



How validation is easier for Galenica with Bizzmine

Bizzmine Digital Quality Management

About Galenica

Galenica supports and guides partners in their pharmaceutical development programs. They are experts at pharmaceutical and analytical development and production of Clinical Trial Material (CTM) for Phase I-III. Galenica also manufactures commercially niched products for the market. They need to comply with the pharmaceutical regulations of the European Union and are authorized and audited by the Swedish Medical Product Agency.



Creating and validating automated business processes have probably never been easier.

Nicklas Helgesson,
Sr QA Specialist & Implementation Project Lead

CHALLENGES



Being a growing and expanding company, a strategic decision was made in early 2021 to **digitalize and automate business workflows to achieve higher efficiency** compared to the existing, mostly paper-based, organization. Bizzmine was selected as the most suitable application to support the identified processes mostly because of its **high flexibility, scalability, and very user-friendly configuration and maintenance**.

SOLUTIONS



We built our business case by thoroughly **examining the time and cost of a number of quality processes that we would likely save through a digitized workflow** and decided to proceed with Actions/ CAPA, Change Control, Deviations, Complaints, and Audits. Having successfully implemented and validated the management of these processes, we are now moving forward with the implementation of document management. We have also trained dedicated users who are now driving the implementation of additional workflows as required by the organization. Training our staff on how to configure Bizzmine was a breeze with the help of the videos and articles on the Bizzmine support portal.



Document Control



CAPA Management



Change Control



Deviation Management



Complaint Management



Audit Management

BENEFITS



1

Easy validation

Bizzmine provides a formalized Validation Documentation Pack with respect to the application's standard and core functionalities. We have about 300 requirements, almost all of which are standard functionalities. This allows us to largely limit our internal effort in validating the computer system and focus only on very critical configurations and the few customizations we made.

2

Easy customization

We can easily create and optimize all the workflows we need in-house, with no or minor external support.

3

Great support

As for Bizzmine's support, we could not be more satisfied. We receive a response very quickly and there is never an issue that is not resolved within a reasonable amount of time. The improvements we would like to see are already in the pipeline in most cases.



GALENICA

PARTNER IN PHARMACEUTICAL TECHNOLOGY



Pharmaceutical Manufacturing



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