

Powder Processing Solutions

Precision Pharmaceutical Processing.

A powder mixing system for active pharmaceutical ingredients.

A reference from JAG Jakob Ltd Process Technology.



A reference from the pharmaceutical industry. Our contribution towards treating chronic illnesses.

Since 2015, a new essential drug has successfully been in use in both dermatology and rheumatology. In order to satisfy the increasing demand, Celgene commissioned us to develop a pharmaceutical powder mixing system.

The process plant has gone into service in Val-de-Travers in the canton of Neuchâtel, at the new production facility of this globally-active pharmaceutical company that is headquartered in the USA.

This demanding project kept us willingly busy for two years, from 2016 to 2018. The greatest challenges lay in fulfilling the high demands in terms of safety, hygiene and documentation.

In this respect, our team drew on its treasure trove of experience from previous projects in the pharmaceutical industry and also acquired new know-how during the course of this project that will benefit future similar projects.

PUBLISHER

JAG Jakob LTD
Industriestrasse 20
CH-2555 Brügg
T +41 (0)32 374 30 30
F +41 (0)32 374 30 31
jagpt@jag.ch
www.jag.ch



Contents

Assignment	4
Solution	6
Skills	8
Advantages	10

Powder mixing subject to pharmaceutical conditions. A challenging task.

Essentially, the job of a powder mixing system is to mix active pharmaceutical ingredients with various excipients and deliver a completely homogeneous end product in powder form.

To this end, all of the dosing and mixing processes must guarantee maximum adherence to the formulation. The operation must require few personnel and must not subject them to any health risks.



High safety level

Dust and possible toxic effects make pharmaceutical substances in powder form a potential danger for personnel. There are also fire and explosion risks (ATEX) in certain situations. These safety hazards must be kept reliably under control by the system when in continuous operation. At the same time, it is vital to exclude the potential danger of impurities and cross contamination.

Precise dosing

One and the same dosing system must be able to cope with different substances in equal measure and achieve a consistently high level of precision. Only slight variations of a few grams per 100 kg of substance are tolerable.

Productive shift system

The system must run continuously in a three-shift operation and handle two batches per shift. The personnel requirement should be limited to a single operative with little need for intervention.

Monitoring

An up-to-date monitoring system should guarantee that the automatic lifters operate reliably in an open working environment.

Traceability

Modern radio frequency identification (RFID) should guarantee the full traceability of all processes and containers.

Fully automatic cleaning

The entire system should clean itself (cleaning in place).

Have your cake and eat it too.

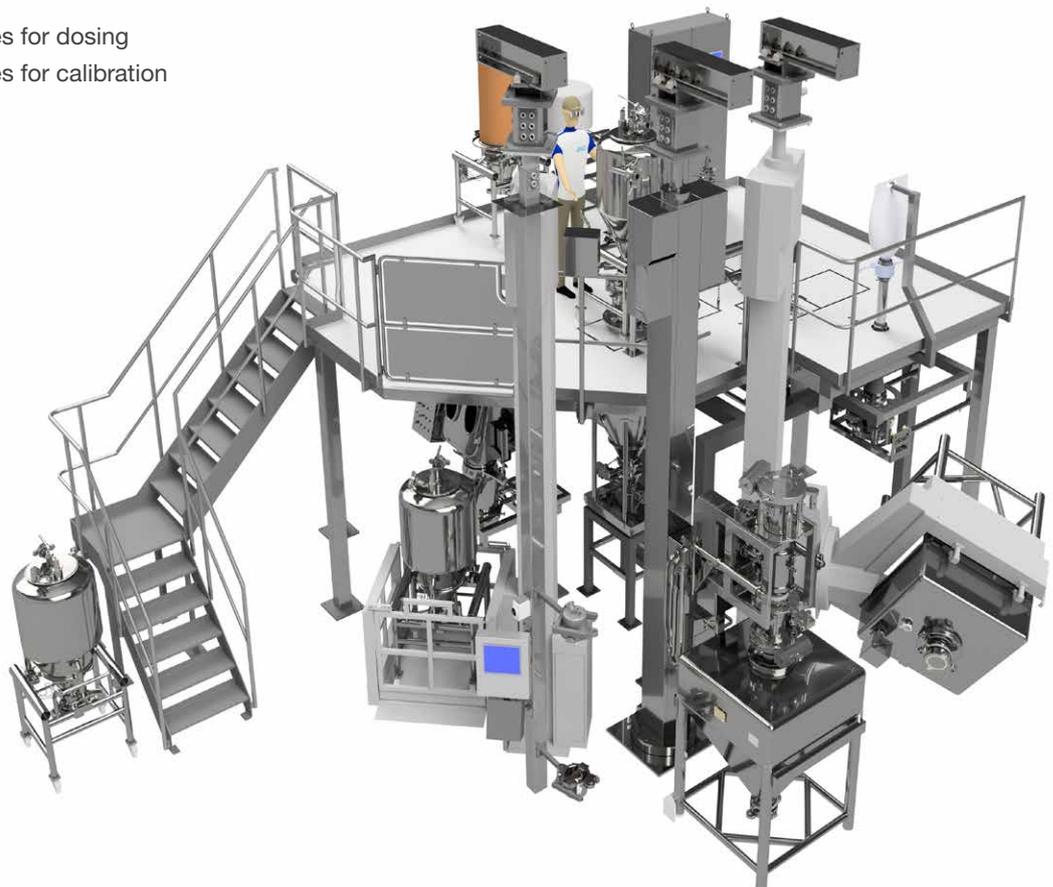
Large capacities and flexible multi-production.

The JAG team developed a highly automated processing plant with two specific production lines, one of which is designed for maximum capacity and the other for maximum flexibility. Both lines take into account the specific demands of processing active pharmaceutical ingredients (APIs).

Line 1: maximum capacity

To be able to cope with large quantities of powder, our team developed a highly efficient conveyor system with mobile transport containers that dock onto a central dosing and mixing station. Docking manoeuvres, the feeding in and removal of substances, dust removal, bar-coding, dosing and mixing – all of these processes take place fully automatically, with only the changeover of transport containers being carried out manually. The mobile transport containers are our own development, equipped with our own JAG PAD dosing system. All of the dosing and mixing processes are controlled at plant manager level using a manufacturing execution system (MES) that we developed and which guides the operative unerringly through the whole formulation. The important elements of this production line are:

- » 4 IBC containers with a capacity of 1,000 litres
- » 2 mobile transport containers for active ingredients (APIs)
- » Additional mobile transport containers for excipients
- » 1 glove box for manually weighing the APIs and transfer to the transport containers
- » 4 fully automatic lifters: carrier, blending, mill and platform lifters
- » Platform with dosing and transfer stations
- » 1 dosing tank
- » 1 set of precision scales for dosing
- » 1 set of precision scales for calibration



Line 2: flexible multi-production

The second production line primarily processes active pharmaceutical ingredients (APIs) with an elevated toxic risk. Specific processing steps are therefore carried out in an isolator with permanent negative pressure. Designed for over five different production runs, this line handles smaller quantities of powder, yet combines high flexibility with a particularly high level of automation. The multi-production line basically includes the following elements:

- » 8 mobile IBC containers with a capacity ranging from 100 to 250 litres
- » 1 blending lifter for IBC containers
- » 1 lifter for excipient containers with a capacity of 70 litres
- » 1 mill lifter for the calibration equipment
- » 1 isolator with sieve and precision scales

GMP

Our automated solution for this system fulfils the pharmaceutical-specific GMP (good manufacturing practice) requirements from hardware to software. It records every action and facilitates precise management of rights and access.

JAG PdiCS

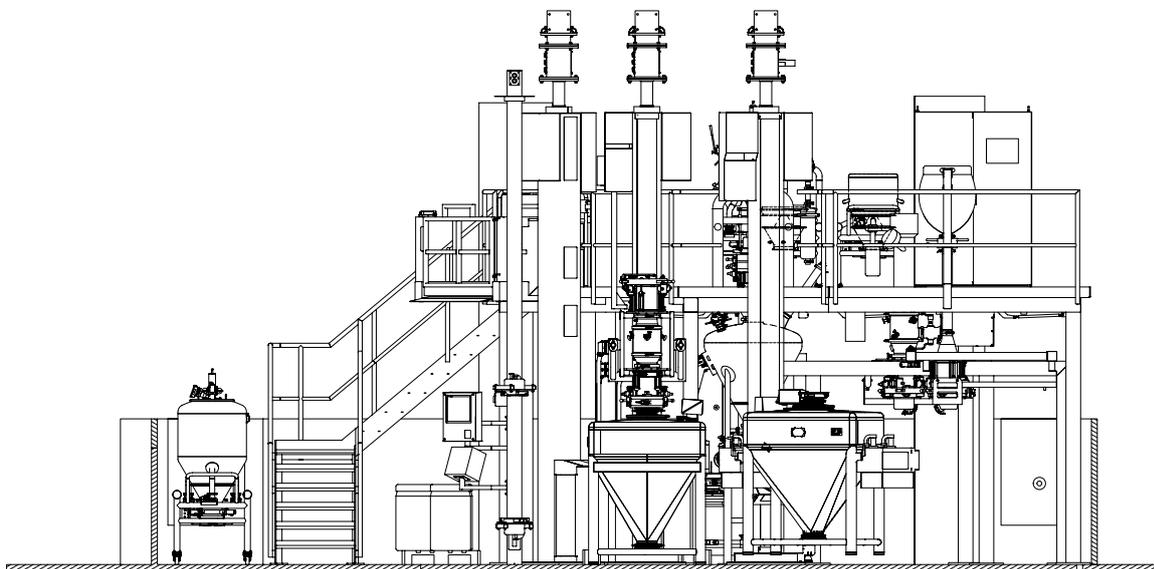
The JAG PdiCS control system lies at the heart of the process automation. It controls all automatic processes and reduces manual activities to an absolute minimum. JAG PdiCS continues to evolve with every project. Our engineers have written separate, sophisticated software for controlling the Celgene system lifters.

Networking

JAG PdiCS communicates with the customer's ERP system via an OPC interface. Thanks to further interfaces with the dosing and calibration scales as well as radio frequency identification (RFID), all key values in the process can be logged fully and without interruption in a batch report.

Cleaning in place

Last but not least, there is no need for any manual cleaning of the process plant. Cleaning in place (CIP) takes care of the fully automatic cleaning of Line 1. The plant cleans itself, so to speak – both to protect personnel and to prevent any potential contamination.





All skills leading to success.

We do not skip any steps.

JAG Jakob Ltd managed the project from the planning phase to the handover of the turnkey system, including training. For every task and every stage in the process, we had capable, experienced employees who cooperated with the customer in a solution-orientated manner. The system was installed by Amotec Ltd, a company that is part of the JAG Group and specialises in installation engineering.

Planning

- » Design
- » Basic engineering
- » Detail engineering
- » Software design
- » Construction management

Plant construction

- » Preassembly
- » Assembly
- » Electrical installation

Programming

- » Automation software
- » System integration

Factory Acceptance Test (FAT)

Commissioning

GMP system qualification

- » IOQ documentation and execution

Training

Support and maintenance

It goes without saying that we will advise and support Celgene during the ongoing operation and with the maintenance of the automatic powder mixing system.

1 point of contact for 1,000 details. Advantages at a glance.

Once again, JAG Jakob Ltd has demonstrated its ability to develop and provide a solution from a single source.

Made by JAG

From planning to programming, from commissioning to system qualification – JAG assembled expert teams from its pool of highly qualified personnel for every step along the way. This is a great advantage for our clients. It means streamlined communication with just one point of contact for all project-related inquiries.

System efficiency

The high level of automation of the production processes and the cleaning processes puts the system right at the top when it comes to efficiency.

Flexible multi-production

In addition to the process plant, which is designed to handle large quantities of powder, the installation also has a multi-production line offering a flexible dosing and mixing system and high safety standards.

In-house software solutions

What makes us stand out from many of our competitors is the fact that we not only integrate existing software solutions, we also develop new software programs and modules ourselves. All of our software solutions offer backward compatibility and are further developed to be future-proof. We guarantee upgrades, support and customer-specific adaptations, and thus investment and operating security for years to come.

Safe operation

Our designs incorporate all conceivable measures to protect personnel against entrapment accidents, falls and dust exposure.

Reduced manual intervention

The perfectly automated interplay between the fixed stations and mobile transport containers and lifters reduces the necessity for manual intervention to a minimum. The fully automated cleaning of the process plant means that no manual work whatsoever is required.



JAG Jakob AG Prozesstechnik
Industriestrasse 20
CH-2555 Brügg
T +41 (0)32 374 30 30
jagpt@jag.ch
www.jag.ch

JAG Jakob SA Technique de procédés
Rue de la Roche-de-Mars 12
CH-2900 Porrentruy
T +41 (0)32 374 34 34
jagpt@jag.ch
www.jag.ch

JAG Process Solutions PTY LTD
420 Victoria Street
Brunswick VIC-3056
Australia
T +61 (0)37 068 58 78
info@jag-ps.com.au
www.jag-ps.com.au