



# pharma-solutions

explosion protection and cleanroom technology





# your safety – our reality

## Important factors in the planning of cleanrooms

- > Separation of flow of materials and flow of personnel
- > Avoidance of dust
- > Protection of personnel
- > Escape routes
- > General plant and occupational safety
- > Central process-control systems for building
- > Operator interface
- > Protection from outside influences
- > Design of ventilation units
- > Quality of equipment
- > Lighting, natural light
- > Qualification and validation
- > Supervision and registration of the data
- > Ensuring that premises are easily maintained and serviced

The pharmaceutical industry is currently accepting and complying with increasingly stricter regulations regarding keeping production processes entirely pollutant and contamination free. These regulations apply to the manufacturing of the products as well as to their content and packaging. All this is occurring for a very good reason; in no field can impurity or contamination, even in the smallest amounts, result in such severe damage to human health as in the field of pharmaceutical production.

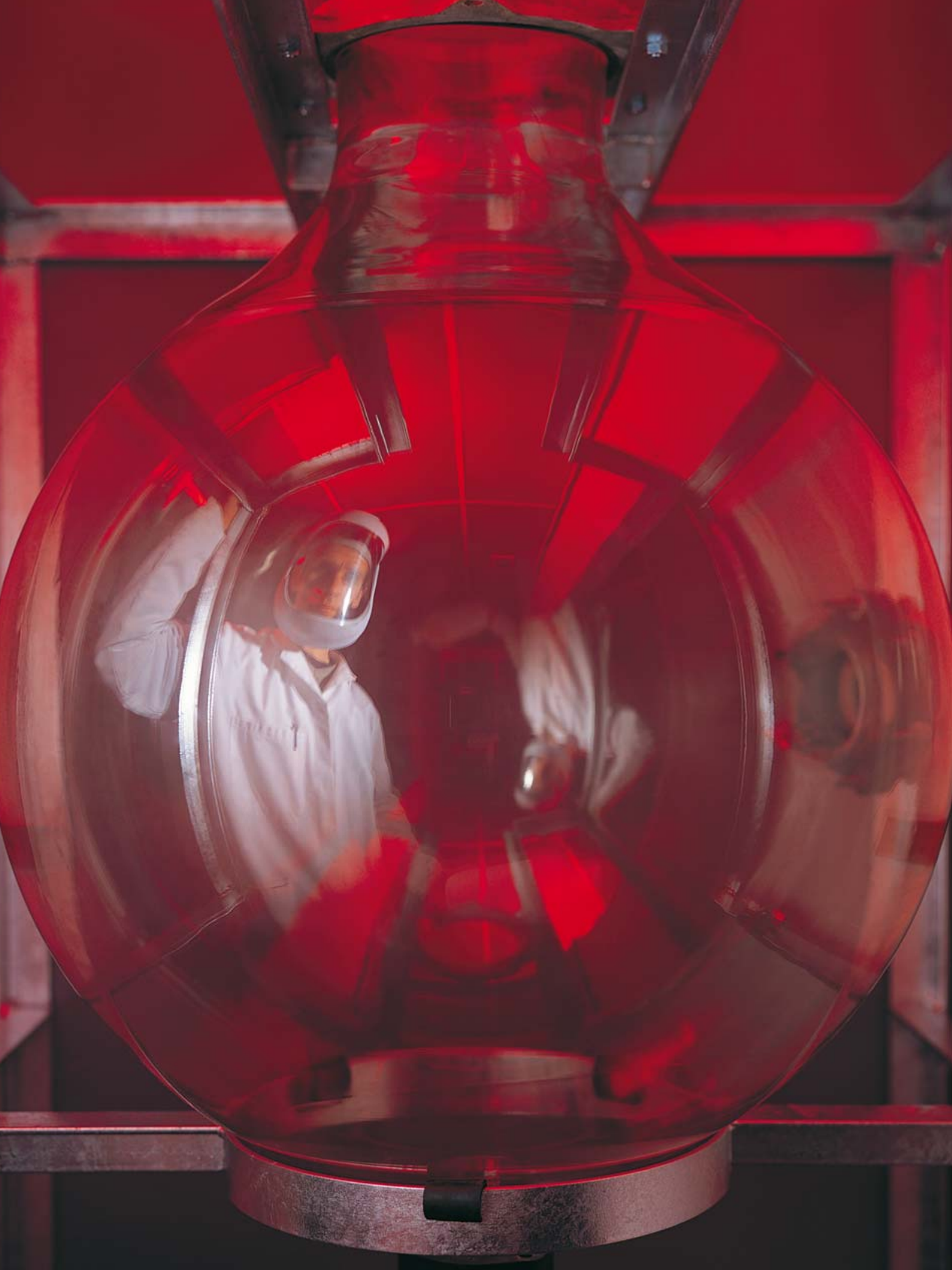
Additionally, the increasing international competition within the field demands permanent innovation with regards to active pharmaceutical ingredients and a constant effort to render production and other processes more effective. The planning of cleanrooms requires close observance of certain important parameters that in other facility planning situations are only minor factors, or not even factors at all.

In the pharmaceutical industry, processes are very often carried out under both explosion-protected conditions and under special safety conditions specific to the industry (e.g. in cleanrooms). For this reason, R. STAHL, as a leading provider of electronic explosion-protected equipment, has established a well-grounded know-how capable of meeting all the special requirements of the pharmaceutical industry. Whether for cleanroom application products, for solutions designed to meet FDA specifications, or for expert advice on the planning of your premises – R. STAHL is your competent and reliable partner.



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# insulin protects life

our technology ensures the production process

## Tasks

- > Planning of fieldbusses
- > Calculation of fieldbus load, fieldbus run times, and reaction times
- > Design and construction of over 250 fieldbus stations with over 1500 IS1 modules
- > Complete documentation in accordance with GAMP standards
- > Commissioning and start-up of all fieldbus stations
- > Implementation of special requests or requirements from the client

The pharmaceutical industry in general, is one of the most important customers for explosion-protected equipment in particular for intrinsically safe automation-engineering products. R. STAHL has proven its competence and professional capability through the fitting-out of the world's largest production plant for inhalable insulin.

Inhalable insulin is a medical innovation which will enable millions of sick people to lead more normal lives. This form of insulin, administered through inhalation, is distinguished by the speed with which it takes effect and will for many patients make insulin injection a thing of the past.

In order to ensure that the active ingredient in this drug can be produced in sufficient quantities in Frankfurt am Main, the world's largest insulin production plant evolved in recent years: a high-technology facility which, thanks to R. STAHL's IS1 remote I/O system, is setting new standards in the field of process automation. The particular challenge posed by this first project involving over 10,000 signals consisted not only in the providing of so many individual components, but also in the scale of the services required, and in meeting of the demands of working together as partners with a wide range of providers on the project for finding solutions to the complex and demanding tasks set by the end-client and the requirements of their enterprise.





# it pays to choose quality

## partnership in machine construction

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### Services provided

- > Advice and consultation for putting new guidelines into practice
- > Working-out new solutions
- > Project planning and manufacturing
- > Complete documentation

### Products

- > HMI systems
- > Fieldbus system technology
- > IS1 remote I/O system
- > Switch cabinet in pressurized enclosure

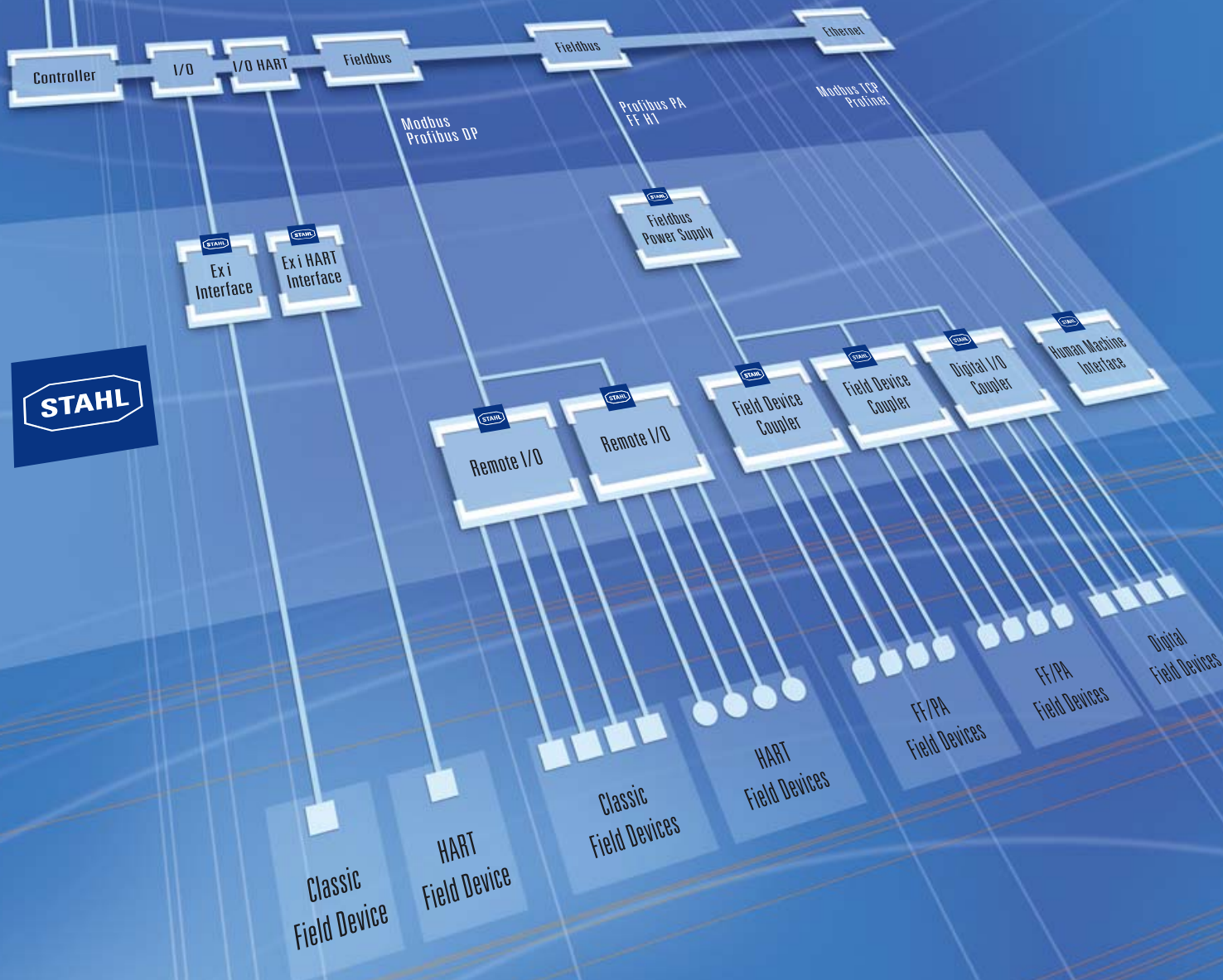
Machines and installations intended for production areas in which there exists a danger of explosion must naturally conform to particularly strict safety regulations. Today, more and more manufacturers are relying on R. STAHL's know-how, in order to meet these often very specific and particular standards, in many cases right from the planning and design stages.

For example, separation technology: The company in question developed a new kind of centrifuge for use in laboratories and smaller production units. Compliance had to be ensured with higher quality requirements from the side of the operating companies and new European guidelines for explosion-protected industrial and manufacturing equipment. Together with R. STAHL, a groundbreaking solution was found which introduced a whole series of innovative elements into the device's electrical fittings.

A fully-integrated control system with pressurized enclosure, executed for the first time completely via fieldbus, ensures that the many and complex automation-related tasks all go off without a hitch. The system is operated and monitored via a terminal with graphic-display capabilities, on whose LCD screen up to 100 images of the processes underway can be displayed. From installation right through to cleaning, from the safe area through to Zone 2, this device combines the best ergonomic qualities with maximum performance efficiency.

This enables the client to conduct, with a minimum expenditure of time and costs, experiments yielding high degrees of meaningful data in areas where a danger of explosion exists – and what is the use of a partnership for development if it is not that of securing the optimum result for the end-user?

Ethernet







# automation

## Components and system-based solutions

- > INTRINSPAK safety barriers
- > ISpac galvanic isolators
- > IS1 remote I/O system
- > ISbus fieldbusses
- > Fieldbus system technology for HART, Foundation Fieldbus H1, Profibus DP, Profibus PA, FDT/DTM & EDD

Manufacturing in industries making use of process technology should, on top of being safe for the staff using it, also be able to deliver a constantly high level of quality at the lowest possible cost without any interruption to production. This production should also react flexibly to the demands of the market with regards to quantity and type of product. The high expectations placed on process technology have been the driving force behind the invention of ever more sophisticated ideas and solutions in the field of automation. R. STAHL offers with its products, system-based solutions, and other services a whole world of possibilities.

Industries making use of process technology tend to be characterized by a significant proportion of their manufacturing processes being processes which necessarily comprise the use of materials involving risk of explosion. For this reason, any automation solutions must be designed in such a way so as to be explosion-protected. In response to this need, R. STAHL offers, on the one hand, a complete range of human/machine interfaces, such as safety barriers, isolators, remote I/O systems, and fieldbus components, and, on the other hand, the possibility to plan, manufacture, and install complete automation systems. Regardless of whether combustible materials are present in gaseous form or in the form of dust; regardless of the specific zone they may be present in; and regardless if there are special SIL or FDA requirements to be met – when you work together with the experts from R. STAHL, you will always be sure to find the optimal solution for your specific automation needs.



# operating/monitoring

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## HMI device series

### Operator Interfaces:

- > Operation consoles come with integrated VDU
- > Configurable with SPSPPlus Win
- > approx. 5", 10.4" to 15" display

### Open HMI:

- > Open systems
- > Sturdy hardware
- > Standard operating systems
- > Over 20 language options
- > Touchscreen
- > 10.4" to 19" display

### Remote HMI:

- > PC terminals
- > Visual displays of the very highest technical standards (15"/19")
- > Twisted-pair connection possible for digital image and signal transmission

For many years, R. STAHL has been the sole manufacturer in the field of operator interfaces offering a complete range of devices designed specifically for industrial application and for application in areas where a risk of explosion exists. As a competent partner and system-provider to the pharmaceutical industry, R. STAHL meets GMP requirements; regulations which are recognized and acknowledged worldwide and compliance with which is obligatory. Modern operator-interface systems represent important components of industrial automation systems. Moreover, our devices have been specially developed bearing in mind the particular requirements of the pharmaceutical industry, such as appropriateness for use in cleanrooms, ergonomic excellence, and surface finish etc.

Tailored to different requirements, there are various display and keyboard sizes that offer a wide range of different modes of operation, such as touch-screen, trackball or joystick modes. The essential focus of the devices is explosion protection. Through different models from different series, it is ensured that the specific needs of all zones are optimally fulfilled. Thanks to their high-quality and hard-wearing construction, the devices are particularly well-adapted for use in such machines as dryers, centrifuges, mixers, and coaters etc. All devices come in plastic or stainless-steel housing and can be either installed in the switch cabinet or set up outside of it on their own individual bases.



# alarm/signalling

## Products

- > Camera system (Ø 55 mm, 435 g)
- > CCTV display with 4-fold image
- > Alarm horns
- > Warning lamps and alarm lamps
- > Devices for local, on-site operation

In fully-automated production plants employing ever fewer personnel, it is important that appropriate observation and alarm installations be installed at the required points within the production plant. R. STAHL also offers a large number of products designed for this purpose. It is always possible to install cameras designed for the monitoring of machines and installations in explosion-protected areas (such cameras come complete with a pan/tilt unit) with a specific view to any one of a whole series of different applications, such as the monitoring of re-filling processes or observation of production lines etc.

The world's smallest officially approved explosion-protected camera, the EC-710 Compact Camera, offers along with the whole Camera System, a wide range of possibilities. Wherever potential or actual emergency situations emerge, the alarm horns manufactured by R. STAHL – being designed in such a way that the sequence of signals or signal-sequence combinations can be set and adjusted to meet the clients needs and if necessary, several such devices can be synchronized with one another – thus ensuring safe and effective warning signals reaching every corner of even the largest sections of a building. The alarm signal lamps – in the form of either permanently illuminated alarm-lights, of rotating, and/or of rotating-mirror beacons – ensure that on the optical level everyone is alarmed and protected from danger as soon as it begins. For local operation at a specific production facility or machine, R. STAHL also offers a wide and varied selection of control units and detector/signalling devices which contribute to the safe handling of any emergency situation.



# lighting

## Products

- > Sheet-steel lamps models 6014 and 6414, containing from 1 to 4 individual lights, 18 W/36 W/58 W
- > Sheet-steel lamp emergency lighting, models 6018 and 6418, containing 2 individual lights, 18 W/36 W
- > Flat sheet-steel lamp (80 mm) models 6012 and 6412, containing from 2 to 4 individual lights, 18 W/36 W/58 W
- > Compact sheet-steel lamp, models 6114 and 6514, containing from 1 to 3 individual lights, 8 W
- > Compact emergency-lighting lamp, models 6118 and 6518, containing a single individual light, 8 W

Production halls, refilling rooms and other facilities in the pharmaceutical industry require lighting systems matching to the particular function of the facility. Safety regulations and standards for Escape and Rescue Routes, EN 50172 and EN 50171 are applicable. For planning and calculation of lighting installations, R. STAHL offers a user-friendly software, which puts you in a position to draw up preliminary plans, independently. The exact planning to meet your specific needs and requirements, as well as project planning for group or central battery units will then be taken on by our experienced engineers. In collaboration with them it will be possible to come to an optimal solution. R. STAHL also offers alternatives with regards to workplace and production-facility lighting techniques, especially designed to meet the specific requirements of the pharmaceutical industry, particularly for cleanroom technology. Lacquered sheet-steel and stainless-steel light fittings with installation frames and flush-fitted glass covering-plates form a smooth and easy-to-clean surface. Central locking, automatic all-pole shut-off when opened, along with the hinge-based opening mechanisms, reduces time and effort for maintenance. These light fittings are equally well fitted for use in central battery systems, or for use as part of a system of lighting indicating escape routes. The stainless-steel light fitting 6012/6412, which only requires a calculated headroom loss of 80 mm, presents, thanks to the glass pane fitted flat into the frame, a form which makes it ideally appropriate for use as ceiling-recessed lighting.



# installation

## Norms and guidelines for cleanrooms

- > Germany: VDI 2083
- > Europe: GMP EU Norm
- > USA: FS 209E
- > International: ISO 14644

## Products

- > Socket distributors with 1 or 2 sockets, 16 A or 32 A as preferred
- > Safety switch 16 A, 32 A, or 40 A, Motor breaking capacity AC3 and AC23 as per IEC 947-3, EN 60947, DIN VDE 0660 Part 107 suitable for isolation as per DIN VDE 0660

Production and assembly processes in the pharmaceutical industry – e.g. in emptying and refilling facilities – can be seriously negatively affected by particulate matter, germ-traces, and other impurities. This can lead to the products becoming unusable or can even endanger the patients treated with the end-products produced in such compromised processes. Thus sensitive pharmaceutical processes and operations are subject to particularly strict demands with regards to non-contamination. Devices produced by R. STAHL have successfully been applied for many years, in the fitting-out of cleanrooms and associated areas.

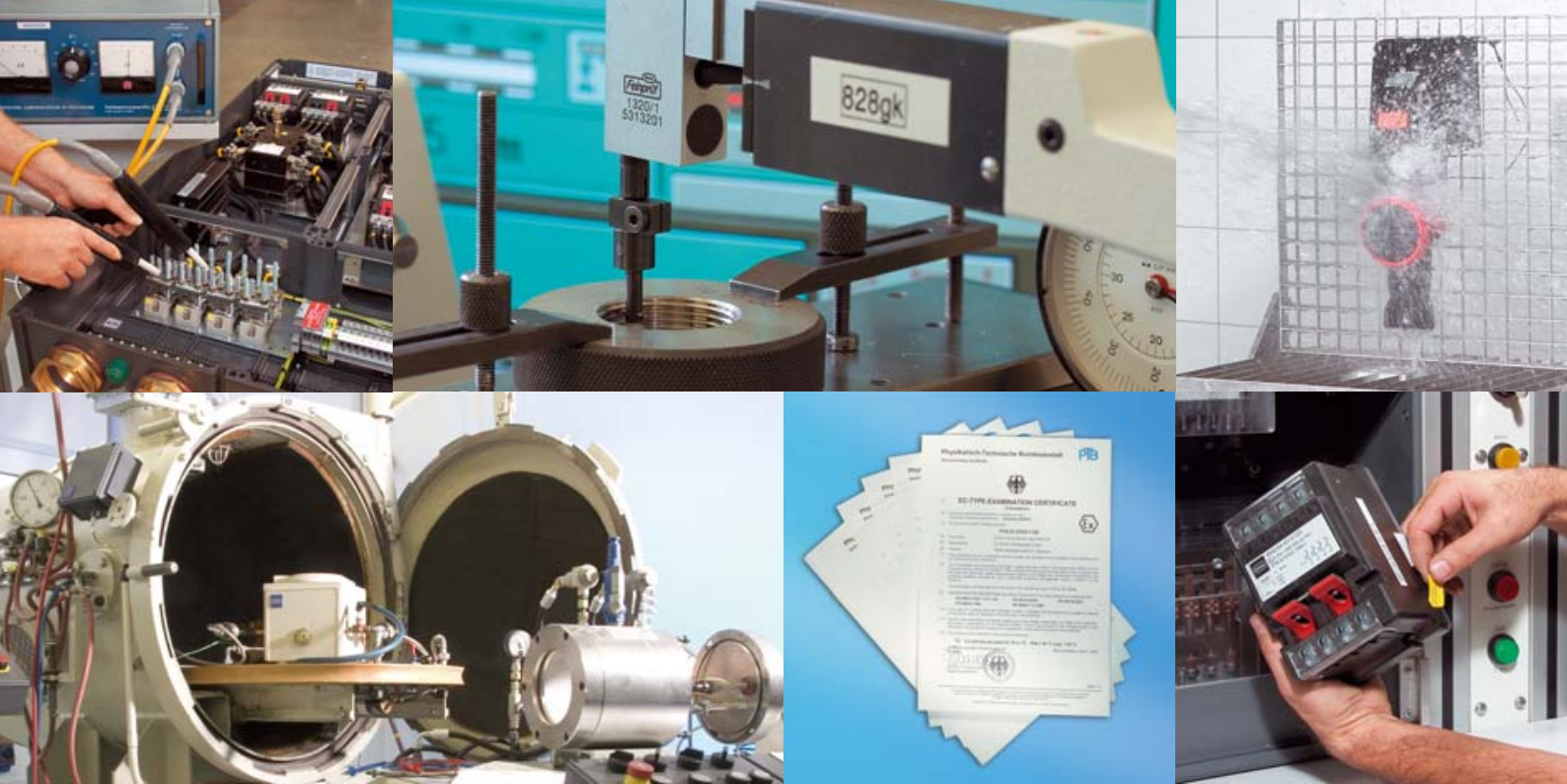
R. STAHL's equipment and components display excellent qualities with respect to particulate-matter emission, ease of cleaning, and ESD characteristics. The surfaces of the devices meet the requirements of the applicable national and international specifications. Thanks to the electro-polished stainless steel surfaces (for example, 1.471; AISI 316 TI) the danger of the particulate matter build-up is reduced to a minimum and cleaning is made easier; a high degree of resistance to abrasion and to various hostile media is also ensured. Plastic components with low specific surface resistance ensure that static electricity is safely discharged. This ESD characteristic also prevents the clinging of particulate matter to the surfaces and the cluster formation of air-borne impurities and contaminations. The materials employed are carefully selected, so that the outgassing of plasticizers and the softening that can result from the use of cleaning materials are safely prevented.

The R. STAHL program comprises not only junction, terminal, and control boxes, but also socket distributors with safety codes and safety switches, which reliably ensure disconnection of electrical energy at load.



DMT





# certificated

## approved worldwide

### Norms and guidelines for pharmaceutical production

- > VDI 2083 (Sheet 8 »Suitability of Operating Equipment for Use in Cleanroom Conditions)
- > DIN 100015-1, IEC 61340-5-1, ESD Corpus of Rules and Regulations SEMI E78 (Suitability of Operating Equipment for Use in ESD-Protected Areas)
- > FDA Guidelines (FDA 21 CFR Part 11)
- > GAMP4
- > DIN ISO 14644-1 and USA:FS 209 E (Classification of Cleanrooms)
- > EG-GMP Norm (Guidelines for Good Manufacturing Practice Part I)

R. STAHL is one of the world's leading manufacturers of explosion-protected components and systems for the pharmaceutical and chemical industry. We offer our clients precisely tailored, technologically groundbreaking solutions including all consultative and other services required by the commission in question.

In our laboratories, recognized and approved by independent inspection authorities, it is possible to directly conduct all important tests and experiments. R. STAHL's quality management team sees to it that high product-quality levels are maintained throughout the whole development and manufacturing phase.

It goes without saying that functionality, durability, and safety tests are all carried out according to the very latest directives and standards. The experts at R. STAHL cooperate with national and international committees, actively participating in the designing and further development of better safety regulations worldwide, based on their many years of experience.

This means that R. STAHL is in a position to design, plan and manufacture for every market in the world according to local regulations and local needs. Our competence is emphasized by international certifications, approvals, and patents, which allow all R. STAHL's products to be applied without hindrance worldwide.



# service

we have you covered

Whether your plant is one concerned with environmental technology, pharmaceuticals, or chemicals – R. STAHL is a partner on whom you can entirely and completely rely. We offer our customers a comprehensive range of services, a thorough documentation of all services provided, and full service from a single source.

- > Working-out of individually-tailored solutions
- > OEM service
- > Technical service
- > Commercial service
- > After-sales service
- > Your enquiries competently answered via our telephone/e-mail hotline
- > World-wide professional sales and marketing network
- > Internet presence with easy contact, information on sites and providers, product catalogue, certificates, documentation of accreditations, articles from the press, publications, information on explosion-protection, client-related e-commerce.
- > Provision of complete solutions for OEM applications
- > Your enquiries regarding the progress of your order answered at any time
- > Flexibility up to the start of manufacturing of your order
- > Quality management
- > Rapid, reliable dispatch, where required within 24 hrs.
- > Comprehensive system-based solutions
- > Devices produced as part of series, or standard solutions, are deliverable immediately on request
- > We deal with international customs and excise documentation, and with international dispatch arrangements, for you
- > Training sessions and seminars





# references

## our great clients

- > Abbott
- > ACTELION
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- > Alphapharma Ltd.
- > ALTANA Pharma AG
- > BASF
- > Baxter Healthcare
- > Bayer
- > Beiersdorf AG
- > Boehringer
- > Cargill Inc.
- > Chefaro
- > Chemshop
- > Chinoïn Ltd.
- > Dow Chemical Company
- > Dr. Reddy's Laboratories Ltd.
- > DSM
- > Du Pont
- > EGIS Pharmaceuticals
- > Essex Pharma
- > Esteve
- > Givaudan
- > Glaxo Smith Kline
- > ICN Hungary Ltd.
- > Janssen Pharmaceutica
- > KRKA Pharma
- > KV Pharmaceutical Company
- > LABORATORIOS BAGO SA
- > LABORATORIOS PHOENIX SAIC
- > LABORATORIOS ROEMMERS SAICF
- > Lanxess
- > LEK Pharma
- > Lilly Pharma
- > Lonza AG
- > L'Oreal
- > Lyondell
- > Merck
- > Novartis Pharma GmbH
- > Organon
- > Pfizer
- > Pharmachemie
- > PharmaZell GmbH
- > Reanal Finechemical Company
- > Richter Gedeon Ltd.
- > Roche
- > Sandoz
- > Sanofi-Aventis
- > Sanotec
- > Schering
- > Schering-Plough
- > SCHWARZ PHARMA
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- > Solvay Pharmaceuticals GmbH
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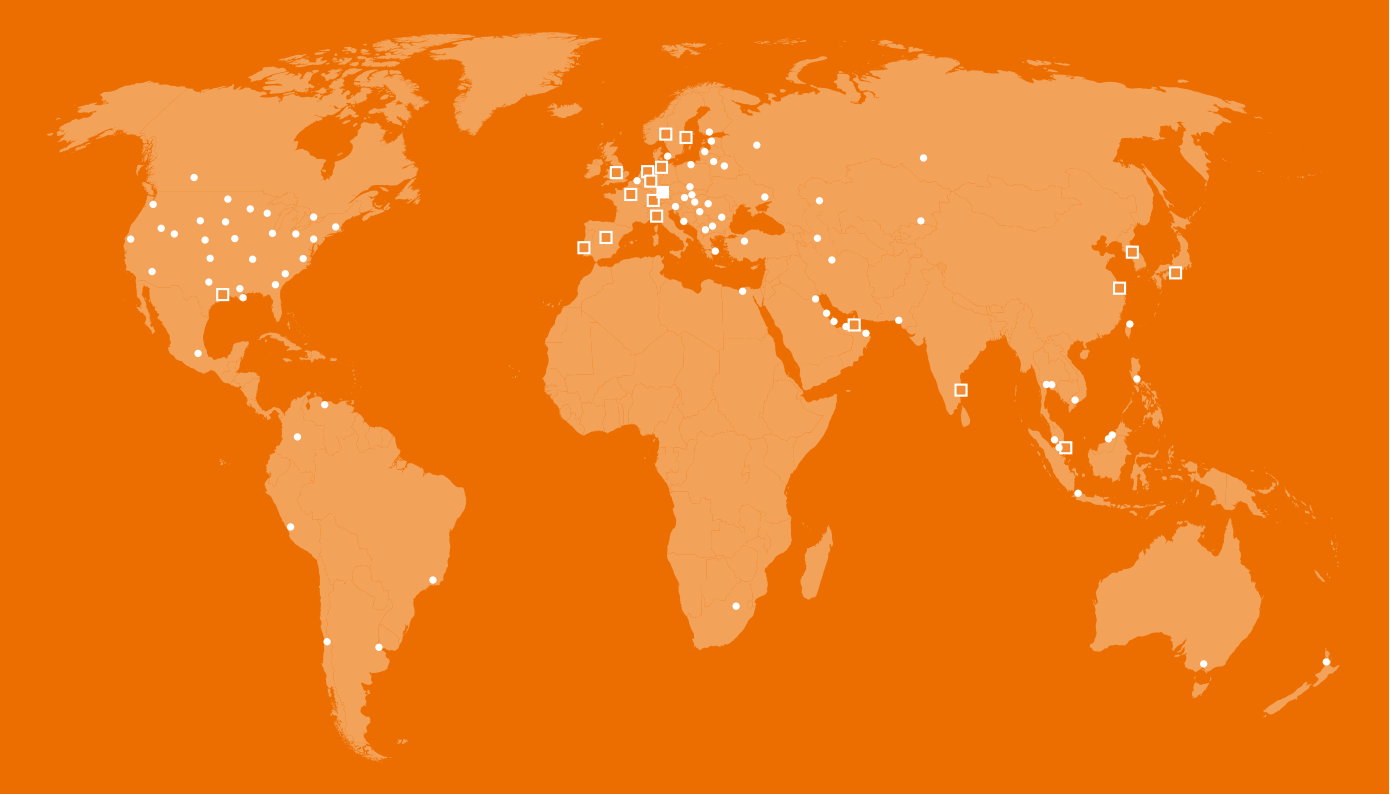
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