

PRESS RELEASE

For Immediate Release
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Dion Label Printing is a Part 11 and Annex 11 Compliant Printer

Westfield, MA (March 20, 2017) - Dion Label Printing is proud to be registered with the FDA and compliant with both FDA 21 CFR Part 11 and EU Annex 11.

Part 11 was established in 1997 by the Food and Drug Administration (FDA) to regulate security of electronic records. The law was established for pharmaceutical, medical, and similar FDA-regulated biotech companies. As a label printer for those industries, Dion Label Printing was required to complete the process to be a compliant printer and provide guaranteed secure printing.

EU Annex 11 was established in 1992 through the European Union and details the steps needed to maintain Good Manufacturing Practices (GMP) in relation to electronic records and systems. GMP helps maintain quality control over items produced to confirm quality is maintained. The law ties directly into Part 11 as quality and compliance is especially necessary in pharmaceutical and medical companies.

Dion Label Printing understands the importance of maintaining compliance as it is mandatory for some

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of our FDA-regulated customers. As a printer, Dion understands it is now our responsibility to maintain compliance with Part 11 and GMP to meet the needs of our customers as they grow into larger markets.

Co-owner John Dion commented, “As the FDA ramps up enforcement under 21 CFR Part 11, our compliance (and also with EU Annex 11) will provide select customers greater confidence in computer software, system and records security at Dion Label as required under the rules. Although the process is initially time-consuming, maintenance of our status will have minimal effect on the cost of product manufactured accordingly.”

Dion Label Printing is a digital and flexographic label printer located in Westfield, MA. Dion prints labels, shrink sleeves, pouches and specialty medical products for multiple industries. Dion Label Printing is a leader in the packaging industry with two HP Indigo presses, five flexographic presses, shrink sleeve equipment, sustainable practices and print options as well as finishing options including hot stamping, cold foil, embossing, and specialty coatings.

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