Compliance and DSCSA

Pharmaceutical manufacturers are held responsible for serialization requirements at every stage within the pharmaceutical supply chain according to FDA rules established for the Drug Supply Chain Security Act, or DSCSA. The relationship between manufacturers and their contract manufacturing organizations is becoming increasingly important to maintain product flow and avoid costly delays, which includes maintaining DSCSA compliance.

WDPrx emphasizes four components for DSCSA compliance that assure client confidence and trust: Communication, Accountability, Planning and Experience.

Communication

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With over 30 years of experience as a contract manufacturing operation, WDPrx values open and regular communication with client manufacturers. Consistent communication and interaction helps minimize misunderstandings and often produces valuable insights to improve efficiency and program success. Rules for DSCSA compliance provided by the FDA are sometimes vague. This increases the potential for problems between some clients and their contract manufacturers. Every WDPrx team works in concert with each other and with each client to promote constructive dialogue that produces clearly defined expectations for the scope of work including all elements of DSCSA compliance.

Accountability

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Agreements between pharmaceutical companies and their contract manufacturers sometimes do not include specifics about DSCSA compliance. According to the law, the brand owner is ultimately responsible to assure compliance for their products. WDPrx works closely with clients to establish clear responsibilities based on detailed flowcharts and project plans. The serialization process affects many areas of the manufacturing and distribution chain including label and package design, primary and secondary packaging and labeling, shipping and order fulfillment. Working together with WDPrx, DSCSA compliance solutions are determined in advance, streamlining workflow, speeding product to market and helping assure successful outcomes.

Planning

The laws surrounding DSCSA compliance are complex and represent the most significant changes in the pharmaceutical industry since the Federal Food, Drug and Cosmetic Act of 1938. Since the signing of the DSCSA into law in 2013, rules are being administered by the FDA and phased in over a ten-year period. Significant investments in capital and human resources are required in order to achieve compliance with DSCSA requirements. Upgrades to labeling and packaging equipment, updates to computer system hardware, software and other technology assets, additional training and education for employees as well as new procedures for warehousing and distribution contribute to the considerable undertaking. WDPrx is a financially stable fully-owned facility that planned well in advance to complete the transition to DSCSA compliance in advance of FDA deadlines. With companies around the country at various stages of DSCSA implementation, WDPrx works closely with every client to understand and adapt to existing circumstances based on their serialization requirements.

planning

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Experience

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Thirty years of continuous operation provides WDPrx with a wealth of experience to anticipate most situations that may affect client satisfaction. The changes brought about by DSCSA are new to most contract manufacturing organizations which must use trial and error to achieve results. WDPrx benefits from affiliation with a DSCSA-compliant third party logistics firm providing services exclusively for the life sciences industry. This practical experience assures highly efficient warehousing and distribution, primary and secondary packaging, training, documentation and regulatory support.

Related Material

White Paper: Adapt Or Die: Contract Packaging Operations At Center of Serialization Compliance