Case Study

How ECCRT and Santen worked together to develop Santen Core Competency Framework to improve work cohesion

It all started end of 2016 when Dr Vincent Baeyens, 'Director, Global Clinical Operations EMEA' at Santen contacted ECCRT with a challenge they were facing as Santen is growing globally: "*There is a lack of consistency in our job descriptions across our clinical operations globally.*"

Active worldwide, Santen has offices in multiple locations (Japan, US, EMEA), which increases the likeliness of variations in job titles and descriptions. Already aware of this, the company had set up a behavioural leadership competency framework SLC (Santen Leadership Competencies) across the organisation.

While it delivered fruitful results, it came to the Top Managers' attention that it was complicated for employees to use and understand on a daily basis because SLCs did not contain sufficient technical information to be used for every day activities. Therefore, **together with Santen, we have worked on a more complete and easy-to-use technical Competency Framework**.

Santen Profile:
Pharmaceutical company employing more than 3,500 people in EU, US and Asia
Project Objective: Develop a Competency Framework for successful Global Clinical Operations
Challenge: Bring consistency in job descriptions.
Year: 2017

Working with ECCRT was the obvious choice for Dr Vincent Baeyens: "*We've known ECCRT for some time already and have been **very satisfied with the quality of their training services in the past***.

Moreover, ECCRT has the internal competencies and experience both in the industry and with CROs among others. Therefore, I discussed this project with Benedikt Van Nieuwenhove, Managing Director of ECCRT, and he introduced me to ECCRT's activities and experience on the development of Competency Framework in Clinical Research. That is when our collaboration on this project started."

What is a Competency Framework?

A Competency Framework is a **standard mapping of competencies to roles**, used to help organisation assess and manage individual and collective work performance. Within our Clinical Research environment, it defines the competency domains and the associated cognitive skills necessary to conduct a high-quality, ethical and safe clinical trial, in accordance with ICH-GCP (R2).

Based on the efforts of the Joint Task Force for Clinical Trial Competency (2013) and on our expertise in Clinical Research, at ECCRT we had taken the Competency Framework concept a step further to fit your specific needs. Indeed, in the ECCRT Competency Framework, we mapped out **10 competency domains and > 70 competencies with > 40 key positions** and our +100 courses portfolio. That is actually one of the strong starting points of our work with Santen.

Scientific Concepts & Research Design
5 competencies
16 courses

Business Acumen
10 competencies
4 courses

Ethical & Participants Safety Considerations
8 competencies
20 courses

Teamwork
5 competencies
10 courses

Investigational Product Development and Regulation
7 competencies
38 courses

COMPETENCY FRAMEWORK

Communication
6 competencies
17 courses

Clinical Studies Operations (GCPs or ISO 14155)
11 competencies
43 courses

Leadership and Professionalism
7 competencies
32 courses

Data Management and Informatics
6 competencies
31 courses

Study And Site Management
9 competencies
31 courses

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Why a Competency Framework?

- Align Santen with International Industry Standard
- Harmonise technical and soft skills requirements in R&D
- Increase personal development ownership within Santen

4 steps to develop Santen GCO Competency Framework

The development of Santen's Global Clinical Operations (GCO) Competency Framework was **based on the strategic vision from the Santen HQ.** It describes which competencies are needed to be a successful GCO group under the umbrella of Santen Global R&D. In order to set up this framework, the following activities have taken place:

1	**2**	**3**	**4**
Confirmation of Project Plan	**Development of backbone of the competency framework**	**Finalize Competency Framework**	**Review Definitions for chosen competencies**
Define objectives, deliverables and key milestones. Define team structure, roles and responsibilities.	Elaborate backbone of the competency framework: key competencies, competencies per level/division/leadership responsibilities, etc. Perform and analyse interviews with a selection of employees from the 3 regions. Prepare a draft set of competencies.	Finalise set of competencies for each level and integrate Santen's feedback.	Prepare definitions and behavioural indicators for the selected competencies. Send final Competency Framework including definitions.

Step 1: Confirmation of project plan

During the **Kick-off meeting**, we have introduced the project plan to the client and discussion was opened on various topics: **timelines, milestones, roles and responsibilities**, etc. On Santen's side, their responsibility was to identify the Project Manager to manage internal stakeholders and co-ordinate enquiries and change requests.

Step 2: Development of the backbone of the competency framework

In the second stage, we worked together on the backbone of the competency framework (key competencies, competencies per level/division/leadership responsibilities, etc) and we gathered previous job descriptions as well as detailed Santen Leadership Competencies. In order to build a competency framework that suits with the daily tasks and roles at Santen, ECCRT has conducted a **set of interviews of diverse GCO functions in different regions (Japan, US, EMEA).**

These interviews were one of the crucial steps for the creation of a tailored competency framework to Santen needs. The questions needed to be adapted to Santen and the current situation, hence a questionnaire validated by Santen was developed.

What conclusions could we draw of the interviews?

1. The team is willing to learn and improve.

2. Function titles could be harmonised between the regions.

3. The collaboration between functions/regions could be improved.

4. Job descriptions are frequently not in full accordance with the role and responsibilities assigned to people.

Step 3: Finalize Competency Framework

Based on these interviews, we have mapped the different competencies that fit the responsibilities within Santen and the current job descriptions. Once reviewed and approved by the Santen team, we integrated the competencies into the final Competency Framework.

Step 4: Review definitions for the chosen competencies

Finally, the 4th stage of this project was to **prepare and provide definitions and behavioural indicators for the selected competencies.** That means that for each competency, we explain what is expected from the employee and at what level. We have divided the levels into 4 categories:

- **Not Applicable**: Knowledge not required at all

- **Aware**: Exposure only to knowledge. Sufficiently aware of the knowledge to be able to look up relevant information

- **Required**: Comprehension & Application of the knowledge. Able to interpret and/or discuss concepts and to use knowledge to solve simple problems based on application of concepts in new settings

- **Expert**: Mastery of the knowledge & effective practical field experience

How can employees make the best use of a Competency Framework?
It includes different steps:

- Analysis of competency required for the function/new responsibility they want to achieve
- Define any GAPs by looking at the behavioural indicators
- Request either training, coaching, or new challenges to acquire new competencies
- Update Individual Development Plan with the line manager and align it with the annual Management By Objective plan

The Santen Competency Framework

After receiving the feedback from Santen on the initial Competency Framework, we could finalize it and achieve final objective. Every step of our project plan has allowed a smooth and efficient development of this tool as a practical platform, including:

- The competency domains fitting Santen's needs
- The various competencies fully described per competency domain.
- Each competency level required per function

Very easy-to-use, this tool allows to have a clear view on what competencies and competency level is expected for each function within the organisation.

Conclusion

Throughout the project life-cycle, Santen and ECCRT have worked hand-in-hand on delivering this project to the end. We are very proud of the result of this collaboration and most of all of Santen's satisfaction: "*ECCRT did certainly meet our expectations. **We now have an objective and global view on the different roles and competencies** within GCO. ECCRT has put a lot of attention in understanding our challenge and responding considering what we had and what we wanted to accomplish. As it touches many functions, we needed a tool that is easy to use, to understand and which doesn't generate extra work for our employees. With this Competency Framework, that is **mission accomplished!**" Dr Vincent Baeyens.

What's next? Further to this project a follow-up project is currently under progress with Santen to go further with the Competency Framework. The plan is to create annexes for their job descriptions based on the Competency Framework and the behavioural indicators. The objective for Santen is to use these descriptions in their recruitment process and have consistent functions and core job descriptions in all their locations. In order to ensure that the Santen team is developing according to the industry standards they asked ECCRT to conduct a benchmarking analysis on competencies required for several functions in Clinical Operations.

Contact us for more information about the Competency Framework

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