

4 PEP

MEDICAL

PRODUCT EXCELLENCE & PERFORMANCE

Growth through innovation

The software suite for your product development process

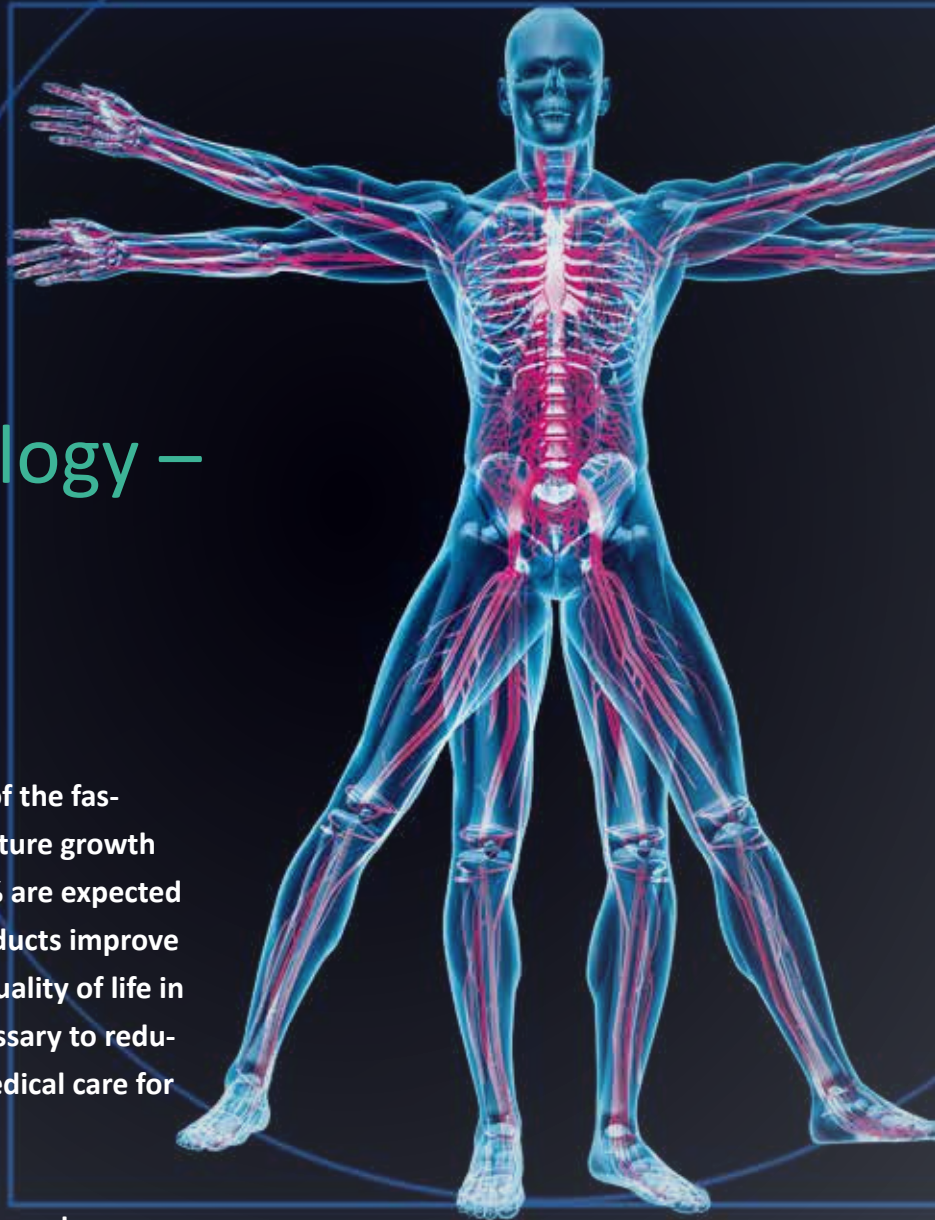


Medical technology – growth through innovation

The medical technology industry is one of the fastest growing sectors and has excellent future growth potential: Annual increases of up to 16 % are expected until 2020! New medical technology products improve patient care and contribute to a better quality of life in an ageing society. Additionally, it is necessary to reduce health expenditures and to ensure medical care for the general public.

This can only be achieved by the continuous development of innovative products. Consequently, the medical technology faces specific challenges.

The conflicting demands of technological innovation versus regulated environment make the way from the research up to the admission of a product in all target countries difficult and long. With ⁴PEP Medical, this way will become more efficient, more transparent and more flexible by presenting the development process comprehensively and interdisciplinary, and by optimizing the product development process.



Innovation and product development – the key to sustainable success

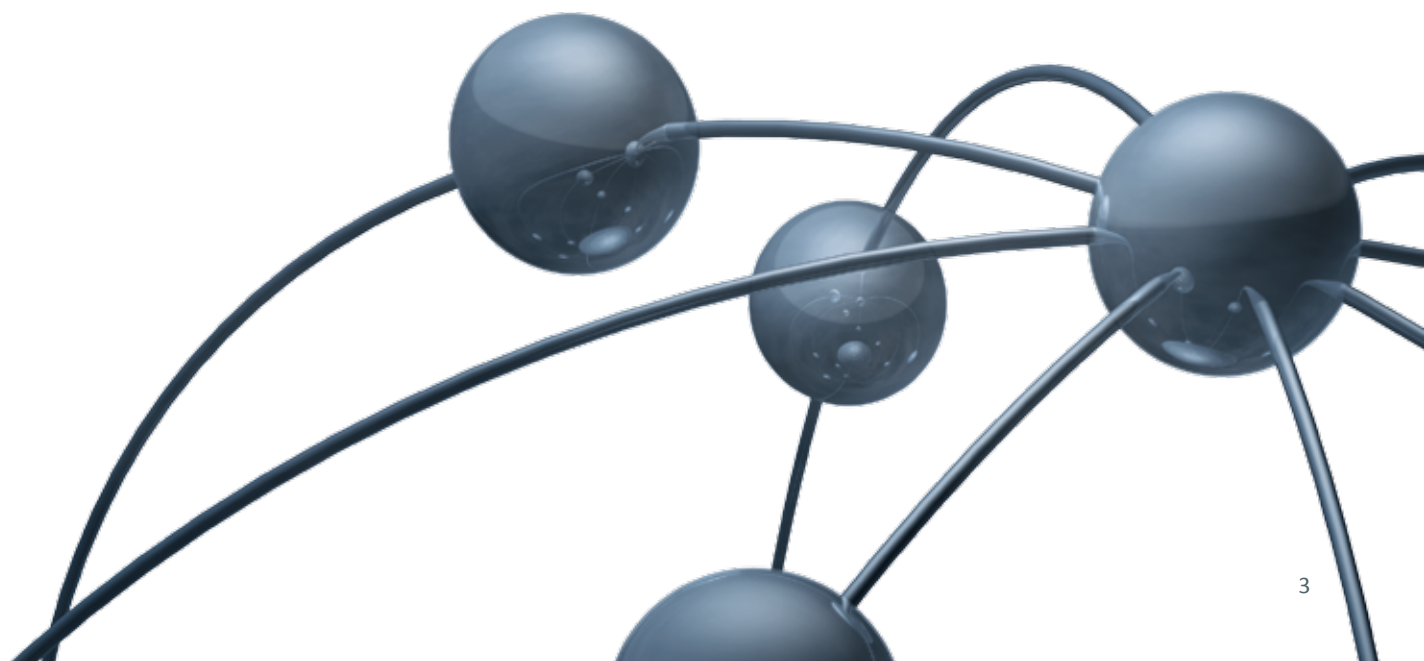
A long period of time passes between the idea for a product and its successful entry into the market, which leaves room for an enormous optimization potential for the medical technology. It is particularly the structured management of the development process that represents a big challenge for many companies. Very often, a phase model with tasks, checklists, milestones and deliverables is in place. But an efficient management and monitoring of the process is impossible in your day-to-day work when IT tools are being used that are unfit for the purpose, for example MS Office and storing files on file servers.

In order to meet the increasing demand for system or process solutions in medical technology, an intensive collaboration across company borders is essential. This way, the complexity of the product development process increases. The processual and technological interfaces between cooperating partners have to be as simple and as transparent as possible. Without the use of a professional business system, this proves to be a more than difficult exercise.

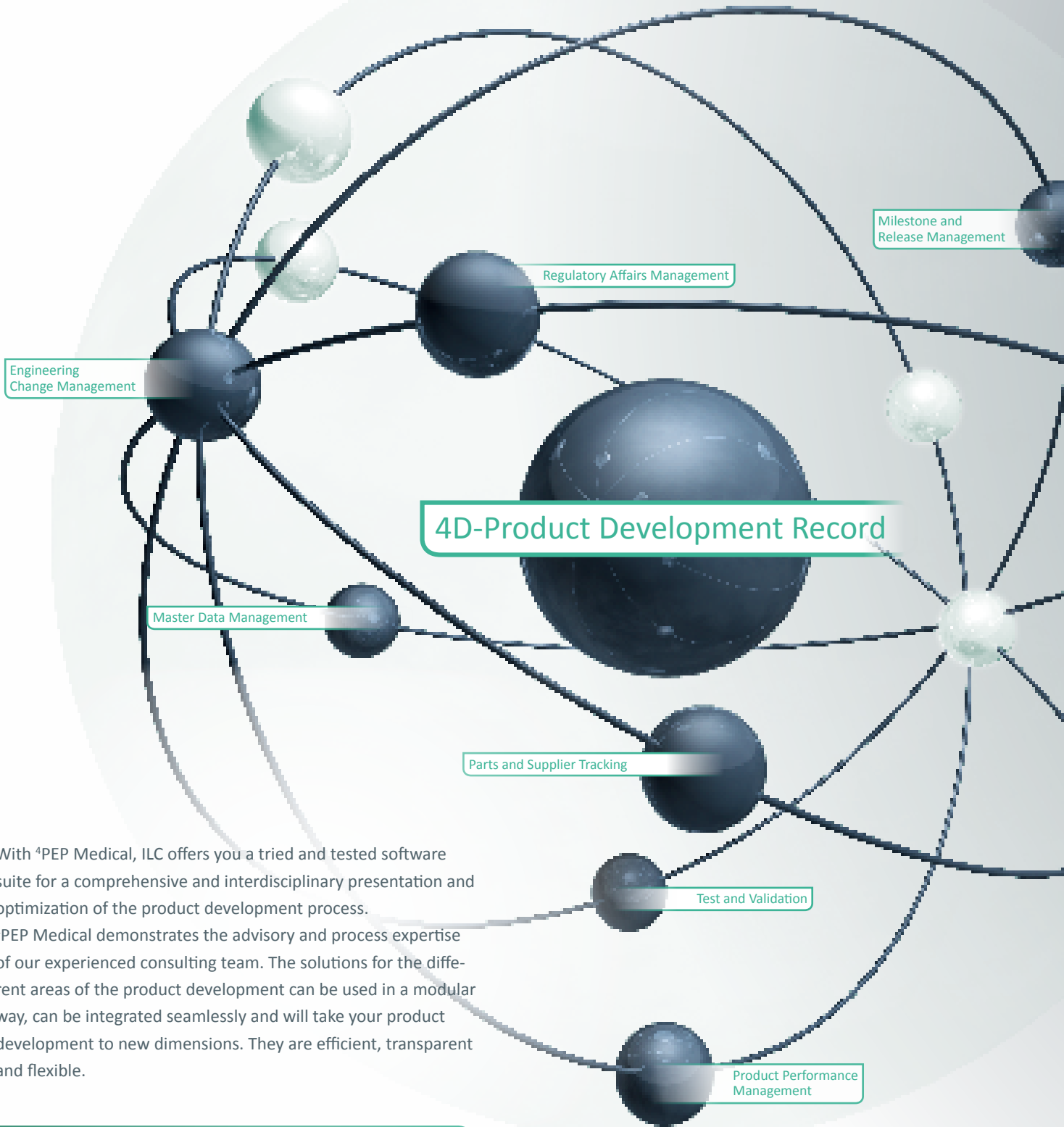
A quick market access is further made difficult by regulatory frameworks with different certification requirements in a global market. At the same time, the product documentation necessary for the certification is already created during the product development. A standardized presentation of each part of the process by an integrated IT system improves the efficiency of the creation of documentation and ensures a reliable process.

A structured and IT-supported management of the development process is the basis for measuring and controlling the product development with a reliable and readily determinable indicator system. This is the key to ensure the success of development projects quickly and early on.

Having up-to-date key performance indicators readily available is of great importance for the effective and successful management of one or more development processes done by businesses competing internationally.



Efficient management of the development process with ⁴PEP Medical



With ⁴PEP Medical, ILC offers you a tried and tested software suite for a comprehensive and interdisciplinary presentation and optimization of the product development process.

⁴PEP Medical demonstrates the advisory and process expertise of our experienced consulting team. The solutions for the different areas of the product development can be used in a modular way, can be integrated seamlessly and will take your product development to new dimensions. They are efficient, transparent and flexible.

**"THE WHOLE IS GREATER THAN
THE SUM OF ITS PARTS."**

Aristoteles

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4D-Product Development Record

- Reliable management of the entire documentation
- Easy editing of documents via the Windows Explorer
- Monitoring of the creation and release of documents in every stage of the development
- Generating of documentation required by regulation (e.g. Design History File)
- One central source of information for all the data concerning a product (single point of truth)
- Integration of documents with master and transaction data

Milestone and Release Management

- Definition of all phases of the product development process
- Setting of milestones and corresponding checklists
- Deliverables to a milestone (project plan, validation plan, bill of material, ...)
- Managing and monitoring of release processes based on workflow and checklists

Regulatory Affairs Management

- Managing of the approval process based on checklists and workflow
- Central management of the full approval documentation
- Reminder function in the time management to meet deadlines
- Support for the STED standard (Summary Technical Documentation)

Engineering Change Management

- Controlled management of product changes across all departments of the company
- Presentation of change initiation, change request, change order and implementation
- Where-used report and usage decision
- Release procedure and digital signature

Master Data Management

- Easy maintenance and change of product master data like material master, bill of material or routings
- Transparent monitoring of the maintenance process
- Flexible master data maintenance in the early stages of the development without mandatory SAP master data creation
- Quick maintenance by providing already existing master data as templates

Parts and Supplier Tracking

- Guided development of the product structure through the stages of the product development process
- Online-status of the level of maturity of every part in the product structure
- Targeted, product-related communication with the supplier
- Freely definable product status (e.g. drawing released, purchase order placed, goods receipt posted)
- Automated comparison of target and actual state with visualization (traffic light display)

Test and Validation

- Planning of test and validation measures in the different phases of the product development
- Derivation and adjustment of product data relevant for the respective test
- Documentation of the test and validation parameters as well as the corresponding test results

Product Performance Management (PPE)

- Extraction of all data that is relevant for a key performance indicator system
- Technical analysis and data preparation
- Provision of visualization in tables or graphics for the departments and the management

⁴PEP Medical – the new dimension for your innovation and development process

With ⁴PEP Medical, you are preparing your product development process for a successful future. With the introduction of ERP systems, it became a standard to have integrated data and integrated processes in the order handling and the accounting. Now, with ⁴PEP Medical it is possible to have integrated data and integrated processes in your product development.

⁴PEP Medical – a new dimension for your product development process:

EFFICIENT

- Prevention of data redundancies 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 product data, documents and to data relating to products from all departments costing, inventory, ...) is central and protected by authorization
- **Project transparency:**
Linking of project information (phases, milestones, ...) with product information (status of parts, version, ...)
- **Process transparency:**
View the current status of release processes, maintenance processes 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

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





Satisfied customers speak for themselves ...

“As one of the world’s leading providers of medical technology, we have very high requirements when it comes to our change management in SAP. With 4PEP Engineering Change Management from ILC, we were able to fulfill these requirements and comply with the high regulatory standards.”

Joachim Buckel,
Demand Manager PLM, Siemens AG, Healthcare Sector

“With 4PEP Regulatory Affairs Management, we control our international approval processes safely and quickly. We were able to always represent our requirements flexibly with the solution from ILC. ILC consultants’ high process competency resulted in a high quality implementation.”

Fernand Portenier,
Head of IT, Ypsomed AG

“With 4PEP Master Data Management, we were able to significantly cut the time needed for the creation of our material masters.”

Steffen Bauer,
Head of IT, Richard Wolf GmbH



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A new dimension of
product development