

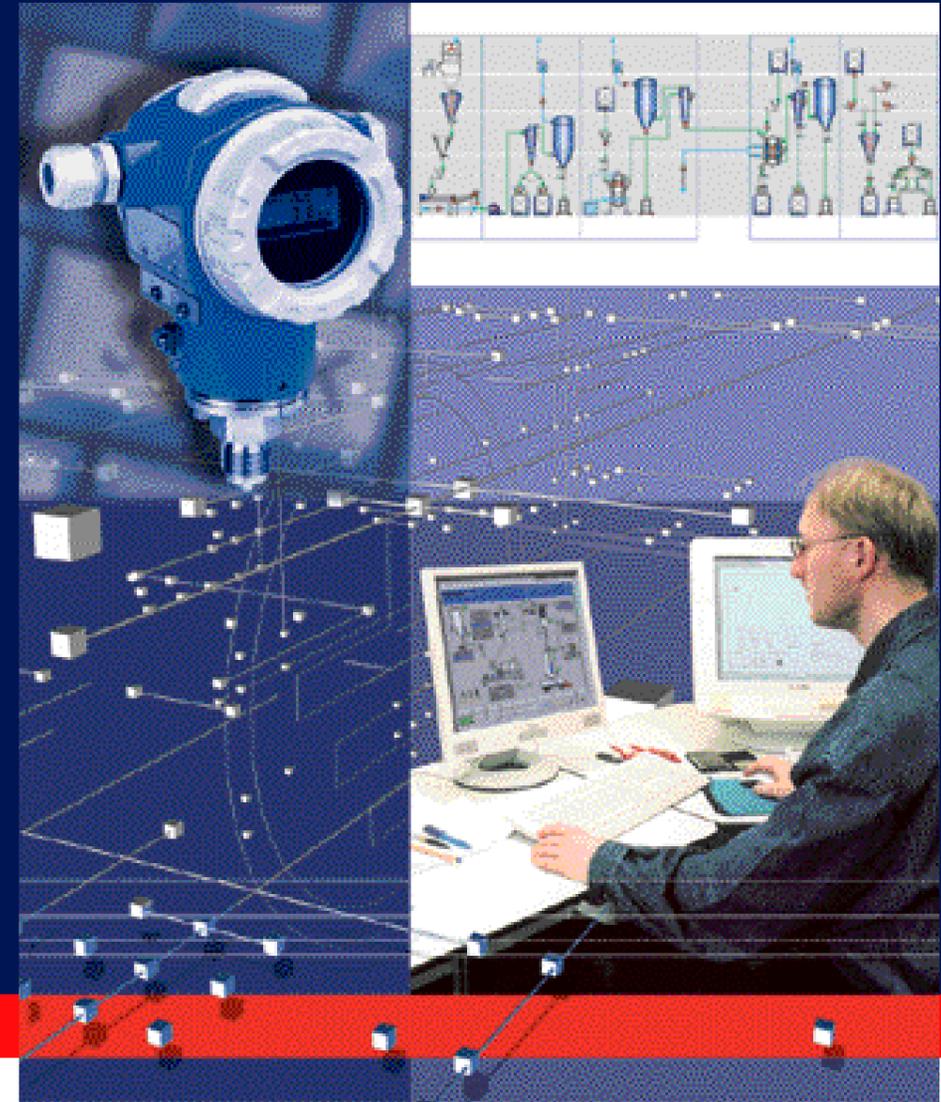
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informative and non-binding. Our quotations are
authoritative with regard to orders.

ALPINE PROCESS AUTOMATION FOR THE FIELD OF PROCESS ENGINEERING



HOSOKAWA
ALPINE Aktiengesellschaft & Co. OHG

Hosokawa Alpine is a member of the Hosokawa Micron Group, responding to global needs through emphasis on materials science and engineering. The Group is an international provider of equipment and technology for powder and particle processing, plastics processing and confectionery products. The Group maintains facilities for research, engineering, manufacturing and service in each of the world's major industrial markets.

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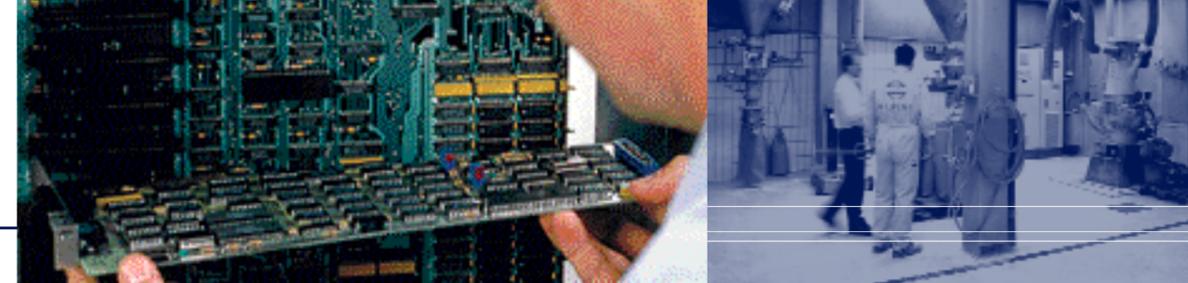


HOSOKAWA ALPINE

PROCESS TECHNOLOGIES FOR TOMORROWSM



Hosokawa Alpine offers optimal process solutions. Process technology and automation engineering are tailored to the requirements and come from one single source.



CONTROL TECHNOLOGIES FOR TOMORROW

PROCESS AUTOMATION

Automation technology from Hosokawa Alpine is nothing more than process technology know-how translated into software and hardware. A team of experienced electrical engineers develops the basic principles for our automation technology and makes sure that the module interfaces mesh optimally and that all modules are seamlessly documented.



PROCESS TECHNOLOGY KNOW-HOW

Together as a team, process engineers and electrical engineers develop the optimum solution for each customer. Dependent on the process and degree of required automation, modular automation components are individually combined. The customers profit from our process technology expertise.



SPECIAL SOLUTIONS

Frequent examples of customised process solutions are medium-voltage control panels for customers of our Minerals & Metals Division, and software packages plus documentation as per 21CFR Part 11 for customers from the pharmaceutical industry.

USER-FRIENDLY AND RELIABLE IN OPERATION

The solutions from Hosokawa Alpine are always user-oriented and proven in practical operation, a result of the many systems we have running under production-scale conditions in our application testing centre in Augsburg.

The practical experience thus gathered has led to constant optimisation of the mechanical process technology and the measuring and automation technology of our systems, meaning we are able to offer our customers a high degree of user-friendliness, zero-defects manufacturing and reliability in operation.

VARIANTS

Building on this system, we are able to react quickly and professionally to customer requirements and wishes, for example, we:

- program the visualisation unit to the required language
- set up a password or recipe management feature
- integrate new components
- carry out risk analyses
- take new standards and directives into account

- include new developments and technologies
- effect the connection to upstream or downstream production stages.

On request, we integrate an automatic on-line particle size analysis with setpoint/actual comparison - e.g. from Malvern Ltd. - not only mechanically but also from an automation technology viewpoint into the process to increase the efficiency of the production system.

DOCUMENTATION

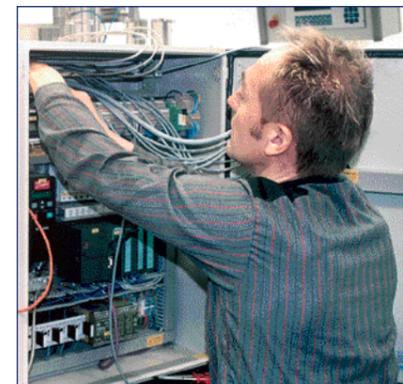
The operating manuals for our automation systems are written and compiled by process engineers for process engineers. This saves your operating personnel time and increases the operational reliability.

ARCHIVING

Every delivered process solution is archived by us on our premises. This gives our customers the assurance of being able to refer to the original program at any time.

ASSEMBLY

The assembly teams comprise electrical engineers and erection engineers who work jointly on completion of the systems. Our electrical engineers are always present during test runs and acceptance tests to check that all customised requirements have been met and function perfectly.



QUALIFICATIONS

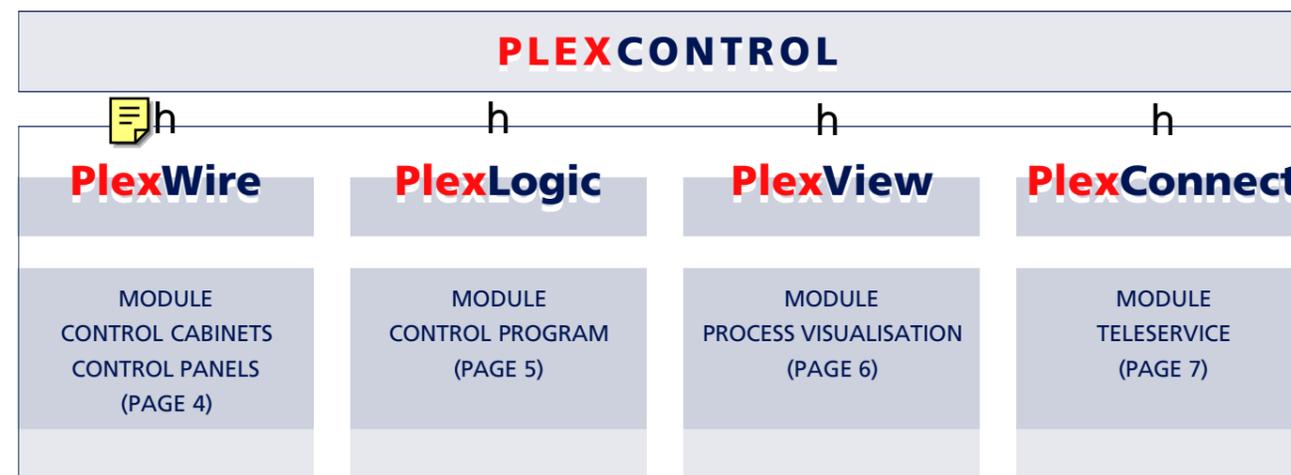
Training has always played an extremely important role at Hosokawa Alpine, not only on the mechanical sector, but also on the electrical sector. Our new generation of mechatronics engineers and electronics engineers for systems engineering is trained in our own workshops in a practice- and customer-oriented manner, thus ensuring a constant high standard of quality.



AUTOMATION MODULES

Our PlexControl process automation system comprises 4 modules, each of which is described in detail on the following pages. The minimum equipment of a system is PlexWire and PlexLogic, which

can be combined with the PlexView and PlexConnect modules dependent on the required level of automation.





The control cabinet
and control
panel module

The control cabinet plays an important role in ensuring an efficient and reliable production sequence. All the safety, switching and operating elements must be coordinated to suit the production process and the environmental conditions at the site of production. Our control cabinets make full allowance for these requirements.

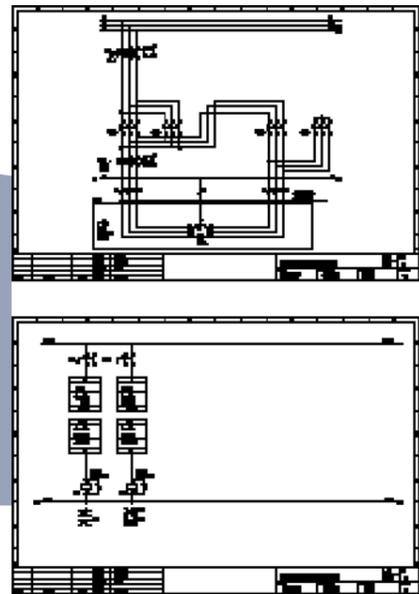
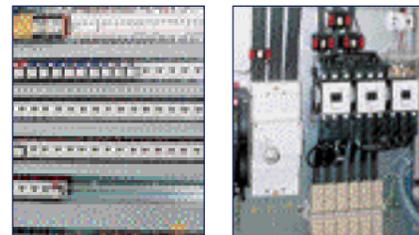
Prior to the planning stage, we investigate the special demands of your production sequence as well as the restrictions created by the supply network, the environmental conditions (e.g. system or control cabinet in a potentially explosive atmosphere, i.e. gas and/or dust), and then systematically convert this knowledge into a viable concept.

We use the object-oriented CAE systems Eltime® and Koramis® for preparation of the circuit diagrams. Because of the modular structure of our circuit diagrams, we are able to design your control cabinet to reliably meet the individual requirements. This also means that besides the prevailing IEC and EN standards, we can factor your own in-house standards into the equation.

The circuit diagrams include the wiring diagrams, terminal designations, cable lists, installation plans, configuration plans for PLCs, general drawings and parts lists for the control cabinets.

The control cabinets are built based on these circuit diagrams. To guarantee a high standard of control cabinet quality, Alpine in-house directives for control cabinets are systematically applied.

Before a control cabinet leaves our premises, it is inspected and tested under acceptance conditions by the responsible electrical or automation engineers to make sure that it fully meets all your requirements in terms of function and quality as well as those laid down in the IEC and EN standards.



The control
program module

The Simatic®S7 automation system is employed for the process control. The programs are generated in Step7's own programming languages AWL and preferably KOP or FUP. They are universally structured and documented.

Tested program modules are used for the structuring, thus avoiding programming errors. The program modules can be retrieved from libraries and permit an efficient program generation for your process control.

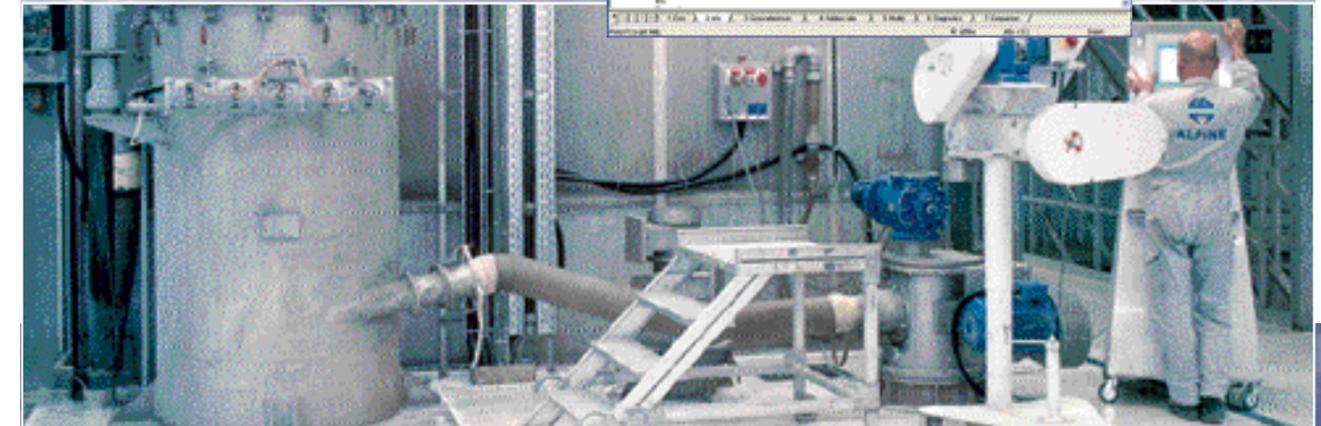
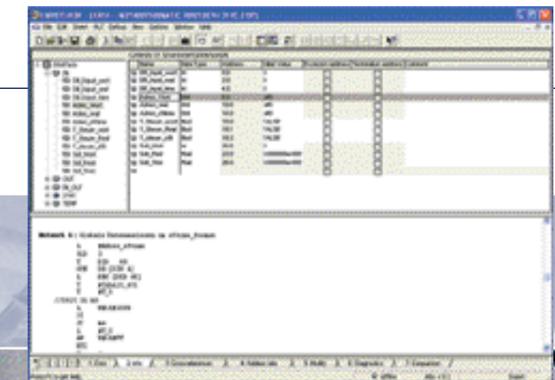
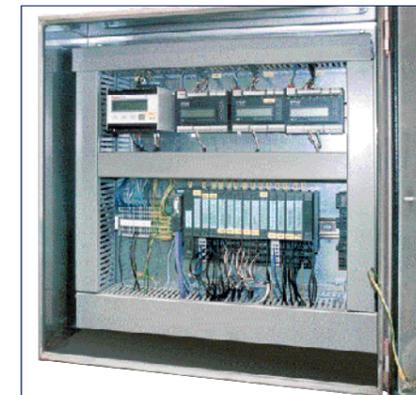
Together with the documentation of the program, for which the Step7 options are made use of, a software program is created that matches your process exactly but is nevertheless flexible enough to allow quick and easy process changes or upgrades.

The software for the process control includes the sequences for automatic, maintenance, and cleaning modes as well as the necessary start-up and shut-down sequences. Over and above this, the required control algorithms and fault handling routines are pre-installed.

Before the process control is delivered, the function of the software is carefully tested by the responsible process and automation

engineers. It is thus possible to concentrate fully on process optimisation during the commissioning phase, without having to worry about whether the unit functions or not.

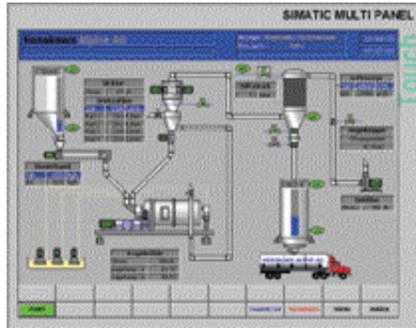
The control program documentation comprises the program listing, the hardware configuration of the PLC as well as various reference documents. The entire documentation package is delivered on CD-ROM. All the control programs, their documentation and date of issue are archived on our premises in accordance with ISO 9001 and can be retrieved at any time.





The process
visualisation module

The process sequence and the process parameters are represented graphically on screen. The system flowchart forms the basis for representation of the process, and is formatted, animated and supplied with the required process parameters. An important criterion hereby is that the flowchart is easy to read and the process sequence easy to follow. Colour-coding is used to highlight important information for the user, whereas less important information is kept in the background.



Besides the functions necessary for operation and monitoring, every visualisation system also includes:

- a fault indication system,
 - a fault indication memory,
 - a password management feature,
 - and a simple on-line trend indication.
- If required, a simple recipe management feature can be created.

The process is also operated by means of the visualisation unit. The user interface is simple in design and the user is guided intuitively through the various menus. The text is in the native language of the user. Menus that are reserved exclusively for maintenance personnel, for example, can be protected by means of suitable access privileges. This eliminates the possibility of operating errors and the necessity of additional training measures.

Dependent on the requirements, there are a number of different visualisation systems available. For simple processes, Windows-CE-based operating and monitoring systems are used. The software elements used are Protool® (Siemens) or Zenon® (Copadata).

In the case of more elaborate processes, where, for example, the requirements laid down in 21CFR Part 11 must be fulfilled, PC-based visualisation systems are used.

The software packages WinCC® (Siemens) and Zenon® (Copadata) are used in these instances.



These visualisation systems also include archives for process data and trend curves, and offer the possibility of creating a recipe management feature and of integrating report generators.

In the case of all systems that must fulfil the requirements stipulated in 21CFR Part 11, the mechanisms necessary for ER (Electronic Recording) and ES (Electronic Signature) are pre-installed.

Besides the program listing, the documentation for the PlexView module also includes a user manual for the visualisation system. The documentation package is delivered on CD-ROM.



The teleservice
module

The PlexConnect module makes it possible to set up a connection between Hosokawa Alpine's premises and your production system in the form of a point-to-point connection via the telephone network (analogue or ISDN). This method ensures that the data security and access security of your system remains intact; by simply pulling the telephone connector out of its socket, you can effectively interrupt any external link to your system.

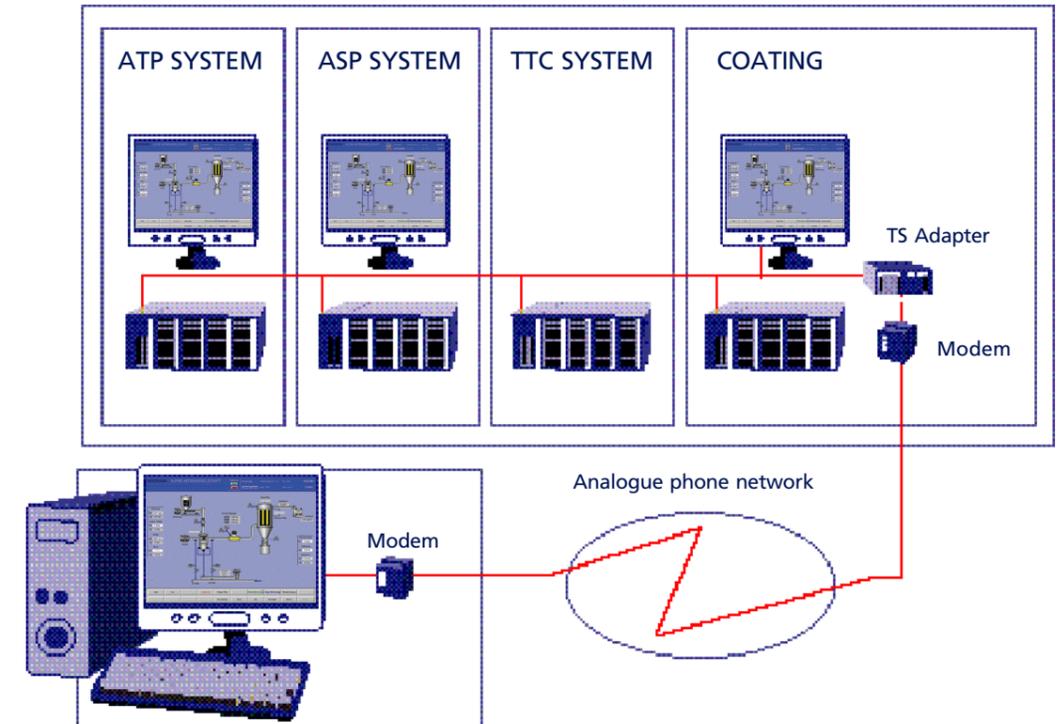
The beauty of the teleservice module is that you can optimise your system and make

changes to both the process control and the visualisation system without any of our engineers needing to be on site. It is also possible to plan system maintenance and in the event of a total breakdown, we can diagnose the fault over the telephone and

prepare the service assignment or maintenance measures in a targeted manner. The availability and efficiency of your system are thus kept at a very high level.



CUSTOMER'S PRODUCTION SYSTEMS



SERVICE STATION AT HOSOKAWA ALPINE



As a measure of optimising the process control, our systems can be equipped with a real-time on-line particle size analysis system.

To order, all of our systems can also be equipped with an on-line particle size analysis system. The analysis system is then either installed direct in the fines ducting or in a bypass ducting, where by the fines are supplied via a sampling station.

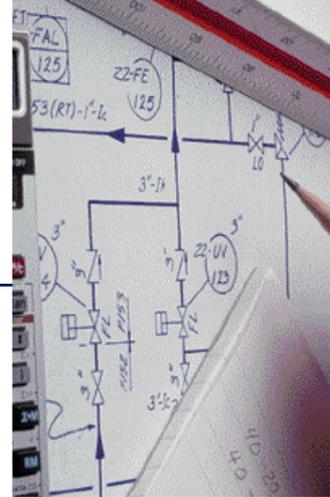
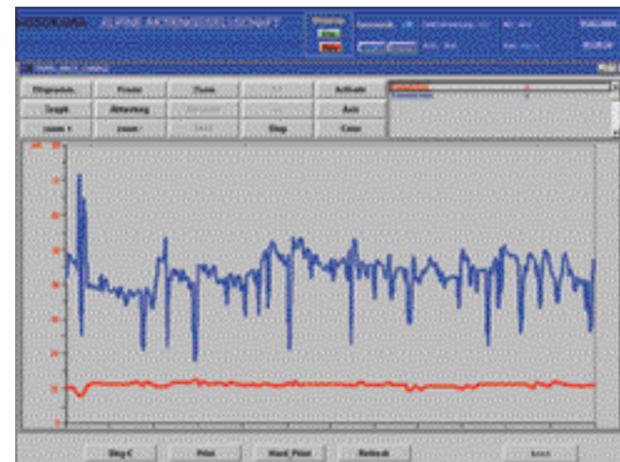


The advantage of such a system becomes apparent during process management. With the on-line particle size analysis system, the production system is always kept at an optimum operating point, e.g. independent of quality fluctuations in the feed product. As a result, end product that deviates from the desired specifications, i.e. oversize or undersize product, is kept to an absolute minimum. And this in turn saves costs when processing high-grade, expensive products and also during the running-in phase, when process experience is lacking.



The software to evaluate the particle size distribution forms part and parcel of the visualisation software, and records and evaluates the measured values. This also means that the user has a standard and universal operating structure available and that special training for the on-line particle size analysis is superfluous.

In view of the fact that the measured values can be allocated to individual batches, the data can also be used within the scope of a quality control system, and suitably edited and output by a report generator.



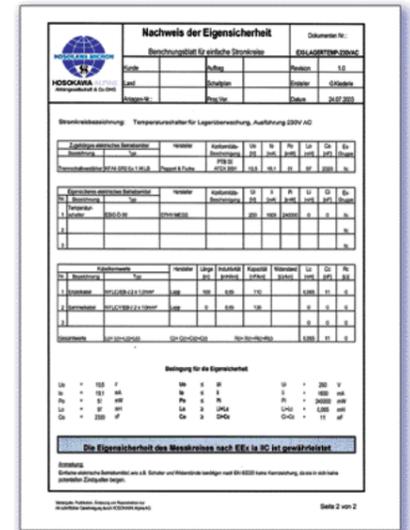
EX I-CABLES

It is very often the case in the chemical, pharmaceutical and foodstuffs industries that potentially explosive products are processed. Our systems offer a high level of safety when processing such products and have proved themselves time and again over the years.

Many applications call for frequent system cleaning, whereby the vapours of the solvents and cleaning agents used are often explosive. Particular care is therefore essential when selecting and laying out the electrical equipment of a system installed in a gas Ex zone and thus in potential danger of a gas explosion.

EX I-CABLES

The process components delivered by Hosokawa Alpine and the associated control panels and cabinets all fully meet the requirements laid down in the prevailing national and international directives, especially 94/9/EC (ATEX).



INHERENT
SAFETY
CERTIFICATE

	GAS-EX			DUST-EX		
	Zone 0	Zone 1	Zone 2	Zone 20	Zone 21	Zone 22
Control panel		■	■		■	■
Drive technology		■	■		■	■
Actuators (valves)		■	■		■	■
Sensors	■	■	■	■	■	■
Measuring technology	■	■	■	■	■	■

■ = available

As a result of the long years of experience in laying out and planning systems in potentially explosive atmospheres, we are in a position to design such systems efficiently and reliably. The solutions that result are tailored exactly to the requirements of our customers and guarantee not only optimum explosion safety but also a high degree of economic efficiency.



Grinding systems for pharmaceutical active substances must be qualified, and by applying our sequence routines, this is always guaranteed.

QUALIFICATION

Essential tasks during the manufacture of pharmaceutical products are to record and archive the process and system data so that they can be duplicated at any time, to protect the data against unauthorised access and to document compliance with these requirements.

During the qualification process, we orient ourselves to the GAMP (Good Automated Manufacturing Practice) and FDA (Food and Drug Administration) directives, in which special automation technology requirements are stipulated.

FROM THE USER REQUIREMENT SPECIFICATION (URS) TO THE PERFORMANCE QUALIFICATION (PQ)

The User Requirement Specification (URS) contains the main product specification and thus the requirements with respect to the grinding system. Using this as a basis, we then define the characteristic parameters of the grinding process, the product fineness, the throughput per hour and finally

compare the URS with the achieved production result in the Performance Qualification (PQ). If the grinding process constitutes only one of several production stages within an entire manufacturing process, the PQ of the complete process is provided by the system user.

FROM THE FUNCTIONAL SPECIFICATION (FS) AND THE SOFTWARE SPECIFICATION (SWS) TO THE OPERATION QUALIFICATION (OQ)

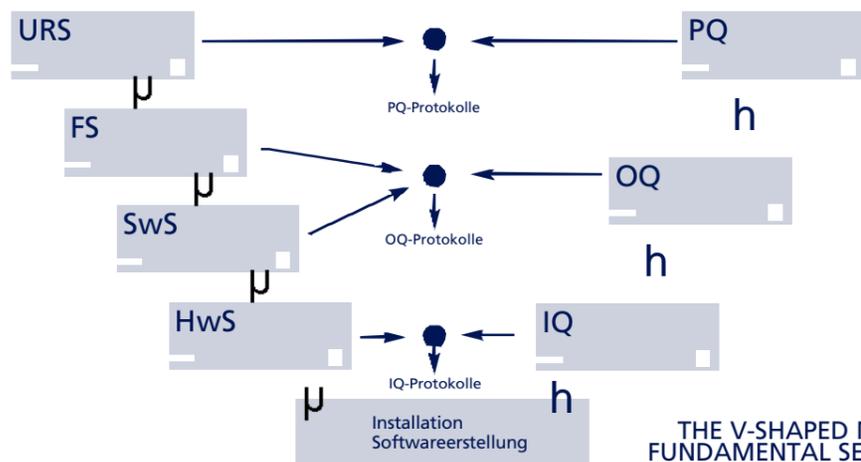
The Functional Specification (FS) is determined together with the customer and includes details of the grinding principle and all major peripheral conditions such as site of installation, Ex-zone categorisation, safety requirements, etc. The FS is documented in the form of a P+I (piping and instrumentation) diagram and a description of the grinding system.

The P+I diagram shows the process-technological sequence within the system and forms the basis of the program sequence plan,

which is generated in the Software Specification (SwS). During preparation of the software, we make exclusive use of development environments (Step7, Zenon, WinCC) and operating systems (Windows 2000, Windows CE) which are already accepted and widespread in industry. The program sequence plan is further detailed in the module specification, which forms part of the Software Specification. This makes it possible to reduce the specification documentation to the



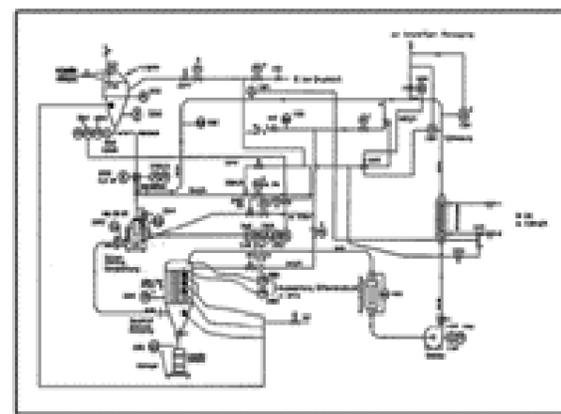
minimum. To permit testing the faultless function of all the sequences defined in these documents, we prepare the Operation Qualification (OQ) protocols, which are simultaneously used to prove the correct function of the grinding system. The advantage of the modular structure of our specification is that double and multiple tests of one and the same function are avoided during the OQ tests. This saves time and furthermore keeps the test records within acceptable limits.



THE V-SHAPED MODEL SHOWS THE FUNDAMENTAL SEQUENCE OF A SYSTEM QUALIFICATION AT HOSOKAWA ALPINE

FROM THE HARDWARE SPECIFICATION (HWS) TO THE INSTALLATION QUALIFICATION (IQ)

In the form of data sheets, the Hardware Specification (HwS) stipulates the components (PC, SPS, field units) that are necessary to fulfil the FS and the SwS. We make exclusive use of equipment and units which are generally considered to be industrial standards, which are accepted by the pharmaceutical industry and for which all the documents and certificates necessary for the qualification, such as equipment data, equipment descriptions, manufacturer's declarations or Ex certificates, are already on hand.



OQ PROTOCOL

The IQ protocol documents that the equipment has been correctly installed, includes cross-references from the equipment data to data sheets, and records the results in line tests, with which the function of the individual units as well as the complete signal flow can be controlled.

All the sequences necessary to qualify a system are defined by us in in-house standards, the protocols and documents are standardised and have proved themselves in practical operation.

Once the system is qualified, we can react quickly and professionally to customer requirements, integrate new components, perform risk analyses, take new clauses in standards and directives into account or integrate newly developed technologies.

