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”Connecting The Dots Looking Backward”: Enhancing Pharma Manufacturing through a Retrospective Quality By Design Case Study

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Introduction: As Steve Jobs famously stated, “You can’t connect the dots looking forward; you can only connect them looking backward.” This reflective insight resonates perfectly in this work. Adopt a Retrospective Quality by Design (rQbD) perspective and connect the dots of past manufacturing experiences to drive continuous improvement and innovation in legacy drug products and their processes. This industrial case study demonstrates the application of Retrospective QbD to improve process understanding, robustness, product quality, and regulatory compliance, as well as highlights its potential to foster industrial innovation, ultimately creating a more adaptive and resilient landscape for pharmaceutical manufacturing.

Method: The rQbD was conducted at a pharmaceutical manufacturing facility. Key steps involved: (1) Access the available information on process development, the history of legacy product manufacturing, and feedback from technicians (2) Define the Quality Target Product Profile (QTPP) (3) Identify Critical Quality Attributes (CQAs) (4) Collection and pre-treatment of raw material and manufacturing data (5) Collect additional data through complementary follow-up experiences (6) Identify Critical Material Attributes (CMAs) and Critical Process Parameters (CPPs) using a risk-based approach based on multivariate data analytics. During step (6), it was possible to identify potentially interesting associations and trends in the collected historical manufacturing data, along with additional generated data.

Results: By obtaining CMAs and CPPs through a risk approach based on historical data, it became possible to gain a clearer understanding of process and product variability. This will enable swifter adjustments with fewer instances of “trial and error” to process parameters through the obtained models while also minimizing downtime and reprocessing, thereby enhancing manufacturing efficiency. The regulatory flexibility within an industrial context that could also be facilitated by incorporating the proposed rQbD framework into the Common Technical Dossier (CTD) of drug products may represent another significant potential outcome of this work.

Conclusions: The findings underscore the benefits of the Retrospective QbD approach in optimising the manufacturing processes of legacy products, driving continuous improvement, and ensuring high-quality pharmaceutical production. This approach not only offers a valuable pathway for the pharmaceutical industry to adapt to evolving technological advancements within Pharma 4.0 and regulatory landscapes, but also emphasizes the industry’s crucial role in this adaptation.

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