improvement activities.

However, the implementation of Six Sigma methodology can help Western companies overcome these challenges. Numerous pharmaceutical companies, including 3M, Baxter Bioscience, Bayer Healthcare, Eli Lilly, Johnson & Johnson, Novartis, Pfizer, Schwarz Pharma and sanofi aventis, are now using Six Sigma to accomplish their corporate strategy.

**New approach**

The Six-Sigma approach is a customer-oriented, highly disciplined and data-driven methodology for eliminating defects in any kind of process, from manufacturing to transactional, and from product to service. This is accomplished through the use of its sub-methodology of define, measure, analyse, improve and control (DMAIC), and its well-defined set of tools.

Combined with lean manufacturing tools, Six Sigma enables a company to systematically identify and eliminate waste and defects from their processes, and thus obtain free capacity for value-adding activities. The Design for Six Sigma (DFSS) approach enables a process to be developed

from the start of a project with zero-defect quality. A Six Sigma defect is defined as anything outside the customer's specifications. Six Sigma processes are executed by Green Belts and Black Belts, and their activities are overseen by Master Black Belts.

**Table 1. Six Sigma implementation**

<b>2001</b>	<ul style="list-style-type: none"> <li>■ Decision for Six Sigma</li> <li>■ Champions training</li> </ul>
<b>2002</b>	<ul style="list-style-type: none"> <li>■ First Black Belt training</li> <li>■ Implementation of Six Sigma position</li> <li>■ Completion of three successful projects</li> </ul>
<b>2003</b>	<ul style="list-style-type: none"> <li>■ First Green Belt training</li> <li>■ Rollout to all site employees</li> <li>■ Completion of four successful projects</li> </ul>
<b>2004</b>	<ul style="list-style-type: none"> <li>■ Green/Black Belt training</li> <li>■ Completion of seven successful projects</li> </ul>
<b>2005</b>	<ul style="list-style-type: none"> <li>■ Winner of the IQPC Six Sigma Excellence Award</li> <li>■ Five projects completed and 12 projects running</li> </ul>

**Dr Ingolf Stückerath of sanofi aventis discusses how his site successfully implemented the Six Sigma methodology as a tool for efficient manufacturing in the twenty-first century.**

# SIX SIGMA AND THE ROAD TO SUCCESS

**Case study: sanofi aventis**

Six Sigma was implemented at Frankfurt Biotechnology, an API site of sanofi aventis, over a period of four years. The site consists of approximately 800 employees and produces five different APIs. All the site's support functions, including human resources, purchasing and quality departments, were involved in the initiative.

In 2001, Aventis provided all its sites with information and technical support about Six Sigma. Although the participation was on a voluntary base, the company's general management were keen to use the new initiative, and the site's middle management thought it would help them reach their objectives. Following initial training, facilitated by Motorola, it was decided that Six Sigma should be implemented at the site.

**Pilot phase**

The pilot phase for the implementation was carried out in 2002. One employee was sent to the first wave of an Aventis company-wide Black Belt training [in parallel with his training the site's first Six Sigma project was carried out].

The Six Sigma system was strictly applied to the project, which proved to be a great success, with realised savings of €3.7m per year. A full-time Six Sigma position was then created, with clear objectives set by the site management team. These objectives were: to develop a plan for implementing Six Sigma at the site; to organise and execute Six Sigma training, to further push and coordinate all the system's activities; to promote Six Sigma within and beyond the site; and to be the link between project teams and management level.

By the end of 2002, three Six Sigma projects were executed, with realised savings of €4.5m. One full-time Black Belt was put in charge of the concept for the rollout of Six Sigma to the entire site.

### Rollout phase

At the beginning of 2003, two more employees were trained as Black Belts, and assigned two Six Sigma projects. In close cooperation with UMS GmbH, a local consulting company, the first Green Belt training was conducted with 11 participants.

A ten-minute film was produced showing the use of the Six Sigma methodology in a realistic role-play. The film was used during the Six Sigma kick-off phase as an introduction and at each training session.

In June that year, the systematic rollout of Six Sigma to all employees of the site took place, with about 60 members of the plant management teams taking part in a half-day workshop. The launch was supported by an information campaign to all 800 employees of the site. In 40 single events, each employee received a one-and-a-half-hour training session, which included a film presentation, a short introduction to Six Sigma and participation in a simulation game.

The event was covered by the communication department in the site's newsletter. By the end of the rollout in 2003, the site had trained five Black Belts and 11 Green Belts. Seven projects were successfully finished, with accumulated savings of €10.6m.

During 2004 and 2005, the site continued its Six Sigma activities with further education of Black Belts and Green Belts. The aim was to have one Black Belt per plant and at least one Green Belt on each shift. A separate position for the coordination of all Six Sigma activities and further development of Six Sigma were established within the site management committee. The first site Black Belt was appointed Master Black Belt. At the end of 2005, the site held one Master Black Belt, nine Black Belts and 51 Green Belts, and 26 projects were performed with savings of €20m per year.

In April 2005, the site's Six Sigma activities were rewarded with the Six Sigma Excellence Award in the category of Best Defect Elimination in Manufacturing at the annual Six Sigma Summit in London, organised by the International Quality and Productivity Center.

At the end of 2005, the site management committee decided to broaden the Six Sigma activities by adding lean manufacturing tools to the Six Sigma toolbox. A Lean Six Sigma Workshop was held and 12 Lean Six Sigma experts were trained in a three-day course. In 2006, the Six Sigma projects will focus on the identification and reduction of non-value-adding activities within the site's processes, with the strategic goal of creating potential for further value-added activities.

### Cultural change

The achievements of the implementation of Six Sigma went beyond monetary savings. Prior to Six Sigma, attempts to improve work processes had not been successful and employee morale about such initiatives was low. The precursor of Six Sigma at the site, Continuous Improvement Process, had been imposed on the site by corporate management and the projects were overseen and tracked by employees from a global department. As well as low employee morale, the initiative's tracking tools, the calculation of savings and the rewarding system for successful projects were poor. Furthermore, the acceptance by middle management was low.

## Employees of all levels saw Six Sigma as part of their job to work on process improvement

The implementation of Six Sigma originally faced a wall of resistance among staff and middle management. When the site first began Six Sigma, the memory of the Continuous Improvement Process still remained, interfering with the momentum of the initial activities. Middle management had supported Six Sigma projects only after pressure from their superiors. There was little interest among all site staff and the activities were viewed as a waste of time and resources; many hoped that Six Sigma was just another new initiative that would come and go quickly.

Following the Six Sigma pilot phase, the situation completely changed. Employees of all levels saw Six Sigma as a part of their job to continuously improve processes. This was not only true for production processes, but also the rest of the company's business processes. The overall accepted method is the systematic approach using the tools of the Six Sigma DMAIC cycle.

The plant management teams now show commitment to Six Sigma through their proposals of new ideas and projects for improvement, their willingness to send employees to Six Sigma training, and their willingness to address and share problems. The use of continuous statistical process control with control charts is now implemented at all plants and driven by the operators. Striving for robust processes is a common term used in target agreements among middle management.

### Success factors

The success of Six Sigma at the site is based on a few crucial factors. In contrast with the Continuous Improvement Process, the Six Sigma approach was decided within the site by the site management team and assisted, not driven, by the corporate organisation. In this way, the site and its employees took ownership of the initiative and felt

responsible for pushing the activities to achieve success. This was supported by the creation of the full-time Six Sigma position at management level and the decision to fill this position with a person from the site. The creation of a Six Sigma committee to ensure a short decision-making process sped up the project's run times and increased cost savings.

The involvement of the internal communication department keeps all employees aware of Six Sigma activities, even those who are not involved in running projects. Each successful Six Sigma project is mentioned in the internal communication and every successful team is rewarded.

The consequent implementation of Six Sigma in small but well-defined steps over a period of two years gave the initiative time to grow and to become accepted at the site. To sustain the results, development never stops. To maintain this development, the site has created a number of continuous activities, which are designed to always keep momentum high:


- *Adoption of a site Six Sigma steering committee.* A site Six Sigma steering committee with Site Head, Site Champions, Master Black Belt and Black Belts on demand

was adopted. The role of this committee is to discuss recent issues and results, make decisions for upcoming projects, plan resources for projects and training, as well as steering and coordinating all Six Sigma activities. The committee meets on a monthly basis and is chaired by the Site Head and facilitated by the Master Black Belt.

- *Six Sigma report.* The Master Black Belt compiles a Six Sigma report on a monthly basis. This report gives a brief description of the status of each running Six Sigma project, a prospective view of future projects and information to other Six Sigma activities on site, such as training. The report is distributed throughout the site's upper and middle management as well as the selected manager of the corporate organisation.
- *Quarterly Six Sigma review meetings.* Six Sigma project leaders give a summary of their progress. The meeting is arranged and facilitated by the Master Black Belt. The participants are the plant management teams and the site management team.


With this use of Six Sigma and the attitude throughout the organisation towards the methodology, Lean and Statistical Process Control, sanofi aventis' Frankfurt Biotechnology site is now ready to conquer all future business challenges. **END**

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