

# Reliability and Maintenance

experience history



## SANOFI AVENTIS: THE HEALTH TARGET ALSO FOR PLANTS

The Sanofi-Aventis Group is the first pharmaceutical group in Europe and it is present in Italy with 6 production plants and a research center where more than 3400 collaborators work.

In the plants, mainly intermediate goods and active principles are produced. Ethical and over-the-counter medicines are produced and packaged. All the sites boast about numerous certifications that allow producing medicines for the European and American markets.

The Anagni plant is 60 Km away from Rome and covers about 46 hectares. More than 22.000 square meters building host the raw material and packaging materials stock, all the liquid production divisions and freeze-dried injections, solids and oral liquids and the final packaging division. The production site counts 1300 raw materials and packaging materials used to produce about 17 solid and liquid products (pills, capsules, mixtures, drops) and 42 sterile



products (liquid and freeze-dried bottles, liquid and freeze-dried phials, syringes, pipes) These are packaged in 294 different ways and sent to 51 countries of the 5 continents.

The high volume of investments allowed building one of the biggest plant of the world for sterile freeze-dried near the production site. In such a delicate sector as the pharmaceutical one, the production compliance is a crucial factor that can't be without a precise, punctual and as much as possible flexible maintenance.

In order to achieve this aim, Sanofi-Aventis decided to manage maintenance accepting the new RCM (Reliability Centered Maintenance) principles as an Industrial Excellence policy.

This methodology with a high added value, has the aim to contribute to the achievement of business targets such as the increase of plants reliability level and the savings from the global management costs.

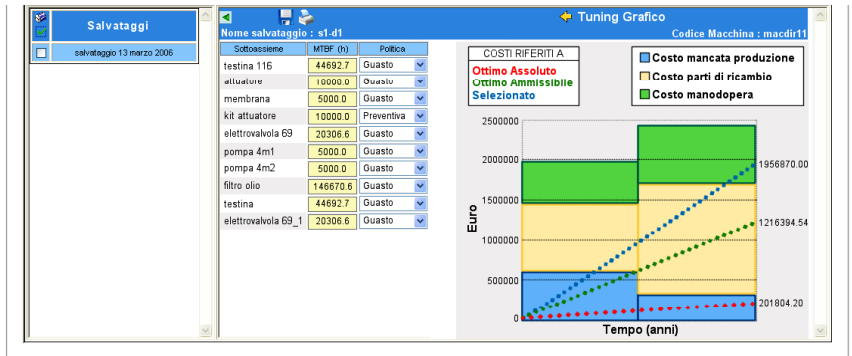
## The collaboration with Inspiring: a new maintenance approach

The collaboration with Inspiring was developed in different phases from the preliminary plant analysis to the personalization solution. Before the **OTM** Inspiring software implementation, Sanofi-Aventis owned only ERP that allows the maintenance management only by an administrative and accounting point of view, without supporting the maintenance engineering activities.

In particular, the plan started with the acquisition of the FMECA analysis module, then developed with the RCM analysis module, till the collaboration for the plant reliability calculating system.



The machine-book (where the maintenance services made are indicated) and the quality documents were analyzed (by searching problems and possible deviations). Through histogram graphs that connect the failure frequency with the damage caused to the plant, the most critical



systems have been identified. It has been studied from a mechanical and electrical-instrumental point of view for about two months. By exploiting the **OTM** decomposition tree, the critical elements were highlighted.

Then their failure modes, the MTBF and MTBM were identified. These parameters helped calculate the hourly costs of maintenance, of examined elements, or the elements under consideration for replacement.

The RCM analysis started with the study of elements reliability and their criticality compared to the examined system and it ended with the calculation of the trade off between costs and benefits. Through the phases, the cost for every applicable maintenance policy is calculated to identify the feasible optimum solution by considering the budget and the available men-hours. Only in this way, it was possible to define a new maintenance plan with higher level of efficacy and efficiency.

Having chosen the maintenance strategy for each critical element, it is necessary to monitor it and to make continuous improvements to achieve better results (Magec methodology- based on objective historical data coming from the execution phase of services carried out).

## What Benefits?

One of the particularities of the realized plan is the implementation of the reliability calculation system that allows creating a graphical plan that explains how the machines are connected to each other following the production flows and calculates their reliability.

**OTM** allows connecting each element with its failure rate and structuring the serial or parallel links between them in a graphical way. This is the real added value of maintenance engineering.

It was not a easy path: but thanks to the right strategic choices taken during the start-up phase and thanks to the professionalism and efficiency of the involved people, superior results have been achieved beyond expectations.



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