Dr. Willmar Schwabe Group - From Nature. For Health.

Engineering Change Management with ⁴PEP in a pharmaceutical environment

The Schwabe Group is an association of companies including several firms in the pharmaceutical and health industry. All of the companies within the Schwabe Group focus on plants as the basis for developing pharmaceuticals and health products. The parent company of the Schwabe Group, the Dr. Willmar Schwabe GmbH & Co. KG, is one of the oldest pharmaceutical manufacturers in Europe with a company history dating back over 150 years. The quality of the Schwabe Group's pharmaceutical products and preparations is at the highest level. From the natural raw material up to the packaged product – every step of the manufacturing process at the Schwabe Group is in the hands of a single source. The implementation of ⁴PEP Engineering Change Management helps the Schwabe Group to guarantee a consistently high quality of the products.

"Using *PEP Engineering Change Management allows us perform a regulatory assessment of any changes and to monitor their full implementation. Additionally, the software offers excellent possibilities to make evaluations in all areas. ILC's assistance in implementing adjustments as well as custom solutions is exemplary."

Andreas Landkammer Quality Assurance



Schwabe Group
From Nature. For Health.

Company

- name: Dr. Willmar Schwabe Group
- headquarters: Karlsruhe
- industry: Pharmaceutical Industry
- products: Phytopharmaceuticals, homeopathy, nutritional supplements
- revenue: 900 m EUR (2019)
- employees: 3,600 (2019)
- www.schwabe.de

Solution

- simple integration of objects that are to be changed
- system-supported determination of affected products
- workflow-supported task processing using defined action plans
- classification and status monitoring of the regulatory activities
- search and reporting function

nitial Situation and Challenges

- established process did not meet formal requirements any more
- completion of the change process without action monitoring and check of change implementation
- integration of the existing Product Data Management (PDM) into the change process
- entering and assessment of pharmaceutically relevant changes

Customer Benefit

- controlled and streamlined changes using workflow support
- comprehensive transparency of all changes and their implementation
- clearly defined processing using an actions cockpit
- information about change progress via email
- GMP conform solution

ILC GmbH Saarpfalz-Park 7 66450 Bexbach Phone +49 (0)6826 189-0 Fax +49 (0)6826 189-189 E-Mail: info@ilc-solutions.net www.ilc-solutions.net