



Le site d'information vidéo de sanofi-aventis

Retrouvez la vidéo rattachée à ce transcript sur www.sanofi-aventis.tv

Find the attached video on www.sanofi-aventis.tv

Nathalie Muller

- I am Nathalie Muller, Regulatory Affairs project manager, at the Regulatory Affairs Division of sanofi-aventis France, and I am responsible for generic drugs.

Regulatory Affairs:

- Regulatory Affairs is a department that is responsible for product regulation with regard to the Health Authorities.

Our main task is to obtain marketing authorizations as soon as possible so we are ready to market generics on the day that the patents for leading products expire.

Our product must therefore be available to pharmacies on the day itself.

In this very tense environment, Generic Regulatory Affairs must obtain marketing authorizations as quickly as possible, but also work in close contact with various stakeholders in the company.

We work with quality assurance, packaging, the supply chain and, of course, business development divisions.

Behind this, there is a whole regulatory side of things to deal with before products can be manufactured on company's sites.

- Sophie, I have come to check the marketing authorization application before it is archived.

- To be able to face competition, sanofi-aventis must be in a position to offer the broadest possible product catalogue. In view of this, the business development division stipulates that we audit product dossiers before buying them to add to our portfolio.

My job:

- I specifically manage generics for the central nervous system and analgesic ranges. I submit new marketing authorization applications for these ranges. I will obtain marketing authorization 18 months after the submission date, and we then have 6 months left to do everything else necessary to prepare for the launch.

Team Spirit:

- It works well. People help each other. It's true that we have our own range of products, but we have the same problems and are faced with the same sort of situations, and we manage to identify solutions in time.

Qualities:

- For Generics, I think you need to be responsive...adaptable...and also efficient.

A success:

- This year, Winthrop experienced a major success with the launch of a drug for gastro esophageal reflux, for which the patent expired in May of this year. It was a huge success. We were present on the market as soon as the patent expired, quickly acquiring market share, and Winthrop established a leading position for itself compared to our main competitors... a great result.

What I like about my work:

- It is the contact with other people. It is part of what drives me to come to work in the morning.

- Nathalie Muller is a young mother who has worked for the past fifteen years and who's happy with her life.