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Continuous reactions and the FDA

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The chemical industry has looked at the use of continuous reactions for many years. In fact, the only industry sector not involved in continuous chemistry has been the manufacturing of pharmaceutical ingredients. More recently, the manufacturing of API's has seen a push into continuous chemistry and the FDA is helping to lead the charge. However, from a regulatory point of view, we may see a major switch in how we produce our products. The concept of a batch will change dramatically and the requirements for validation will need to be adaptive to a new manufacturing paradigm. In addition, the switch to continuous reactions could benefit the overall economic and safety of drug production. This presentation will look at the issues around manufacturing API's and the regulatory changes required moving from batch to continuous. The presentation will focus on the definition of the batch and the critical parameters working in continuous reactions.

Biography

James R Bruno has over 40 years of industrial experience working in the manufacturing and development of API's. After many years of working in lab through senior positions in the pharmaceutical manufacturing sector, he has began consulting in 2002 working with emerging pharmaceutical company to help to develop their API's and dosage. In addition, he has continued to consult in the area of new technology including continuous chemistry, chromatography and various other chemical transformations'. His objective has been to bring new technologies into the commercial work to safely and economically produce API's. He has obtained his Master's in Chemistry from St. Joseph's University in Philadelphia and MBA Degree from Rider University located in Lawrenceville, NJ. He is also served on the Scientific Advisory Board. He has published numerous papers in many of the pharmaceutical journals.

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