

Life Science ECM System & Services

Company

Carnegie Technology Associates is a nationally recognized consultancy founded in 1996 to focus exclusively on providing information technology and regulatory compliance solutions to the life sciences industry. Our clients include start-up companies, as well as leading companies in the life sciences industry.

Technical Expertise

We specialize in building the information technology infrastructure, as well as the policies and procedures for regulated data management.

All our consultants have extensive experience with the selection, implementation, validation, and support of GXP computer systems for use in pre-clinical, clinical, and marketed product data management.

Approach

We use a no-nonsense, risk-based approach on each of our projects to ensure that the least burdensome path is taken to achieve maximum system utility and regulatory compliance. This approach also helps us to consistently complete projects on time and within budget.

Life Sciences ECM System

Since document management is such a critical activity in the life sciences industry, it is important to select a document management system that meets all business and regulatory requirements, and can be licensed, deployed, and supported for a reasonable cost.

The Life Science ECM System – based on the Nuxeo ECM platform (www.nuxeo.com) – is an ideal choice for the life sciences industry since it complies with all the requirements of the FDA regulation for electronic records and electronic signatures (i.e. FDA 21 CFR Part 11) and can be used successfully in any GXP regulated environment for a fraction of the cost of any other ECM system.

Life Sciences ECM Services

We offer a full range of services for the implementation, validation, and support of our Life Sciences ECM System.

Implementation

To ensure that the document management system we deliver meets all your needs we begin with a core set of requirements and, through a configuration workshop, refine these requirements to capture your specific business and regulatory needs.

Validation

We begin with your specific user requirements and develop a full set of document deliverables spanning the analysis, design, build, test, and rollout phases of the validation life cycle.

All of our tasks and document deliverables are based on the GAMP 5 standard and clearly demonstrate that the system we deliver is fully validated for its intended purpose.

Support

The support models for our Life Sciences ECM System include incident-based support, and annual-based support.

We also provide a full range of consulting services to assist with the development of custom reports, and custom extensions of the system.

Offices

We have offices in the following locations:

- San Francisco, CA
- La Jolla, CA
- Chicago, IL
- Cambridge, MA
- Princeton, NJ

For details regarding our Life Sciences ECM System and related services, please contact our managing director Lawrence Rich at 415.726.3875 or lrich@ctaconsulting.com.