# THE SHORTEST WAY
# FROM ENGINEERING TO QUALIFICATION.

Think. Work. Integrate.

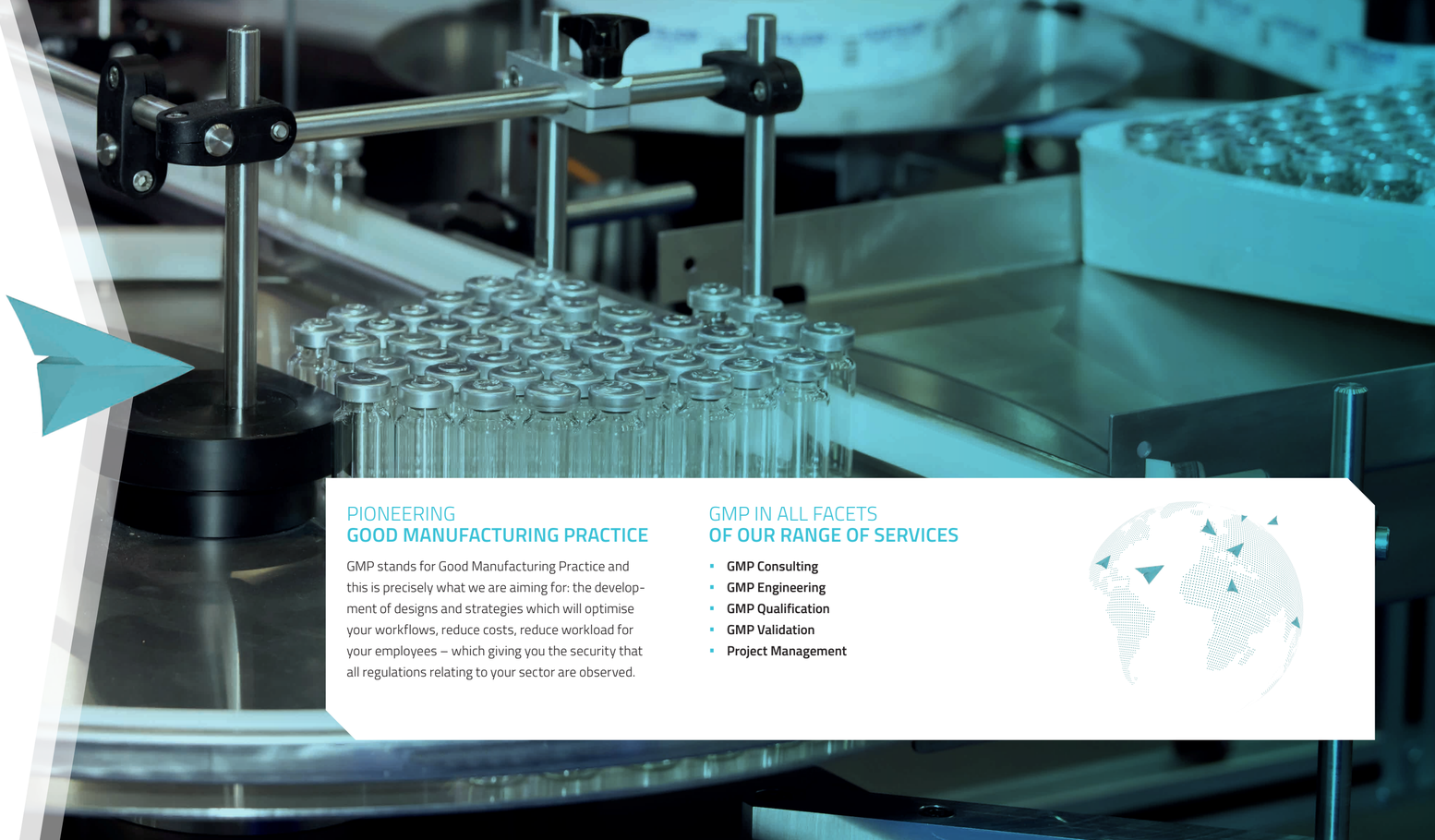
PITZEK
GMP CONSULTING

# Quality. Precision. Common sense.

## Pitzek GMP Consulting

### THE MOST EFFECTIVE WAY
### TO GOOD MANUFACTURING PRACTICE

Decades of experience in consultancy in pharmacological, biological and food technology mark us out and make us skilled and reliable partners. We deliver innovative ideas and strategies aimed at reducing costs and optimising your processes. In doing so, we place quality as the highest priority.
This is the key to successful industrial companies in the global context.



### PIONEERING
### GOOD MANUFACTURING PRACTICE

GMP stands for Good Manufacturing Practice and this is precisely what we are aiming for: the development of designs and strategies which will optimise your workflows, reduce costs, reduce workload for your employees – which giving you the security that all regulations relating to your sector are observed.

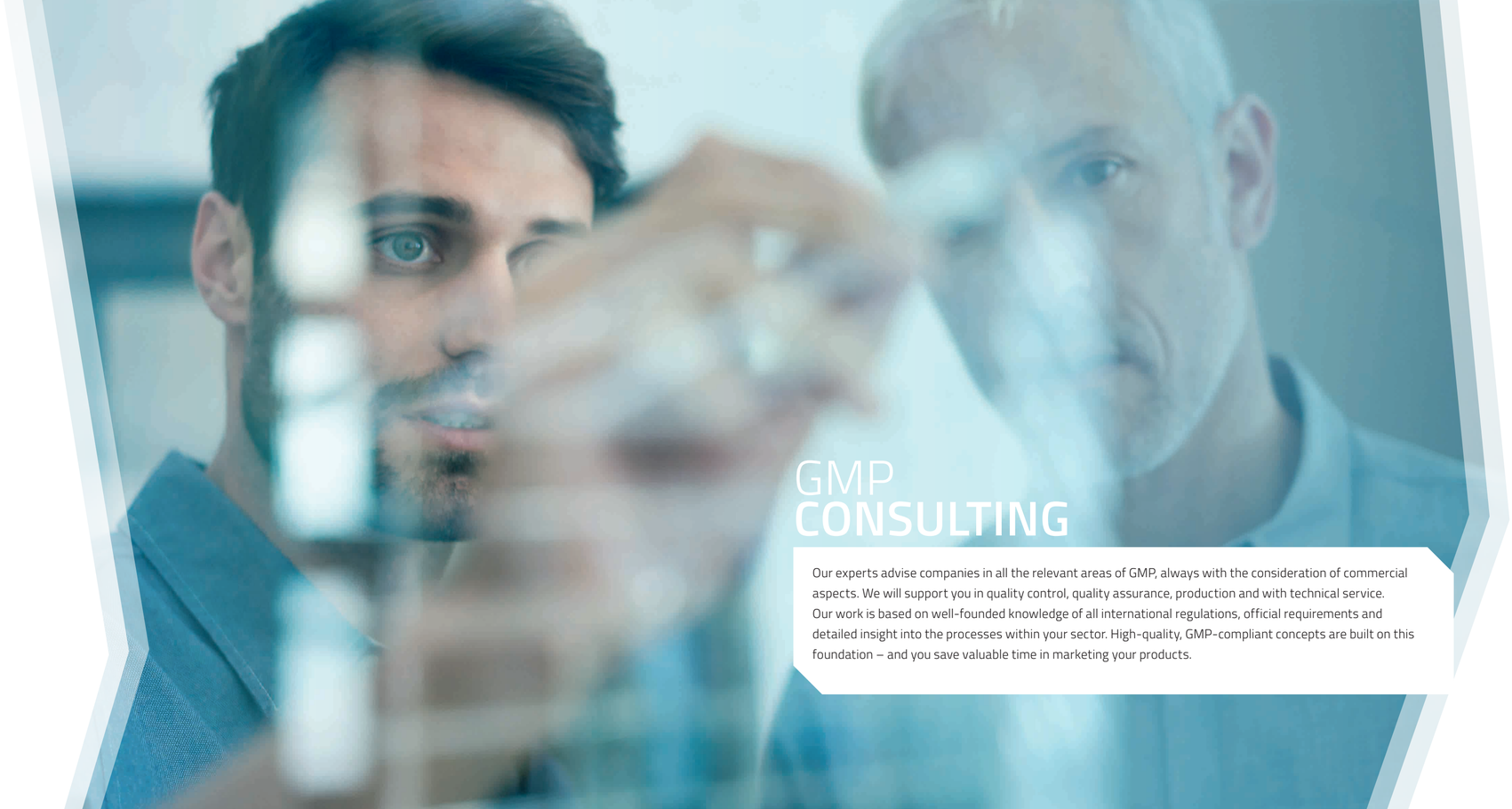
### GMP IN ALL FACETS
### OF OUR RANGE OF SERVICES

- **GMP Consulting**
- **GMP Engineering**
- **GMP Qualification**
- **GMP Validation**
- **Project Management**

# Think.

## THE SIMPLEST WAY
## TO INTERNATIONALLY SUCCESSFUL BUSINESS

Skilled consultation is our business – and your benefit. Pitzek GMP Consulting supports globally active companies in the pharmacological, biological and food industries in making their processes and systems even simpler and more efficient, complying with regulations and meeting demands. This is always based on the most up-to-date specialist knowledge and years of experience .



## GMP
## CONSULTING

Our experts advise companies in all the relevant areas of GMP, always with the consideration of commercial aspects. We will support you in quality control, quality assurance, production and with technical service. Our work is based on well-founded knowledge of all international regulations, official requirements and detailed insight into the processes within your sector. High-quality, GMP-compliant concepts are built on this foundation – and you save valuable time in marketing your products.

# Work.

## THE MOST DIRECT WAY
## FOR MARKETING YOUR PRODUCTS

Our expert team will support you in planning your GMP-compliant installations using the most up-to-date tools and technologies. On request, we would also be happy to act as Works Lead Engineers for you.

## PROJECT MANAGEMENT

If you entrust your project management to the experts of Pitzek GMP Consulting, you are guaranteed smooth, simple processes. We have been planning industrial installations in the fields of pharmacology, chemistry and food. We can thus support you in all project phases, from project definition to successful conclusion. Every single one of our consultants has completed an engineering degree – skills that you can rely upon. For you that means comprehensive freeing up of your own resources and high adherence to schedules.

**Our services include:**

- Definition of project aims
- Setting up project structures
- Definition of milestones
- Resources, schedule and budget planning
- Projectmeetings
- Award of Contract
- Supporting and final documentation
- Management of partial projects
- Management of external suppliers and providers

## GMP ENGINEERING

We will support you in your entire project planning, from the awarding process up to order placement including Basic and Detail Engineering. Our specialists will produce the URS and the entire specification for you, deal with enquiries from machine suppliers and evaluate the tenders from a technical and commercial point of view. We always keep focus on budget, quality and deadlines.

## GMP QUALIFICATION/VALIDATION

Pitzek GMP Consulting will carry out the complete implementation of GMP-compliant qualification and validation projects, whether that is in the production of pharmaceuticals, active substances, cosmetics or foodstuffs and animal feeds. In this way, our experts contribute to you being able to market your products even faster.

**Our services include:**

- Creation of a Master Plan
- Preparation of technical documentation (e.g. User Requirement Specification)
- Creation of Specifications and lists of Requirements

### QUALIFICATION

The highest level of quality assurance is the highest priority to us as any deviation have a direct influence on the health of the consumer. Through our services in comprehensive qualification, our experts will ensure fault-free functioning of installations, product quality and the fulfilment of all binding official requirements of the health authorities.

### VALIDATION

Within the process of validation, our specialists will create a firm foundation for bringing the final product to the market. This includes confirmation that the technical installations have been qualified and deliver safe reproduceable results. Processes, cleaning systems and IT can be validated. An expert risk assessment forms a basis on which we can carry out a validation plan pursuant to precise regulatory stipulations, (EU-GMP-guidelines, FDA, PIC/S etc.).

# Integrate.

## THE MOST RELIABLE WAY
## TO WELL-FOUNDED SECTOR KNOW-HOW

With our team, we work in a loyal, focussed and personal manner. Keeping to deadlines and absolute reliability are our guiding principle. Taking responsibility for our actions and maintaining a high profile is essential for us. In this, we check proportionality very critically by standards of reasonableness.

## MEDICINE **TECHNOLOGY**

We are a problem solver, project manager, auditors as well as gmp-hands-on consultants. Further, we offer interim solutions and support. This is done for the quality management, development, manufacturing and supplier quality management for medical device manufacturer and his suppliers. Relevant norms/ regulations and laws ISO 9001, ISO 13485, 21 CFR part 820 (FDA) will be considered at all times.

**Our main focus covers:**

- Equipment and facility qualification, process validation, cleaning validation, computer system validation (CSV) and product validation
- Deviation and complaint management
- Document management incl. document reviews
- Change management
- Risk management
- CAPA management
- Audit management (audit preparation and follow up, conduct internal audits)
- Supplier (quality) management that includes supplier selection, supplier qualification supplier audit and supplier monitoring (e.g. tool making, injection moulding, packaging, implants and surgical instruments manufacturing)

IN TUNE WITH TECHNICAL EXCELLENCE

## ISOLATOR- AND FILLING- **TECHNOLOGY**

Our long experience in sterile filling technology with isolator technology gives our customers a high level of security. That is because we offer holistic support, in planning, design and implementation of regulation-compliant installations. If you wish, we will take over complete project management, leaving you to concentrate on other things, e.g., the development of new products.

**Our services include:**

- Consultation in the procurement of new installations and machines for sterile filling processes and Fill & Finish appliances in sterile areas.
- Creation of tender documents
- Evaluation of proposals
- Conception of risk-analysis workshops
- Mock-ups, which we conceive and implement either under own auspices or together with you

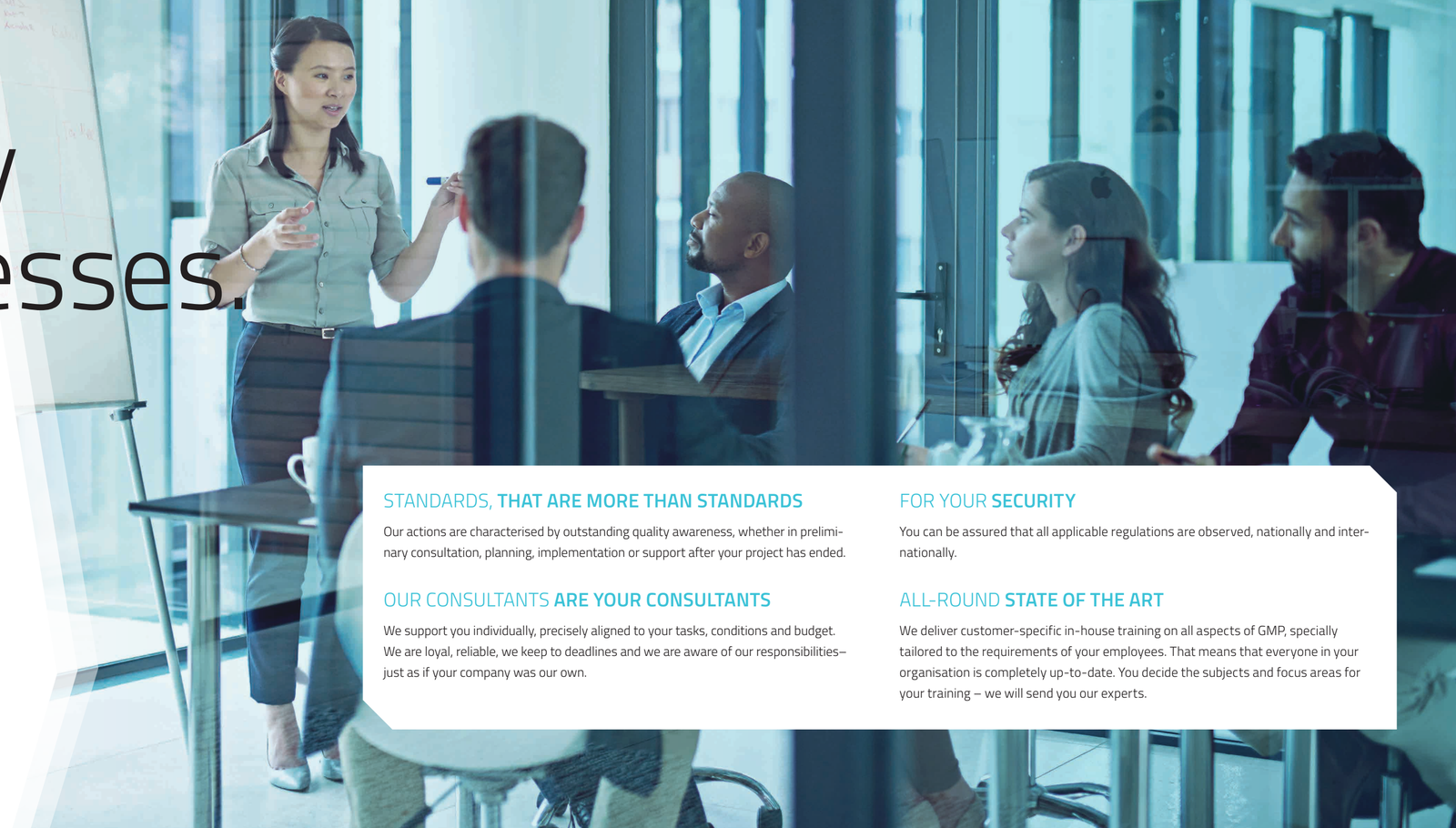
## HOMEO**PATHY**

In the field of homeopathy, it is not just the general requirements of the pharmaceutical industry that have to be fulfilled, but also those of the homeopathic drugs register (HAB). That makes it even more important that you can depend on outstanding knowledge of the sector: The Pitzek GMP Consulting experts have professional experience and projects experience in homeopathic companies. This means they are very familiar with Hahnemann's homeopathic principles and take every care to ensure compliance with these requirements, always considering efficiency and cost-effectiveness. We combine the most up-to-date technology and methods with traditional homeopathic practice.

# To manage highly challenging processes.

## THE SAFEST WAY
## TO THE DESTINATION

Our experts have extensive experience in the sector from international projects and in all areas of GMP. Permanent qualification of employees ensures that our specialists are always at the cutting edge, be that in issues concerning technologies, project management or legal requirements.



## STANDARDS, **THAT ARE MORE THAN STANDARDS**

Our actions are characterised by outstanding quality awareness, whether in preliminary consultation, planning, implementation or support after your project has ended.

## OUR CONSULTANTS **ARE YOUR CONSULTANTS**

We support you individually, precisely aligned to your tasks, conditions and budget. We are loyal, reliable, we keep to deadlines and we are aware of our responsibilities– just as if your company was our own.

## FOR YOUR **SECURITY**

You can be assured that all applicable regulations are observed, nationally and internationally.

## ALL-ROUND **STATE OF THE ART**

We deliver customer-specific in-house training on all aspects of GMP, specially tailored to the requirements of your employees. That means that everyone in your organisation is completely up-to-date. You decide the subjects and focus areas for your training – we will send you our experts.

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