

Statement on Food and Drug Administration (FDA) 21 CFR Part 11



Media Cybernetics is aware of the 21 CFR Part 11 regulations for the Pharmaceutical industry

We have studied the regulation and are confident to report that since our release of Image-Pro Plus v4.5, and Image-Pro Premier v9.0 up to and through Image-Pro v11.0, the entire Image-Pro product line has contained partial support for 21 CFR Part 11.

Media Cybernetics' Interpretation of 21 CFR Part 11

Image-Pro (originally released as "Premier v9.0" and now Image-Pro v10) was released in 2012 and contained some features designed to assist companies that are regulated by the Food and Drug Administration of the United States. Our understanding of the regulation is that our product, Image-Pro, cannot be compliant by itself. Each regulated company must implement a system of compliance. This system of compliance should contain proper administration of regulations within the company, and proper implementation of products that support 21 CFR Part 11 regulations. Our product supports compliance of portions of 21 CFR Part 11 through the features described below:

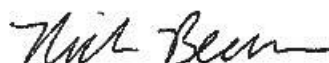
Audit Trail - The Audit Trail records, in a graphical display, all Image-Pro events to an in-product viewer and log file located on the hard drive. FDA regulations require both application level and image-level (electronic record) audit trails. Our Audit Trail provides both records, allowing a company to save full history of application-level use and of a document's changes, with embedding capability. This information enables a company to show how individual files were created and altered by Image-Pro's image processing features. Additionally, the FDA states that audit trail files must be read-only. Our audit trail file is not inherently read-only, but as the Microsoft Windows operating systems must be in place to run the application, the operating system has robust security features which can be employed by the pharmaceutical company to ensure that the log file is not editable.

Image Signature - The Image Signature feature creates a "fingerprint" of an image. This feature generates a checksum value that is based on the data within an image. The value is unique for a given image. If the image data changes in any way, the "fingerprint" would also change. The "fingerprint" can be sent directly to a report file. If this report file is made to be read-only through the OS, it can serve as an authenticator of the image data. We feel this feature helps support the electronic records portion of 21 CFR Part 11 by showing whether image data is intact or changed from a given point in time.

File Signature - The File Signature feature creates a "fingerprint" of an image file. An image file includes the image data and all headers or other tagged information associated with the file. This feature generates a checksum value that is based on the data within a file. The value is unique for a given file. If the file data changes in any way, the "fingerprint" would also change. The "fingerprint" can be sent directly to a report file. If this report file is made to be read-only through the OS, it can serve as an authenticator of the image file data. We feel this feature helps support the electronic records portion of 21 CFR Part 11 by showing whether image file data is intact or changed from a given point in time.

Media Cybernetics' Quality System

If your organization has registered one or more copies of Image-Pro Premier and needs documentation to support compliance issues, Media Cybernetics can provide information concerning its software development quality system once a nondisclosure agreement is in place between Media Cybernetics and the interested organization. We have documents and procedures in place to provide Quality Assurance during Software Development, product release and post release support. In addition, Pharmaceutical companies can audit Media Cybernetics at their expense provided that the proper notification and arrangements are made in advance.



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