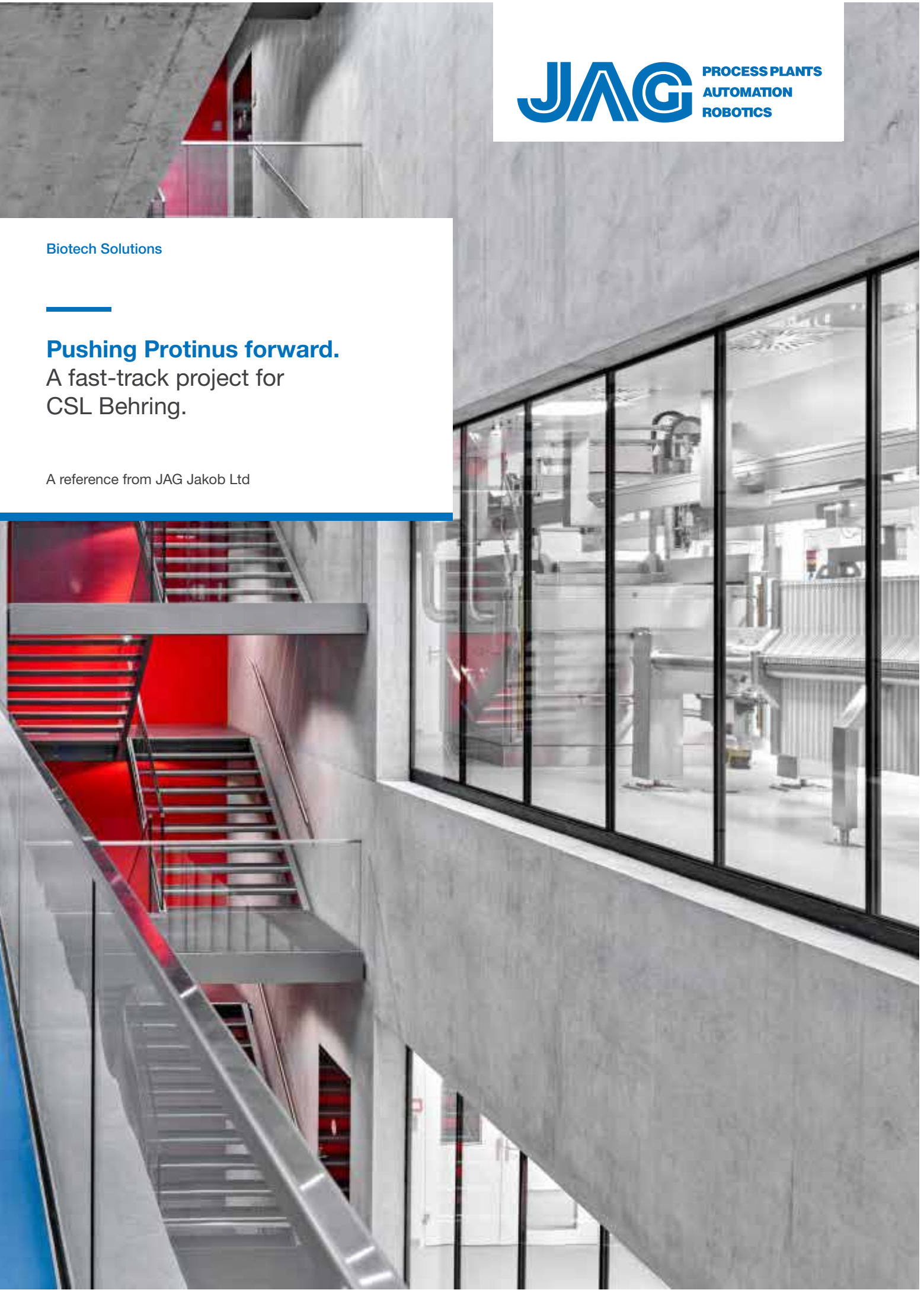

JAG PROCESS PLANTS AUTOMATION ROBOTICS

Biotech Solutions

Pushing Protinus forward.

A fast-track project for CSL Behring.

A reference from JAG Jakob Ltd

A breathtaking, multi-faceted project.

Our contribution to a state-of-the-art manufacturing facility in biotech.

“Protinus” is a well-chosen name meaning “forward” and “further” in Latin. It stands for a massive expansion of manufacturing capacities which gives hope to 90’000 additional patients dependent on life-saving immunoglobulins (IgG). To achieve this ambitious goal, the biopharmaceutical company CSL Behring had a multi-storey production building erected and connected to the existing Logistics and Service Center in Berne.

Our contribution to Protinus was to provide the multi-batch process plant with a buffer system and to completely automate the plant.

Protinus in figures:

» Facility:	2 modules for IgG manufacturing
» Investment volume:	CHF 300 million
» Project duration:	2017 – 2020
» Start of production:	2021
» Laid pipes:	61,318 m
» Length of wires:	725,300 m

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Contents

Challenges	4
Solution	6
Components & software	8
Summary	10

The challenge: A tight schedule for high demands.

JAG's expertise ensured fast and efficient delivery.

«It was a fast-track project from the very start. Unbelievable work was done at the Protinus construction site to keep to the schedule. Nobody believed it was possible, but we made it a reality.»

Pierre Caloz, former Head of Manufacturing EU & APAC - CSL Behring

Producing biopharmaceuticals such as immunoglobulins includes finely tuned process stages to isolate them from the blood plasma, to purify and to concentrate them. Buffer solutions from salts and phosphates are indispensable in this downstream processing.

We have been entrusted with the task of engineering the buffer system and integrating it into both production lines (modules V and VI). In addition, we were given the task of completely automating the plant to maximize productivity.

A challenge we have successfully met:

Massive construction of equipments

» 19 buffer tanks for buffer preparation
» 6 powder feeding stations
» 12 CIP satellites
» Powder conveyors for buffer production
» Buffer production and distribution

Complex automation

» Complete automation of both production lines
» Installation qualification (IQ)
» Operational qualification (OQ)

Respect of a tight schedule

We have already accomplished the same task twice with success: in CSL Behring's production sites in Switzerland (modules I and II) and Australia (modules III and IV) between 2007 and 2017. The Protinus plant (modules V and VI) is the continuity of the predecessor facilities. However, quite different and especially challenging was the extremely tight schedule. We had to step up a gear to deliver excellent work in strictly limited time frames and make the Protinus project a success while meeting all the deadlines.

Protinus milestones

» End of 2017: Briefing
» June 2019: Commissioning started
» June 2020: Operational qualification of module V finalized
» August 2020: First product batches for process performance qualification (PPQ) of module V
» January 2021: Operational qualification of module VI finalized

Our solution: Choreographing all factors of success.

Experience, know-how, and teamwork.

«In terms of automation, JAG's expertise ensured fast and efficient delivery in line with CSL Behring's quality standards. That's why we chose JAG.»

Dominik Cimpersak, Senior Project Manager Protinus

Both profound expertise and a close teamwork contributed significantly to the fact that we were able to complete all tasks to the client's full satisfaction. After all, having automated the previous plants (modules I to IV) was a great advantage.

Teamwork in the JAG Group

We worked closely with our sister company amotec AG für Montagetechnik, specialized in manufacturing and installation of sophisticated process plants and complex pipeline systems. All parts of the buffer system were prefabricated in our shop floor and then delivered to and integrated in the Protinus building, which was still under construction at the time. Up to 70 of our employees were working in two shifts on site. Wiring and construction were done in parallel to increase efficiency.

Automation proves its advantages - efficiency and cost savings

» A round-the-clock-operation (24/7)
» 2 day-time production shifts alternating with a cleaning shift at night (CIP)
» Maintenance during operation
» Reducing downtimes and outages
» Reducing staff requirement and human error rate

Advantages of Protinus, automated by JAG:

» Multi-batch processes

» In-process monitoring (IPC)

» KPI-based performance analysis

» Automatic cleaning and steaming in place (CIP/SIP)

» Electronic batch record (EBR) and paperless files

» Recipe-controlled operator guidance

» Recording and analysis of operational and production data

» Access control

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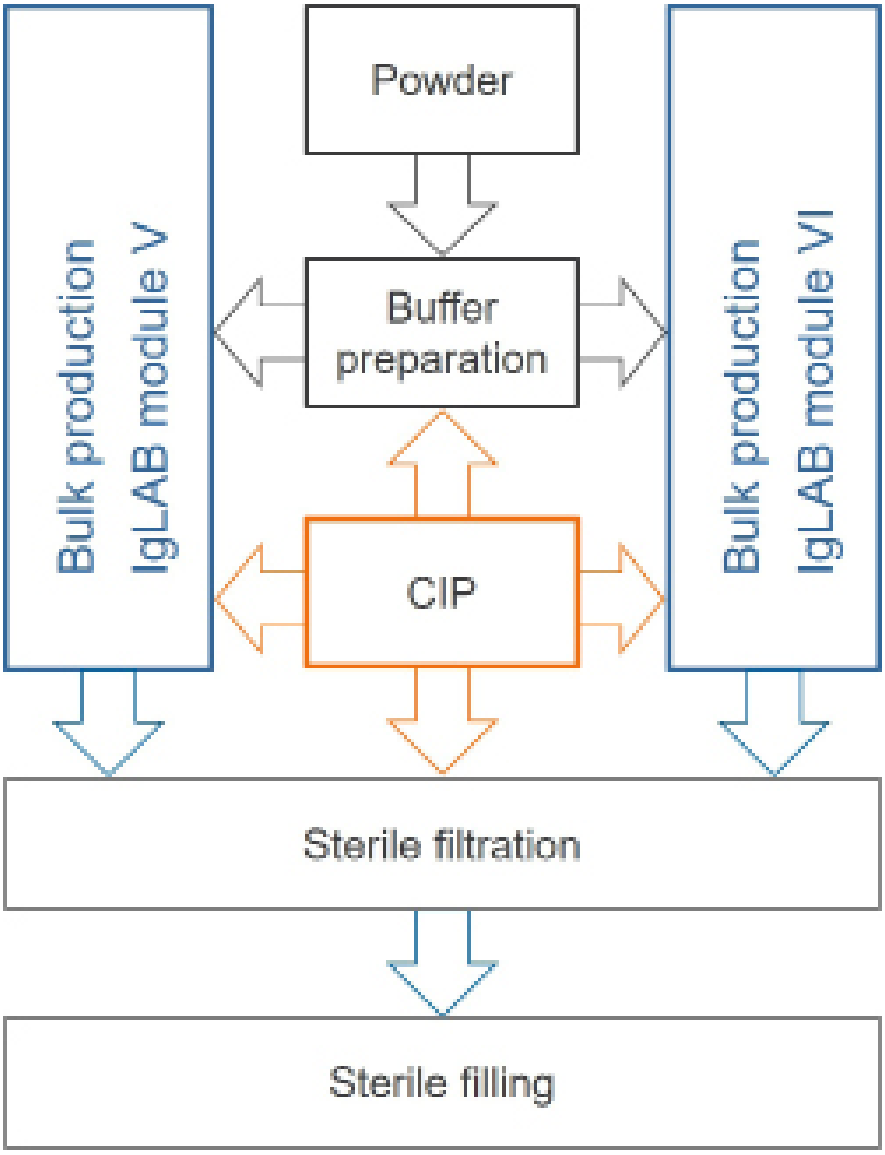
The result: A true multi-batch plant.

Maximum capacity utilization and efficiency.

The centrepiece of the Protinus plant are two identical production lines, modules V and VI, which can be operated individually. A true multi-batch plant. The automation allows for daily start of one batch each per line with a throughput time of 4 days.

Shared systems for buffer preparation and supply, CIP and SIP ensure an overall solution with maximum production capacity and highest plant efficiency, optimally clocked and synchronized with subsequent sterile filtration and aseptic filling.



What makes a high-performance system.
An overview of the key components and software.

We are pleased to introduce you to the components and the programs that keep the Protinus plant running. All are in-house developments by JAG.

JAG PAD
Powder Discharge & Dosing Device

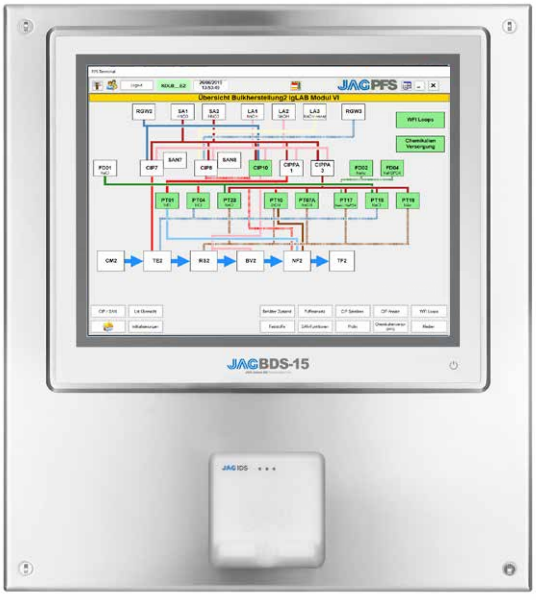
A pneumatic drive lifts the cone to allow the powdery material to flow through the annular gap. Even flaky and bulky powder can be easily discharged by constantly raising and lowering the cone. The JAG PAD ensures high dosing accuracy.

JAG SW
Diverter Valve

Specially developed for pneumatic transport systems, the JAG Diverter Valve ensures a reliable connection. It is ideal for use in sterile rooms. The extremely compact construction allows it to be installed in the tightest of spaces .

JAG FLD 32
Fluidising Nozzle

Since temperature and humidity affect the flowability of powdery materials, the JAG Fluidizing Nozzle improves flow behavior by disrupting powder bridging and coagulation tendencies. To achieve this, the fluidizing nozzle blows pulses of compressed air along the inside of the container. Existing plants can be easily retrofitted with this device .



JAGMES

JAG MES Advanced manufacturing execution system is specially designed for large, complex, and highly automated production plants. It allows to manage, control, and fully record parallel processes with complex recipes. JAG MES Advanced is particularly suitable for pharmaceutical and biotech applications.

JAGBDS-15

The JAG BDS-15 Touch-Panel-PC with Intel Celeron Quad Core technology and a Windows 7 operating system is used for commanding, controlling, and visualising the automated process. The JAG BDS series units were specially developed for demanding applications and can be installed in both control cabinets and standalone operator interfaces on site, in sterile rooms or elsewhere on the process line .

Your one-stop-shop for a wide range of skills and services.

Comfortable and easy.

As our contribution to the Protinus project proves, we are capable of fully automating even extremely complex and large-scale production processes in the pharmaceutical and biotech industries. Added to this are our engineering process technology and construction competences. Whatever you need, you get a wide range of skills and services from a single source. In other words: JAG is your one-stop-shop supplier.

Project management

We disburden our clients from all organizational tasks, resource planning and all monitoring jobs: schedule, budget, and performance parameters. Finally, we ensure a timely delivery of a fully qualified plant in accordance with GMP/GAMP standards.

Planning and engineering

We take care of all planning work from basic engineering to the elaborated design documents (2D/3D) and specific software solutions including the definition of traceability and documentation.

Assembly management

We build, assemble, test and commission the complete plant, both mechanically and electrically. Above all, we speed up implementation by performing all pre-assembly work in our own workshops.

Software implementation

We implement the automation software with all the necessary standard software modules.
It goes without saying that we do all the configurations and tailor the software to the customer.

Validation and qualification

We guarantee and provide design qualification (DQ), factory acceptance test (FAT), site acceptance test (SAT), installation qualification (IQ) and operational qualification (OQ).

After-sales service

Thanks to our Service Level Agreements, clients benefit from round-the-clock service, online and telephone support, servicing, maintenance, and repair work.

Added values galore

We are happy about the trustful, long-standing cooperation with CSL Behring and are proud that our skills and services are helping to alleviate the suffering of patients who depend on a therapy with immunoglobulins. Even under extraordinarily challenging conditions, we met all the targets (schedule, quality, and budget) and have contributed to a top result in many terms:

» A state-of-the-art manufacturing facility, fully automated
» Flexible multi-batch operation 24/7
» System efficiency and maximal productivity
» Reduced downtimes
» Exclusion of human error through automation and staff reduction

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