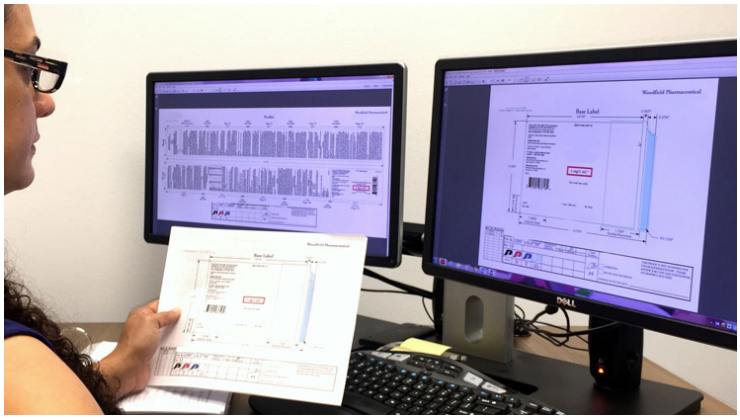
Regulatory Support

Function

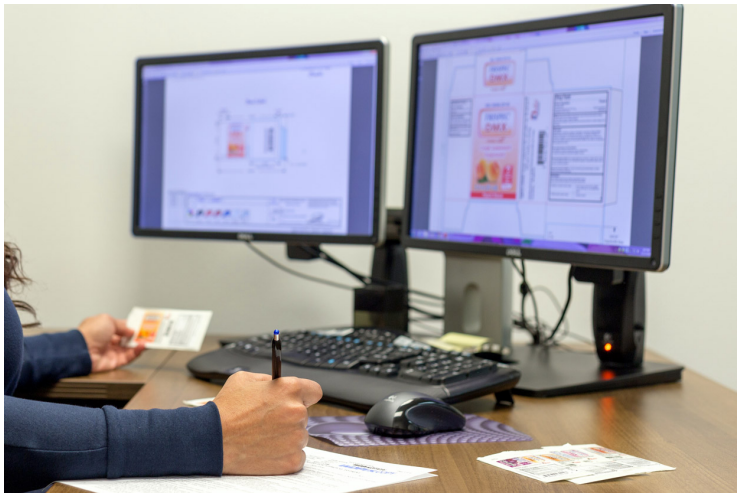
Effective regulatory support paves the way for approval from government and other authorities enabling production and commercialization of pharmaceutical drug products. The WDPrx Regulatory Support team functions throughout development, manufacturing and distribution to assist with timely completion and submission of documentation, as well as to provide optimal pharmaceutical analytical services.

Compliance



Federal regulatory agencies continue to implement more strict compliance guidelines for pharmaceutical drug products. The maintenance of current compliance requirements and the implementation of new regulations are the responsibility of the WDPrx Regulatory Support Department. Comprehensive knowledge of requirements is necessary to design quality systems to comply with regulations. Regulations in the packaging and labeling department are subject to rules established in the Drug Supply Chain Security Act (DSCSA). WDPrx is compliant with current DSCSA regulations.

Drug Listing



Section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires firms that manufacture or process drugs in the U.S. to register with the FDA. Proper registration of pharmaceutical drug products makes it possible to improve public safety by monitoring usage, tracking potential product shortages and determining products that are marketed without prior approval.

Clinical Trial Supplies

Clinical trials are complicated programs demanding precise coordination of multiple procedures. Common components of clinical trial programs include project management, randomization generation, clinical packaging, labeling, blinding, distribution and when required, return and destruction.

The WDPrx Regulatory Support department begins with a complete understanding of project scope by reviewing a clinical trial protocol. A written Quality Agreement is created that meets client protocols. Expertise from Development, Manufacturing, Regulatory, Packaging and Labeling are called upon to establish operations within cGMP guidelines and also other regulatory bodies including GCP, GLP, CFRs and ICH.

Stability studies are conducted to analyze chemical and physical properties, excipient compatibility, manufacturing process and interaction with packaging.

When all elements are in place and authorization is received, the packaged investigational materials are dispensed on a timely basis.

Related Material

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