

# SOP-Management

Full support for your SOP landscape, combined with the best expertise.

## Why do we need SOP-Management?

The pharmaceutical industry is characterized by many regulations. To be GMP-compliant, processes, and workflows must be clearly and precisely defined in the form of SOPs (Standard Operating Procedures). Every action must be carried out equally and unmistakably by every employee. The personnel at the machine must therefore be appropriately trained. Only under these conditions can a consistently high quality of the products be guaranteed. However, many pharmaceutical manufacturers lack the time to document their work processes in sufficient detail.

## What will be delivered within the project?

One SOP is delivered within the project. SOPs must be described in such detail that every action can be clearly understood by every employee. Thanks to our expertise, we know the regulatory requirements very well. If required, we therefore provide support not only for individual SOPs, but also for setting up entire SOP landscapes. This ensures the required quality, and our customers remain GMP-compliant.

## What steps does an SOP include from creation to implementation?

Depending on whether a template is already available or full support is required, the level of support for SOPs can vary greatly. Therefore, as part of the package, the scope of the project is worked out in a workshop. Then the current state of the SOP landscape is reviewed and the number of SOPs or templates to be written is defined. For this purpose, it must also be planned within the workshop which processes will be specifically documented and to what degree.

### Project components

- Check customer's validation master plan
- Creation of initial QPP
- Definition of roles
  - Acceptance criteria
  - Overview of documents
  - Risk evaluation of process
- Qualification strategy (classical vs. agile)
- Workshop
- Revision of the QPP
- Communication with (sub-)suppliers
- Approval/Finalisation QPP
- Travel expenses (optional)

**Deliverable:** One (1) approved SOP (approx. 7.0 days effort per SOP) based on existing templates

## Your benefits



### Expertise

You can rely on our team of experienced pharma technology experts! Thanks to years of expertise, we know exactly what is crucial for writing SOPs.



### Peace of mind

Sit back and relax while we successfully complete your projects for you. Benefit from the highest quality without the stress of worrying.



### GMP compliance

Our experts know the pharmaceutical regulations inside out and ensure that your SOPs remain GMP-compliant at all times!



### Time-to-market

We know our machines best. Thanks to our unique Körber Ecosystem synergies, we optimize the process and accelerate your time-to-market.



### Availability

Our expertise is available to you anytime, anywhere. If required, we can supply you with an entire team at locations worldwide to develop your SOP landscapes.

