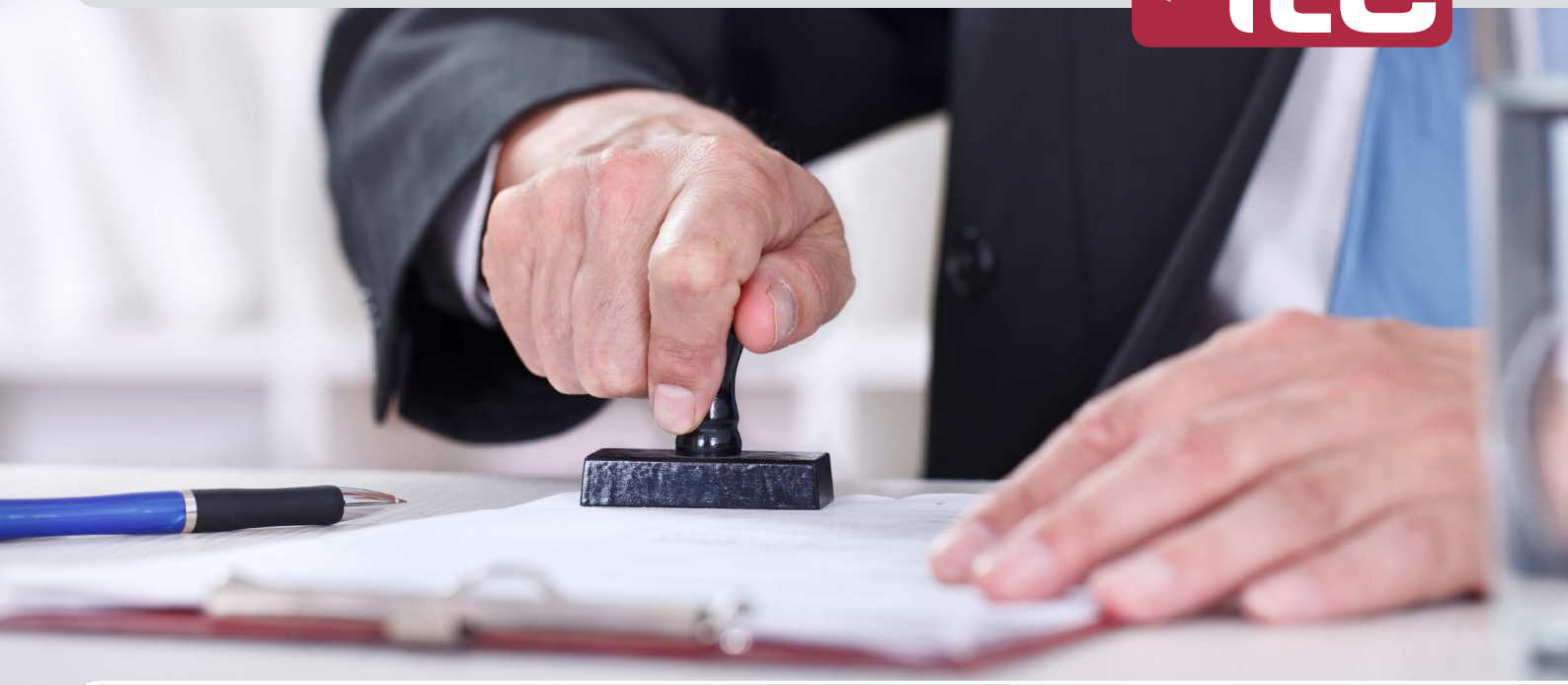

[4]PEP Regulatory Affairs Management

International Product Approval – transparent, fast and safe

Keep track of the approval process

If you market your products internationally, you need to deal with a large number of approval processes in several regions and countries. This usually means that you have to submit a more or less comprehensive documentation to the relevant authorities. Very often, a new application for approval has to be submitted in case of major product changes or if certain deadlines have expired.
With **[4]PEP Regulatory Affairs Management**, ILC presents an innovative SAP®-based solution. It allows you to unite national and international approval process on a single platform. This enables you to optimally plan product approvals, implement them safely and save time through automated processes.

Challenges in product approval

- **Complex regulations:**
  A large number of different approval regulations have to be observed in the various markets.
- **Deadlines and time limits:**
  The deadlines for the approval of products that are subject to authorization have to be monitored and met in all countries.
- **Comprehensive documentation:**
  It is usually necessary to submit a comprehensive documentation for the approval. The documentation status has to be transparent at any time.
- **Management of the approval process:**
  The management and monitoring of the approvals is often done manually or using IT tools that are unfit for the purpose.

Efficient approval processes with [4]PEP

- The entire **approval process** is stored in dossiers on the basis of checklists and can be adapted individually. You will keep track of the entire regulatory affairs process.
- A **time management** with reminders and status messages helps you to manage the approval process optimally. The program will guide you throughout the product lifecycle, even in case of reapprovals.
- Project participants have **centralized access** to dossiers, documents, correspondence, the current project status, as well as to personal work packages.
- Creation, approval and submission of **documents** in one system creates transparency at all times. You can determine which documents were sent to whom and when by one click.

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The components of Regulatory Affairs Management

Dossier Management

The Dossier Management guides you in the approval process and throughout the entire product lifecycle. A dossier contains documents, attachments and checklists. It is linked to additional dossiers associated with the product. You can easily create, edit and manage work tasks and work packages and assign them to the respective staff or teams in charge. You can comfortably access and browse the individual documents and attachments thanks to the clearly defined cockpits. You can link dossiers directly to material numbers in SAP® ERP. The STED standard (Summary Technical Document) is supported.

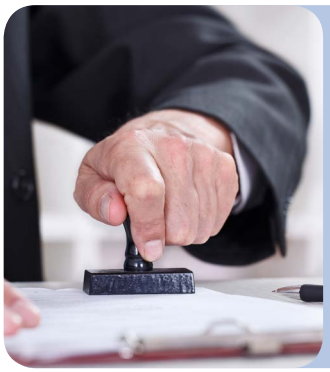
Document Management

All documents relevant for the approval are managed in the document management cockpit of 4PEP. These include particularly technical documents and documents concerning the compliance with national and international legal requirements. You can attach correspondence to the respective dossier. Checklists show insight into which documents are already available and whether additional documents have to be requested. A predefined workflow assists you in the creation, management and release of documents. The precise labeling of versions and the status management provide additional insight into the variety of documents. You can increase process safety with an optional digital signature.

Submission Management

The Submission Management guarantees the necessary transparency during the process. You have an overview of the current status of the approval process at any time. You can see which documents were sent out to whom and when by one click. You can also easily determine which documents were used in which dossier. Periodically as well as individually configurable reminders automatically indicate upcoming deadlines for reapprovals.

4PEP Regulatory Affairs Management is the IT tool for your national and international approval processes. Thanks to the innovative software you can keep track of all deadlines, documents and necessary steps. You are able to save time and gain reliability in the approval process due to the effective planning, controlling and instant setup of all necessary process steps.



“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

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