Pharmaceutical manufacturing is crucial to global healthcare and requires a higher, more consistent level of quality than any other industry. Yet, the traditional pharmaceutical batch manufacturing has remained largely unchanged in the last fifty years due to high R&D costs, shorter patent durations, and regulatory uncertainty. This has led regulatory bodies to promote modernization of manufacturing process to continuous pharmaceutical manufacturing (CPM) by introducing new methodologies including quality by design, design space, and process analytical technology (PAT). This represents a shift away from the traditional pharmaceutical manufacturing way of thinking towards a risk based approach that promotes increased product and process knowledge through a data-rich environment. While both literature and regulatory bodies acknowledge the need for modernization, manufacturers have been slow to modernize due to uncertainty and lack of confidence in the applications of these methodologies.

This paper aims to describe the current applications of QbD principles in literature and the current regulatory environment to identify gaps in literature through leveraging regulatory guidelines and CPM literature. To aid in closing the gap between QbD theory and QbD application, a QbD algorithm for CPM using an integrated flowsheet model approach is also developed and analyzed. This will help to increase manufacturing confidence in CPM by providing answers to questions about the CPM business case, applications of QbD tools, process validation and sensitivity, and process and equipment characteristics. An integrated flowsheet model will aid in the decision-making process and process optimization, breaking away from traditional methods extensively covered in literature.

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Approved for distribution by Ahmad Elshennawy, Committee Chair, on October 18, 2017.

The public is welcome to attend.