

NEWSLETTER

March 2015

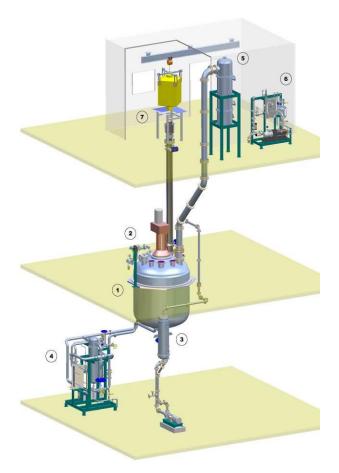
Batch reaction and distillation systems

Chemical and pharmaceutical production plants are relatively costly. Therefore a big challenge for every project manager is to reduce investment cost without compromising on safety, plant reliability and of course final product quality.

Raschka Engineering's value engineered "fit for purpose" design combined with local sourcing will provide our valuable customer western technology made in China. Raschka Engineering has set up a number of cooperation and license agreements with western companies which provide access to technology and limit the imported value for key elements to the bear minimum. The process units described in this newsletter have been applied in several projects; this proven technology has been continuously improved working closely with the operation team of Lonza. Some of these standardized production modules maybe useful for your needs and we would be more than happy to share our experience with you and discuss any specific requirements you may have.



Batch reactor system



1. Batch reactor

Reactor to be required in stainless steel, hastelloy cladded or glass lined material with agitator and mechanical seal type which are selected depending on product properties, operating conditions and cGMP requirements. Designed for easy cleaning and quick changeover in case of multi purpose applications, with dip pipes equipped with special cleaning adaptors, reactor cover and vapor line equipped with CIP nozzles for efficient and reliable cleaning.

2. Sampling system

Process monitoring depends heavily on the ability to take representative samples. Raschka Engineering has designed a system which enables sampling with minimum pre rinse and facilitates easy and fast cleaning in case of product change. This sampling system can also be delivered for acid resistant applications.

3. External heat exchanger

Heat transfer area of heating and cooling jacked of reactors are often insufficient for an accurate temperature control, especially for glass lined reaction equipment the heat transfer is often a limiting factor, in this case an external heat exchanger with circulation is a preferred option. Because graphite as heat exchanger material, especially when purchased in the local market, does not meet the customer requirements, Raschka Engineering has designed a cost optimized solution using only minimum of hastelloy material combining it with SS304 and glass lined material.

4. Temperature Control Module (TCM)

For accurate temperature control of the reactor, external heat exchanger or condenser either for the purpose of heat removal or energy supply, Raschka Engineering has successfully realized skid mounded, standardized heating/cooling units for a temperature range from -25 to 180 degree C. Low temperature module is available for stainless steel or hastelloy reactors providing a temperature range from -90 to 150 degree C. These units are usually independent secondary circuits operated with water free heating media.

5. Condenser

Condensation of vapor is usually done in heat exchangers using stainless steel, hastelloy or graphite as material of construction. Some condensers maybe operated with temperature control module (TCM) in order to regulate condensation temperature as close as possible to freezing point in order to reduce off gas losses and to account for limited vacuum capacity. Especially when operating under cGMP conditions graphite HE is not the material of choice, while full metal solutions turn out to be very expensive. Raschka Engineering has designed a cost optimized solution using only minimum of hastelloy material combining it with SS304 and glass lined material.

6. Vacuum pump module

A reliable vacuum pump is essential for stable continuous process and for reproducible conditions in batch processes. Especially treatment of corrosive gases under vacuum requires careful design of the vacuum unit in order to prevent from any condensation. In addition, vacuum pumps have to be rated as a potential source of ignition and such systems need to be designed, installed and controlled (operated) accordingly. Raschka Engineering offers a proven design, using a dry running machine incorporated in a skid mounted process unit, where installation, control system and safety devices respect the recent ATEX requirements. A large number of such modules are operated in small and large scale chemical and pharmaceutical production plants.

7. Solid charging

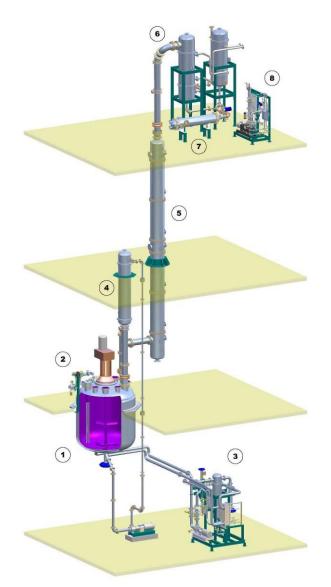
Charging from drums, bags or big bags is a common operation within chemical or pharmaceutical production plants. However there are some major concerns related to this unit operation:

Safety: explosive gas mixture can easily be formed by insufficient blanketing with nitrogen, powder often contains additional oxygen when introduced into the reactor and static electricity is a constant source of ignition.

Foreign particles: Especially when operated under cGMP, cross contamination and clean room design combined with adequate HVAC and filtering systems will be key to meet customer and regulatory inspections.

Designing a large quantity solid charging system for a reactor requires adequate design and an experienced design team. Raschka Engineering has many years of experience in designing, maintaining, operating and auditing such systems.

Batch distillation system



1. Batch distillation vessel

Main vessel made of stainless steel, hastelloy cladded or glass lined material with agitator and mechanical seal type which are selected depending on product properties, operating conditions and cGMP requirements.

2. Sampling system

Process monitoring depends heavily on the ability to take representative samples. Raschka Engineering has designed a system which enables sampling with minimum pre rinse and facilitates easy and fast cleaning in case of product change. This sampling system can also be delivered for acid resistant applications.

3. Temperature Control Module (TCM)

For accurate temperature control of the reactor, external heat exchanger or condenser either for the purpose of heat removal or energy supply, Raschka Engineering has successfully realized skid mounded, standardized heating/cooling units for a temperature range from -25 to 180 degree C . Low temperature module is available for stainless steel or hastelloy reactors providing a temperature range from -90 to 150 degree C. These units are usually independent secondary circuits operated with water free heating media.

4. Falling film evaporator

Especially for temperature sensitive products, an external heat exchanger is sometimes used to introduce the right level of energy at a minimum temperature difference between product and heating medium. Such problems are often solved by using a falling film evaporator. Raschka Engineering has calculated, designed and commissioned such systems in various dimensions and material combinations.

5. Distillation column

Depending on the product portfolio or thermal separation requirements, such columns can vary in diameter and length. The selected type of packing and distributor are essential in order to achieve the desired product separation. Product properties as well as operational conditions sometimes require column interiors resisting to a wide pH-range. Raschka Engineering has designed and commissioned low cost options using a combination of material between glass lined steel, ceramic and PTFE

6. Condenser

Condensation of vapor is usually done in heat exchangers using stainless steel, hastelloy or graphite as material of construction. Especially when partial condensation is required, two or more condensers have to be installed and some of them will be operated using a temperature control module (TCM) in order to achieve partial condensation. Especially when operating under cGMP conditions, graphite HE are not the material of choice, while full metal solutions turn out to be very expensive. Raschka Engineering has designed a cost optimized solution using only minimum of hastelloy material combining it with SS304 and glass lined material.

7. Phase separation

After the condensation, further liquid/liquid separation is often required using the density difference between two non miscible liquids in a decanter. Simple but effective level control of such systems can be found in many applications designed by Raschka Engineering, both in acid resistant and stainless steel applications.

8. Vacuum pump module

A reliable vacuum pump is essential for stable continuous process and for reproducible conditions in batch processes. Especially treatment of corrosive gases under vacuum requires careful design of the vacuum unit in order to prevent from any condensation. In addition, vacuum pumps have to be rated as a potential source of ignition and such systems need to be designed, installed and controlled (operated) accordingly. Raschka Engineering offers a proven design, using a dry running machine incorporated in a skid mounted process unit, where installation, control system and safety devices respect the recent ATEX requirements. A large number of such modules are operated in small and large scale chemical and pharmaceutical production plants.





BigBag Filling

Vacuum pump module



Temperature Control Module

In this context, Raschka Engineering's service could include:

- Feasibility studies, option evaluation, authority engineering
- Conceptual design, URS, Basic design
- Environmental assessment
- Cost estimation
- Detail design (equipment, piping, instrumentation, electrical, civil)
- Risk analysis
- Procurement, quality supervision
- Schedule and cost control
- Qualification, Documentation and maintenance manuals
- Operator training
- Maintenance and on call service

An extensive service list is available on our website: <u>http://www.raschka-engineering.com</u>

Raschka Engineering Ltd

Raschka Engineering Ltd. Liestal, Switzerland (previously known as Lonza Engineering) now reflects the superior and well known Raschka FBI technology in its name together with its wholly owned subsidiary Raschka Engineering & Consulting Co., Ltd. China provides customer oriented services with a professional. experienced and highly motivated engineering team. We have 20 years of successful project management experience in China which makes us a perfect partner for the chemical. pharmaceutical biopharmaceutical and industry. A board range of services with a project reference list underlining our capabilities is available upon request.

Raschka Engineering has successful managed multiple complex projects such as continuous operating plants for the production of food and feed additives as well as active pharmaceutical ingredient plants including waste gas and liquid waste treatment facilities.

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