

REFERENCE



Matuszak-Hygiene GmbH & Co KG
CFR 21 Part 11 Compliant Validation
for a Pest Control Documentation System



The Customer

Matuszak-Hygiene GmbH & Co. KG offers life science companies services for individual pest control. The cloud-based online monitoring system "DocMaH" was developed as an additional component, which maps documentation processes in a legally compliant manner.

The Project

The validity of "DocMaH" should be checked and ensured.

The Task

As the online documentation system was already in productive use, an experience report was to be compiled to verify the quality-relevant functions. Any gaps with regard to the validation capability of the software were to be identified and possible solutions defined.

The Realization

In the experience report, the functions and processes for system operation were examined and evaluated as part of a subsequent risk analysis. As "DocMaH" is an open system in accordance with CFR 21 Part 11, the implementation of two-factor authentication was proposed to strength the system security, which was implemented by the system supplier during the project. In addition, design documents (HDS and SDS) were created together with the supplier. These documents enable a GMP-regulated customer to understand the implementation of the requirements and thus better assess the functionality of the system. Quality-critical functions were defined in the risk analysis and associated test specifications were created. This basic documentation can be used by the customer in a validation project.

The Result

The online pest control system "DocMaH" fulfills all requirements of CFR 21 Part 11 and can therefore be used in GMP-regulated industries and validated according to GAMP 5. The documentation created supports the validation and simplifies the implementation of the system for the customer.

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Key Performance
<ul style="list-style-type: none"> • Experience report according GAMP 5 • Risk analysis • Test specification • Software documentation • CFR 21 Part 11 Compliance