

# Euthymics Bioscience Chooses GlobalSign's FDA-compliant Digital Signature Solution to Streamline Document Exchange

## SOLUTION SUMMARY

Euthymics Bioscience's existing paper-based workflow involved hand-signing and manually managing document distribution, storage, and retrieval. Realizing that this method was not only increasing costs, due to the overhead of archiving, mailing, and faxing documents, but also extending project schedules and deadlines, they sought to replace it with an FDA-compliant digital signature solution.

Using GlobalSign's PDF Signing solution allows Euthymics to streamline their document sharing process, reducing the overhead costs associated with manually signing and distributing documents and speeding up document delivery times. The solution is compliant with Title 21 CFR Part 11, which outlines the FDA's requirements for digital signatures, and is automatically recognized by PDF reading software, making it easy for recipients to know the document's origin and that it hasn't been modified.

*"By combining a physical token and a password to protect access, GlobalSign's PDF Signing solution delivers both security and convenience to end users.*

*Having secure digital signature hardware for use on a widely supported Adobe Acrobat platform is very helpful. By using a program such as Adobe Acrobat, any recipient receiving the digitally signed document can open the PDF document as they normally would and the digital signature will display the name of the signer and a timestamp."*

Anthony McKinney  
President and CEO  
Euthymics Bioscience, Inc.

## Challenge

Euthymics Bioscience, a biopharmaceutical company focused on neuroscience, was required to hand-sign large volumes of documents and manually manage the process of distribution, storage, and retrieval of all signed records. This manual process extended project schedules and deadlines and resulted in high overhead costs due to archiving, mailing, and faxing the documents.

Recognizing the disadvantages of relying on paper-based workflows, Euthymics sought a digital signature solution that would automate and streamline the exchange of documents, and, most importantly, comply with federal regulations regarding electronic signatures and records. Title 21 CFR Part 11 of the Code of Regulations establishes FDA guidelines under which electronic records and signatures and considered trustworthy, reliable, and equivalent to paper records.

## Solution Requirements

- Streamline exchange of documents from remote locations
- Comply with FDA regulations on digital signatures (Title 21 CFR Part 11)
- Easy for end users to adopt

## Solution

GlobalSign is an authorized participant in Adobe's Certified Document Services (CDS) program, meaning all PDF Signing certificates are instantly recognized by PDF reading software. PDF Signing certificates are stored on FIPS-compliant USB tokens, enabling the digital signature process to meet all regulatory requirements and criteria for securing electronic information in the pharmaceutical industry. Digitally signing a PDF with a GlobalSign PDF Signing certificate is the virtual equivalent of sealing a document and adding a wet-ink signature. It assures the recipient that the document is authentic, comes from a verified source, and the contents have not been tampered with since being published.

## Results

Reaction from both authors and recipients of the digitally signed documents has been positive. Since Euthymics' deployment of PDF Signing, it has been widely accepted and adopted both internally throughout the company and externally through third party partners. Euthymics customers, employees, and third party partners quickly adapted to the new digital signatures due to their integration with Adobe Reader, a free product that does not require the purchase of any third party applications, technical experience, or knowledge.

GlobalSign's PDF Signing solution has provided Euthymics with a streamlined, portable process to expedite and improve current document sharing and security workflows. This streamlined process has significantly reduced the cost, time, and complexities of the old, paper-based workflows. Adopting a digital signature solution has resulted in decreased overhead costs associated with document storage, security, transportation, delivery, and archiving, and shortened document delivery times by reducing approval cycle times, handling, and distribution of documents from remote locations.

## About Euthymics Bioscience, Inc.

Euthymics is a private San Diego-based biopharmaceutical company focused on developing next generation treatments for neuropsychiatric disorders. Euthymics was co-founded in early 2009 by Anthony McKinney, Frank Bymaster, and Gary Tollefson, former leading members of management from Orexigen, a San Diego biotechnology firm.

Additional information regarding Euthymics Bioscience is available at <http://euthymics.com/>.

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