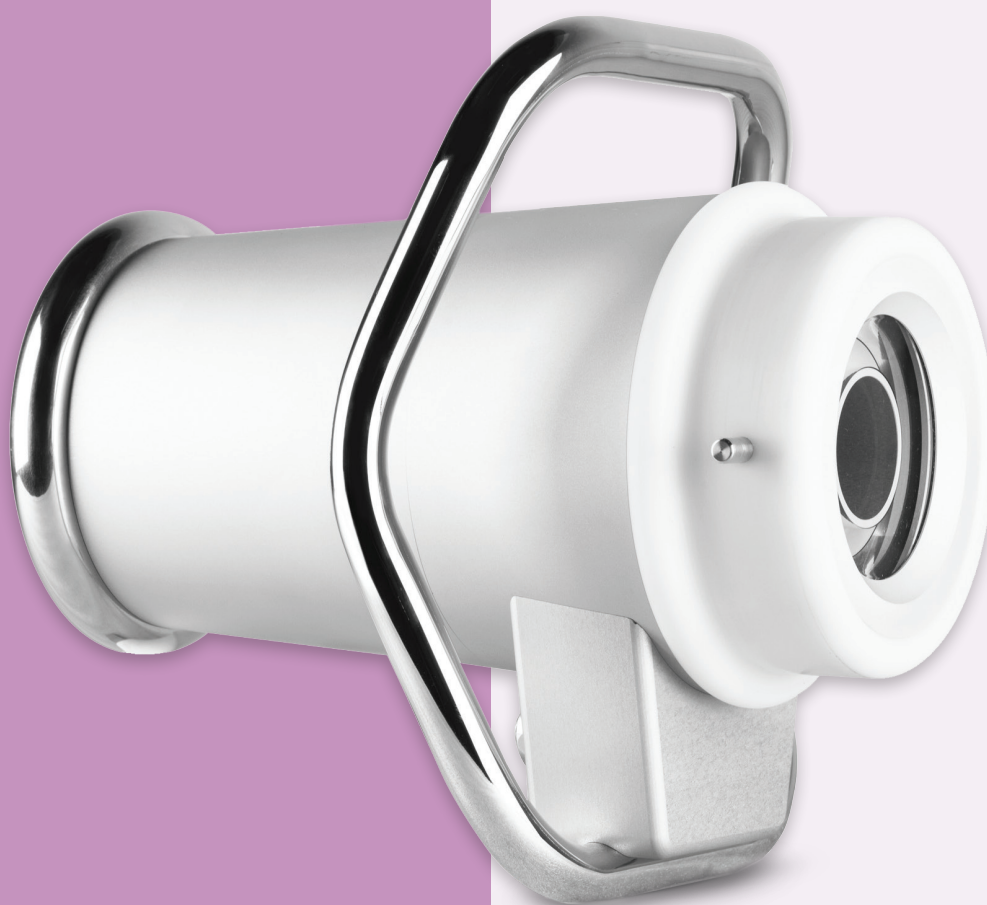


PATVIS APA

Process analytical technology
visual inspection system for
automated particle analysis



SENSUM

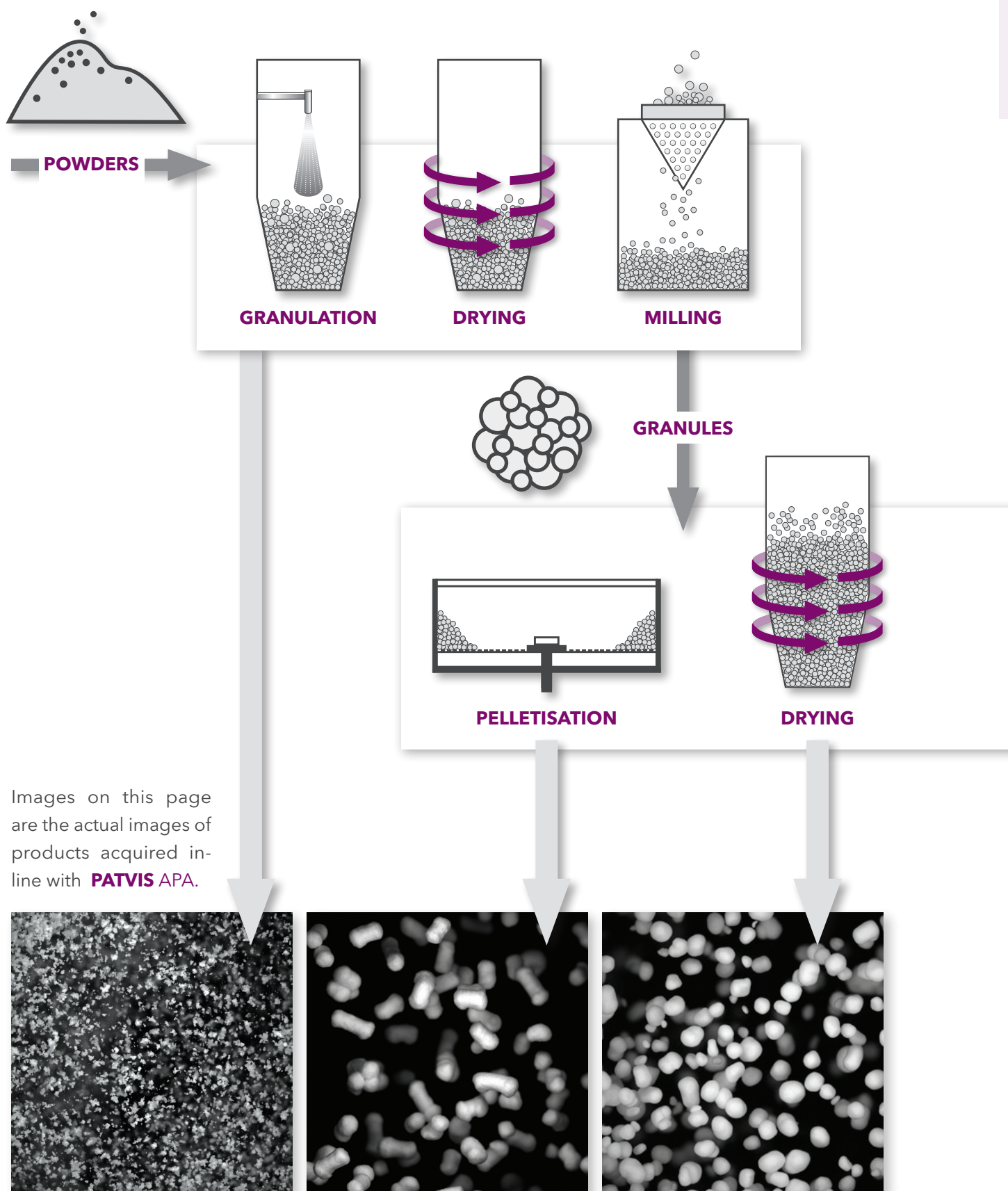


- IN-LINE OR AT-LINE PROCESS MEASUREMENTS
- SIMPLE INSTALLATION IN R & D OR PRODUCTION OF SOLID DOSAGE FORMS
- PORTABLE, ERGONOMIC AND TOOL FREE
- ATEX AND FDA CFR 21 PART 11 COMPLIANT

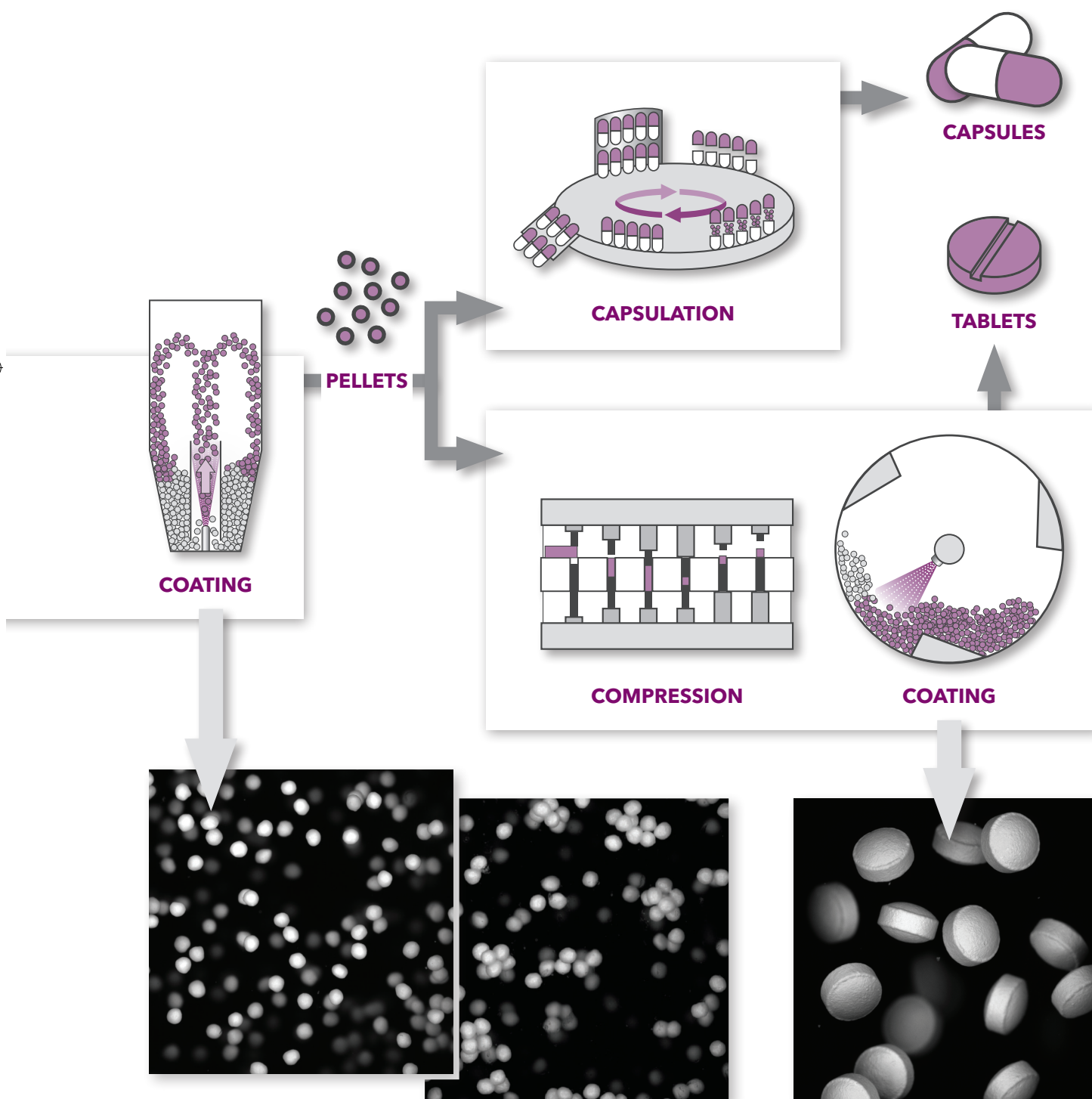
*Computer
Vision
Systems*

QUALITY IN PRODUCTION CHAIN

DOWNSTREAM PROCESSING: From powders to granules, pellets, capsules and tablets.



The performance of each processing step in the production chain defines the quality of the final product. With processes being pushed for higher quality, yield and efficiency, process understanding becomes critical for creating opportunities of continuous process improvement. Process understanding starts with making the process visible by real-time measurements. Visualize, measure and control your processes in real-time to understand and manage challenges as detected rather than deal with quality issues post hoc. Build the quality into your products.

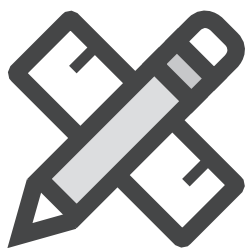
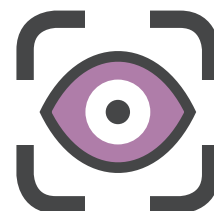


VISUALIZE, MEASURE, CONTROL

PATVIS APA is designed for real-time visualization, monitoring and diagnostics of process development, scale-up, transfer and production. There are three levels of **PATVIS APA** operation and you choose the level of leveraging the acquired visual information of the process, delivering the benefits of quality by design.

LIVE VIEW

Mounted directly on process equipment, **PATVIS APA** provides a live view of the product. A high-speed camera with a telecentric optical system assures noninvasive acquisition of detailed images for clear visualisation. Live view allows saving of all images of the process for later qualitative or quantitative analysis, which is especially useful for in-process product behavior observation and better process understanding.



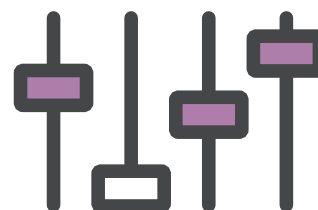
REAL-TIME MEASUREMENTS

PATVIS APA offers accurate measurements of CPP's with exceptional particle rate and excellent statistical strength in real-time, which is key to process optimisation. Proprietary and speed-optimised image analysis algorithms provide numerical data through an intuitive graphical user interface for immediate process feedback.



PROCESS CONTROL

PATVIS APA offers software compliance to GAMP and FDA requirements and can be integrated with interfaces of production equipment for increased autonomy with automatic process monitoring, alarming and control.



REDUCE COSTS

PATVIS APA offers a true utilization of on-line, in-line and at-line process analytics and control solutions, enabling a smooth transition to cost-effective batch and continuous production. This is achieved by reducing the time to market and production cycle time, reducing out-of-specification batches, increasing productivity and improving quality.

AGILE RESEARCH AND DEVELOPMENT WITH FULLY PORTABLE AND FLEXIBLE SOLUTION



- Transferable from a laboratory to a production facility
- Same measurement approach during process scale-up
- Flexibility in the way data is acquired (in-line, at-line, off-line)
- Qualitative and quantitative process monitoring and evaluation in real-time
- New insights into process dynamics and related physical phenomena
- Calibrationless measurements with excellent statistical strength
- Transparent, raw data output for data mining

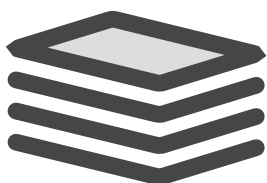


RELIABLE PRODUCTION WITH IMMEDIATE PROCESS FEEDBACK

- Continuous visual insight into the process for the operators
- Intuitive graphical user interface with the ability to pause, zoom and save images for process visual examination
- Timely detection of disturbances and sporadic events
- Monitoring current batch to reference batch deviations
- Automated alarming and process control



EFFECTIVE AND EFFICIENT QUALITY CONTROL WITH TIMELY MEASUREMENTS THROUGHOUT PROCESSING



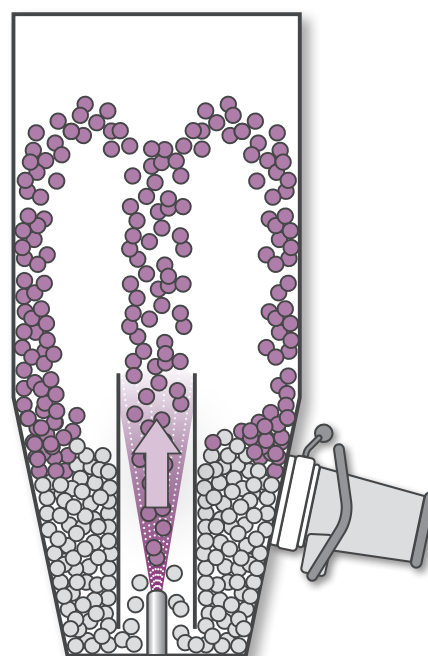
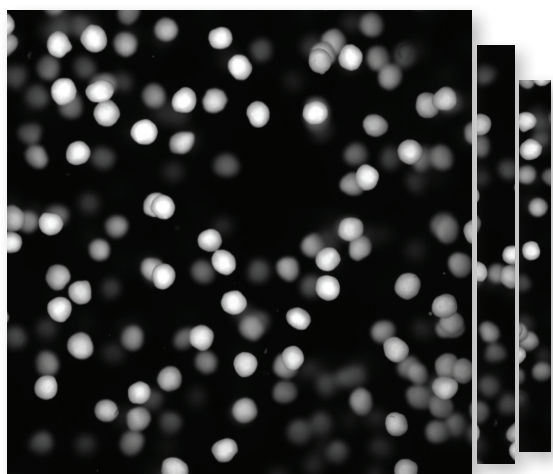
- An additional tool for aid in process troubleshooting and root-cause analysis
- Short and long-term batch to batch reproducibility
- Documenting and reporting process states and changes
- Reports including complete statistics of the CPP's with example images of the process

FLUID BED COATING

Pellets are typically drug-loaded with API (layering) or film-coated to modify the API release kinetics, thereby achieving delayed or extended release. Characteristics of coated pellets, such as **Pellet coating thickness** and **Pellet agglomerate fraction**, are critical process parameters that determine the process performance in terms of product quality, product yield and production time.

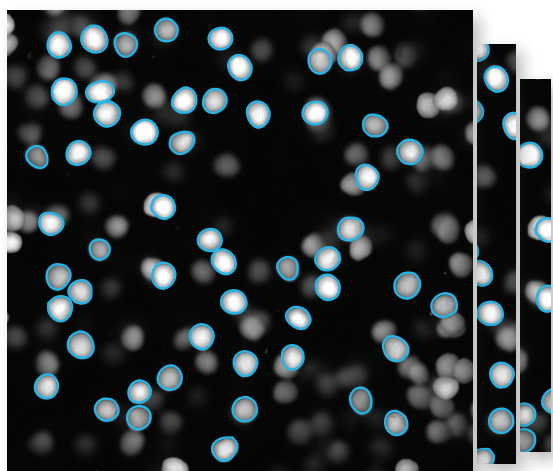
1. IMAGE ACQUISITION

Live view is an alternative to manual observation of process through window but with particles zoomed in and/or shown in slow motion.

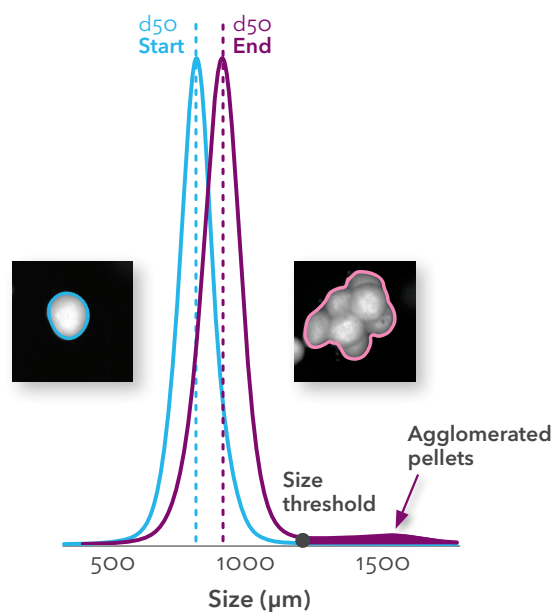


2. IMAGE ANALYSIS

Measuring **Pellet coating thickness** and **Pellet agglomerate fraction** in-line ensures a controlled process and product.

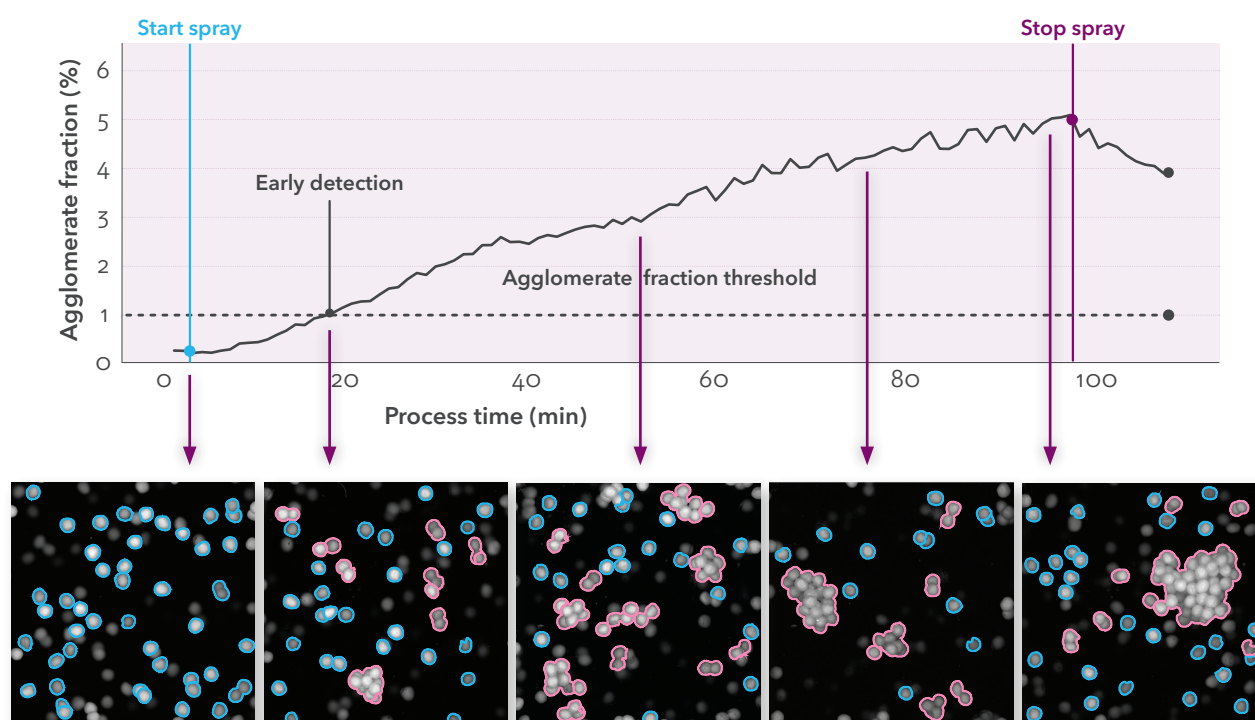
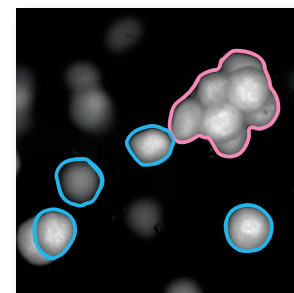


3. ESTIMATION OF PROCESS PARAMETERS



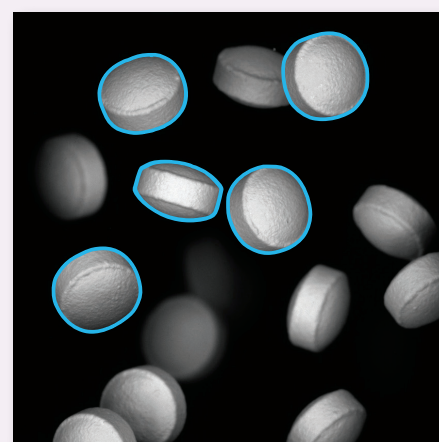
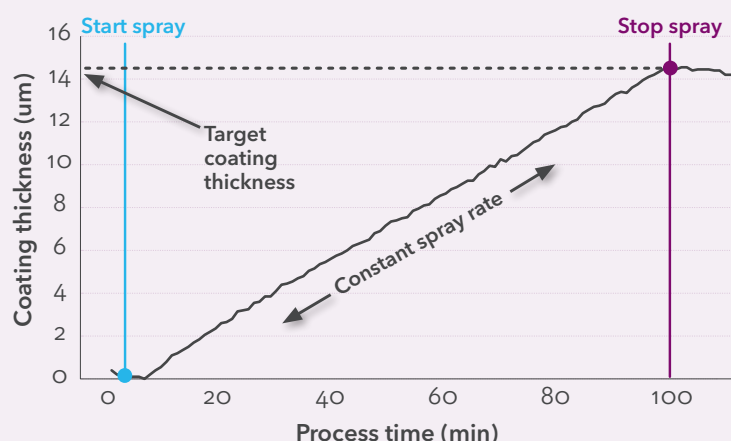
PELLET AGGLOMERATION is an inevitable property of the coating process. Obtained agglomerates are a common cause for process down time and directly affect the final product yield and coat integrity.

PATVIS APA enables early agglomeration detection with visual confirmation of agglomerates. Quantification of the amount of agglomerates in the process provides means for timely intervention. In this way, agglomeration can be tightly controlled.

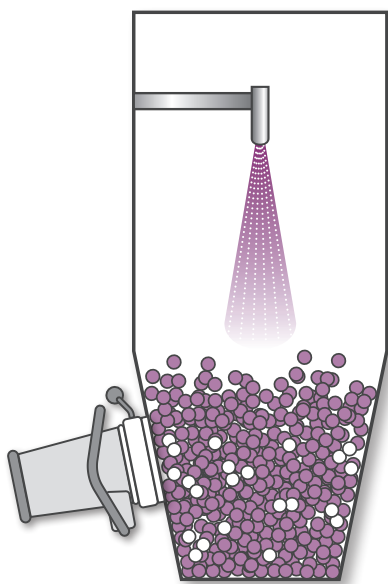


PRECISE COATING THICKNESS control is rapidly gaining importance with an increasing amount of modified release formulations on the market. Drug release and drug loading are characterized by the thickness of the coat.

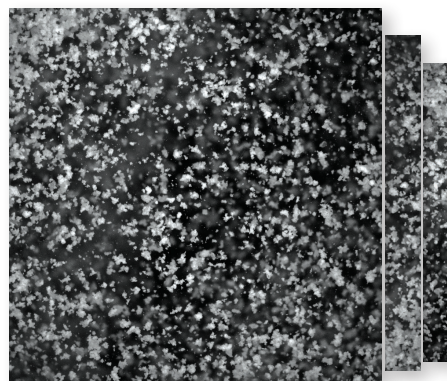
PATVIS APA enables coating thickness estimation based on particle size increase even for thin film coatings on pellets and minitablets. The coating process can be terminated reproducibly when the desired end coating thickness is obtained.



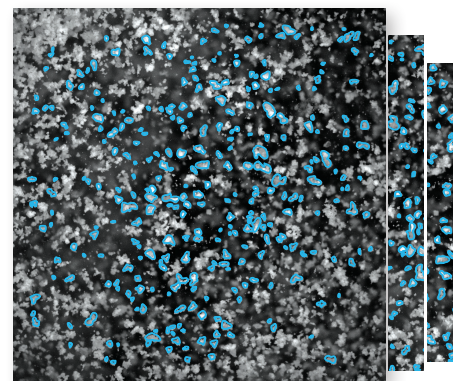
WET GRANULATION IN FLUID BED



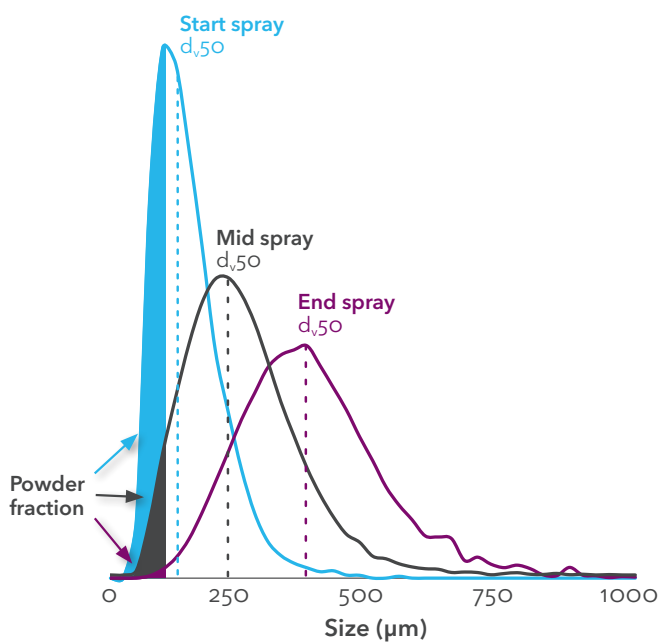
1. IMAGE ACQUISITION



2. IMAGE ANALYSIS

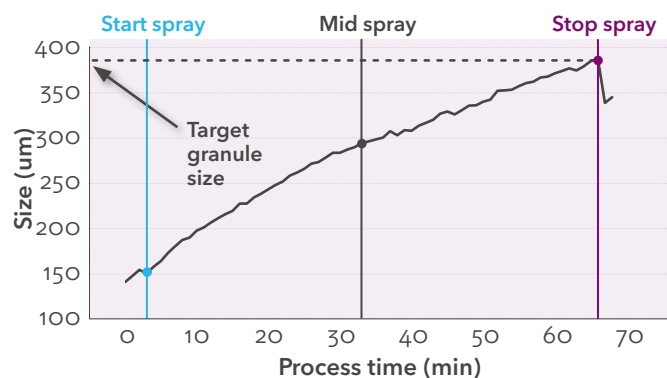
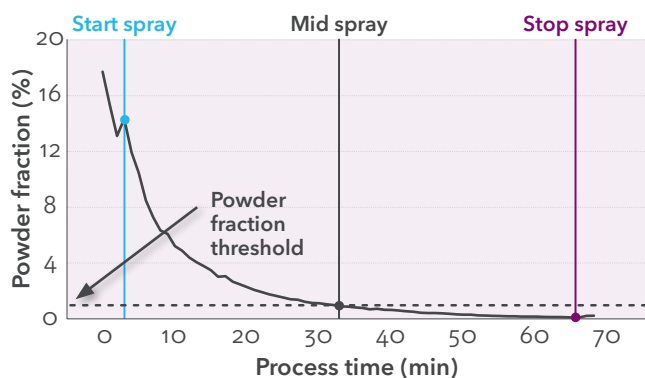


3. ESTIMATION OF PROCESS PARAMETERS



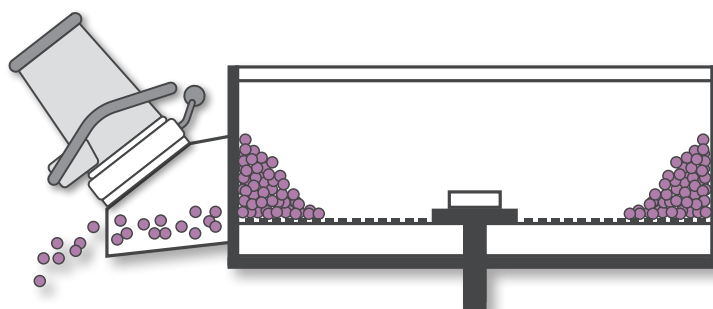
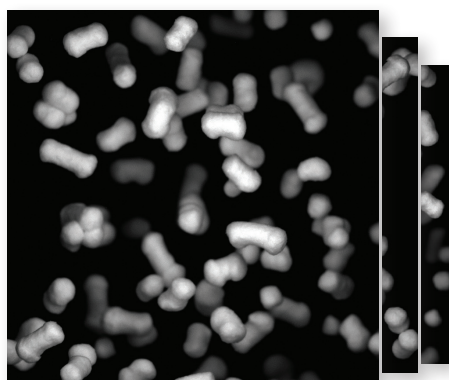
By agglomerating powders into granules, material improves flowability and compactability and is less prone to segregation. **PATVIS APA** can be used to monitor the progress of the granulation process in-line, estimating the evolution of the **granule size distribution**.

PATVIS APA can obtain various statistics related to granule size distribution, such as average granule size or fraction of powders in real-time. This can be used to detect deviations or determine the process end-point. The granulation process is considered finished when powders are agglomerated and/or a target granule size is achieved.

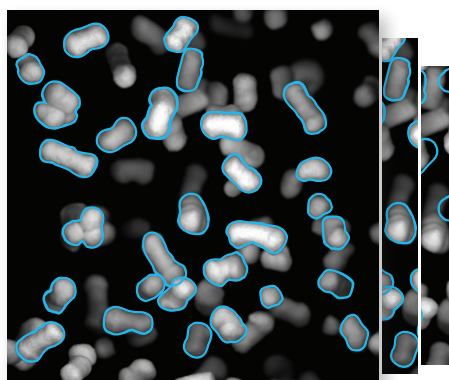


PELLETISATION USING EXTRUSION-SPHERONIZATION

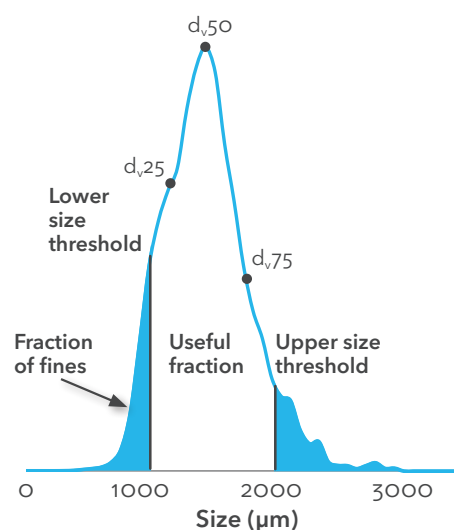
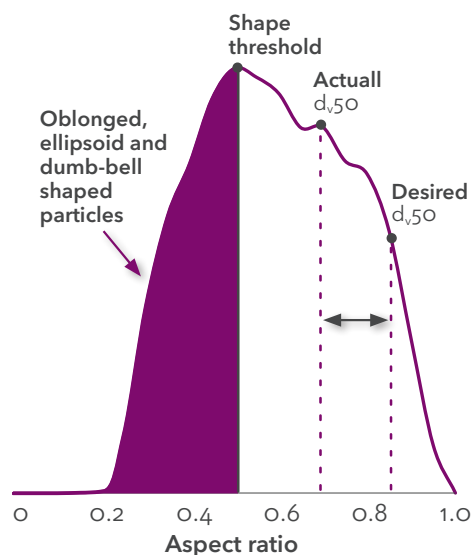
1. IMAGE ACQUISITION



2. IMAGE ANALYSIS



3. ESTIMATION OF PROCESS PARAMETERS



The objective of pelletisation is to produce spherical pellets with narrow size distribution and good abrasion resistance. **PATVIS APA** can be used to evaluate visually and numerically the **size and shape distribution of produced pellets**, which are key variables affecting the extrusion-spheronization process yield and quality.

Breakage and plastic deformation of extrudates during the spheronization phase result in particles of various shapes and sizes.

PATVIS APA can rapidly detect the buildup of OOS particles (fines, agglomerates, non-spherical particles...) on each batch and quantify the deviation from expected values based on measured particle size and shape distribution at the production line.





SPECIFICATIONS

HIGHLIGHTS








- In-line image acquisition with excellent image quality
- Real-time image processing with high accuracy of calibrationless measurements
- Exceptional sample measurement rate with timely data aggregation
- Advanced real-time data analysis with excellent statistical strength



MEASUREMENTS

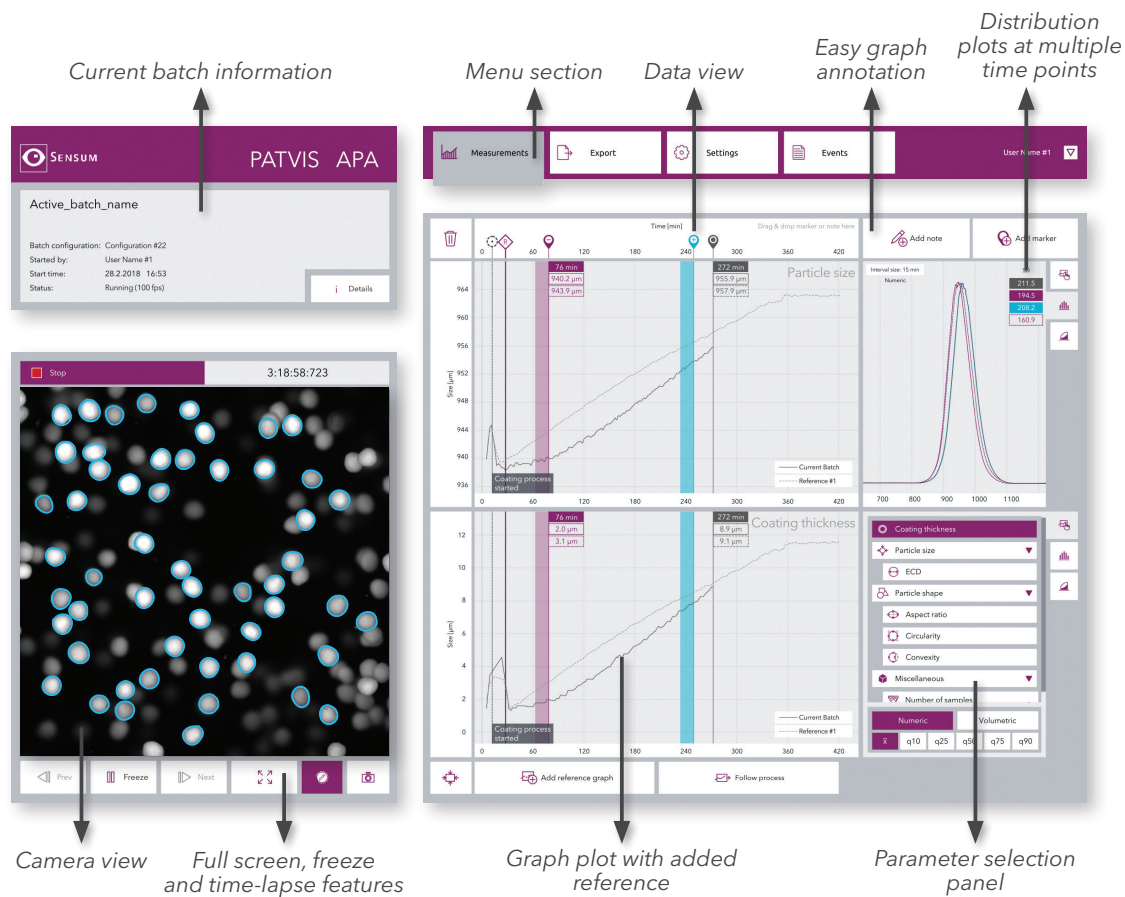
 PARTICLE SIZE RANGE 100 - 5000 µm	 MAXIMUM PARTICLE SPEED 10 m/s	 MEASUREMENT SPEED Up to 30.000 particles/s (Ø 1 mm)	 MEASUREMENT PRECISION < 2 µm	 FRAMES PER SECOND Up to 100	 STANDARD FIELD OF VIEW 16 × 16 mm	 DATA OUTPUT PDF and XML batch report, raw particle data, images
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TECHNICAL DATA

 APPLICATION Particles, granules, pellets, tablets	 CAMERA B/W or color	 OPTICAL SYSTEM Telecentric	 ELECTRICAL CONNECTION 230V 1/N/ PE 2A	 DIMENSIONS L × W × H L = 300 mm W = 270 mm H = 280 mm	 WEIGHT 9,5 kg	 CERTIFICATES ATEX 1, 21, CE
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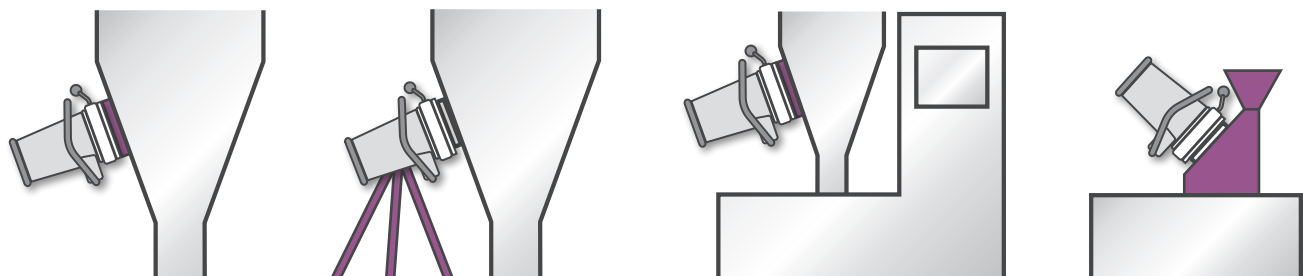
INTERFACE

Visual and numerical data are displayed in real-time through an intuitive graphical user interface that complies to FDA requirements. Running batch can be easily annotated and evaluated against previous runs. Complete process statistics with images can be exported in human-readable format. A raw particle data output is available for data mining.



INSTALLATION

Installation options range through the entire downstream processing of solid dosage forms. Noninvasive and contactless operation together with custom interface solutions assures no modification or revalidation of the processing equipment. On-line, in-line or at-line flexibility enables simple integration into process workflows and a smooth transition to cost-effective batch and continuous production.

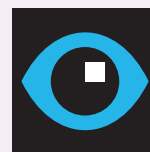


PROCESS WINDOW
INSTALLATION

TRIPOD
INSTALLATION

LAB-SCALE
INSTALLATION

AT-LINE
INSTALLATION



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