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Biosimilars: Lessons learned from development to commercial launch

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In this presentation I will discuss my experience launching of commercial biological and first biosimilar product from development to manufacturing to post marketing with special emphasis to building Quality by Design and Quality across the Product Lifecycle. I will discuss lessons learned from R & D (Clone Selection, Cell Bank Characterization, Expression and Yields), Technology Transfer to Product Development (up to pilot scale), and Analytical Development and specification set-up as per EP and validation of pilot batches, analytical and stability indicating methods. I will further discuss the pains of cross-functional teams and buy-ins from senior management, technical and marketing functions. Building a commercial launching group and collaborative executions to meet the timeline to launch the product. I will also discuss cost comparison manufacturing quality biosimilars in both highly regulated versus rest of the World. Is this strategy leading to successfully make Quality commercial batches of highly complex biological product (Upstream & Down Stream)? In this presentation, I will also discuss the role of Cross- functional teams, the management and suppliers. We will compare the cost & time for effective implementation of Quality by Design and building Quality across the product launch and life cycle management.

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