

Verta Life Sciences | Molecule to Market Consulting.
Supporting Life Science Companies; Develop, Manufacture, Register, Launch, and Supply their Products.

CMC REGULATORY - CASE STUDY

ISSUE:

The company had planned CMC Post-Approval Change of a controlled release tablet which involved a change in manufacturing site, scale (batch size) equipment and process.

OBJECTIVE:

Based on a substantial body of prior knowledge, a hypothesis was developed that process control was the greatest risk in the technology transfer, not the product stability. Two multivariant models were developed evaluating process design space and stability.

DELIVERABLE:

The final outcome was that 3 batches of stability were waived resulting in a cost savings of \$350K.

The new approach provided a rationale for selecting the biobatch, enabled a different approach to process validation and provided for continuous verification, established a foundation for evaluating future changes using product and process knowledge.

Contact Us

To learn more about how Verta Life Sciences can help you, please contact us:

Email: experts@Vertals.com
Head Office: Verta Life Sciences,
LLC
3737 Glenwood Ave,
Suite 100
Raleigh, NC 27612
USA
US Phone: +1 919-787-1921
Free phone: +1 888-565-3179

Website: www.Vertalifesciences.com
EU Office: Verta Life Sciences
Unit 1782, PO Box 92,
Cardiff, CF11 1NB
UK
UK Phone: +44 (0)2921 25 0830