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PRESS RELEASE

deltaDOT software enables users to comply with the FDA's data requirements

London, UK, 24th January 2017 – deltaDOT Ltd announced that:

By working with external consultants, deltaDOT now offers an upgraded version of its control and analysis software which has been designed to aid users in achieving compliance with CFR 21 part 11 from the USA's Food and Drug Administration. This package contains technical controls to help meet requirements including checks to ensure that only authorised users can access the system, maintaining audit trails of user actions, generating complete and protected data files and the application of electronic signatures to data.

Nigel Stokes, deltaDOT's Managing Director commented that "We worked with a firm of external consultants (Optra Systems) for over 6 months on software validation relating to the above CFR standard. The aim of the exercise was to ensure that our software provided the tools which our clients need to comply with the regulations, to check that all data produced by the system could be validated, and to put a Quality Management System in place to control any future changes to the software. We are very pleased that this work was completed on time and within budget."

Dr Stuart Hassard, deltaDOT's Chief Scientific Officer added that "With these new software tools we are enabling the use of our technology throughout the bioprocess, and are allowing our clients to make higher quality products using our cost effective process analytical technology. Recent advances in monoclonal, biosimilar and gene therapy viral vector characterisation have greatly increased the range of valuable applications which our instruments can address."

About deltaDOT Ltd

deltaDOT has developed and commercialised highly innovative Life Science instrumentation. The analytical technology is based on an innovative approach to Capillary Electrophoresis. deltaDOT's patented multipoint sensor system together with the proprietary computing algorithms gives superior resolution, accuracy and repeatability compared to similar laboratory instruments. Successful applications of the technology have been found in detection, separation and analysis of proteins, nucleic acids, carbohydrates, viruses and bacteria, drugs, chemicals and a wide range of other analytes.

deltaDOT now sells the HPCE-512 instrument (pictured below) which is the value engineered version of the company's previous product. The HPCE-512 has many improved features such as optional carousel cooling for the samples; the accurate temperature control of samples awaiting analysis is a requirement for high end characterisation work done for example by pharmaceutical clients.

Find out more about deltaDOT Ltd at <http://www.deltadot.com>

deltaDOT HPCE-512 High Performance Capillary Electrophoresis instrument

