4PEP

CHEMICALS & PHARMA

THE BETTER WAY TO PLM

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[4]PEP Chemicals & Pharma — Research and Development for Life

The research and development of new products in the chemical and pharmaceutical industry is characterized by long lead times and particularly high expenditures. Correspondingly, the potential for efficiency-promoting and cost-saving measures in R&D is high.

Furthermore, it is essential to secure the safety of business processes in a highly regulated environment. Product approval is another hurdle that may entail unpleasant consequences.

ILC knows the challenges of the chemical & pharmaceutical industry and supports you on your way to efficient development processes with excellent consulting services and outstanding software solutions.

Innovation and product development – the key to sustainable success

A long period passes between the idea for a product and its successful entry into the market, which leaves room for enormous **optimization potential in the chemical and pharmaceutical industry**. It is particularly the structured management of the development process that presents many companies with major challenges. Very often, a phase model with tasks, checklists, milestones, and documentation to be created is in place. However, the **efficient control and monitoring** of the process is impossible in your day-to-day work when IT tools are being used that are not suited for the purpose, for example, MS Office and file storage on fileservers.

In order to meet the increasing demand for system or process solutions in the chemical and pharmaceutical industry, an intensive **cooperation across company boundaries** is required. This leads to a significant increase in the complexity of the product development process. The process-related and technological interfaces to partners must be kept as simple and transparent as possible – an almost impossible undertaking without the use of a professional business system.

In addition, quick market access is made increasingly difficult by regulatory framework conditions with different **certification requirements in a global market**. At the same time, the product documentation necessary for the certification is already created during development. A standardized mapping of these sub-processes by an of document creation and ensures a high level of process reliability.

Ultimately, a structured and IT-supported management of the development process provides the basis for measuring and controlling product developments using a reliable and promptly determinable system of key indicators. This is the solution to ensure the **success of development projects** quickly and early on. The availability of up-to-date key performance indicators is a critical factor for the effective and successful management of one or more development processes done by businesses in a **competitive international market**.

ILC

Product Record, Gates, and Deliverables

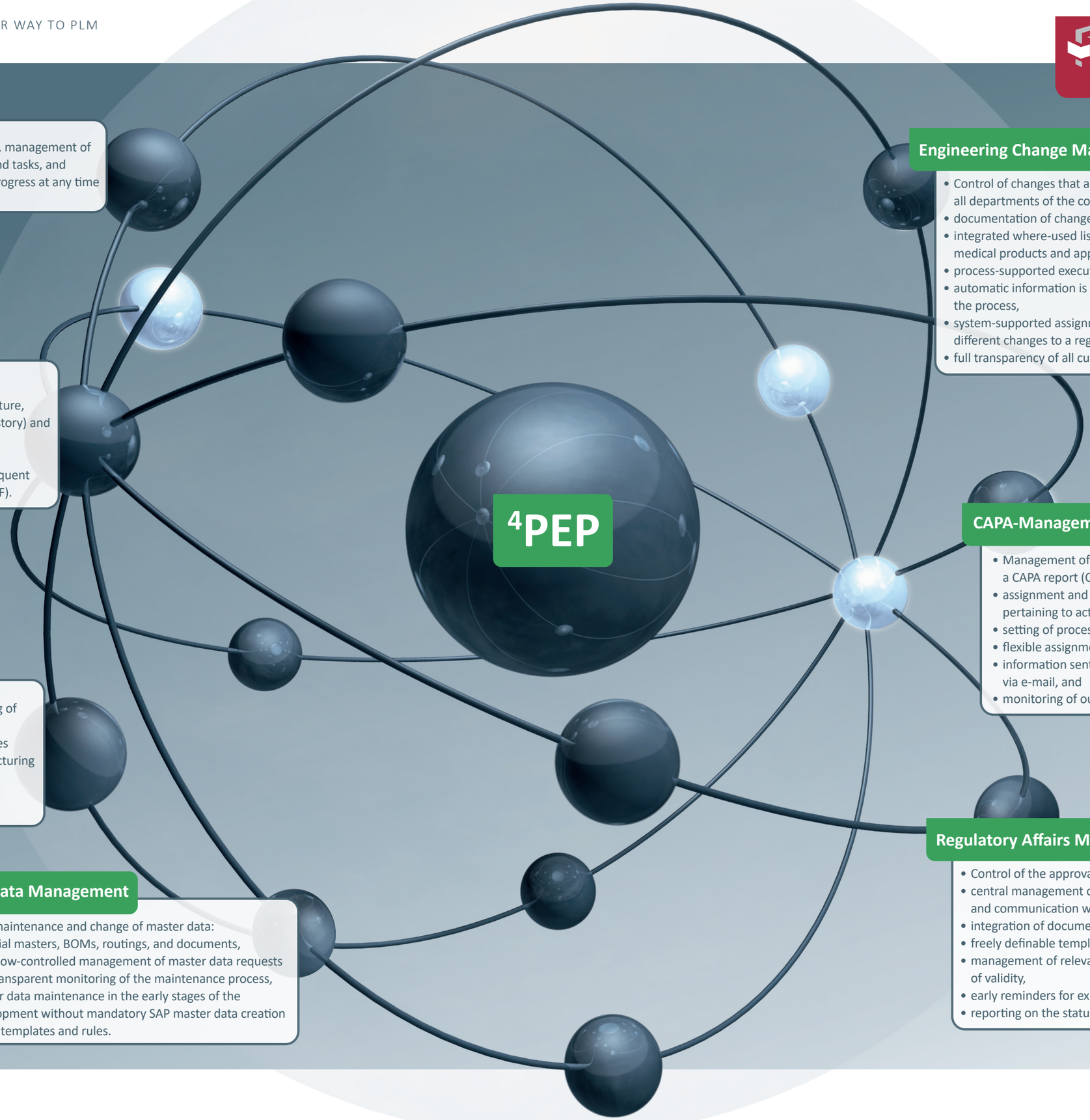
- Project creation, PEP tailoring, management of phases, gates, deliverables, and tasks, and
- transparency of the project progress at any time to the level of deliverables.

Engineering Change Management

- Control of changes that are relevant for regulations across all departments of the company,
- documentation of change evaluation and change decision,
- integrated where-used list to determine, which finished medical products and approvals are affected,
- process-supported execution through defined action plans,
- automatic information is given to everyone involved in the process,
- system-supported assignment of regulatory data from different changes to a regulatory activity (variation), and
- full transparency of all current change processes.

Requirements and Document Management

- Redundancy-free digital archive, freely definable templates for the document structure,
- freezing of states as a baseline (mapping of the history) and comparison of different states,
- document release with a digital signature, and
- management of requirements as a basis for subsequent processes and import from external systems (ReqIF).



CAPA-Management

- Management of nonconformities and actions in a CAPA report (Corrective and Preventive Action),
- assignment and management of documents pertaining to actions,
- setting of processing sequences and target dates,
- flexible assignment of agents,
- information sent to everyone involved in the process via e-mail, and
- monitoring of outstanding actions.

Production Process Planning

- Freezing of states as a baseline (mapping of the history),
- development of manufacturing structures (M-BOM) and extraction of SAP manufacturing bills of material,
- creation of routings, and
- resource management.

Regulatory Affairs Management

- Control of the approval process,
- central management of all documents, information and communication with authorities,
- integration of documents,
- freely definable templates for the document structure,
- management of relevant standards and monitoring of validity,
- early reminders for expiring approvals and
- reporting on the status of current approvals.

Master Data Management

- Easy maintenance and change of master data: material masters, BOMs, routings, and documents,
- workflow-controlled management of master data requests and transparent monitoring of the maintenance process,
- master data maintenance in the early stages of the development without mandatory SAP master data creation
- use of templates and rules.

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[4]PEP Chemicals & Pharma – research and development for life

With [4]PEP Chemicals & Pharma, you are preparing your product development process for a successful future. With the introduction of ERP systems, it became standard to have integrated data and integrated processes in order processing and in accounting. Now, with [4]PEP Chemicals & Pharma, it is possible to have **integrated data and integrated processes in your product development**, too.

EFFICIENT

- Prevention of data redundancy and of multiple entries of data
- Reduction of time spent on searches
- Reliable, controlled and **complete documents and master data**
- Easy compliance with external norms and requirements

TRANSPARENT

- **Data transparency:**
  Access to all product data, documents and to product-relevant data from all areas of the company (costs, inventory, etc.) is central and **protected by authorization**,
- **Project transparency:**
  Linking of project information (phases, milestones, etc.) with **product information** (status of parts, version, etc.),
- **Process transparency:**
  View the current status of release, maintenance, and change processes!
- **Key performance indicator transparency:**
  The integrated database allows you to extract and analyze real key performance indicators using IT. The long-term success of your development project is secured **by gaining knowledge immediately** and by quickly implementing measures.

FLEXIBLE

- [4]PEP Chemicals & Pharma meets the requirements of the customers and provides **tailored solutions.**
- **Changes** in processes, organization or data models **can be implemented quickly.**
- [4]PEP Chemicals & Pharma is **scalable** in order to be used by a range of applications, from small to midmarket to large and international ones.

CHEMICALS & PHARMA REFERENCE SOLUTION

In our **Reference Solution**, we pool many years of project experience that we gained through working with customers in the chemical and pharmaceutical sector. We do not come to you empty-handed but with a **specific best practice approach**, where reference requirements, processes, and data models are outlined in a clear and concise form so that we can discuss them with you. This does not only save you **time** with regard to the project, but you can also be sure that the basis of our joint work is a **tried-and-tested approach**, which can be supplemented as necessary to meet your specific requirements. This concept is also supported by our **industry-specific [4]PEP reference system**: We have already anticipated the scope of the best practice approach in the system and developed it accordingly. Customizing as well as features, functions, and processes are directly available to you. In addition, our reference test cases guarantee the **optimal quality assurance** of the system.

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Satisfied customers speak for themselves ...

"Using **[4]PEP Engineering Change Management** allows us to 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, Dr. Willmar Schwabe GmbH & Co. KG

Schwabe Group
From Nature. For Health.

"With the implementation of **Product Master File** and **[4]PEP Engineering Change Management** on the basis of ILC's reference solution, a majority of our requirements were mapped. We are very satisfied with the execution of the tasks and the concrete project results. ILC's team gave us outstanding support in every way."
Michael Bogus, Manager of IT PLM Services, Sartorius AG

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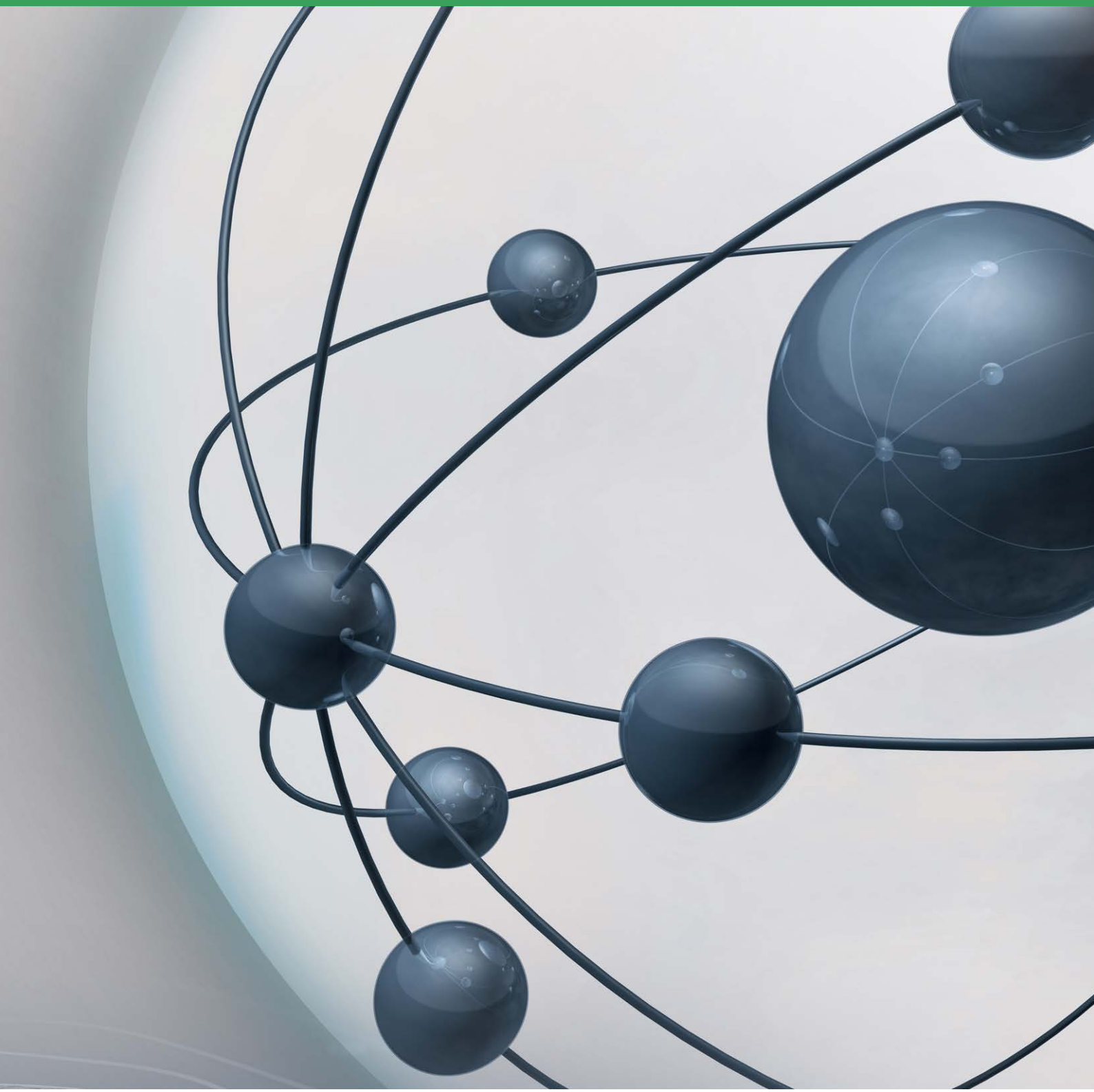

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