

CLINICAL PRODUCT PACKAGING

Regulation

Clinical product packaging is highly regulated with FDA compliance regulations for product labeling becoming increasingly stringent with new 21 CFR part 11 and Structured Product Labeling regulations ensuring product integrity and traceability.

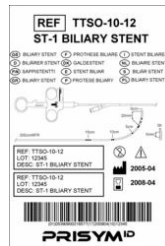
Adherence to these regulations is not only required for US companies selling product in the USA but also for any company seeking to export biopharmaceutical, in-vitro diagnostic kits and devices, medical device, nutraceutical, pharmaceutical, vaccine products to the USA. International regulatory authorities from Asia to Europe are implementing similar standards.

Companies who do not comply with these regulations risk high profile court cases and large financial penalties. Many Life Science market leaders have already taken steps to make sure their manufacturing, distribution and supply processes for clinical products comply with new regulations.

Security

The increase in the counterfeiting of clinical products and packaging materials means secure identification, product information and traceability is vital to all Life Science companies manufacturing and distributing biopharmaceutical, in-vitro diagnostic kits and devices, medical device, nutraceutical, pharmaceutical, vaccine products.

Secure and concise audit trails during the manufacturing and packaging processes allow for full traceability of a products lifecycle. The most vital stage of a products packaging is the container labeling. The product label comprises product and manufacturing information including batch and dates. New labeling technology allows the traceability of production and packaging operators while maintaining required levels of privacy for the manufacturers.



Most software applications currently in use by clinical product manufacturers do not adhere to the specific requirements of the FDA and other leading bodies. Many solution providers implement technology for pharmaceutical companies, which are not fully validated or compliant to current international law.

Future FDA audits will scrutinise medical device and drug manufacturing processes and the ability to provide full traceability for a pharmaceutical product in accordance with international regulations.

For more information about Clinical Product Packaging including our range of package labeling products and services please contact +44 (0)118 936 4400 or email info@prisymid.com