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The Potential of Continuous Processing in Secondary Manufacturing

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Pharmaceutical secondary manufacturing has long stood in stark contrast to the drug discovery end of the business, as well as to other sectors, when it comes to innovation such as continuous manufacturing. Is that about to change? The traditional business model is breaking down with consequent pressures on all parts of the pharma value chain. Manufacturing's contribution to improving yield, reducing time, cost and waste is increasingly critical. Regulation which previously had insisted on batch testing is now moving to be much more supportive of real time product release and process analysis, heralding a future where the validation and establishment of continuous manufacturing will be easier.

Integration of each process stage is crucial for continuous manufacturing. However, pharma companies tend to work with 'islands of automation' where every unit of operation is more or less an independent from an integration point of view.

Another key barrier is that these changes require companies to work in a more multi-disciplinary way, crossing system worlds. For the first time, if you are in analytics you have to speak to people in process control and so on. Multi-disciplinary teams are an absolute must but not everyone is ready for that. The relatively slow uptake of process analytical technology (PAT), crucial for continuous manufacturing, following the FDA's 2004 PAT initiative, highlights the challenge facing companies.

Mindset changes and internal culture changes will be key to the successful introduction of PAT as a first step towards continuous manufacturing. The companies that are first to overcome the barriers will not just reap the reward of increased competitiveness. Because of the stage of its introduction, they have the opportunity to implement the technology to a higher level than in industries where it is already established. From being a laggard, secondary manufacturing has the potential to become a trendsetter.