First rate uniFication:

Broad format range, constant high output, Class A environment and ex-proofed

Specific requirements – special solutions. A line for flammable (alcohol based), sterile, liquid and viscose fluids with a broad format range up to 1000 ml is a rarity in pharmaceutical manufacturing. The first of its kind is going into service at Schülke & Mayr GmbH.

it is the combination of special product characteristics that led to this line with so many special solutions. For example, the alcohol content of the liquids: the low surface tension of the liquids in combination with the high filling volumes and relatively high output requires a large diameter filling nozzle. to prevent drippage, special closable filling nozzles were implemented. other gel-like products are sensitive to shear forces, and needed to be filled with a higher degree of accuracy. Due to the large range of dosing volumes and product containers, in addition to the fact that there was not weighing equipment available that could meet the build criteria, a mass flow metering system proved to be the ideal solution. these and other fine details are part of a complete line based on the Kugler Linoclean and Linoline platforms.

"Special..." in every possible way special solutions can already be found in the sorting units which receive plastic bottles via an elevator. this type of sorting unit was first implemented in this line, for large format bottles being processed in a grade "B" environment. all containers are sorted centrifugally. in order to erect the horizontal lying bottles, tensioned belts are used. "righting fingers" which are typically used instead, could not be used due to the room classification and processing environment. once the bottles have been set upright, a rotation station triggered by an optical sensor, turns incorrectly oriented asymmetric bottles, so that their orientation is uniform when entering the process machines.

schülke

40 ml up to 1000 ml are filled without the need for additional dosing size parts

the first process machine is the Linoclean air rinsing unit. to obtain the best rinsing results and ensure a validatable process, the bottles are upended on the rinsing nozzles. upon completion of the rinsing, bottles are set upright onto a conveyor and queued up to the 2-up linear transport system of the Linoline. this explosion proof machine is encapsulated by raBs, whereby the filling area is accessed through two glove ports. Filling is performed by 12 filling nozzles which dive into the containers and advance with the bottles in an intermittent transport mode. each of the 12 mass flow meters is dedicated to the filling of its respective bottle. the servo driven transport system utilizes a user programmable acceleration/deceleration algorithm to minimize the swash of liquid in the bottles during transport, and to maximize output.

the mass flow metering system makes best use of its strengths given the particular challenges in this project. the system utilizes a process of constant readjustment during the filling process to achieve and surpass the required dosing accuracy of 0.5 % standard deviation. Furthermore, mass flow metering is a closed system, and compared to peristaltic systems, hoses are not subject to mechanical stresses and fatigue. this was an important factor for the explosion proof protection. For the same reasons, potentially damaging shear forces on the product also remain low. at the same time, the dosing system is also capable of handling medium viscosity products, such as wound gels. one last advantage: all format sizes from 40 ml up to 1000 ml are filled by the dosing system without the need for additional dosing size parts.

closable filling nozzles, mentioned at the beginning of the article, are one case of innovative thinking. the cone at the opening of the nozzle is pulled closed at the completion of every dosing cycle. elastomeric seals are not required, as each nozzle and cone are mated and honed as a pair. When gels are being filled, these tend to draw stringers. When the sealable nozzles close, they effectively "cut" the stringers which would otherwise threaten to drip onto the machine or soil the bottles. in some cases, when filling under the fill level of the bottles to prevent foaming, drops of product will remain on the exterior of the filling nozzle. in this case, after the nozzles have retracted from the bottles, a drip tray is automatically positioned under the nozzles to capture any drops during lateral movement of the nozzle bridge. Both of these functions – the closable filling nozzles and the drip tray – serve to ensure a clean fill, a clean machine and a clean final product.

ATEX-certification

in addition to the passive measures taken to fulfill the explosion proof criteria in the filling area, active measures such as air evacuation in the filling zone have been implemented. aerosols created during the filling process are thus removed. upon request by schülke & Mayr, optima additionally installed gas warning sensors in the machine substructure. these devices force a shut-down of the machine before a potentially explosive mixture of flammable aerosols form, and alleviate the need for other complicated explosion proof measures, while further enhancing the eX classification of the machine.

the Linoline can do more than just filling. Within the same machine frame, closing of the bottles also takes place. in the case of schülke & Mayr and the current bottles and closures, 3 closing steps are required. spare room for the later addition of a 4th closing station was part of the design. closures are fed into the machine by an elevator and sorting unit. the closures are separated and lightly screwed on the bottles by a pick-and-place station. a second station finishes torquing the closures to a pre-defined and measurable torque value. spray pumps can also be processed. the special feature here, is that the dip tubes on the spray pumps are actively straightened and centered over the bottle opening during the pick-and-place process. Depending on the type of closure, the 3rd station is used to pick-and-place a protective dust cap on the previously applied screw cap or pump. control features consist of a color sensor which detects cap color, and a device for determining skewed or cross-threaded caps. Bottles which do not meet the criteria of the control features are rejected within the explosion proof area.

Manual working positions have been integrated into the line and can be used to process special formats or small batches. a further feature is the incorporation of a sampling function, in which a product can be drawn directly from the product piping for Qa control. the initial setup is manual, in which a valve with a sampling bottle is put into the liquid product path. the operator initiates the sample function on the HMi and the sampling bottle is filled.

the entire media path, including sterile filtration and sample valve can be cleaned and sterilized in place (ciP / siP). all product and non-product contacting removable parts, including those on the Linoclean air rinsing machine, are autoclavable.

Core project data:

Class ”A” sterile processing in a class “B” room. | 100 bottles/minute output across the entire automatic processing range | 12 formats for liquid and semi-viscous products currently processed. Further room for expansion on the machine, and a reserve area for a further closure | Contractual filling accuracy of 0.5 % standard deviation was met and surpassed in filling trials. | the project duration from purchase order to FAT was 15 months.

Interview
with Jörn Alexander,
in charge of process technology and operations at schülke & Mayr GmbH

Mr. Alexander, to begin with, a background question: One could assume that products used for disinfection are per se sterile, and that sterile production is therefore not necessary. Why has Schülke & Mayr invested in a sterile production line?

Firstly, even bacteria can survive in an environment which would normally be lethal to it. as spores, they can live for decades without requiring nourishment or energy. When the environment becomes conducive to life, metabolic processes are reinstated, and a spore reverts to viable bacteria again. Well known examples of such spores are Bacilus anthracis (anthrax), clostridium tetani (tetanus), and Bacillus cereus or clostridium perfringens which are responsible for food poisoning. spores are resistant to alcohols and should therefore not be allowed into the product. For this reason, all skin, hand and wound disinfection must, depending on their product group, be processed in clean room environments a, B or c. our sterile surface disinfecting agent perform®, manufactured for the pharmaceutical industry are manufactured under hygienic class “a” conditions. even the packaging materials are gamma sterilized and brought in through decontamination airlocks.

Which types of products are manufactured on the Kugler line?

currently, packaging of 3 different product types is planned. alcohol based hand and skin disinfectant, wound disinfectant and surface disinfectants for the pharmaceutical industry.

What was the main reason for investing in new production technology?

our products which required ”sterile” class “a” manufacturing environments were previously outsourced to contract manufacturers. With our new structure, manufacturing and filling have merged together, also with respect to the automation we have implemented. We are now capable of highly efficient manufacturing of these products ourselves.

I presume that a defined User Requirement Specification existed before the project began, which outlined what the new equipment needed to be capable of. Were you already then certain that everything was possible with just one production line?

Based on our project management system, the specific requirements for capital equipment to be purchased needs to be scoped out by our team and written into a requirement specification. this is usually the most time consuming part of a project. We look at which processes currently cause us problems, and how we can optimize. the crucial part of our requirements was to be able to process different containers ranging in size from 40 ml to 1000 ml at an output of 100 bottles per minute. only 2 suppliers were up to the task. oPtiMa’s presented solution essentially fulfilled all of our performance requirements laid out in the specification.

Where did you have to make compromises?

as i said, essentially all of the requirements were fulfilled. in individual points we made some compromises, such as where our specifications for visualization on the operator terminal differed from the oPtiMa standard. We looked for solutions together, and found them. on the one hand we had a technologically advanced equipment line with a degree of standardization, and on the other hand a specific user interface which we wanted for fast localization (…of problems). We simply made use of both advantages.

Were there items in the specification to which you had a specific idea in the beginning, but to which you were convinced of a different solution which OPTIMA offered?

Generally speaking, we look forward to points for discussion. they allow both parties to develop further. and yes – there were such points. We were quickly convinced by the proposed linear rake transport system. the more boxy containers get, the more transport scrolls and wheels are prone to fail. the chosen solution proved itself to be the right solution in test runs.

What were the three most important criteria for you in the user specification?

First on the list was compliance with the clean room classifications. next were the high output of 100 bottles per minute for all formats and a technically flexible line which includes fast changeovers and things which are ultimately closely related to fast changeovers such as the automatic cleaning concept and the ciP/siP.

How many different bottle and cap formats are you processing?

there are 11 different bottle formats and 7 unique closures. there are round bottles and square bottles ranging from 40 to 1000 ml. the closures consist of different hinged flip-caps with tamper evident rings, and spray pumps which are screwed on or pressed on, both with tamper evident rings. there are also normal tamper evident screw caps and measuring cups or press-on spouts.

»the crucial point of our requirements was to be able to process different containers ranging in size from 40 ml to 1000 ml at an output of 100 bottles per minute. only 2 suppliers were up to the task«

From a technical standpoint, were there any solutions on the line which took you by surprise?

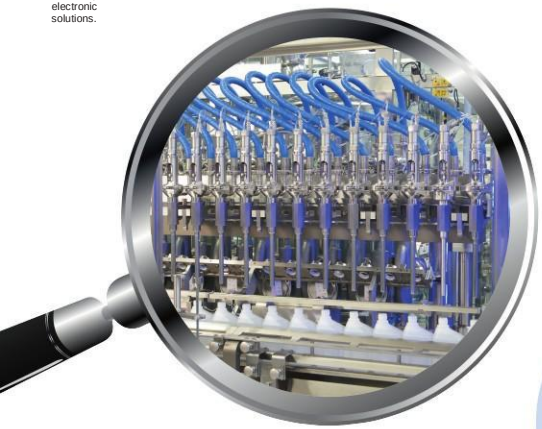
the bottle unscrambling and bottle righting really surprised us. originally, we saw a solution from optima consumer, developed for use in the cosmetics industry. the unit functioned on a basic mechanical principle. Granted – we were a little skeptical. the unit was technically and hygienically re-engineered and brought to pharmaceutical standards. the result that optima provided was simply fantastic. the origin of the machine from the cosmetics sector is not recognizable. in my opinion – as far as practicable – simple solutions are often better and more reliable that complex electronic solutions.

A significant factor in this project also involved cooperation with further vendors...

Yes. at schülke we also had project managers for the different sections of the project. For instance, for manufacturing, automation, monitoring etc. were all represented. We communicated closely for decision making. in the same way, other companies involved in site construction cooperated well with one another to clarify important interfaces ahead of time. all companies worked together with a view to success.

How happy are you with the overall success of the project? Is it too early for verifying feedback?

We all very much enjoyed working together with optima. everyone working on the project was focused and dedicated – heart and soul. You could feel the vigor and enthusiasm.
sat is scheduled to be completed by the end of august. in 4 weeks we'll be taking acceptance of the line which we specified in our user requirements. it already looked good at the Fat.



a sHort sYnoPsis

Schülke & Mayr GmbH

the company, founded in 1889, played a key role in combating the Hamburg cholera epidemic in 1892 with its' iysol® product. Lysol is considered to be the first branded disinfectant. in 1990, octenisept® was introduced to the market as a non-stinging wound disinfectant for both professionals and consumers. today, schülke & Mayr, with its' headquarters in norderstedt (near Hamburg), has a manufacturing portfolio of more than 200 different specialty products for wound care, antisepsis, disinfection and specialized chemicals, is involved in research and development, develops proprietary active ingredients and holds more than 190 international patents. Last year, the company had a turnover of approx. eur 180 million, and has been a part of the air-Liquide group since 1996.