

Genzyme Europe: Advanced Project and Programme Management for Clinical Studies

Genzyme is one of the world's leading biotechnology companies. It has more than 10,000 employees throughout the world who are united by a common goal: to make a major positive impact on the lives of people with debilitating diseases.

Why did Genzyme Europe contact MCE?

Project and programme management are increasingly important for biotechnology, healthcare and life sciences companies. Genzyme Europe wanted to bring in external expertise to work with its people to fine-tune their skills and make sure that they were up-to-date with the very latest thinking and best practice in these areas. This would help Genzyme Europe to maintain its own standards of excellence in line with project and programme governance structures in the industry.

Genzyme Europe identified five solution providers. Based upon an RFP (request for proposal) and an MCE demonstration, Genzyme Europe selected MCE to provide the external expertise it required.

Project Management vs. Programme Management

Project Management

Project management is the centralized management by an individual to plan, organize, control and deploy key milestones, deliverables and resources from conception through retirement, according to customer goals. Often project managers are skilled to use specific templates and techniques to manage through the preferred project life-cycle.

Programme Management

Programme management is the active process of managing multiple global work streams or projects which need to meet or exceed business goals according to a pre-determined methodology or life-cycle. Programme management focuses on tighter integration, closely knit communications and more control over programme resources and priorities.

Source: International Association of Project and Program Management (IAPPM).

How did MCE work with Genzyme Europe?

Understanding the Situation at Genzyme Europe

MCE's Associate met with Clinical Operations Director Roelf Zondag. The MCE Associate wanted to discuss the requirements

timely escalation of issues and risks, and to do this in line with global project and programme governance structures. Project and programme managers must establish effective collaboration and alignment between the different departments involved. We want to manage through systems, using metrics, not micro-management."

"Both workshops were very successful and triggered constructive discussions during and after the session. We are now applying what we learnt in the workshop to our project and programme management activities."

Roelf Zondag, Clinical Operations Director, Genzyme Europe

document that Genzyme Europe had put together reflecting its needs. He also wanted to know more about the organization itself, how it worked and its particular strategy, and the current project and programme management activities at Genzyme Europe, and the people issues related to these. This information would help him put together the right solution for the company.

He learned that Genzyme Europe had already established global project and programme management structures in the following areas:

- New product development
- Clinical studies
- Market authorization
- Product launches
- Regulatory approval

Teams of specialists at Genzyme Europe ran the above activities with strict adherence to international guidelines, regulations and quality standards.

Analysis of the situation at Genzyme Europe

Mr Zondag wanted to focus on project and programme management in the area of clinical development. He explained that "We want to develop proactive behaviours in defining, validating and controlling the scope of clinical projects and programmes and the

Mr Zondag and MCE agreed that the development should:

- Create a common understanding of the roles and responsibilities of project and programme managers
- Establish project and programme management best practices
- Harmonize the way of conducting projects and programmes

Deciding on the right Customer Specific Solution for Genzyme Europe

The MCE Associate, who now felt that he had sufficient information to progress, met with Mr Zondag and a group of Genzyme Europe directors and managers to review the proposal that he had put together. He also gave a demo to the group to show MCE's interactive and practical approach to development.

Genzyme Europe were happy with the proposal and demo. They agreed that the best solution would be a workshop on advanced project and programme management for conducting clinical studies.

Development of the Solution

Genzyme Europe and MCE worked together to customize the workshop content to the specific needs of Genzyme Europe. Relevant case studies, team exercises and pre-reading materials were compiled for a three-



Roelf Zondag, Clinical Operations Director at Genzyme Europe

Genzyme

Since its founding in 1981, Genzyme has grown from a small start-up to a diversified enterprise with revenues of \$3.8 billion in 2007. Over the past two decades Genzyme has introduced a number of breakthrough treatments in several areas of medicine, which have provided hope to patients who previously had no viable treatment options. Genzyme products are helping patients in nearly 90 countries.

Genzyme aims to continue to expand its global infrastructure and invest in both internal R&D and acquisitions. It is well-positioned for future growth, with one major new product launched in 2006, a number of significant products early in their lifecycle, and approximately 20 pivotal clinical studies for new products and indications underway or about to begin.

www.Genzyme.com

day workshop. The workshop would cover both project and programme management processes and metrics as well as proven techniques for addressing team issues and ongoing stakeholder management.

Implementation of the solution at Genzyme Europe

MCE and Genzyme Europe agreed to start with a pilot delivery of the workshop before the launch of the workshop outings. In January 2008 this pilot session was organized for a cross-functional group of senior managers and practitioners. The feedback from the pilot session allowed MCE and Genzyme Europe to fine-tune the workshop by determining the right sequence, timing and duration of the topics and by finalizing workshop materials.

The first delivery of the advanced project and programme management workshop took place in April 2008 for managers from Europe.

Specific to Genzyme Europe, the workshop covered:

- **Project management for the life sciences industry:** adopting proven methods, tools and techniques for project management in the life sciences industry, and industry-specific best practices

- **“Concept-to-value” - the project management process:** the project lifecycle, from strategy definition to value capture, and project management techniques for managing the project lifecycle end-to-end
- **The programme management function:** the specific role of programme management in detail, including programme scoping, programme leadership and programme monitoring and control
- **Project management excellence:** the correlation between project management maturity of companies and project success rates. How organizations can support, control and lead project efforts
- **Dealing with uncertainty and risk:** how project and programme managers can proactively and reactively deal with unexpected events that might affect project and/or programme success
- **Skills and techniques for dealing with complex issues:** how people factors on projects can be dealt with to ensure continued alignment and collaboration from all project and programme stakeholders
- **Change management:** ways to effectively guide and coach personnel throughout the process of behavioural change. How to best overcome resistance to change

A second workshop on advanced project and programme management for conducting clinical studies took place in September 2008 to a different group of Genzyme Europe managers.

Results and Benefits for Genzyme Europe

Clinical Operations Director Roelf Zondag explained: “Both workshops were very successful and triggered constructive discussions during and after the session. We are now applying what we learnt in the workshop to our project and programme management activities”.

Key success criteria included:

- An understanding by everyone of when to apply project management and when to apply programme management
- The consistent application of risk management practices for projects and programmes – to ensure best results
- More delegation from team members when carrying out projects and programmes
- The application of steering projects and programmes via performance indicators and metrics