

Media Cybernetics Software and Food and Drug Administration 21 CFR Part 11

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

We have studied the regulation, attended seminars and workshops to gain insight into the regulation, and will continue to do more in the future. In addition, we are actively working to implement these findings into our products. This effort is evidenced by the fact that since our release of Image-Pro Plus 4.5, the Image-Pro product line has contained some support for 21 CFR Part 11.

Media Cybernetics' Interpretation of 21 CFR Part 11

Image-Pro Plus 4.5 was released August 15, 2001 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 Plus versions 4.5 and higher, 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 AutoPro (Macro) script, all Image-Pro events to a log file located on the hard drive. In other words, this is an application-level audit trail. FDA regulations require both application-level and image-level (electronic record) audit trails. Our current Audit Trail does not provide individual record auditing, but with some work, a company can save this information 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 Windows 2000 or Windows XP Professional operating systems must be in place to run the application, the operating system has robust security features which can be employed 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 include 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.

Supplemental Support for 21 CFR Part 11

We have established a strategic marketing relationship with VelQuest Corporation (35 South St. Hopkinton, MA 01748 (508) 497-9911), whose products and services focus on the unique needs of the pharmaceutical development and quality control operations. Our engineering collaboration has assured that Image-Pro Plus version 5.0 and higher can operate under the auspices of the SmartShell™ product from VelQuest. This relationship enables custom installations that need to incorporate image analysis using the Image-Pro Plus product line.

Media Cybernetics' Quality System

If your organization has registered one or more copies of Image-Pro Plus 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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