Your competent partner for Drug Regulatory Affairs

Drug Regulatory Affairs

eCTD Service

Regulatory Advice

Regulatory Writing & Artwork

Maintenance

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Topic

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Company Profile

My team makes pharmadocs what it is – a purposeful and responsible company in which every employee contributes to success. And this is also reflected in the work we do for our partners.

Peggy Schorn, Managing Director

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Pharmadocs GmbH & Co. KG is an international service provider for the pharmaceutical industry that specializes in the authorization of medicinal products for human use.

We take on your projects starting from the planning through the preparation and submission of the regulatory registration documents up to the complete life cycle management. Only qualitatively perfect work results leave our house. We cooperate closely with the relevant authorities and always work according to national and international laws, regulations and guidelines.

Our claim is not only to admit the products, but to optimize the documents and processes in such a way that our customers can continue to work with their data in the best possible way in the future.

Our History

Today

INTERNATIONAL PARTNER FOR PHARMACEUTICAL APPROVAL

In the area of drug approval, pharmadocs GmbH & Co. KG has become an international partner for the pharmaceutical industry. The company continues to strive for progress in order to provide excellent service to its partners.

2019

OUR SEAL

Since 25.03.2019, pharmadocs has been certified by DEKRA according to ISO 9001 quality management. Just like the DEKRA seal itself, pharmadocs stands for safety and quality.

2014

CHANGE OF THE COMPANY NAME

In September 2014, the renaming of e.K. to GmbH & Co.KG.
With this step pharmadocs sets new course and creates the possibility for the progressive development of the achievements and competences.

2012

eCTD

pharmadocs equips itself with the eCTD tool and now offers the creation, submission, archiving and administration of approval-relevant documents in electronic form.

2012

MOVING TO LIGHT ROCK

Due to the growing number of employees, the office in Schwürbitz no longer offers enough space. On 20.02.2012 the move to Lichtenfels takes place in the Pabstenweg 10. The new office building allows larger office space, a separate meeting room and group workstations for project teams.

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2011

BUSINESS DEVELOPMENT & MARKETING

Business development and marketing will be expanded more strongly. This allows pharmadocs to act faster and more targeted on the market, to drive the development of the company and to respond more closely to customer wishes.

2010

EMPLOYEE TRAINING

Internal training for employees is introduced. New employees receive a practice-oriented induction phase and receive targeted training for the company's work structures. Employees are trained and supported through internal and external seminars.

2010

MOVING TO SCHWÜRBITZ

The small office no longer meets the spatial conditions and claims. By relocating to Schwürbitz, pharmadocs is offering its employees in the new office building more suitable room layouts and a better infrastructure. In addition, the EDP and security technology will be upgraded. pharmadocs can win the first major customers as a partner.

2009

GRÜNDUNG

Peggy Schorn (*Tuchen) founds the company pharmadocs in Michelau. Short time later, she hires her first employees.

City of Lichtenfels

The story of Lichtenfels

The roots of Lichtenfels go back to the year 1000. At that time, a castle was called Lichtenfels, which stood on a „light rock“. In 1231, Duke Otto I of Andechs-Meranien commissioned the founding of Lichtenfels. The central location on the Main and the direct connection to the old streets were ideal. The market square at that time, on which all lanes and paths united, is still central to the city today.

Lichtenfels as „German basket town“

As early as the 18th century, baskets were produced in Lichtenfels and sold on markets and on front doors. The rural Lichtenfels is well known as the „German basket town“ and for its traditional wicker markets. The ancient craftsmanship of the braiding is held here in honor. The basketwork can learn interested in Germany‘s only technical college for baske-try, the innovation and design center of the German Flechthandwerks.

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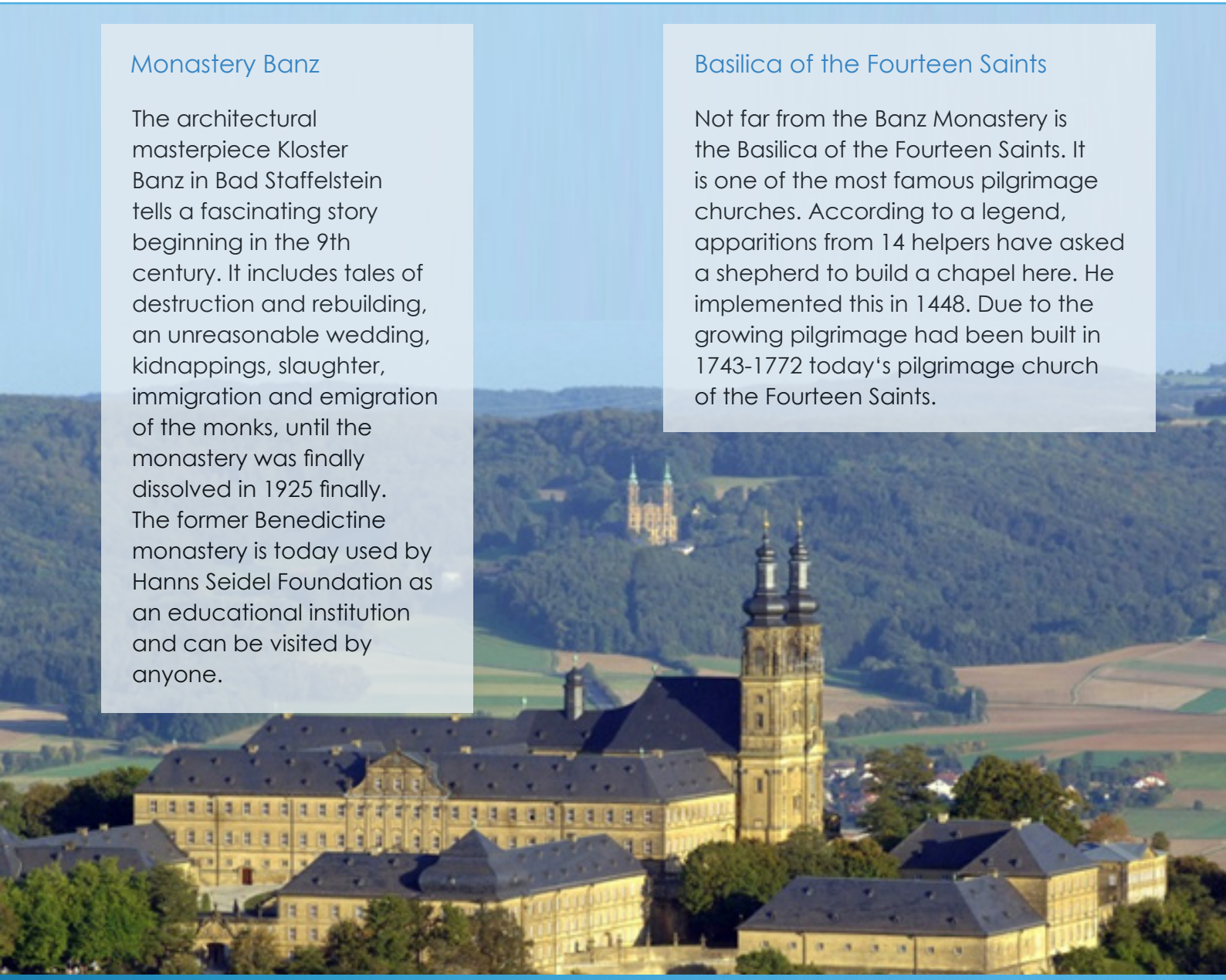
Monastery Banz

The architectural masterpiece Kloster Banz in Bad Staffelstein tells a fascinating story beginning in the 9th century. It includes tales of destruction and rebuilding, an unreasonable wedding, kidnappings, slaughter, immigration and emigration of the monks, until the monastery was finally dissolved in 1925 finally. The former Benedictine monastery is today used by Hanns Seidel Foundation as an educational institution and can be visited by anyone.

Basilica of the Fourteen Saints

Not far from the Banz Monastery is the Basilica of the Fourteen Saints. It is one of the most famous pilgrimage churches. According to a legend, apparitions from 14 helpers have asked a shepherd to build a chapel here. He implemented this in 1448. Due to the growing pilgrimage had been built in 1743-1772 today's pilgrimage church of the Fourteen Saints.



Our customer is our partner

For us, the customer is not king, but partner! Because in a partnership, you deal openly, confidently and conscientiously with each other. Of these advantages, a king can rarely benefit.

Our partners benefit from the extensive expert knowledge of our trained employees. They value our transparent, structured and careful way of working. We not only work on their projects but also think for our partners and are always available as consultants.

In addition, the absolute secrecy is always at the forefront. Neither on public platforms nor in discussions with other companies will we become ours Reveal partners or their projects.

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Our mission statement

On an equal footing with the authorities

We do not see the requirements of the authorities as a foreign language, but bring the wishes of our partners into line with the requirements of the authorities.

High quality standard

With our quality management system, we permanently ensure fast and smooth project processing with high-quality results.

Satisfaction guarantee

We ensure that the approval of the health product complies with the legal regulations for a long time. The necessary documents are always handed over to the authorities properly and at the right time.

Memberships

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As an international service provider for drug approval, we are a member of the following associations:

- German Society for Regulatory Affairs
- Pharma License Club Germany

Our services

Drug Regulatory Affairs

We realize the approval of your health products.

eCTD Service

We create your registration documents in eCTD format.

Regulatory Advice

We work with you to develop the right approval strategy.

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Regulatory Writing & Artwork

We create legally compliant texts for your products.

Maintenance

We take care of the maintenance of your drug approval.

Quality Management
ISO 9001
www.dekra-seal.com
DEKRA
certified

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As part of the approval process, all pharmaceutical quality, efficacy and safety documentation of the medicinal product will be prepared in the Common Technical Document Format (CTD) in accordance with the applicable regulations and submitted to the competent drug regulatory authority. We produce quality and complete approval documentation according to the latest regulatory requirements. An approval management that is optimally adapted to our partners ensures that our partners will be able to work with their data in the best possible way in the future.

Our services

- Strategy development and planning of approval procedures
- Authority correspondence and advice on authority matters
- Submission, implementation and supervision of national procedures (EU and non-EU) and mutual recognition procedures (MRP), decentralised procedures (DCP) and centralised procedures (CP)
- New registration dossiers for human drugs
- Modules 1 - 5 CTD (NtA Vol. 2B)
- Evaluation and updating of existing registration dossiers and creation of the necessary modules
- creation, review and updating of product information texts coordination of translations
- eCTD creation
- Electronic submission of applications for approval (eSubmission)
- EudraVigilance (xEVMPD): Product Initial Report

eCTD Service

Since 01.01.2019, the eCTD obligation applies to all registration and amendment requests and is standard throughout Europe. We fulfill all technical requirements and have the necessary knowledge for a smooth submission of the registration documents in the eCTD format.

Our services

- Preparation, validation and submission of the registration dossier in eCTD format
- Reformatting to eCTD
- Creation of an eCTD baseline
- Maintenance of the eCTD dossier in Life Cycle Management
- Digitisation of paper documents

Regulatory Consulting

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The potential of a drug depends on different market factors and a large number of regulations. We know the legal requirements and know which possibilities and peculiarities exist nationally and internationally. Accordingly, we approach your regulatory issues in a targeted manner, advise you comprehensively and develop the right concept.

Our services

- Evaluation of internal and external processes
- Strategy development for process optimization
- SOP creation and implementation
- Product evaluation, classification and classification of the product category
- Analysis of existing data and preparation and request for the necessary documents
- Strategy development for approva
- cost-benefit analysis
- due diligence
- Consultations with drug authorities

Regulatory Writing & Artwork

From the development and testing phase, as well as over the entire product cycle, numerous results are obtained which have to be worked up in a structured and comprehensible way. We use this data to create legally compliant medical texts in high quality and according to the latest regulations.

Our services

- Creation and revision of labelling, instructions for use and specialist information in English and German
- Review and release of the artwork
- Revision and review of advertising materials
- Creation, review and updating of product information texts
- Creation of Company Core Data Sheets (CCDS)

Maintenance

Regulatory requirements may change at any time, which in turn calls for urgent adaptation measures for already marketed medicines. We evaluate these with care and know how to intervene in good time.

Our services

- Evaluation of existing dossiers
- Updating existing dossiers
- CMC-compliance check
- Creation of administrative and country-specific documents (module 1)
- Creation, verification and updating of product information texts
- Coordination of translations
- Communication with authorities
- Planning, implementation and submission of variations
- Planning, execution and submission of renewals
- Coordination and submission of Periodic Safety Update Reports (PSUR)
- Appointment and deadline planning of variations, renewals, complaints and conditions
- EudraVigilance (xEVMPD): deadline management and maintenance of existing database entries (EURD / DLP)

Our quality standard

We always strive for optimization measures of the internal processes in order to be able to react quickly to new standards. Then we aligned our vision and our mission.

Our seal

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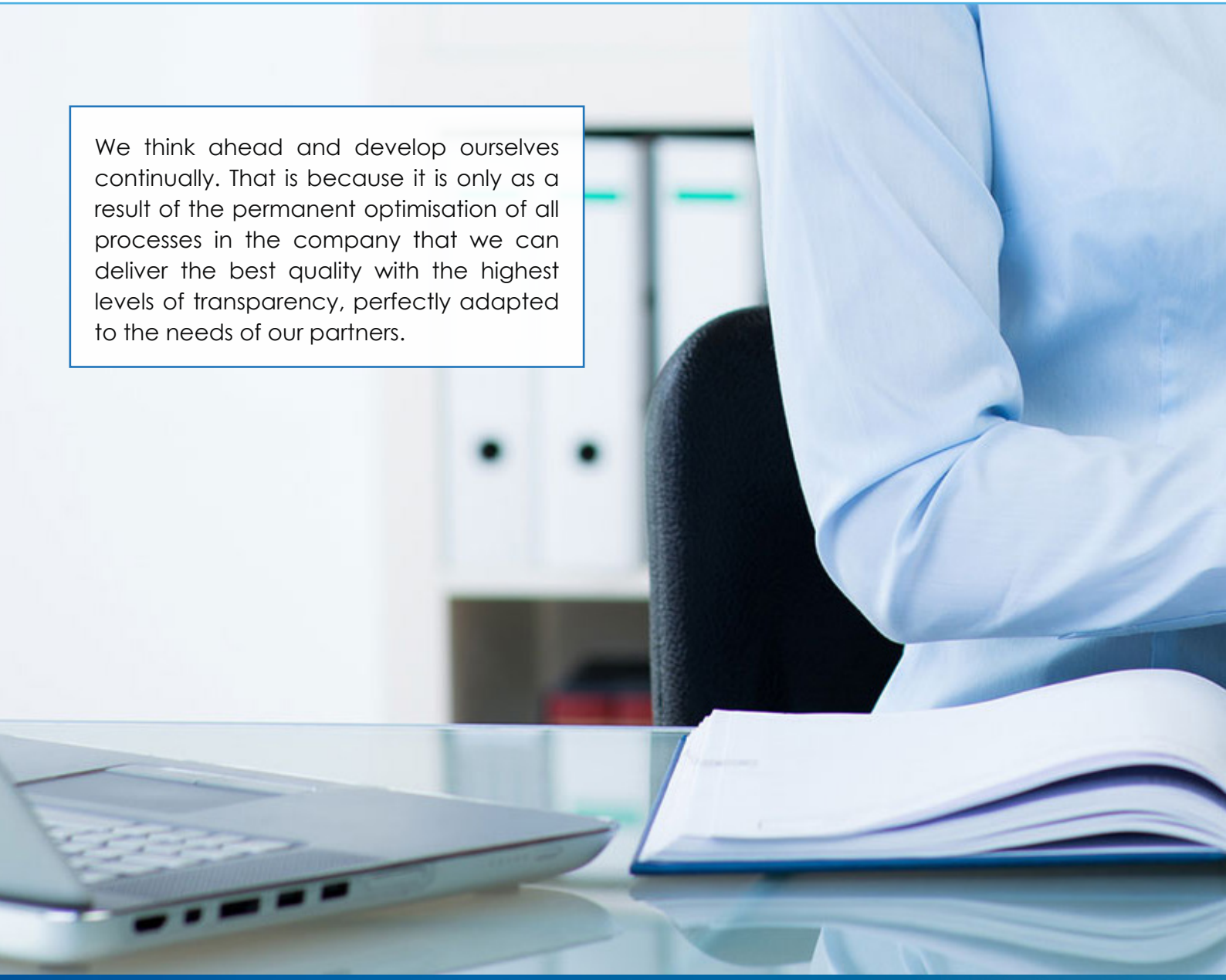
We are absolutely convinced of our services and strengths, which is why it was a matter of the heart to have them confirmed by a neutral and independent body.

We have done it now and are no doubt proud of it! Since 25.03.2019 we have been certified by DEKRA according to ISO 9001 quality management. Just like the DEKRA seal itself, pharmadocs stands for safety and quality.

With this proof, we would like to help you choose the right partner for your company and give you a transparent performance confirmation of our daily work. Constant improvements, a high level of customer orientation and an above-average motivation of our employees must be present in order to even reach the quality management standard of DEKRA. Our promises in our services are confirmed and proven – true to the motto: "Trust is good, control is better!"

Our vision

We think ahead and develop ourselves continually. That is because it is only as a result of the permanent optimisation of all processes in the company that we can deliver the best quality with the highest levels of transparency, perfectly adapted to the needs of our partners.



Our mission

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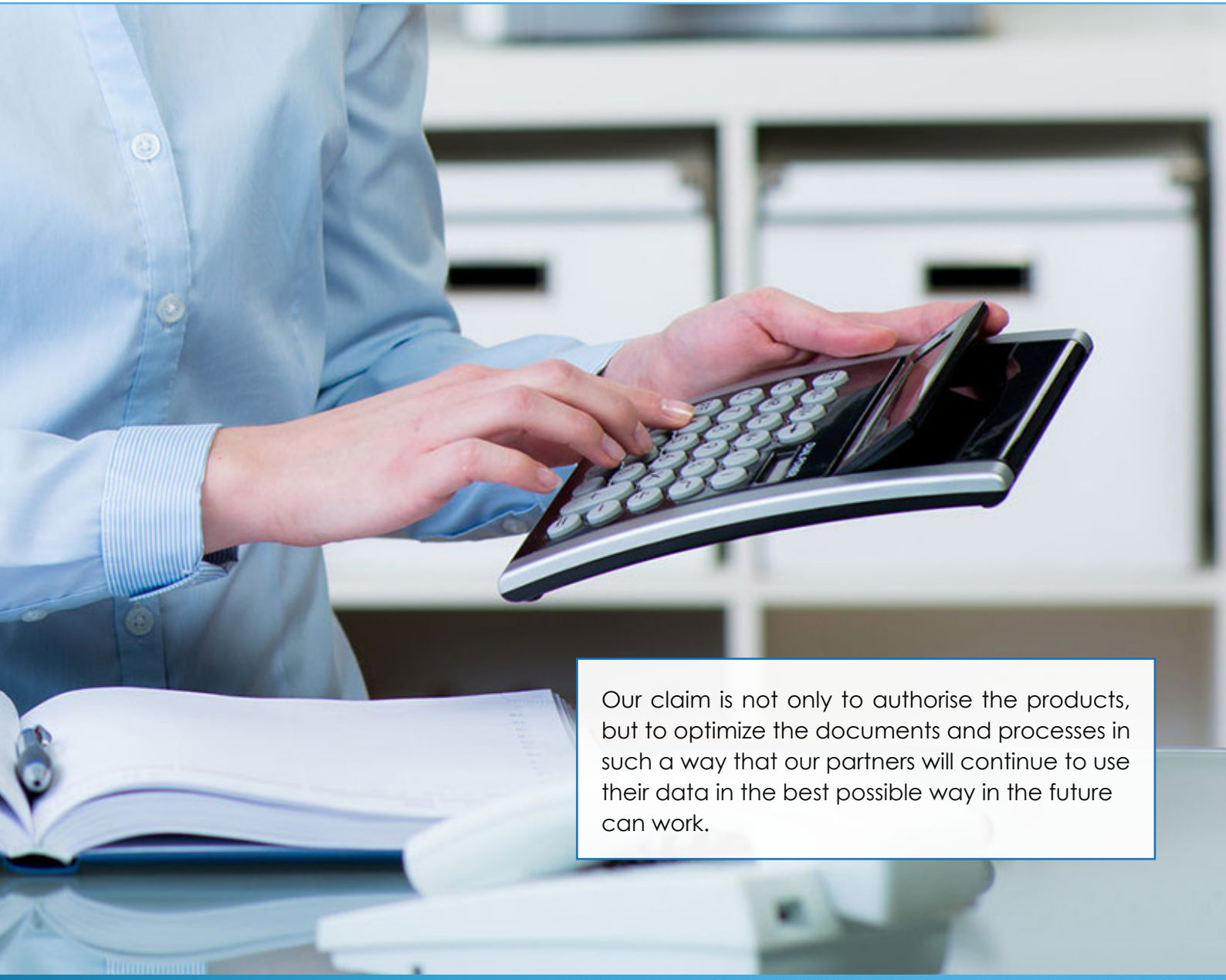

Our claim is not only to authorise the products, but to optimize the documents and processes in such a way that our partners will continue to use their data in the best possible way in the future can work.

Benefits for our partners

- Extense expertise in marketing authorisation
- Transparent, structured and goal-oriented approach.
- First-class support with us as a consultant at your side
- Competent partner who thinks for you and your products

Contact us without obligation -

Your products are in best hands with us!

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