

BLOCK[®]
Clean Room Solutions



PHARMACEUTICS, BIOTECHNOLOGIES, HEALTHCARE DEVICES

Complex deliveries of buildings and technological units
compliant with EU GMP and FDA regulations

RELIABLE
PARTNER

EXPERIENCE
SINCE
1991

MORE
THAN **350**
CUSTOMERS

250
IMPLEMENTATIONS
AND PROJECTS
ANNUALLY

MORE
THAN **400**
EMPLOYEES

0,5 mil. m²
OF CLEANROOMS
ERECTED

Creating conditions

ABOUT US

BLOCK® is a respected multi-national group of companies operating in many countries with a history that goes back to 1991. We bring complete, functional, cutting-edge projects to fruition, with a focus on advanced technology (high-tech) and high quality environments (clean rooms).

We are design, engineering, project delivery, and implementation company with an experienced team of technicians, technologists and engineers who manage and turn project ideas into reality. We offer our customers comprehensive services in project planning, manufacture, construction and subsequent servicing. Our solutions guarantee the optimization of capital and operating costs and consistently emphasize protection of the environment.

We provide fabrications for the pharmaceutical, biotechnological, healthcare, science and research, microelectronics and automotive industries as well as for other industrial buildings utilizing cleanroom technology.

Our implementations are strengthened by our own production program.





Turnkey facilities ①

Complex services and realization in full: Consultancy and guidance, securing financing, planning activities, development and production, implementation, engineering services, qualification and validation, service.



BLOCK® clean rooms ②

Systems for built-in cleanrooms compliant to GMP standards. Our own development and production.



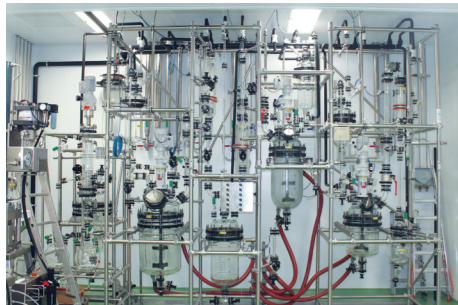
Equipment ③

Reactors and tanks, Filling lines, Packaging lines, Lyophilizers, Tableting machines, capsule filling machines, Fluidization driers, Homogenizers, etc.

RENOWNED EXPERTS IN THE FIELD

We supply **complete facilities including structures and technological units for use in the fields of biotechnology and medical engineering that are compliant with EU GMP and FDA regulations.** We specialize in the supply of facilities meeting the most demanding requirements of cleanliness (cleanrooms) for work with HPAPI and increased biosafety level (BSL).

We can confine the production process in an isolator/RABS whose design we elaborate and also manufacture ourselves.



Technological mains/product distribution systems ④

Clean media as PW, WFI, PS; Technological gases and other technological media; Process steam; Waste management; Product distribution systems; CIP/SIP systems.



HVAC&R (heating, ventilation, air-conditioning and refrigeration) ⑤

Complete system of heating, ventilation, air-conditioning and refrigerating equipment.



BLOCK® isolator technology ⑥

Tailor-made production, supply and installation of isolator technology to the customer's specifications.



BLOCK® laboratories ⑦

Built-in laboratories, supply of laboratory furnishings, equipment and accessories.



Accompanying facilities

Administrative facilities, storage rooms, restrooms, other necessary facilities.



BLOCK® special furnishings

Stainless working, perforated or washing tables, stainless sinks, washing troughs, metal racks, stainless mobile tables and handling cars.



ELEGANT SOLUTIONS

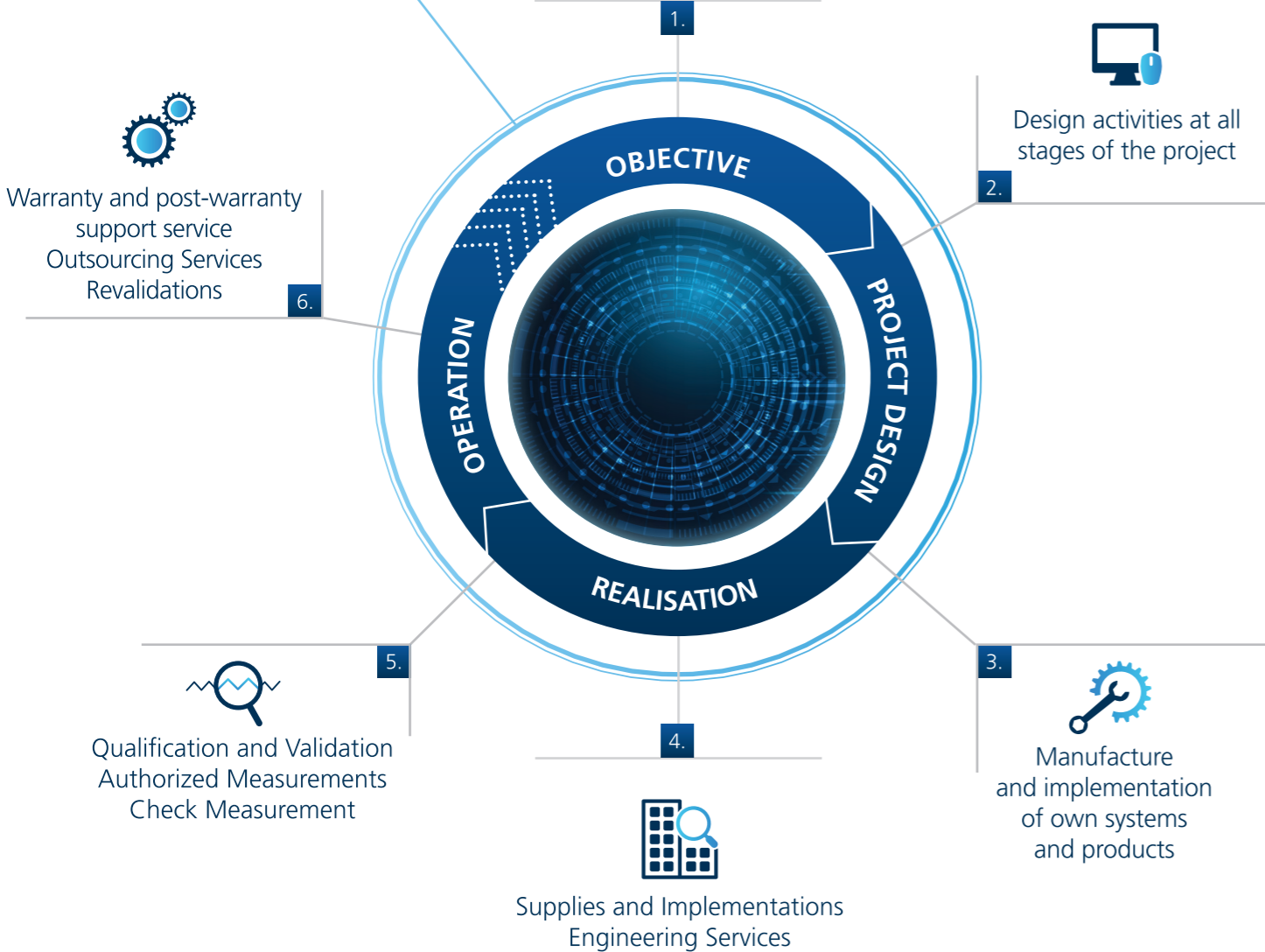
Emphasis is placed operational safety in every case. We guarantee the parameter stability foreven the most demanding processes inresearch, development, production, control, and distribution of pharmaceuticals. Our supplies and services meet high demands on quality, safety and environmental protection whileimplementing state-of-the-artapproaches to the maximum degree.

Exacting and highly specific demands emerge in the fields of pharmacology and biotechnology. These demands are fulfilled in co-operation with technologists from partnering organizations and companies. BLOCK a.s. designs optimum solutions, the concept of which is the most advantageous from the perspective of requirements on production and operation, construction requirements, operational costs and minimization of environmental impact. Every project is tackled with a maximum level of import laid upon the observance of specified requirements on production parameters. By applying state-of-the-art technical knowledge, we reach significant energy savings in operations and maintenance.

As we deliver technological sets, we observe the philosophy of GEP attitude and guarantee that our projects meet EU GMP and FDA requirements.



WE PROCESS
BIM
BUILDING
INFORMATION
MODELING



WE DELIVER YOUR PROJECTS ON A TURNKEY BASIS

We complete your projects with turnkey implementation, i.e. comprehensive realisation of projects from the initial technical design, through the execution of all necessary stages of project documentation, to implementation, commissioning, measurements, testing, validation, warranty, and post-warranty service.

For wide-ranging project needs

- Complex, large capital projects with cleanroom technology
- Complete supplies for capital project segments and units
- Supplies of operational facilities, technological units and internal equipment

We provide

- New constructions
- Refurbishments or modernizations of existing structures
- Expansion of production capacities

We are partners throughout each phase of your project.





Consultation and advice
Customer technical support
Export financing

- Consulting, guidance and technical support at preparation of construction intention of any demanding technologic groups
- Consulting in the GMP sphere (good manufacture practice) and QA (quality assurance)
- Expert evaluation and audits in the GMP sphere
- Energetic audits and concepts, audits for environment
- Technical support for clients at selection of technologic equipment for pharmaceutical, chemical and electro technical industry
- Schooling and lecture activity
- Securing of export financing



Design activities

We have a strong design team that uses modern 3D software. We provide processing of design documentation for all project stages:

- Volume and build-up studies, technology studies, feasibility studies
- Project documentation for area management
- Basic design
- Project documentation for building supervision
- Elaboration of tender documentation
- Project documentation for construction realization
- Construction, possibly work documentations
- Elaboration of validation documentation

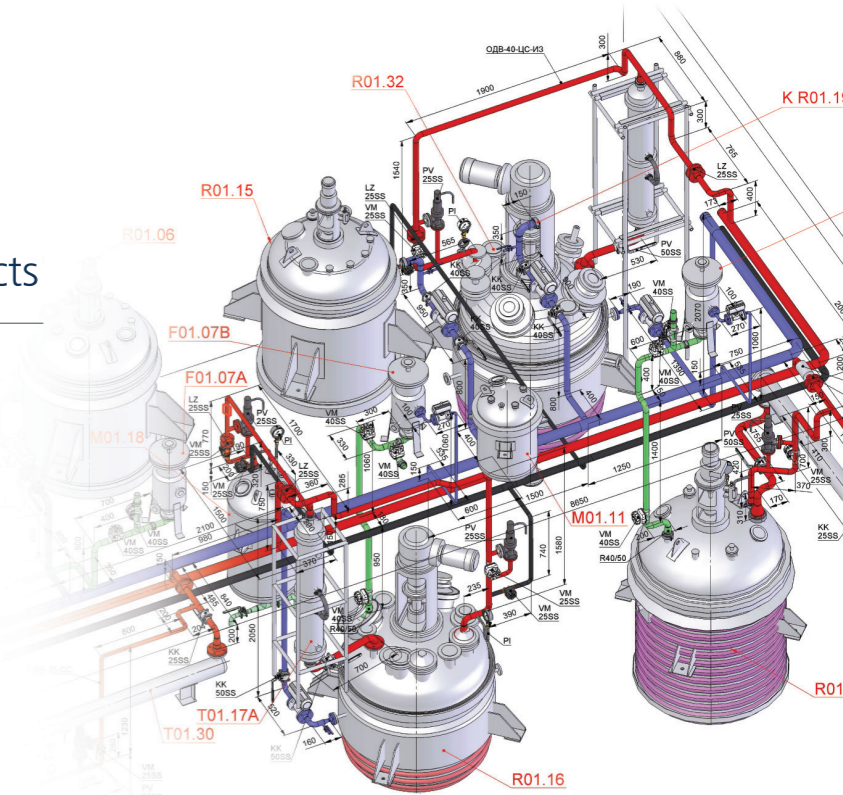


Manufacture and implementation of own systems and products

Our implementations are strengthened by our own production program.

We employ our own teams for development, design and production. These groups of accomplished experts work closely and flexibly with each other and can react quickly to the specific requirements of your projects.

Our three production sites are located in the Czech Republic, Slovakia and Russia.



We utilize our own realization teams, with experience since 1991.



Delivery and realisation of engineering services



Qualification and validation Licenced measurements Measurements



Service Outsourcing services

We provide comprehensive delivery and realisation of:

- Construction
- Building supervision
- Realization of inner distributions
- Placing clean rooms
- Equipment of interiors by technology
- Equipment of interiors by furniture
- Regulation
- Putting into operation
- Commissioning

We perform qualification and validation of:

- Clean rooms, Isolator workplaces,...
- Systems (clean media, control systems...)
- Equipment (technological, laboratory, healthcare equipment,...)
- Processes

We have licenced laboratories covering:

- Measuring fibre dust and cleanness class in inner area of constructions
- Investigation and measuring micro-climatic parameters in inner area of constructions
- Investigation and measuring micro-climatic parameters in working area

BLOCK® offers **service** at repairs, inspections and revisions of manufacturing areas and devices in pharmacy, electrical engineering, chemistry, health service and other similar industrial areas. We have own team of experienced service engineers and technicians regularly schooled at partner companies (e.g. Daikin, Gea, Flair).

- Guarantee and after-guarantee service
- Service with service contract on intervention time up to 24 and 48 hours

Outsourcing services

Complete building administration



We are partners throughout each phase of your project – we provide complex services for the entire building lifecycle.



Biovera Tech Hall



TURNKEY CONSTRUCTIONS – COMPLEX SUPPLIES

We have long-term experience in following areas

- Production of substances (API, HAPI)
- Production of non-sterile medicaments (solid and also liquid forms, liniments, emulsions, sprays, aerosols)
- Production of sterile medicaments (injections, emulsions and liniments, aerosols)
- Production of radio-pharmaceuticals
- Production of medicinal products of modern therapy
- Production of medical technology products
- Biotechnological production (substances, vaccines)
- Production of veterinary medicaments
- Development and control laboratories
- Vivaria
- Pharmaceutical storage rooms





BLOCK® CLEAN ROOMS COMPLIANT TO GMP REGULATIONS

We provide two BLOCK® systems for the construction of clean rooms compliant with EU GMP standards where the decisive parameter is the prevention of particle and microbial contamination.

- System for built-in cleanrooms – Forclean GMP
- System for built-in modular cleanrooms

Both systems comply with all international GMP regulations. These GMP requirements are met both by individual products and by the cleanrooms as the whole. All components of these systems have been developed and produced internally. All components of our systems that are compatible each to other; it is known as the EASY TO ASSEMBLY trend. Thanks to this fact, it is possible to construct facilities of the highest quality according to process requirements.

- Wall systems
- Doors and accessories
- Suspended ceilings
- Lighting
- Covings and accessories
- HVAC components
- Built-in furnishings
- Other accessories – built in lock, pressure indicator, contactless switch, etc.

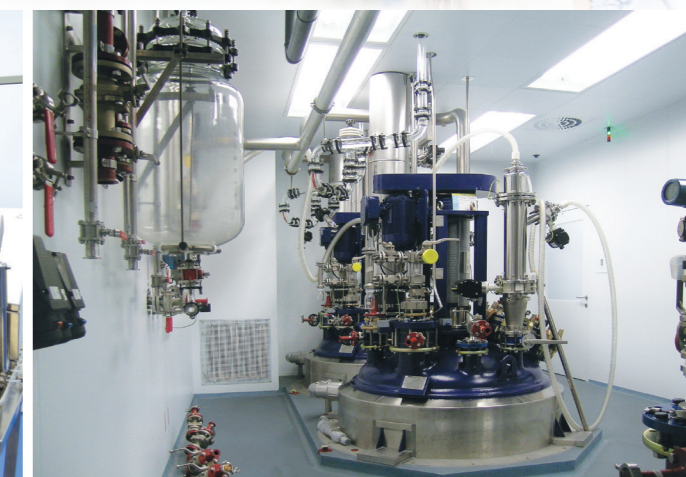




TECHNOLOGICAL EQUIPMENT (PROCESS TECHNOLOGY)

Our solutions for facilities also include the supply of technological equipment. We cooperate with recognized technological specialists as partnering organizations. We employ a highly qualified team of experts for drafting and design, assembly, initiation and validation even for the most complicated technology.

- Reactors and tanks
- Filling lines
- Packaging lines
- Lyophilizers
- Tableting machines, capsule filling machines
- Fluidization driers, Homogenizers
- Bioreactors
- Centrifugal machines, ultrafiltration units





TECHNOLOGICAL MAINS / PRODUCT DISTRIBUTION SYSTEMS

We realize technological mains/product distribution systems made from special materials according to the desired resistance – from various types of stainless steel, plastics and glass. Technological mains include the supply of reactors, coolers and other technological apparatuses.

Our team will suggest and supply reliable sources and distribution systems of clean media (demineralized water, purified water, water for injections, clean steam, compressed air, special gases, etc.).

- Clean media as PW, WFI, PS
- Technological gases and other technological media
- Process steam
- Waste management
- Product distribution systems
- CIP/SIP systems





HVAC&R (HEATING, VENTILATION, AIR-CONDITIONING AND REFRIGERATION)

The operational reliability and stability of pressure cascades are high priorities in the implementation of systems for heating, ventilation, air-conditioning and refrigeration. When designing an HVAC system, we deal with the optimization of investment and operational costs. When putting a system or product into service, we check all operational and emergency conditions. We have practical experience in the design and realization of HVAC systems for the most demanding technological processes.





BLOCK® ISOLATOR TECHNOLOGY

Tailor-made production, supplies and installations of isolator technology according to customer's specific requirements.

We can confine your production process in an isolator/RABS. We have developed solutions for weighing, formulation or filling processes and other technological appliances. We manufacture our own BLOCK® isolator product range which complies with tightness class II pursuant to ISO 10648-2.

- Individual solutions of isolator technology and RABS, based on our own modular system
- Tailor-made product– you decide the form and design of the isolator from the very beginning
- Development in every detail of production and distribution processes including ergonomics
- Complete project support from the order through development right up to operational support
- Our own patented PURITER vaporized hydrogen peroxide generator for the sterilization of isolator chambers, pass-through cabins and cleanrooms.





BLOCK® LABORATORIES

Complex solutions and supplies of GLP- and GMP-compliant laboratories.

Complete supplies of laboratories contain

- Built-in laboratory rooms with defined environment parameters
- Supply of HVAC systems with our thinkingLAB system solution
- Equipment with furnishings, laboratory instrumentation and accessories
- Supply media distribution elements and distribution mains

We use our own BLOCK® system of furnishings and equipment (laboratory furnishings, chemical hoods, microbiological and laminar boxes, boxes for work with microorganisms). The ForlabSystem is fully compatible with the Forclean and Forclean GMP systems. By combining them, a complete facility for any type of protected laboratory may be realized.

As a complex solution in air-conditioning, we have developed the thinkingLAB system, which ensures considerable savings in operational costs.



A TEAM OF PROFESSIONALS

We have our own teams of accomplished experts who closely and flexibly work with each other: our own design, drafting and planning, development, production, validation, and service teams.



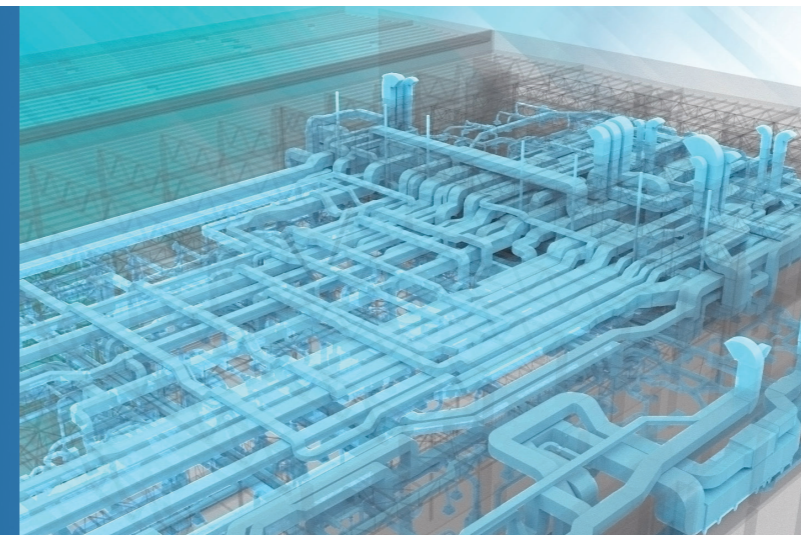
DETAIL ACCENTUATED

Processing of details is essential for rooms with high demands on environment quality. Thanks to our in-house production we are able to provide custom-made adaptations of products to specific your project requirements.



TAILORMADE SOLUTIONS

Thanks to a large TEAM OF PROFESSIONALS and our IN-HOUSE PRODUCTION we are able to respond quickly and flexibly to meet your project's specific requirements.



DETAILED AND TAILOR-MADE SOLUTIONS FOR THE REALIZATION OF THE MOST COMPLICATED PROJECTS

IN-HOUSE PRODUCTION

Our implementations are strengthened by our own production program. We have three manufacturing facilities – in the Czech Republic, Slovakia and Russia. We manufacture components for built-in clean rooms, isolator technology, technological equipment and special furnishings.

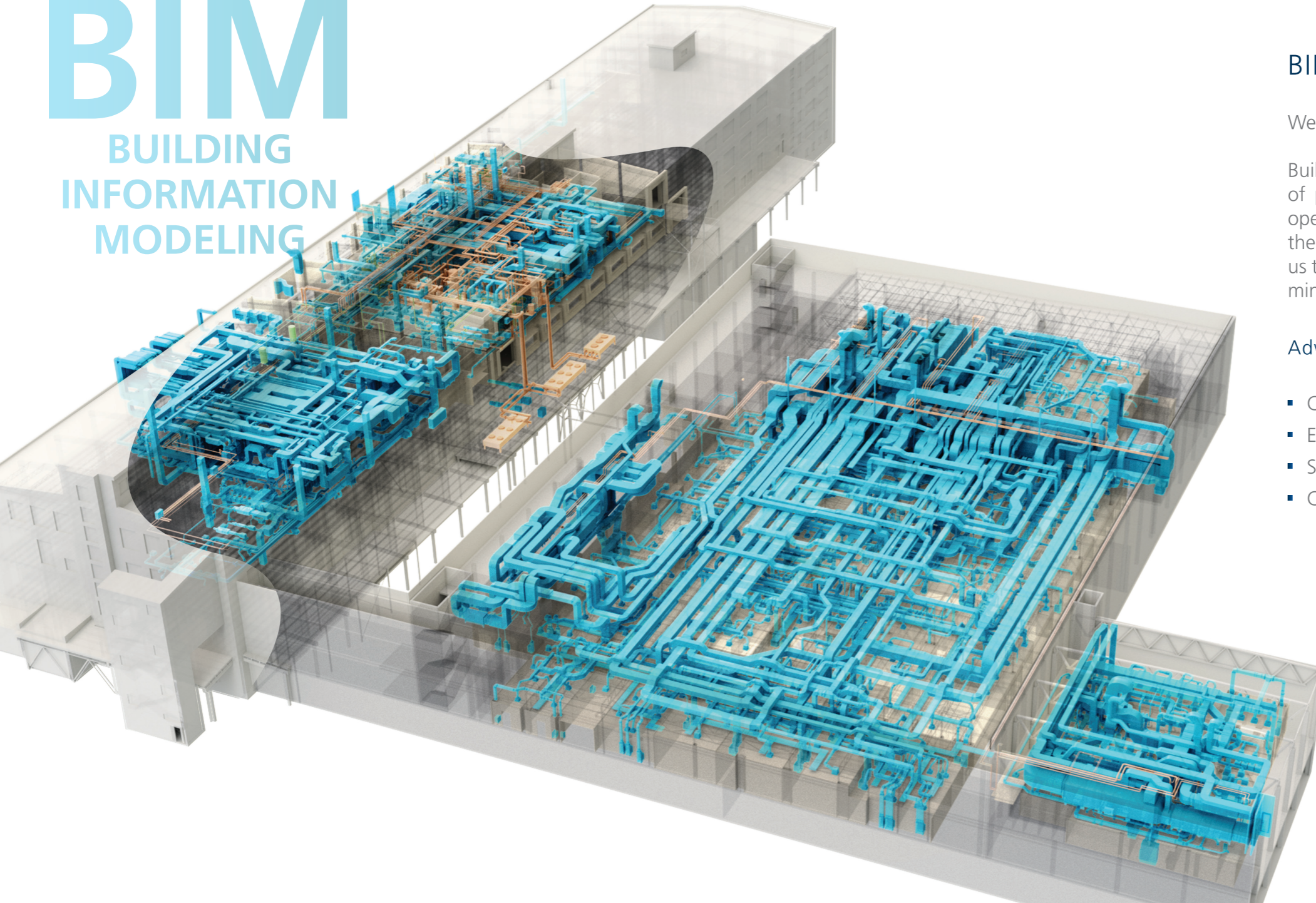


OPERATION RELIANCE

You can rely on our solutions. The units delivered by us have been tested under a long-term operation.



WE PROCESS BIM BUILDING INFORMATION MODELING



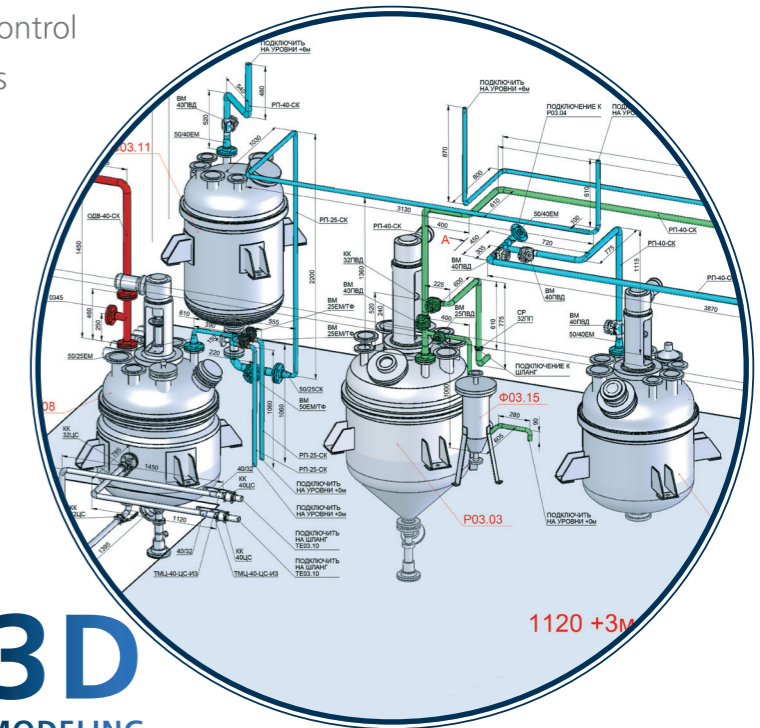
BIM AND DIGITIZATION

We work with the BIM system and support digitization in the building sector.

Building Information Modeling of a building is a digital representation of physical and functional characteristics of a facility. BIM serves as an open knowledge database and facilitates the sharing of information during the design phase, the construction and the use of a building. BIM enables us to set up and manage projects more quickly, more economically and with minimal environmental impact.

Advantages of BIM

- Complete-project control
- Elimination of faults
- Saving of time
- Cost saving



3D
MODELING



ASSOCIATION MEMBERSHIP

In order to offer you the best quality services, we support the continuous education and development of our employees and membership in related organizations.



ISPE – The International Society for Pharmaceutical Engineering

ISPE is an international community of pharmaceutical professionals who possesses expert knowledge and create high-quality, cost-effective GMP solutions. ISPE members gain wide and multifaceted advantages that increase their understanding in the pharmaceutical industry, enable them to join similar professionals worldwide and gain abilities to resolve GMP and regulator questions.



VIP 3000 – an interest association for Pharmaceutical Constructions

VIP 3000 is an association focused on the support of all technologies related to the planning and implementation of up-to-date pharmaceutical industrial facilities, cleanrooms and related specialized rooms.



Swiss Clean Room Concept

The Swiss Clean Room Concept is a community of experts in pharmaceuticals in Switzerland.

CERTIFICATIONS



ISO 9001:2008, ISO 14001:2004, OHSAS 18001:2007

- ISO 9001:2008 –since 1997
- ISO 14001:2004 – since 1997
- OHSAS 18001:2007 – since 2011 (former OHSAS 18001)

OUR CUSTOMERS





Creating conditions

Switzerland: BLOCK Technical AG, Fadenbrücke 10, 6374 Buochs | Tel.: +41 41 610 95 14 | E-mail: info@blockcrs.ch
Germany: BLOCK Technical AG, Ginsheimer Strasse 1, D-65462 Gustavsburg | Tel.: +49 6134 29 154 10 | E-mail: info@blockcrs.de
Czech Republic: BLOCK a.s., U Kasáren 727, 757 01 Valašské Meziříčí | Tel.: +420 571 670 111 | E-mail: info@blockcrs.cz
Slovak Republic: FOR Clean a.s., Vrbovská cesta 39, 921 01 Piešťany | Tel.: +421 33 79 89 111 | E-mail: forclean@forclean.sk
Russia: ООО БЛОК, 125047, г. Москва, ул. 4-я Тверская-Ямская, д.33/39 | Tel.: +7 495 787 42 11 | E-mail: info@blockcrs.ru
Russia: ООО «ФОР Клин», 603003, г. Нижний Новгород, ул. Баррикад, д. 1 | Tel.: +7 495 787 42 11 | E-mail: info@blockcrs.ru

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