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Risk based development and manufacturing of biosimilars

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The development of biosimilars presents a unique risk profile to biopharmaceutical companies when compared to proprietary biologics development. This risk profile will be examined and used to explain why biosimilars must be developed and manufactured differently than originator molecules, in order to insure commercial success. For biosimilars, commercial endpoint oriented process development should start earlier for biosimilars than for originator products. To buy down risk, at-scale manufacturing may be desirable as early as nonclinical / phase I manufacturing.

Biography

Neil Schauer is the Principal Consultant at Schauer Biologics Consulting where he provides strategic planning and tactical support for process development and manufacturing activities at startup and established biologics companies. At Avaxia Biologics, he was Senior VP of Technical Operations; where he was responsible for process development, manufacturing, quality and program management. In previous positions (Inspiration Biopharmaceuticals, Hospira, Millipore, Biogen Idec and Genetics Institute\Wyeth), he held positions of increasing responsibility associated with biologics: technology, manufacturing, process development and project\program\portfolio management.

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