



A Pathology Lab on the Right Path

Tox Path Specialists LLC, a pre-clinical drug development firm.

“Reports are our big deliverable,” explains Jake Butt, Research Associate at Tox Path Specialists LLC, a pre-clinical drug development firm supporting companies and other institutions developing neuroactive pharmaceuticals, devices and other therapies.

Working with 50+ active company, academic and CRO clients, Tox Path provides a range of pathology services dealing primarily with the Central Nervous System. Each week the Frederick, MD based laboratory generates multiple reports averaging 40-50 pages. The occasional report comprises 2000 pages.

“Before we took the steps to go paperless, printing, signing, shipping and archiving the reports was a drag on our operation,” he explains.

“The paper also slowed down our clients.”

In Q2/2013 the company concluded it needed to embrace digital technology and looked for the best way to do it.

“We looked at a number of options, and decided that, given our Good Laboratory Practice requirements, we wanted to use a standardized signing capability with an FDA and EMA track record. This saved us the effort in going through a costly internal regulatory validation process.”

Like most global biopharmaceutical companies and other organizations, Tox Path decided on identity credentials based on the global SAFE-BioPharma standard. The company uses them ex-

clusively to apply digital signatures to electronic documents.

For the past six months the firm’s senior people have been signing reports digitally and they, and others, use their credentials to digitally-sign a variety of internal documents, including those for version control.

“The time and date stamp and document protection features of the SAFE-BioPharma signatures are very useful to us,” Jake explains, adding that clients, especially, appreciate the time stamp feature.

Was it difficult implementing SAFE-BioPharma signatures?

“There were a few initial glitches, but SAFE-BioPharma was on top of the process with strong support. Getting set up was typical of getting underway with most tech implementations. Once set up it’s been smooth sailing.”

Are all clients on board with digitally-signed, paperless documents?

“It’s a company-by-company preference. A minority aren’t comfortable with paperless, so we process their reports the old-fashioned way. We print, sign, FedEx, etc. It takes time and it costs more, but some habits can be hard to break.”

Will that change with time?

“My colleagues and I think so. It’s transformed how we do business at Tox Path, and most of our clients have embraced the process. It’s simply a matter of education and time.”