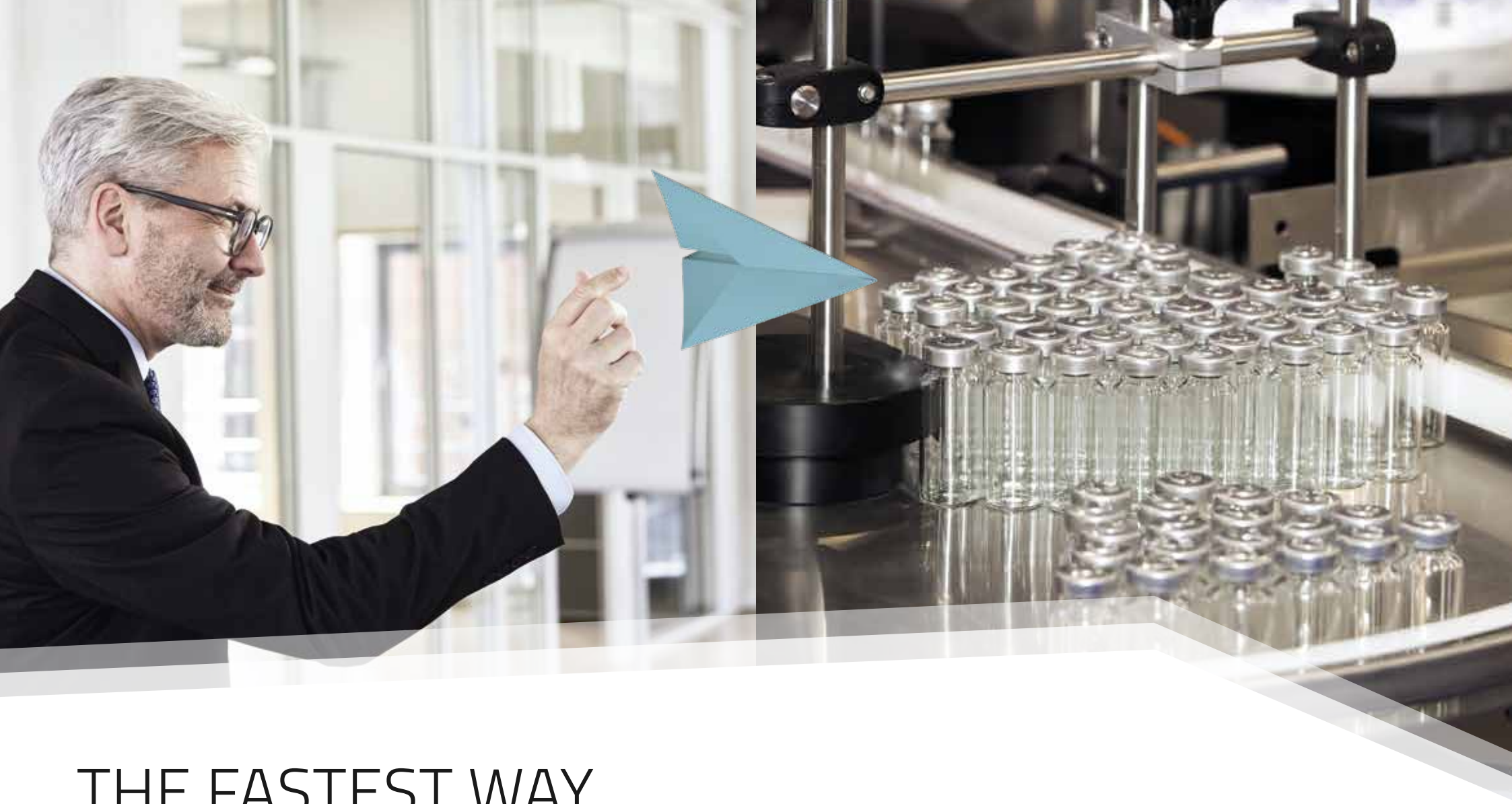


THE FASTEST WAY
FROM PLANNING TO IMPLEMENTATION.

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 marks 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 / Projectmanagement**
- **GMP Engineering**
- **GMP Qualification / Validation**
- **Quality Management System**
- **Technology Transfer / Computersystem Validation**
- **Automation Technology**

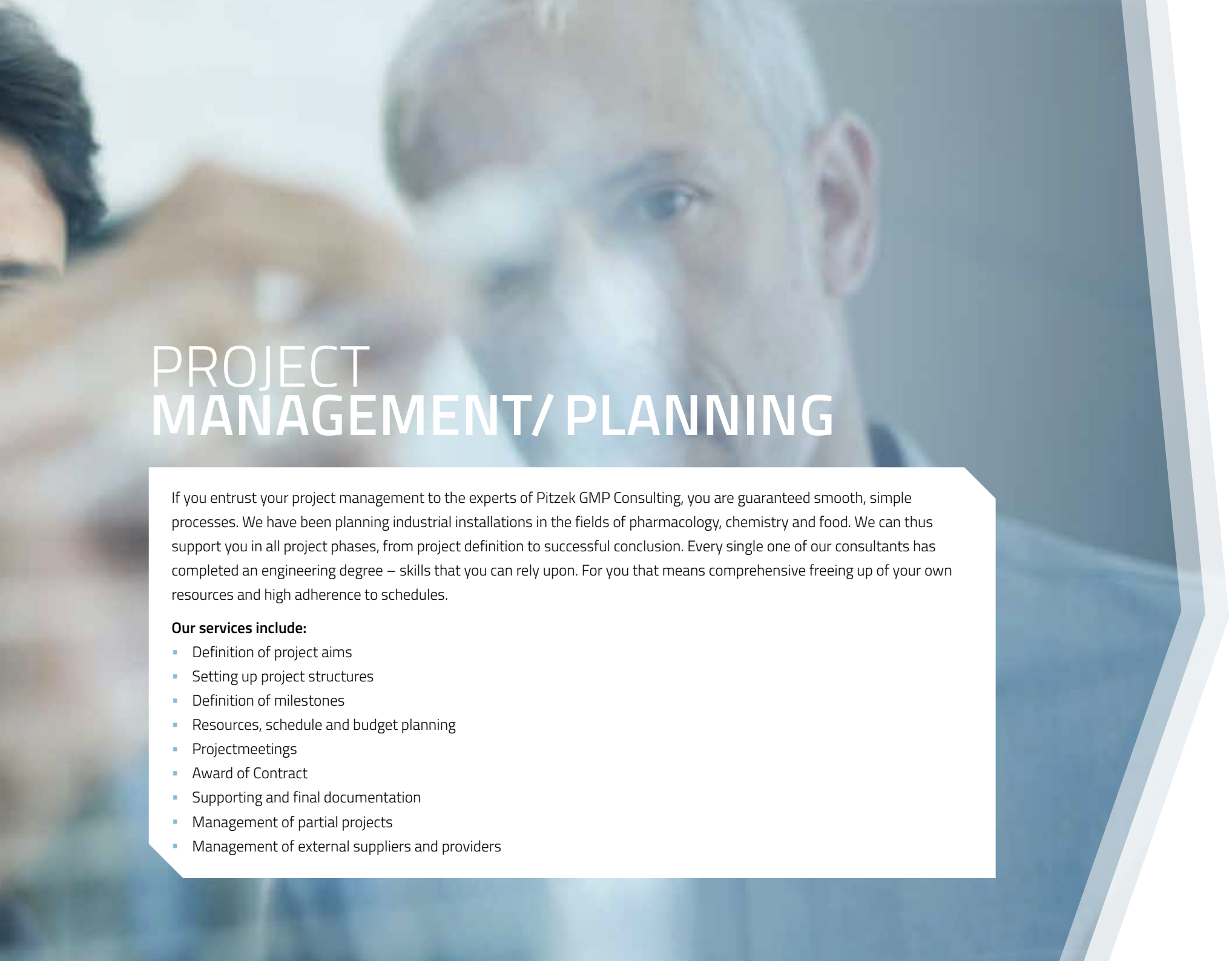
Think.

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 by 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.



PROJECT MANAGEMENT/ PLANNING

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

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.

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 installations/devices 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 COMPLETE WAY
FROM THE AWARD UNTIL THE ORDER

We have answers to all your GMP relevant questions about your desired measures and the securing production. In doing so, we always pay attention to quality.

QUALITY MANAGEMENT SYSTEM

We make you EU and FDA ready

The quality management system (QMS) applied in the pharmaceutical and cosmetics industry contributes to product safety and quality of your products.

Within this framework, we support you in conception and planning up to the preparations for audits and inspections. Our portfolio also includes the adaptation of your documents to your changed framework conditions.

Our diverse and practical expertise lies in the field of classical pharmaceuticals, APIs, medical biotechnology, biomedicine and the cosmetics industry.

Services in general:

- Establishment of a QMS in accordance with current requirements incl. preparation of of the QM manual
- Support for cross-site process harmonization
- Identification and elimination of QMS weaknesses and deficiencies (gap analysis)
- Critical review of existing processes and the production process including identification and assessment of risks
- Comprehensible technical preparation of your processes and associated documentation for all involved employees
- Preparation and implementation of training courses for your employees at all hierarchical levels on the subject of GMP and the quality assurance system
- Support in the execution of self-inspections and support during official inspections

Services Hygiene:

- Development and revision of hygiene concepts for your company
- Professional support of the conceptual pre-planning of your cleanrooms including determination of ISO/GMP classes
- Consulting both for your internal cleanrooms and out-sourced processes
- Preparation and implementation of clean room/hygiene training courses for your employees at all hierarchical levels incl. dressing procedures
- Consulting regarding the implementation of pest control requirements
- Preparation for service provider qualification audits

Special Competences

THE FASTEST WAY
TO RESULTS-ORIENTED PERFORMANCE

Our experts have extensive industry practice in international projects and all areas of GMP. Permanent qualification of employees ensures, that our experts are always up-to-date in technologies, project management as well as legal requirements.

TECHNOLOGY **TRANSFER**

A technology transfer is what happens when a pharmaceutical company wants to move from an existing production site to a new production site. Tech-Transfer in the pharmaceutical industry means more than copy & paste! There are often reasons to move an existing product to another location or to build additional capacity. Most people talk about "copying the existing assets and processes".
It sounds simple, but there's more behind it. The manufacturing process is influenced by many factors. That's why quality must be paramount in a tech transfer. Critical characteristics of the product must be known and taken into account.

We assess:

- Manufacturer's original information, raw materials, critical process parameters, equipment and batch size in consideration of scale up and FDA guidelines
- We check the transmission protocols in order to record the process correctly
- Development of transfer tools and a thorough process – transition to validation

There are 4 key positions that also need to be challenged to ensure successful technology transfer:

- Packaging line testing
- Stability display methods
- Cleaning validation
- Health and safety review

COMPUTERSYSTEM **VALIDATION**

Computer validation is the documented testing of software or a computer system. As a manufacturer of pharmaceutical products, it gives you documented proof that computer-controlled or automated systems perform consistently, in compliance with predetermined regulations.
With many years of experience, we offer you tailor-made computer system validation. We test your software for practicality and reliability. We will demonstrate together with you in a comprehensible manner that your computer system will function correctly after changes, modernization or even rescheduling and are suitable for the purpose used.
Automated systems are tested and validated in accordance with US and EU regulations. This gives you inspection security through documented measures and various tests.

Our Services:

- Risk analysis according to GAMP 5
- Creating of quality project plan
- Validation schedule and process validation
- Creation of important engineering documents
- Preparation of qualification documents
- Creation of test plans
- Execution and documentation of FAT and SAT tests
- Creation of test logs
- Execution of Design Qualification (DQ)
- Execution of installation qualification (IQ) and functional qualification (OQ)

AUTOMATION **TECHNOLOGY**

With our longtime experience, we offer you customized planning and handling of your automation projects. Automation increases your efficiency and plant availability while also benefitting both quality and safety.

A seamless, digitally recorded and legally compliant workflow is perfect for traceability and anti-counterfeiting. The error rate is significantly reduced by the automatic recording of your production data. Your relevant production data and resources are available at the right time. Even the smallest deviations are detected, ensuring that operators can intervene in a controlled manner.

Based on the recorded data, performance checks and implementation of potential improvements can be carried out. By optimizing the process automation, we can carry out a use-specific and predictive maintenance of the plant. For us it is important to consider the entire life cycle of your plant and show solution-oriented proposals.

Excerpt performance hardware:

- Infrastructure concepts for power systems, undersupply, production networks IT and OT
- Planning of electrical distributions, I/O signals and exchange between system manufacturers, interface communications
- Coordination with renowned system integrators

Excerpt performance software:

- Computer system validation (see excerpt services)
- Concepts for data integrity in third-party systems, such as MES, LIMS, ERP, SAP, etc.
- eQMS (electronic quality management system)
- GAP analyses according to valid regulations also FDA
- Coordination and support of system migrations

Special know-how

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.

CLEAN MEDIA **PHARMA-CEUTICAL & BIO-TECH INDUSTRY**

Water is the most widely used raw material in the pharmaceutical and biotech industry, so water and other ultrapure media, such as ultrapure steam, are indispensable components of numerous processes.
For reliable production without impurities, high-quality drinking water, purified water, water for injections and also ultrapure steam are required.

We know the complete process and know what is possible.

We advise you on the optimization of your systems and processes and are happy to support you in the implementation of qualification/validation or in studies for process optimization. Together with you, we develop and implement the best possible process solution, of course in compliance with the highest quality and safety standards.

IN TUNE WITH TECHNICAL EXCELLENCE

ISOLATOR- AND FILLING **TECHNOLOGY / CONTAINMENT**

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.

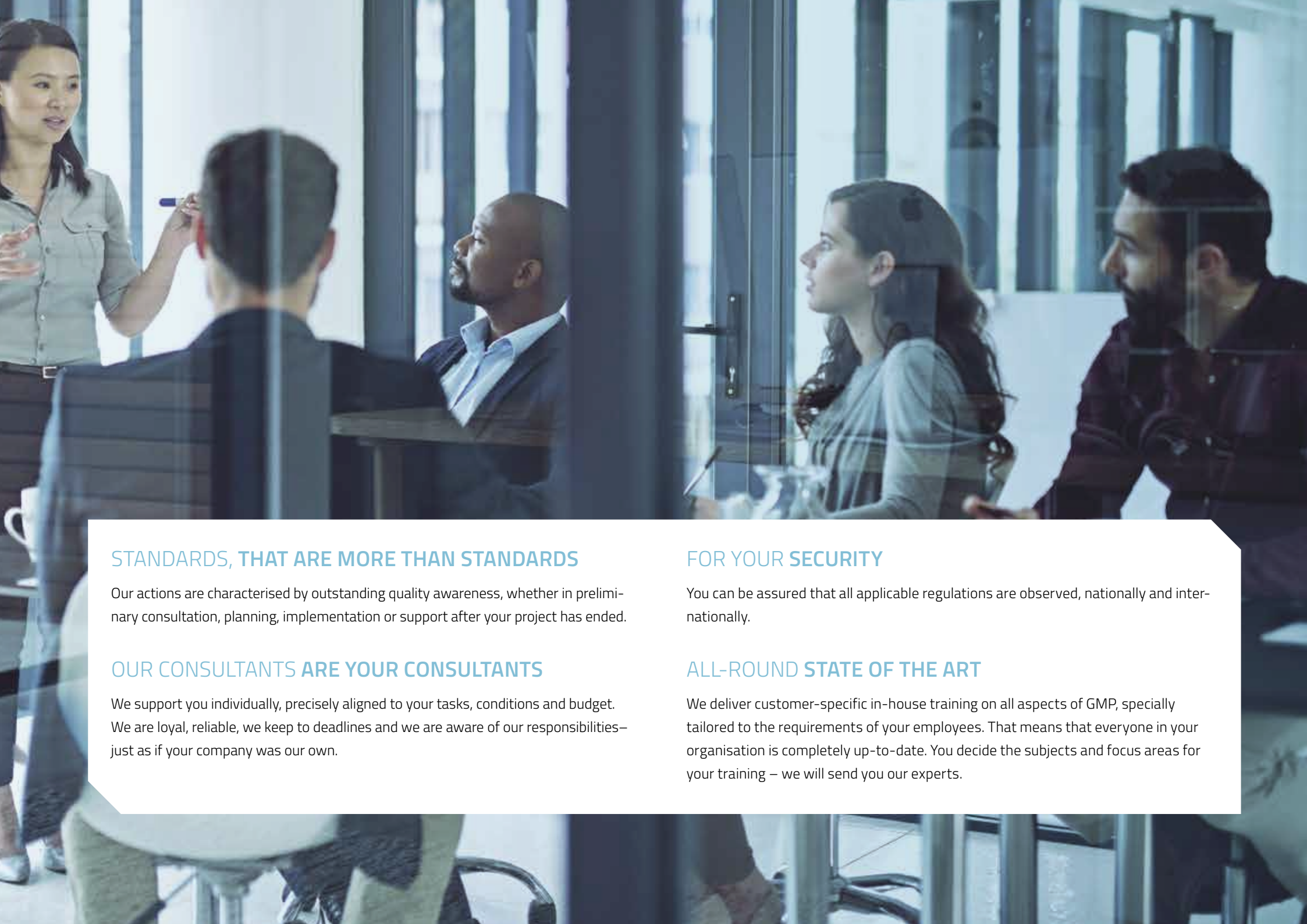
Our services include:

- Consultation in the procurement of new installations and machines for sterile filling processes and Fill & Finish appliances in sterile areas, as well as for solid production, such as tablets and capsules
- 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

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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