Latest trends in heat transfer tech in pharma industry

Naresh Agarwal

THE India pharmaceutical market has been witnessing a healthy growth of over 25 per cent in the past years and we expect the industry to sustain this trend in the coming future. Indian pharma industry is the world's third largest in terms of volume and 13 th largest in terms of value, as per a recent sector analysis report by Equity Master.

The market is dominated majorly by branded generics which constitute nearly 70 to 80 per cent of the market. Pharma manufacturers recognize some of these as API (Active Pharmaceutical Ingredient) and formulations. Apart from generic drugs, there is a growing demand for healthcare products like nutraceuticals, probiotics and infant food substitutes. Pharma manufacturing has seen a rapid change over the last few years. Growing need to be competitive, stringent quality and hygiene norms for processing, FDI regulations have further pushed the technology upgradation in pharma processing.

Heat transfer is the core of processing products as there is always a need to either heat or cool any product. Usual processes in pharma manufacturing plants include heating, cooling, condensation, distillation, separation, mixing, evaporation and similar processes. These are primarily carried out with process equipment in the form of reactors, distillation columns, evaporator, heat exchanger, condenser, heater, cooler, reboiler etc. Product and process conditions like temperature, pressure, holding time, flow rates, volumes are derived for the capacity of the plant, equipment and peripheral components.

Innovation in heat exchanger design has been necessitated by the rapid growing technology demands in process industry for higher productivity at lower cost and energy consumption. Heat exchanger design today needs to be energy efficient, withstand a range of process materials taking impact of factors such as varying products, temperature, pressure, corrosion, fouling, etc. New heat exchanger types are developed for specific process application depending on the need for energy conservation. Pharma plants have been using heat exchangers of various types viz; stainless steel, graphite, glass, etc. which would occupy more space, have product compatibility issues, leading to reduced plant efficiencies and lower quality of end product. Use of these also resulted in plant downtimes, high running costs and energy wasted due to improper designs. Many of the end products were unable to meet international standards due to contamination.

Growing domestic and international demand led to entry of many of multinational groups in the market looking for expansion opportunities due to good resource availability. This has also changed the outlook of pharma companies towards processing and quality, necessitating better process and heat transfer technology, enhanced design and manufacturing capabilities to meet the standards. Thrust is increasingly on good quality output, better efficiencies, increased productivity and reduced cost of operations. Globally, the equipment design standards have seen rapid change to adapt to the processing requirements.

Pharma manufacturers have become more particular about material selection. Material of construction of heat exchangers is changing to alloys like a range of stainless steels, nickel alloys, titanium, tantalum, etc. Not limited to plain shell and tube, pharma companies are showing preference to corrugated tube heat exchangers, enhanced patterns of plate designs in plate heat exchangers which have given the additional advantage of compact space of operations. This has resulted in good efficiencies and better return on investment. Today heat exchangers are used for varied application ranging from condensers to coolers, heaters, recuperators, vent condensers to reduce storage tank solvent loss, heat recovery from effluent, skid mounted hot water systems, single and multi fluid heating / cooling systems, evaporation systems to reduce effluent volume coupled with solvent recovery, amongst others.

This enhancement in technology has given the following advantages and benefits to pharmaceutical companies:

- Optimal plant and equipment design.
- Customized to suit varied products and capacities.
- Compatibility of equipment

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Quality metrics: Carrot & stick

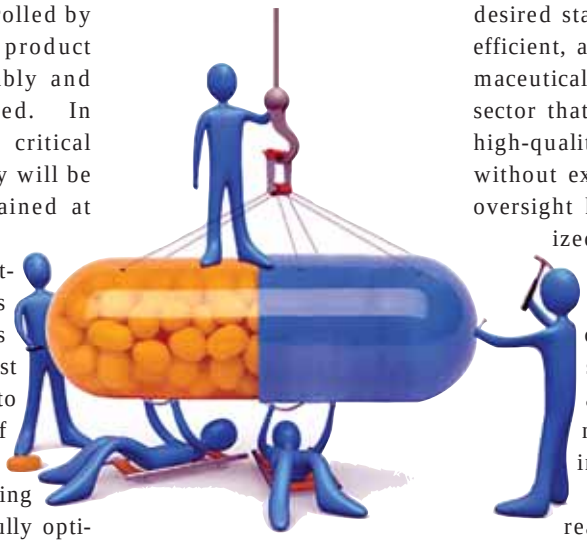
Brian Carlin

THE FDA quality metrics initiative has elements of carrot yourself carrot?). Increased attention to finished product and stick: compliance with baseline metrics (stick?) and quality metrics will drive greater scrutiny of the impact of optional metrics to demonstrate quality culture (a do-it-excipient variability, a rich source of special cause variation.

What happened to QbD?

Quality by Design (QbD) assumed that if all critical sources of variability are identified, and controlled by the process, then product quality can be reliably and accurately predicted. In practice, not all critical sources of variability will be identified and explained at time of filing.

'The number of post-approval supplements received for review has increased over the past decade, in part owing to our current practice of 'locking in' an applicant's manufacturing process before it is fully optimized. A burdensome regulatory framework requires manufacturers to submit supplements as they strive for process optimization.'



This may explain why the desired state of 'a maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high-quality drug products without extensive regulatory oversight has yet to be realized. Despite QbD, quality risk management, pharmaceutical quality systems, process analytical technologies and other initiatives:

"we have not fully realized our 21st century vision for manufacturing and quality-- there continue to be indicators of serious product quality defects"

As a result, FDA intends to use industry quality metrics data to develop risk-based inspection, reduce risk of drug supply disruption, and improve their evaluation of drug manufacturing and control operations.

'Establishments that have highly controlled manufacturing processes have the potential to be inspected less often (as a lower priority for inspection) than similar establishments that demonstrate uncontrolled processes (as a higher priority for inspection).

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Energy holds the key for growth

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and process material.

- Least cost of ownership.
- Low downtimes for maintenance schedules.
- Reduced maintenance costs.
- Good automation and process hygiene.
- Better heat recovery and reduced load on environment.
- Keeping scope for future capacity expansion.

Concern for the environment has also played a key role to further develop technology. New solutions for healthcare foods and supplements are added to the demands from pharma, food and allied businesses. Companies are ensuring to provide 'all-inclusive' solutions for primary processing which can be directly integrated to the packaging section. Nutraceutical, probiotic and infant food substitute manufacturers are giving preference to setting up small pilot plants for trials as well as large units for mass production. Good practices in design and manufacture of processing equipment as well as global design methods have helped equipment manufacturers and pharma companies standardize the platform of understanding and ensure process output.

Energy conservation and optimal utilization of resources remains the key around which technology will evolve with further R&D. Though these changes involve an initial investment, it becomes a suitable sustainability proposition for the pharma companies as the longevity and productivity of the plants improves. And finally, larger variety of products will require greater flexibility in production and closer integration along the whole pharmaceutical chain. There is a lot of Government focus on the pharmaceutical sector which will ably complement the organic and inorganic growth of this industry. Pharmaceuticals as an industry is also among the top five in attracting foreign direct investments (FDI) in India. Given the momentum, the pharmaceutical sector needs to adapt quickly to improving efficiencies in production, where heat exchangers play a key role. Newer technology led by green energy initiatives will also contribute to improved design and better growth for the pharmaceutical sector in India. ◆

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