ZAK

The Clinical Research Organisation

Preamble

Whenever we get asked whether we would have founded our company knowing what to expect we answer without hesitation: yes!

For almost 20 years we have been a successful service provider in the fields of clinical trials, regulatory affairs, medical writing and pharmacovigilance. This solid foundation of know-how and experience enables us to react quickly to market developments, to continuously expand our service offerings and to consolidate our in-depth knowledge. Thus, we are able to offer our clients a wide range of customized and professional services.

In order to demonstrate our company's capabilities and to further improve our services we are aligning our established business processes with the requirements set by the quality management standard ISO 9001.

In this brochure we would like to show you our company's development, the scope of our services, our fields of competence, and last but not least, our commitment to quality.

Dedicated to service.

Dr. phil. Mag. Pharm.
Jean-Jacques Chirikdjian
CEO

Mag.
Ingrid Hochmayer
Regional Head of Clinical Operations

Company history

Based on an inner calling

to contribute to the

development of effective and

safe therapies for patients.

ZAK-Pharma Dienstleistung Ges.m.b.H. was founded in 1997 as an independent Clinical Research Organisation (CRO). Since then, we have gained extensive experience and expertise in clinical research and related services as well as a wealth of knowledge in several therapeutic areas.

All projects are managed at our company's headquarters in Vienna and are executed either nationally or internationally.

We therefore perceive our quality management system as a key management tool and we define clear and sustainable processes. These processes support our orientation towards our clients and help us to continuously and systematically analyse and improve our performance.

Throughout the company

our staff is composed of

experienced specialists with

first-class educational and

scientific backgrounds who

complete frequent trainings

to ensure that they stay at the

forefront of their fields.

CHRONOLOGY

1997

Foundation of the company and start of business operations at the headquarters in Vienna. Starting from our core competence in the fields of regulatory affairs we have continuously broadened our range of services for the pharmaceutical industry.

1999

Foundation of the Czech Republic representation situated in Brno as well as of the Hungarian office in Budapest that cover both the Czech and Hungarian markets and are served by resident employees. This facilitated the expansion of our business operation area to the surrounding middle and eastern European countries.

2001

Foundation of our Slovak Republic representation in Bratislava and the establishment of our local services in the Slovak Republic. The continuous growth of our network strengthened the combination of the local presence and the central transnational project management.

2001 to date

Further expansion by the establishment of local offices in Como (IT) and Lugano (CH) as well as development of cooperative arrangements with local CROs in Bulgaria, Germany, Poland, Romania, and the Czech Republic.

Mission Statement

Zero deviation

As a service provider we are not only committed to our clients to meet the targets of our projects but also to monitor the individual project steps and to ensure maximum transparency.

Our team of experts is trained to fulfil these requirements with state-of-the-art project management methods.

"Each order we receive has a clearly defined target and we measure our performance based on successfully meeting or exceeding this goal."

Attention to detail

We consider active listening, precise research, finding of solutions and consequent action as the foundation of our services. Also within the highest complexity we pay attention to the detail and consider correctness and accuracy the top principles when handling with confidential data.

This attitude allows constant improvement of our services and is synonymous with the satisfaction of our clients.

"We focus our attention on the wishes of our clients as well as on the legal and professional requirements of our working environment."

Know-how and competence

Our services are based on the knowledge, experience and competence of our employees. Hence we provide customised training, continuous further education and professional as well as individual support to all members of our staff.

The development of the individual and the constant exchange of knowledge and experience within our team form the basis for our competent client support.

"Our clients benefit greatly from our expertise and competence."

QUALITY MANAGEMENT SYSTEM

We have defined our common vision and determined our fundamental values and our philosophy in our mission statement.

This statement conveys the principles upon which our employees are working together towards a common goal. These principles are intended to ease the cooperation and to support the proactive efforts of the individual while working within our corporate framework.

Clearly defined processes facilitate the achievement of the corporate objectives and the effectiveness of these processes can be measured and controlled by performance indicators.

Internal audits provide regular monitoring of the process performance and serve to continuously improve our quality management system. The management carries out regular analyses for an overall assessment of all activities.

This management review includes the evaluation of the development and effectiveness of all operational and quality-related aspects as well as of the subsequently implemented measures that again may influence our vision, our mission statement, our goals and our processes.

This actively managed circle facilitates constant learning, improvement and development and enables us to reach our goals as efficiently and effectively as possible.

QMS

Quality is the primary feature and decision criterion for our clients. Consequently we follow the path to the future with the highest demands.

Scope of activities

MANAGEMENT OF CLINICAL TRIALS

Clinical trials are required for the approval of medicinal products and medical devices or to add new indications. The focus is generally put on the proof of efficacy and safety of the investigational product. We manage phase I – IV studies by accurately observing the legal requirements, our clients' work instructions and product-specific needs. We manage all phases of the project starting from the selection of appropriate study sites and obtaining all necessary study approvals up to the finalisation of the study report.

MANAGEMENT OF NON-INTERVENTIONAL STUDIES

In non-interventional studies data about approved medicinal products that are used in accordance with the summary of product characteristics are collected and analysed. As the limitations for the inclusion of patients, for concomitant medication and diseases as well as for the treatment itself are clearly lower in these observational studies than in clinical trials, the safety and acceptability of medicinal products in broad clinical routine is mirrored. Thus, non-interventional studies may also reveal very rare side effects and interactions and consequently enhance drug safety.

REGULATORY AFFAIRS SERVICES

It is necessary to obtain approval from the appropriate authorities prior to the launch of a medicinal product. For this the proof of the product's efficacy and safety is required because the primary objective is the minimisation of drug risks caused by unsafe or ineffective drugs. Within the scope of our regulatory affairs services we perform submission processes for new medicinal products according to Austrian law up to approval. Further, we handle the life cycle management of approved drugs complying with all requests from the authorities and/or from our clients.

MEDICAL WRITING

Our medical writing service includes all projects that focus on the compilation of medical reports. We can prepare non-clinical and clinical overviews and summaries, summaries of product characteristics, patient information leaflets as well as study protocols and reports for our clients. Translations of these documents (German <-> English) round out this service. As a matter of fact all legal regulations are consistently followed.

PHARMACOVIGILANCE SERVICES

The clinical development of a medicinal product requires the investigation of both the desirable and undesirable effects. However, the monitoring of a drug after its launch is of particular importance. Our pharmacovigilance services include the systematic and complete documentation of reports concerning drug safety that are received from health care professionals or patients (eg. suspected side effects) as well as the follow-up and timely routing of these reports to the responsible marketing authorisation holder and/or to the competent authorities.

Process management

Our stringent process orientation helps us to continuously improve our organizational and operational structures.

On the previous and on the following page our company's process map is displayed. From this it is apparent how we understand process management and how we understand our complete business activities as a combination of defined working processes.

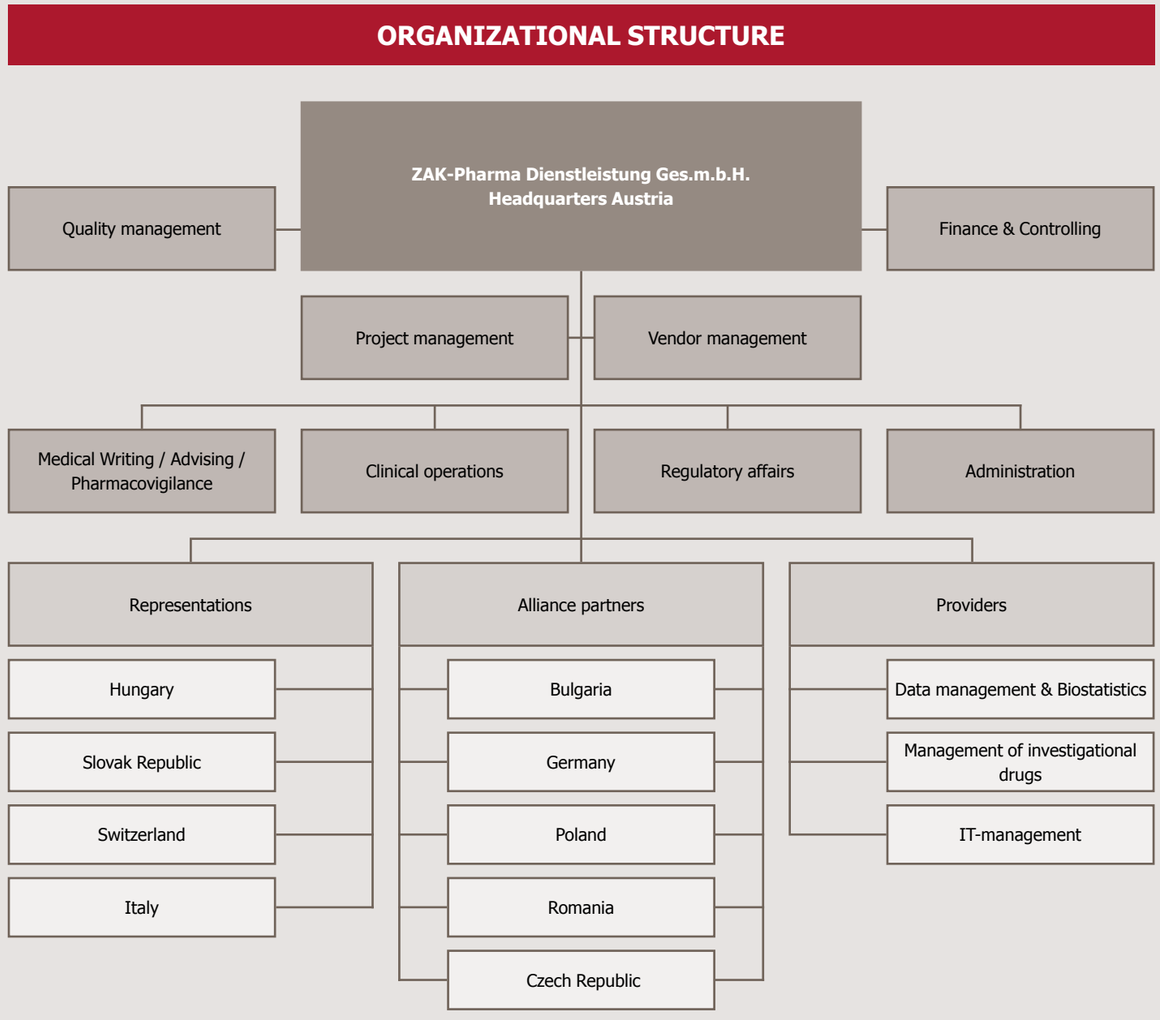
In the centre of the process map are the five service fields of ZAK-Pharma Dienstleistung Ges.m.b.H.

At the intersections – i.e. preceding and following these core activities – are further sub-processes that complete the chain of operations in the realization of a client project. This chain starts with the first contact or project enquiry and ends with the final conclusion of the commissioned project.

The focus on these processes gives us a clear overview and also a visualisation of the workflow management within our company.

However, in order to meet the specific needs of the pharmaceutical industry, we adhere to detailed standard operating procedures (SOPs), working instructions, forms, etc. as well as to all applicable regulations.

ORGANIZATIONAL STRUCTURE



Process management

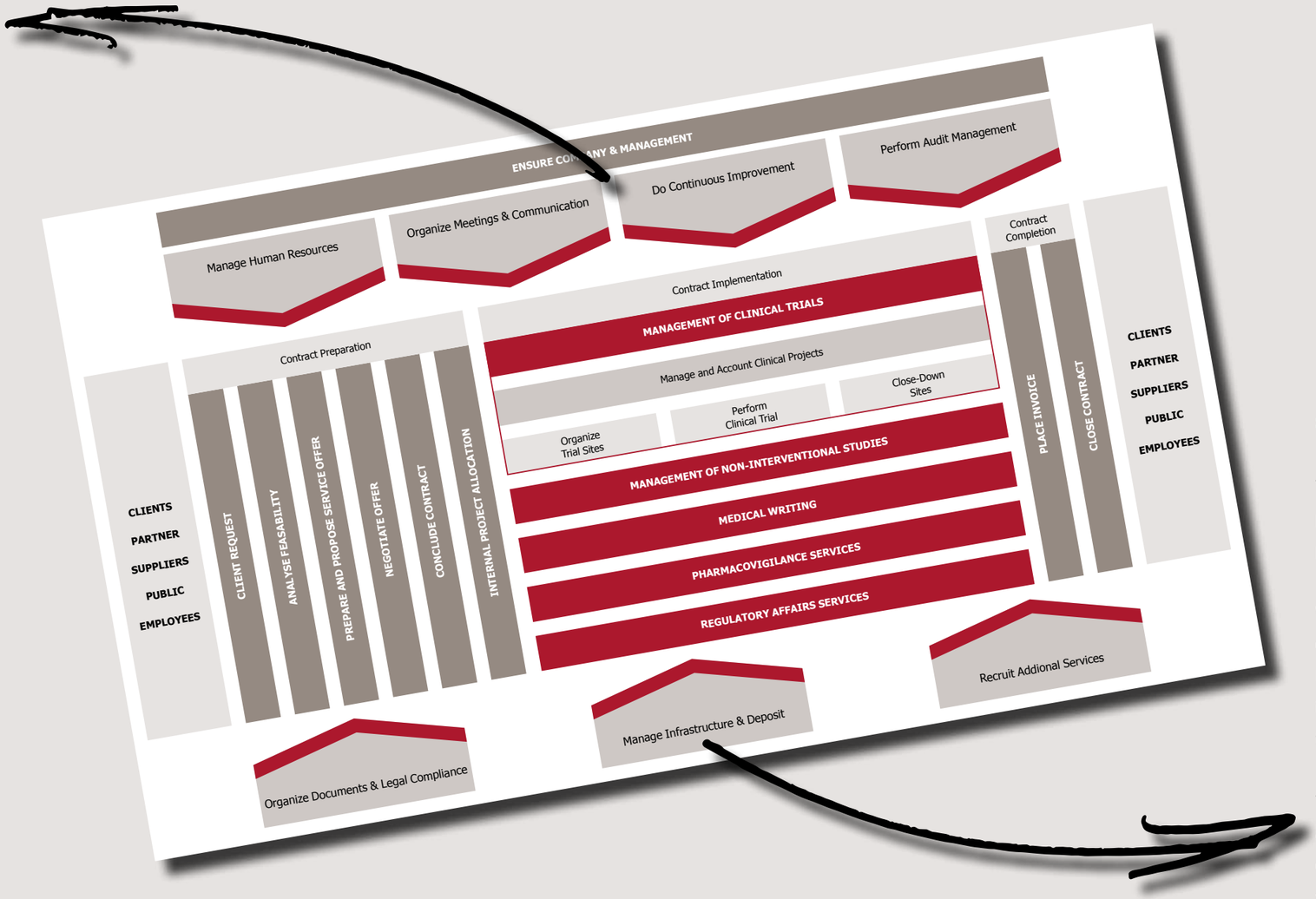
MANAGEMENT

Our process-oriented quality management system serves to realize our business objectives.

It contains all regulations that cover the management, the guidance and the assessment of our company as well as those assuring constant professional growth and development of our staff.

The system also outlines all of our internal communication processes as well as all our activities for the prevention of failures, for sustainable development and for the implementation of corrective measures.

A central role is finally given to our operational audit system that we have established both for internal use and in response to our clients' needs within the commissioned projects.



SUPPORT PROCESSES

The understanding of the entity and the interaction of all processes within our company enables us to arrange improvements as needed.

Within our support processes we define our standards of document control and ensure conformity with the law. Further, we highlight the management of our complete infrastructural facilities including our secure storage area that we use in a project-related manner for clinical trials.

The final support process deals with the commissioning and assessment of subcontractors. In this step we conclude our process thinking and incorporate external service providers that act on our behalf into our processes and standards.

Business locations

Know-how

ZAK HEADQUARTERS AND REPRESENTATIONS

Vienna
Budapest
Bratislava
Como
Lugano

ZAK ALLIANCES

Bucharest
Hamburg
Prague
Sofia
Warsaw

RANGE OF EXPERIENCE

Clinical trials
Regulatory affairs
Medical writing
Pharmacovigilance
GCP-audits
SOP-compilation
Consulting

References

Angelini	Finceramica	Procter & Gamble
Affiris	GlaxoSmithKline	Octapharma
AstraZeneca	Helsinn	Sanochemia
Bayer	Johnson & Johnson	Sorin
Boehringer-Ingelheim	Kolassa & Merz/Merz	Stada
Biogen Idec	Lundbeck	Teofarma
Croma-Pharma	Laboratoire Expanscience	TRB Chemedica
CSC	Lannacher	Wyeth
Cyathus Exquirere Pharmaforschung	Lek Pharmaceuticals	Yamanouchi/Astellas

CERTIFICATE

ECONOMIC CHAMBER VIENNA

Vienna, November, 15th 2012

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Scope of application:
ZAK-Pharma Dienstleistung Ges.m.b.H. / A-1130 Vienna / Amalienstrasse 48/8
Normative exclusions:
Section 7.3, development from ISO 9001:2008
Justification:
The company does not perform product development according to the normative declaration
Responsible for the content:
ZAK-Pharma Dienstleistung Ges.m.b.H. / A-1130 Vienna / Amalienstrasse 48/8
T: + 43 1 879 38 95
F: + 43 1 879 38 95 18
i.hochmayer@zakpharma.at
www.zakpharma.at

Concept and text:
xero Qualitätsmanagement GmbH, Karin Glanner, CMC
Photos, graphic arts and layout:
Michael Schaefer-Design GmbH, Mag. Michael Schaefer
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ZAK
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Headquarters

ZAK-Pharma Dienstleistung Ges.m.b.H.
Amalienstrasse 48/8
A-1130 Vienna
T: + 43 1 879 38 95
F: + 43 1 879 38 95 18
i.hochmayer@zakpharma.at
www.zakpharma.at