



Ethypharm selected *STATISTICA* to improve new drug manufacturing parameters and validate lab comparison tests

KEY POINTS

Business
Ethypharm

Overview

- European leader in drug delivery
- Patented development technologies
- Partnered with pharmaceutical companies worldwide

Challenges

Needed an effective way to collect and present quality control information describing disparate manufacturing processes and laboratory testing.

StatSoft Solution

STATISTICA

Results

- Robust data handling quickly produces actionable comparison reports
- Graphics quality and detail render data understandable to all stakeholders

“STATISTICA is powerful software that addresses the pharmaceutical development needs of Ethypharm.”

— **Loïc Peron**

*Analytical Development Manager,
Ethypharm
March 15, 2013*

BACKGROUND

Ethypharm designs, develops, and produces oral modified released medicines through a network of 140 partners. As the European leader in innovative drug delivery, our patented technologies used in the development of new medicines offer multiple benefits to patients’ health: enhanced efficiency, easier administration, facilitated compliance, and reduced side effects.

CHALLENGES

1. The pharmaceutical development staff often must compare finished product batches that have been manufactured under different conditions such as compression presses, manufacturing sites, device parameters, dosages, etc.
2. The analytical development staff must transfer analytical methods to different laboratories (including those of subcontractors) in order to provide sufficient information to guarantee all laboratories control final products in an appropriate manner.

HOW STATISTICA HELPED

1. Laboratory data is analyzed in *STATISTICA* to study the impact of various processing parameters. The graphs from *STATISTICA* provide very informative and fast answers about process variabilities and enable scientists to understand quickly the influence of each parameter.
2. We use *STATISTICA* to compare and validate laboratory submissions. We want to prove that the means of each laboratory are equivalent within practical, preset limits. To achieve this, a confidence interval is computed on the difference of means and compared to an acceptance criterion.

RESULTS

The quality of *STATISTICA* graphs combined with computed statistics provide quick answers. In fact, the graphs provide so much information that there is usually no need to analyze descriptive statistics in order to draw conclusions. *STATISTICA* is a powerful software program that addresses the pharmaceutical development needs of Ethypharm. The graph quality is key for presenting illustrations on projects and many study reports, making data more understandable to everyone.

