Compliance with cGMP is easy with Bizzmine at CARBOGEN AMCIS

Bizzmine Digital Quality Management

About CARBOGEN AMCIS

CARBOGEN AMCIS produces cholesterol and vitamin D products for the pharmaceutical, feed and cosmetics markets. The scale of production ranges from kilograms to tonnes. Due to the wide application of the products, many laws and regulations also apply. This makes a high degree of quality management an absolute must.

> **"**
>
> *For us, Bizzmine brings transparency, compliance and traceability of our quality registrations.*
>
> Jeroen de Jong, Manager QHSE

CARBOGEN AMCIS
BRINGING YOUR SCIENCE TO LIFE

🏢 Pharmaceutical Manufacturing

🌐 www.carbogen-amcis.com

bizzmine

CHALLENGES ⌄

Before the implementation of Bizzmine, all our quality processes were paper-based. This had the disadvantage that there was no control over the execution of the processes, documents could get lost, and there was no linkage between the processes. Also, creating an up-to-date status of the quality processes was time-consuming. **In that way it was difficult to meet the high standards of pharmaceutical production legislation and to comply with cGMP, ISO, and FDA requirements.**

SOLUTIONS ⌄

The Bizzmine workflow module has made our processes for CAPA, MoC, complaints and deviations paperless and compliant with the requirements of **21 CFR Part 11** (Electronic Signatures).
We can also use the software for applications that are **not quality-related**. We found out that a workflow for our **CAPEX** (Capital Expenditures) is easy to arrange and control within Bizzmine.
Also for the **proposal and approval of improvement plans**, Bizzmine seems to be very interesting. We designed a workflow that perfectly streamlines the requests for large projects, from requests for reviews of the different parties to the required tasks and notifications of what is happening in the project.

Change Control (MoC)	CAPA Management	Deviation Management	Complaint Management

BENEFITS ⌄

1 **Fast and efficient**
With good preparation for the design of the forms and workflows, Bizzmine implemented the deviation, CAPA, and MoC application within two days. After the implementation, the Bizzmine team provided quick and efficient support.

2 **Scalable across sites**
After the site in Veenendaal, the branches in Switzerland, France, the UK, and China can also set up the same workflow modules within Bizzmine. We can do whatever we want in the flexible platform without having to deploy extra people.

3 **Multilingual**
Our users can choose the language they prefer. The fact that the software also recognises and supports Chinese characters is a nice bonus.