Qualified Consulting – Meaningful Analyses – Custom-Made Software

Efficient Quality Assurance with Excel-Based Software

During the transfer from the chemical to the pharmaceutical production, the homogeneity of supplied batches is often of great importance for a trouble-free further processing. In the project considered, the active substance of a pharmaceutical preparation is required to be as uniformly distributed as possible in the production batch. For this purpose, a milling and mixing process is used. After filling the containers the achieved homogeneity is verified by sampling. It must then be decided whether the batch fulfills the quality requirements.

AICOS Technologies developed for a pharmaceutical company a custom-made, Excel-based software solution that combines flexibility and user-friendliness. This powerful solution does not only offer an evaluation of the homogeneity. It also determines the number of containers to sample, the number of samples per container as well as the producer and consumer risks. Numerous plots are available for the visualization of the analysis results. The software use is very comfortable as it is embedded into the usual Excel environment.

The algorithms used for judging the homogeneity were also developed by AICOS Technologies. They rely on specification limits that were determined in close co-operation with the production managers of the pharmaceutical company. The software was validated according to GMP guidelines and is now routinely used in two divisions. Thereby the number of complaints from the next production stage was substantially reduced.

Flexible, easy and GLP-compatible Laboratory Data Analysis

For the central analysis laboratory of a chemical company, AICOS Technologies developed an extensive software solution for the management and analysis of X-ray spectrometry data. The system consists of a data base for managing calibration and sample data and includes functions for the analysis of series of measurements. The analysis establishes the concentration of chemical elements in the sample on the basis of user-specified inputs such as the mass absorption coefficient and background values. The software can also be used for the empirical determination of the mass absorption coefficients. The results are summarized in an easily understandable report. SQL queries of data and reports can be easily performed over menus. In this way, e.g. analyses can be repeated using other calibration data.

A three-level, password-protected user hierarchy defines different access rights. An administrator can e.g. modify even the report template, while an ordinary user can create, recall and read data and reports, but cannot change or delete any of them. The system was developed and validated according to GLP standards.

In comparison with the standard software of the spectrometer, this solution is much better tailored to the needs of the customer. It uses a better calibration model and presents the results in an easily understandable report form. Furthermore, the backward traceability of the analyses is substantially improved by the integrated data base functionalities.
Optimal Production Capacity thanks to Simulation Studies

Each production plant faces an environment in which the demand and/or the product mix change continuously. On the other hand, the equipment design cannot be adapted so often, such that disturbing bottlenecks, unnecessarily long waiting times and overfilled inventories often are part of the unsatisfactory daily business.

In a cost optimization project for a synthesis and formulation plant of a specialty chemicals company, the number and configuration of the production devices was to be optimized. The aim was to release capacity by systematically eliminating bottlenecks and deadlocks, such that in the future part of the existing equipment could be used for other purposes and thus investments could be avoided. In close cooperation with the plant, AICOS Technologies developed a detailed simulation model of the production flows. Using animated Gantt charts, logistically optimal processes for the single products were worked out. Then, the interaction of the products and the behavior of the intermediate storage places were examined, considering different values for their size and for the number of existing containers. The result: an optimal dimensioning of the storage places was found and devices with a total value of two million euro can now be used otherwise.

For assuring an efficient analysis, the simulation software SIMBAX was used for the study. It is tailored to the needs of the process industry and thus facilitates the consideration of specific aspects, e.g. campaign production, continuous processes, container handling, manpower and utilities.

Meaningful Analysis of Toxicity Studies

In the area of the pharmaceutical, but also of the cosmetics and of the food industry, admissibility and innocuousness studies become ever stricter. AICOS Technologies disposes of the necessary statistical know-how for the correct analysis of the corresponding toxicological studies, in particular in cases in which standard techniques are not sufficient.

In co-operation with a contract research laboratory AICOS Technologies conducted several toxicity studies in which regulatory authorities and customers had special quality requests on the statistical analysis. These included among others:

- the sensitive area of the sampling strategy for laboratory animals,
- the statistically-secured confirmatory comparison of several treatment groups for the determination of the effective dose of a toxic substance,
- the correct estimation of dose effect, time trend and treatment effect in a study where the laboratory animals were exposed to different doses of the toxic substance during a long period.

AICOS Technologies assumed in each case the development of appropriate statistical methods, the choice of an appropriate statistical software package (e.g. SAS) as well as the data analysis. In this way, it was possible in all cases to satisfy the requirements of the customers. In one of the studies, it even was proven that the application of inadequate standard methods would have led to false conclusions.

Are you interested in further information? Fax this page to: +41 61 686 98 88!