4PEP

MEDICAL

THE BETTER WAY TO PLM

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4PEP Medical — Growth through innovation

The medical technology industry is one of the fastest-growing sectors with excellent prospects for the future. In view of the growing world population and aging societies, the research departments of medical technology companies have plenty of work to do. New medical technology products provide better patient care and contribute to a higher quality of life. It is also important to reduce health care spending and ensure medical care for the general population.

All this can only be achieved through the continuous development of innovative products. The medical technology sector faces specific challenges, as the way from the research to the approval of a product in all target countries is often long and rocky, particularly with regard to the conflicting demands between technological innovation and a regulated environment. With 4PEP Medical, this path becomes more efficient, transparent and flexible through the comprehensive and interdisciplinary mapping and optimization of the product development process.

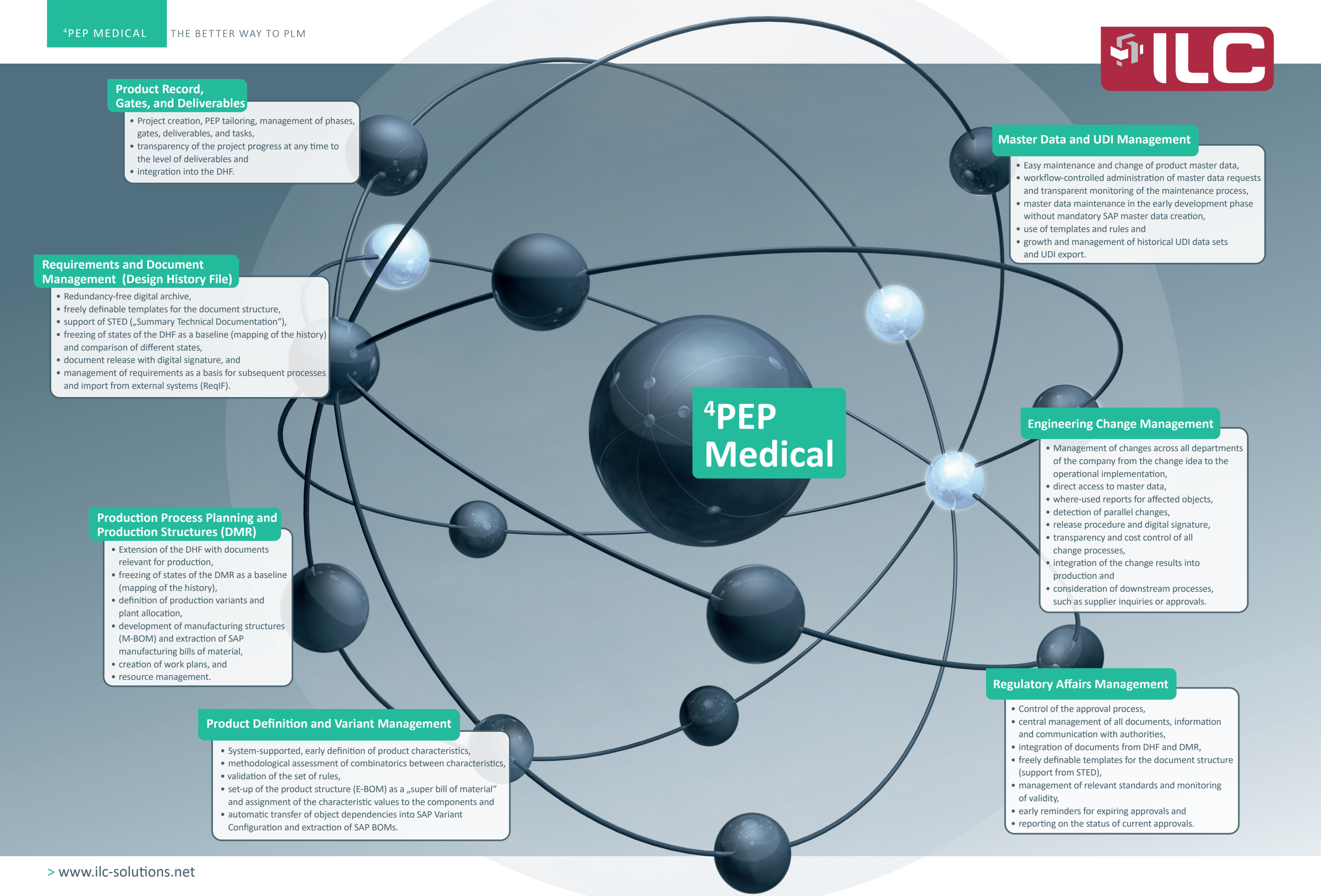
Innovation and product development - the key to sustainable success

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 in medical technology.** 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, and milestones is in place, but an **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 medical technology, an intensive **collaboration across company boundaries** is essential. This leads to a significant increase in the complexity of the product development process. The process-related and the technological interfaces between cooperating partners must be kept as simple and transparent as possible – this is a more than difficult undertaking without the use of a professional business system.

In addition, quick market access is made difficult by the 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 **integrated IT system improves the efficiency** 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 in a **competitive international market**.



Product Record, Gates, and Deliverables

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

Requirements and Document Management (Design History File)

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

Production Process Planning and Production Structures (DMR)

- Extension of the DHF with documents relevant for production,
- freezing of states of the DMR as a baseline (mapping of the history),
- definition of production variants and plant allocation,
- development of manufacturing structures (M-BOM) and extraction of SAP manufacturing bills of material,
- creation of work plans, and
- resource management.

Product Definition and Variant Management

- System-supported, early definition of product characteristics,
- methodological assessment of combinatorics between characteristics,
- validation of the set of rules,
- set-up of the product structure (E-BOM) as a „super bill of material“ and assignment of the characteristic values to the components and
- automatic transfer of object dependencies into SAP Variant Configuration and extraction of SAP BOMs.

Master Data and UDI Management

- Easy maintenance and change of product master data,
- workflow-controlled administration of master data requests and transparent monitoring of the maintenance process,
- master data maintenance in the early development phase without mandatory SAP master data creation,
- use of templates and rules and
- growth and management of historical UDI data sets and UDI export.

Engineering Change Management

- Management of changes across all departments of the company from the change idea to the operational implementation,
- direct access to master data,
- where-used reports for affected objects,
- detection of parallel changes,
- release procedure and digital signature,
- transparency and cost control of all change processes,
- integration of the change results into production and
- consideration of downstream processes, such as supplier inquiries or approvals.

Regulatory Affairs Management

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

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

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

MEDICAL REFERENCE SOLUTION

In our **Medical Reference Solution**, we pool many years of project experience that we gained through working with customers in the medical technology 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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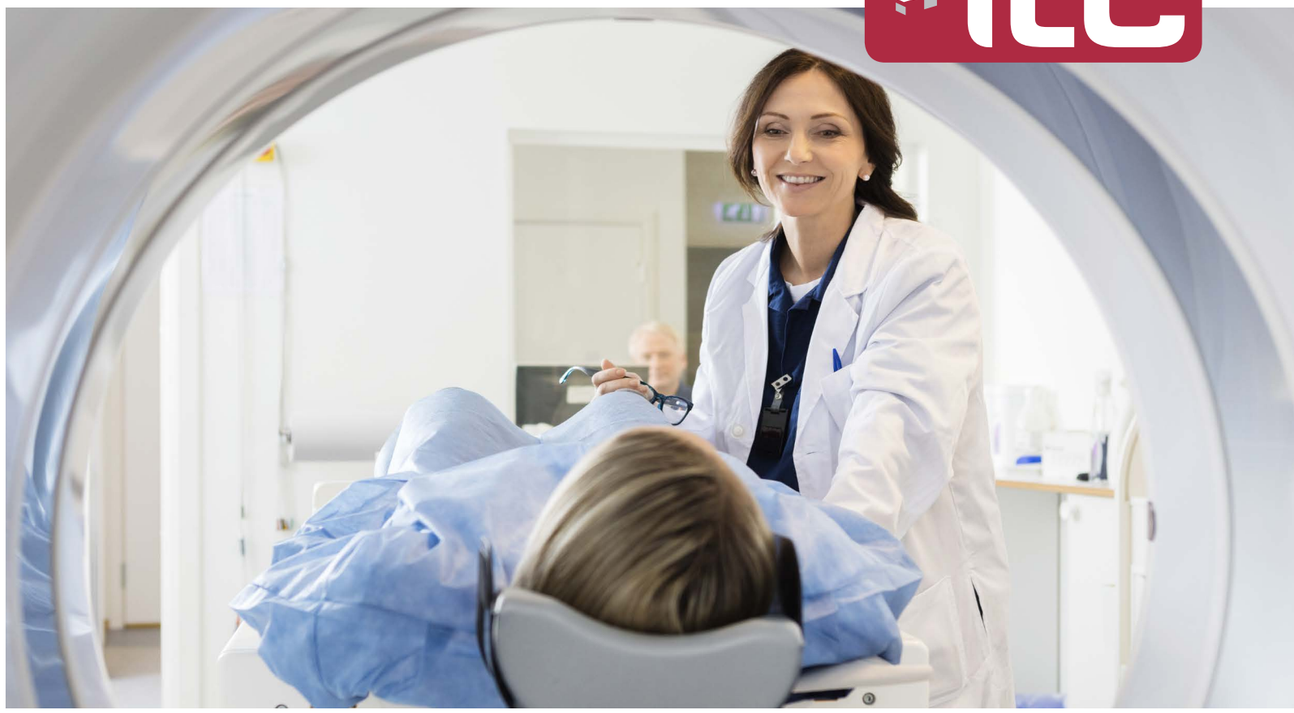

Satisfied customers speak for themselves ...

"As one of the world's leading providers of medical technology, we have very high demands when it comes to our change management in SAP. With [4]PEP Engineering Change Management from ILC, we were able to **fulfill these demands** and maintain our **high regulatory standards**."
Joachim Buckel, Demand Manager PLM, Siemens Healthcare Division

"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 was 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

"With [4]PEP Regulatory Affairs Management, we control our **international approval processes safely and quickly**. We were able to constantly 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 [4]PEP 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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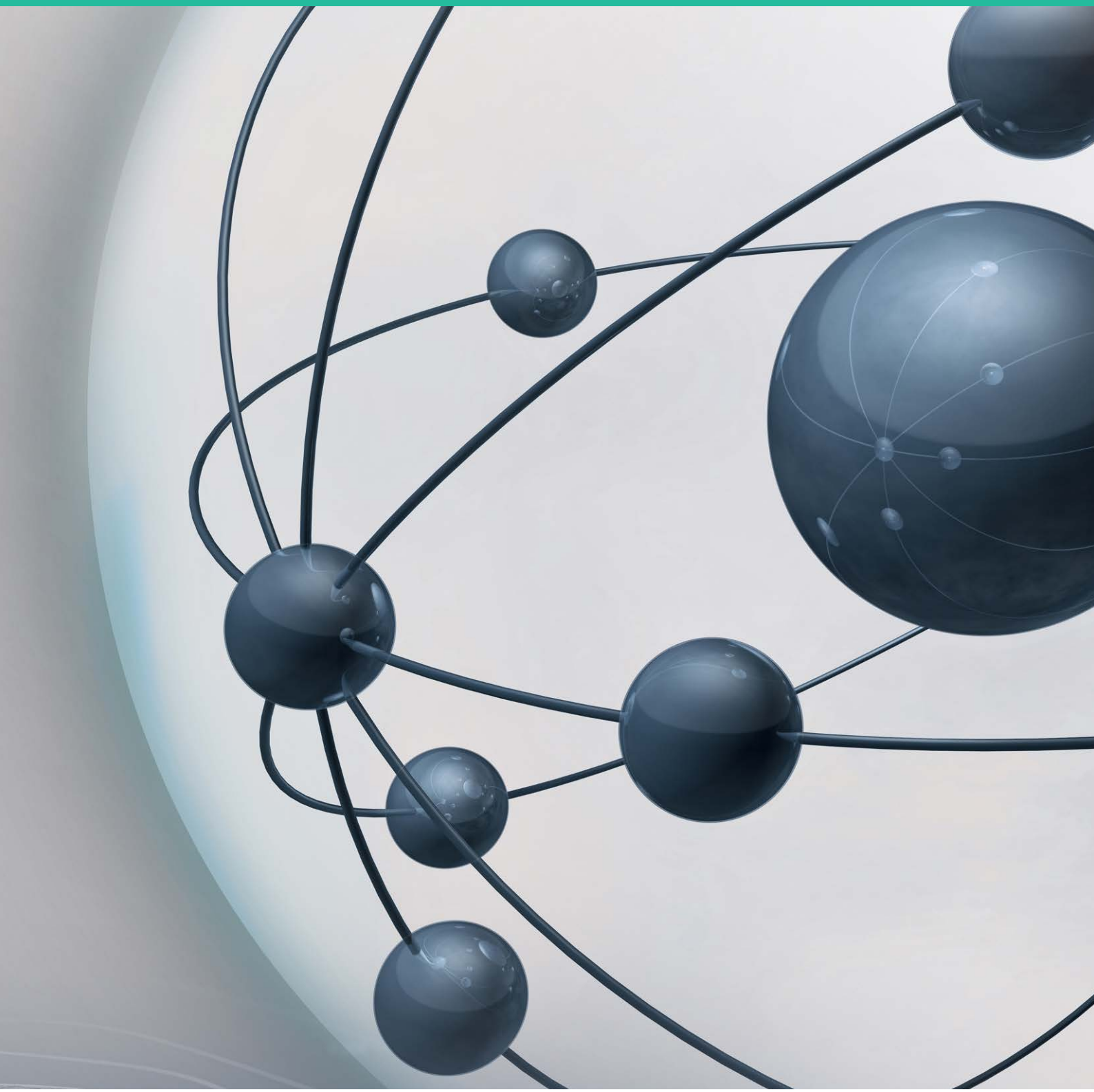

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