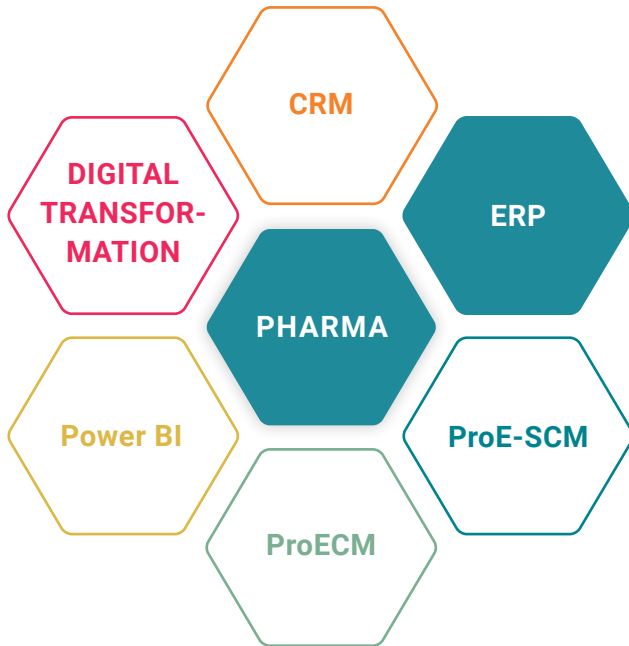


ERP for the pharma industry



and Ayanda

EVERYTHING AT A GLANCE



CLIENT

Ayanda GmbH | www.ayanda.com

FOCUS

Custom production of softgel product

COMPANY SIZE

200 Employees

OPERATING MODEL

On-Premises

COUNTRY

Germany

CHALLENGE

An internal ERP system with a modern interface that can be connected to external systems and which simplifies internal processes.



SOLUTION

Validated introduction of Microsoft Dynamics NAV 2009 and YAVEON ProBatch 1.50 and update to versions NAV 2018 and YAVEON ProBatch 8.50.



USE

- An ERP system that meets the requirements of computer system validation
- Effortless audits



It is 6.28 pm on a Thursday in November of 2019. PING. An email pops into the inbox of Patrik Allman, Head of Compliance Management at YAVEON. It is a message from a customer. Head of IT at Ayanda GmbH, Petra Duchra, worked with YAVEON to introduce a validated ERP system. “We had a customer audit today, in which the auditor was very interested in the computer system validation. We explained our approach and he reviewed examples of the chain of documents from the MBPML and the validation plan, through to the URS, FS and risk analysis, and the test plans and validation reports”, Ms. Duchrau wrote in her email.

What did this mean?

Computer system validation can be simple - with the right partner

Validating processes when introducing new digital systems is much easier today than it was a few years ago. That’s because the procedure has become more and more routine. A further advantage: An experienced partner, who has developed their products based on relevant specifications, such as GAMP 5, provides companies with experience and expertise on which they can rely. The result is a standardized implementation that optimizes the risk-based approach and reduces the amount of documentation required since the system can be classified as parameterizable standard software (GAMP Level 4).



Taking a new approach

What approach should you take if you are preparing for an update to an existing system instead of planning a standardized new implementation? How to ensure that companies in specific data areas are separated, while transaction data is fully converted? “Our motto, in this case, is to leave the beaten track and use creativity and know-how in computer system validation,” explains Patrik Allmann, Head of Quality and Compliance Management at YAVEON AG.

Ayanda GmbH faced precisely this challenge.

Ayanda and YAVEON - an initial project

The head office of Ayanda GmbH is Pritzwalk, a small town in Brandenburg, situated almost halfway between Hamburg and Berlin. As a contract manufacturer, the company produces softgel capsules on behalf of customers, drawing on many years of experience in producing of pharmaceutical and nutraceutical products. Due to this experience, company more than meets the high industrial standards expected.

A merger of three European subsidiaries from Norway, Finland, and Germany took place in 2008. With the integration of the companies, it quickly became clear: It is simply impossible to converge products and companies without a uniform ERP system, combined with common master data. Back then, Petra Duchrau was looking for a suitable software partner: “While doing some research on the internet, I came across the YAVEON website. The products seemed to fit. I found the YAVEON ProBatch industry solution and the validation experience particularly interesting.” Ms. Duchrau contacted the company directly. The resulting conversations and meetings brought the entire management team on board. “It was clear from the first second that the consultants at YAVEON were knowledgeable about validation. Right from the start, the cooperation was excellent, and we were on the same page.”



Starting from the then head office in Norway, the first project with YAVEON began: the introduction of the ERP system Microsoft Dynamics NAV and the industry solution YAVEON ProBatch. YAVEON ProBatch is fully integrated into the ERP system and extends it with the relevant functions for the pharmaceutical industry.

Ayanda makes particular use of the following functions:

- Quality management
- Production
- Audit trail
- Batch management
- Scale connection

One project, one goal: Uniformity

“The goal was clear: to build a complete solution that could be rolled out uniformly at the locations in Finland, Norway, and Germany,” recalls Patrik Allmann. For this purpose, a separate system was set up in each country based on a core solution, in which country-specific adjustments were made, but the master data was harmonized. The highly complex production processes were challenging. It was not easy to find a solution to map these completely in the ERP system. After a detailed analysis, a number of modifications, and intensive training of the users in production, we found the right path. The project started in January 2010, and by October of the same year, validated ERP systems were already in use in Finland and Germany.



The next project: Update

Ayanda continues to grow: In December 2016, the German headquarters became part of the SIRIO group. On the market since 1993, the group is a specialist in the pharmaceutical and food supplement industry. With this development, Ayanda was certain: An independent ERP system was required. The company also wanted to seize the opportunity to invest in a modern solution and optimize its processes.

The project had the following goals:

- Introduction of a modern user interface
- Create the prerequisites for integrating external systems. • Reduce adjustments and bring them closer to the industry standard
- Integration of the key functions of Ayanda into the new ERP system
- Conversion of all transaction data into the new system (including cGMP-critical data)
- Maintenance or establishment of the validated status
- Compliance with the principles of data integrity (ALCOA +)

Highly specific measures

The company's development showed that classic ERP implementation as standard was not possible. Although the GAMP 5 model allowed for the comparison of system functions, the generation of User Requirement Specifications (URS) and Functional Specifications (FS), the identification of development requirements, and a GMP risk assessment - Ayanda was faced with an additional challenge: A complete update with data conversion involves several test phases over several releases and contains numerous iterations. The actual conversion of the data only takes place as part of the go-live, because until then, the work continues in the existing system. It is also possible to adapt the conversion and software right up to go-live. Why is this necessary? This is due to the actual work being done: The reason is that the existing system is still in operation, with changes being made right up to the last second. Real (data) constellations can change again and again.

Together with YAVEON, Ayanda found a suitable method for the validation: The approach follows the GAMP 5 model; necessary documents such as URS and FS were prepared and approved during the project process. Also included: Risk analysis and test plans for data conversion. Functional and acceptance tests were also carried out on the validation system using test data from the current iteration status of data conversion.

»It was clear from the first second that the consultants at YAVEON were knowledgeable about validation. Right from the start, the cooperation was excellent, and we were on the same page.«

Petra Duchrau

Addressing data conversion with oversight

By far, the most significant changes were made in adapting the old system. All iterations consistently included test conversions. Because a substantial amount of data had to be modified, it was impossible to describe paths and changes precisely. Inconsistencies in the data were immediately identified during each conversion process and eliminated until the conversion was successful without an error message. Tests were also carried out in each phase:

- Has all data been converted (completeness)?
- Did data have to be re-entered?
- Do the most important functionalities work?

Based on the knowledge gained, Ayanda and YAVEON created an independent and formal test plan. The scope was based on Risk Analysis III - i.e., GxP-critical processes and functions with the associated data. As a result, the tests were composed of:

- Error messages from the conversion
- Completeness of the records
- Correctness of the data (random samples; sample size must be defined based on the risk analysis)
- Functionality of the software (in the course of the functional tests)

A successful go-live

The formal test of the conversion was carried out as part of the overall system qualification and thus on a validation system. Since up-to-date data is required for the actual go-live, the objects and necessary configurations data could be imported from the qualified master system.

Important: All data was converted to go-live. Before the system was released, further tests were carried out to ensure the accuracy of the data:

- Error messages from the conversion
- Completeness of the records
- Correctness of the data (random samples)

The definition of the respective test scope was risk-based. Based on previously defined conversion checklists, it was also confirmed that all required activities were complete and that the implementation ran without error messages. The system went into operation on January 1, 2019.

Looking back with satisfaction

Regardless if she considers the first project or the update project, Petra Duchrau is satisfied. She and her team felt they were guided well through the process and were able to ask questions at any time - this personal contact was particularly crucial in the initial phase. "It was very important to us that we could do the validation ourselves. This is of particular concern to the pharmaceutical industry." Ms. Duchrau also remembers many web sessions during the course of the project. The remote work progressed smoothly and saved both sides a significant amount of time and money. From the beginning, Ayanda users enjoyed working with the ERP system and have realized further advantages since the update: The system is very adaptable and intuitive to use, especially in the administration area. The ability to export lists to Excel is also beneficial. The training of new employees is now easier because a profile can be created for each user in advance. The user only sees the functions that are relevant for their work.

More time to concentrate on daily tasks

And what about Ms. Duchrau's email? The message to Patrik Allmann was a positive one. Ms. Duchrau was writing to thank him for his valued support and competent advice during the project. Thanks to the successfully introduced validated ERP system and the industry solution YAVEON ProBatch, Ayanda approaches every audit with confidence, and so is free to concentrate on daily operations.



YAVEON

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