

## Expansion instead of new construction

A reference from JAG Jakob Ltd.

### Expanding an existing processing facility into a multi-purpose facility is often a better option

The space available for production systems at CSL Behring in Bern is limited, and there's also not much room for new systems and equipment. In addition, the extensive time pressure often involved in the construction and commissioning of a new production system requires the development of innovative solutions, whereby solid and close cooperation with partners plays a major role here.

#### Optimal utilisation of system components and space

Faced with a situation in which it had decided to manufacture the base material for a clinical study of a new drug, CSL Behring chose to expand its existing Cytogam production facility into a multi-purpose facility (multiple-line system) rather than build a new one. The expanded facility can manufacture both Cytogam and the material for the clinical study. This approach ensures better capacity utilisation of the jointly used system components, as well as optimal use of limited space.

In addition, expanding an existing facility rather than building a new one significantly reduces investment and operating costs, as well as the construction time involved.

In this case, the machines used to manufacture buffer solutions, along with the

auxiliary equipment (for compressed air, steam and water) and the cleaning units (CIP/SIP), are already in place and can be used for operations on both production lines. The production plant for Cytogam and the material used in the clinical study is located in Campania.

#### Prevention of cross-contamination in changeovers

Switching the products manufactured on a production line (production changeover) is a critical process. Under no circumstances may cross-contamination be allowed to occur between the proteins contained in the products.

CSL Behring and JAG put a great deal of effort and expense into the development of a concept for process changeovers that can be used to ensure that no proteins are left in the jointly used production-system components when production of the other product begins.

Here, the jointly used production system is divided into two physically separate areas (for pre virus inactivation and post virus inactivation) located in front of and behind a virus filtration unit. The process changeover is performed separately in each area. This approach makes it possible to reduce throughput times and improve the facility's capacity utilisation. Each area also has its own physically

separate CIP cycle for cleaning system components and pipelines, as well as its own CIP station. In order to safely rule out the possibility of cross-contamination, a self-cleaning system for product changeovers has been installed at the CIP stations.

#### High degree of capacity utilisation and maximum process reliability

Through its intelligent management of production and cleaning processes in both sections of the facility, as well as the use of locking and release mechanisms for manufacturing and cleaning processes, the process control system enables optimal utilisation of the facility during production changeovers, while also ensuring the prevention of cross-contamination in all situations.

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**“The great dedication displayed by the specialists at JAG, along with the expertise they contributed to the project, played a major role in ensuring its success.”**

Adrian Hegnauer, Project Manager Engineering Services CSL Behring AG

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### Minimal effort and expense for re-qualification

JAG faced the challenge here of having to expand and upgrade the existing process control system with a minimum of effort and expense for the re-qualification of the existing manufacturing process. In addition, the hardware modifications and expansions, and the implementation of the automation software, had to be completed within a very short time in

order to ensure that the interruption to Cytogam production operations would be as brief as possible.

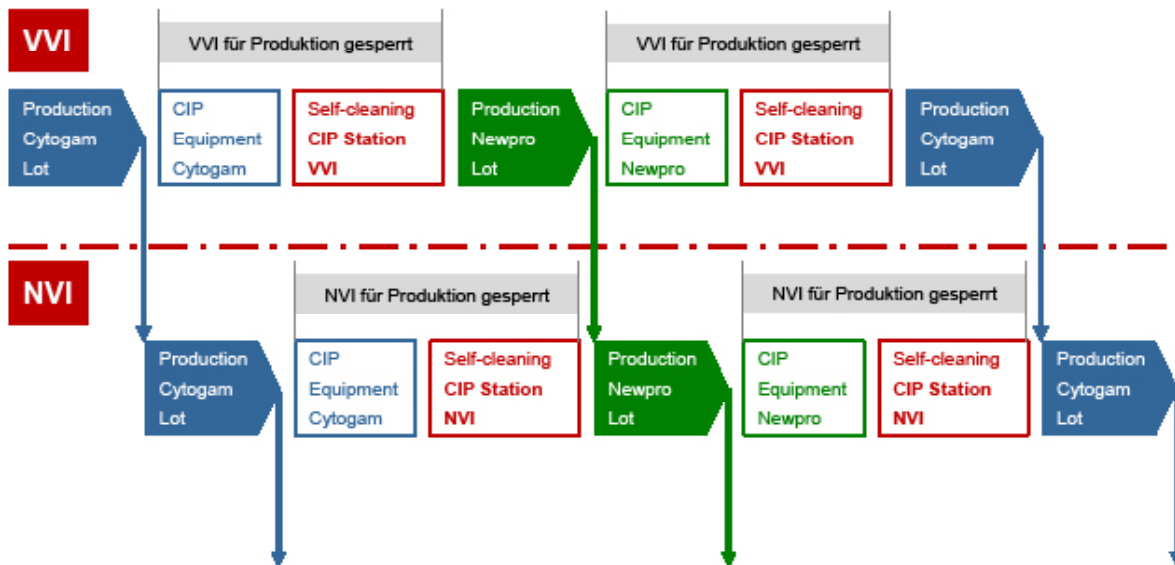
### Automation solution with an advantageous modular structure

Because of the modular structure of the JAG control hardware and software, only a few specific software modules had to be modified and re-qualified for use in

the joint production system. An exact copy of the production control system was set up at JAG for the factory acceptance test (FAT). This comprehensive FAT made it possible to commission the control software (including qualification and re-qualification of the manufacturing processes for the clinical study material and for Cytogam) in just a very short time.

## Multi-Purpose Plant

Campaigns changes (Product changeover)



In a production changeover, production systems are blocked in the areas for pre virus inactivation and post virus inactivation until the self-cleaning process in the respective area has been completed. The separation of a facility into pre virus inactivation and post virus inactivation areas with a separate CIP station for each makes it possible to manufacture a batch in one area while the cleaning process runs in the other.



A process control system (PCS) guides the production-system operator, prompting him or her to launch processes, for example. Such a system can also block a process changeover or the launch of a process if the system or any of its components is not yet ready for such an action, or if there is a danger of cross-contamination.

Friederike Zaubitzer, Manager Deputy Bulk Hyper-Ig CSL Behring AG was impressed by **“the way colleagues from internal units and engineers from JAG worked together to develop and implement the new system. We’re all very proud of what we achieved in just a short amount of time.”**