TraceLink and Clarkston Consulting Deliver Serialization Success for a Pre-Commercial Biopharma



A pre-commercial biopharma preparing its first U.S. launch needed DSCSA compliance but lacked key processes, master data, and validation. TraceLink provided the serialization solution, while Clarkston Consulting built the strategy to make it work.

Key actions included:

- Developing a serialization roadmap for U.S. compliance and future global launches
- Aligning master data with SAP and loading it into TraceLink
- Creating SOPs, work instructions, and process documentation
- Leading validation with CPO and 3PL partners
- Overseeing TraceLink configuration and go-live readiness
- Coordinating ERP and QMS integration to reduce overlap

Results:

- DSCSA-compliant, validated serialization system enabled first U.S. launch
- Scalable platform for future markets and evolving requirements
- Clear, pragmatic roadmap balancing short- and long-term needs

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- Alignment with industry best practices and strong cross-functional governance

Together, TraceLink and Clarkston delivered not only compliance, but also a foundation for commercialization, expansion, and growth.

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