

## **Great that you have adopted process supporting External QMS Software Packages**

Before you consider whether the CPDS approach is compatible with all your process support software, we strongly support any of your significant existing implementations. Utilize these packages as they are, ensuring their complete and well-documented implementation.

Packages such as Veeva Systems, Scilife and TrackWise are:

- Process-based: Designed to streamline and optimize specific processes
- Process flow supported: Facilitating smooth and efficient workflows
- Responsibility and authority assigned: Clearly defining roles and responsibilities
- Performance monitored and reported: Enabling continuous performance tracking and reporting

These packages/modules primarily focus on system processes and supporting processes, such as training. We recommend assessing the quality of your QMS implementation and ensuring the availability of detailed process flows. The CPDS process approach can easily serve as the benchmark for evaluating your existing documentation.

For instance, we highly recommend visualizing most of your training modules. Excellent packages, like Veeva, support 'movie-based' training, which is far more engaging and effective compared to the traditional 'read and understood' method. Transitioning to visual instructions can result in significant improvements.

Our process approach extends company-wide, with the most significant impact and change occurring in primary processes. With a well-crafted quality plan (which we can assist you with) and a carefully planned implementation, your state of control will continuously improve.

The main area for improvement we observe concerning these external modules is the quality of the implementation. One common issue is deviation and CAPA (Corrective and Preventive Actions) management. The quality of investigations documented in these modules often lacks completeness, thoroughness and timely resolution. Many companies face a backlog of open cases, with new cases inflowing faster than they can be closed.

By adopting CPDS modules and focusing on identifying and addressing root causes, you can significantly reduce this unacceptable condition of non-compliance.