



MOONBAY
TECHNOLOGY

PIPELINE EDM™

Regulatory Document Management

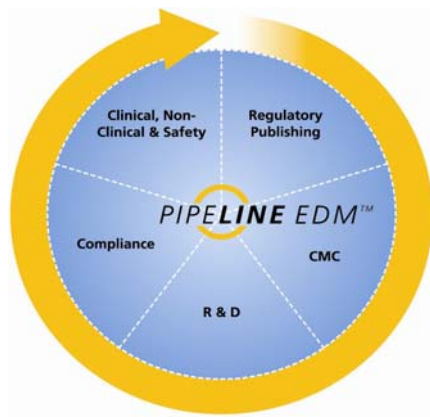
Hosted IT Answers by Distributed Compliance Solutions

What is DCS?

DCS (Distributed Compliance Solutions) presents a *“solution of partnerships”* to provide hosted, turn-key compliance solutions.

DCS is designed specifically for small and medium businesses who need to meet regulatory requirements, but lack the IT infrastructure or resources to purchase and maintain the necessary systems and tools, in-house.

PIPELINE EDM is Based on SaaS Technology with a Web User Interface that is comprehensive, yet simple, *PIPELINE EDM* dramatically saves time and money for companies already strapped for resources. *PIPELINE EDM* reduces the total cost of system ownership as the only IT requirements are an internet connection and a browser.



Why *PIPELINE EDM™*?

Based upon real-world experience within Pharma and Biotech companies, Moonbay Technology has developed a web-based application, *PIPELINE EDM*, that has two seamlessly integrated components: regulatory document management and electronic publishing. *PIPELINE EDM* transforms your documents to be submission-ready providing significant time and operational efficiency that can save months of labor-intensive compilation.

***PIPELINE EDM* is Powerful, Yet Straightforward**

PIPELINE EDM provides the features of an enterprise based document management system by providing document check-in, check-out, version control, workflows and audit trails.

***PIPELINE EDM's* Technology is Smart**

The workflows built into *PIPELINE EDM* follow the general practices of the biotechnology and pharmaceutical environments.

21 CFR Part 11 Compliant and Validated

PIPELINE EDM complies with 21 CFR Part 11 requirements. DCS maintains Moonbay's compliance documentation, such as procedures for Installation Qualification (IQ), Operation Qualification (OQ) and Performance Qualification (PQ), disaster recovery, change control, acceptance testing, and system monitoring.

Distributed Compliance Solutions host servers and software already configured with Moonbay's software and best practices.



DCS Services

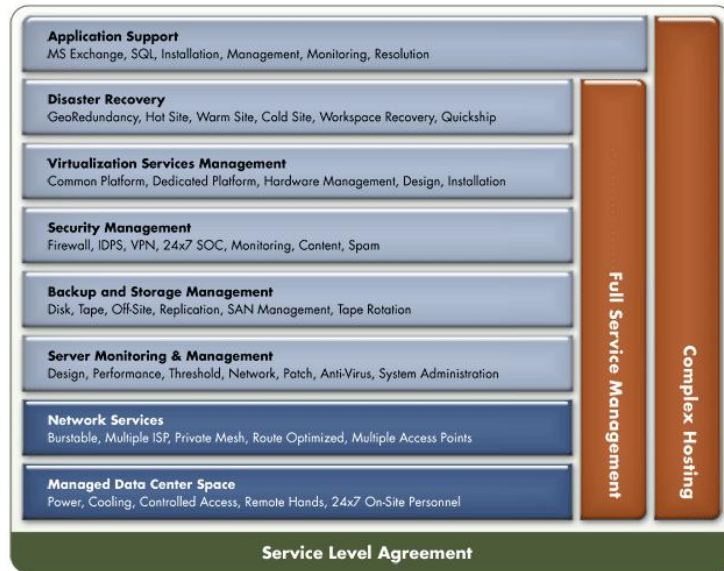
In the initial stages of drug development, life science and biotechnology companies need to focus their talents, time and financial resources on research and development. And yet, there is an obvious need for collaboration with outside vendors and partners while controlling content and protecting IP.



DCS provides the solution with a price structure that reduces IT costs dramatically over purchasing and maintaining the necessary IT structure in-house.



Managed Data Center services provided by Peak 10 of Richmond



DCS and our Hosting Site

Our hosting partner, Peak 10, provides 'state of the art' facilities. Each site provides highly skilled technical personnel, 24x7x365 and are engineered with multiple levels of security, uninterruptible power, redundant HVAC systems and fire suppression. Data backup solutions are included and disaster recovery services are available, including auto hot-site failover. All this, means around-the-clock monitoring and management of your critical content.

Regulatory Compliance

The sites are SAS 70 Type II compliant. SAS 70, is an auditing statement issued by the Auditing Standards Board of the American Institute of Certified Public Accountants (AICPA). SAS 70 defines the professional standards used by a service auditor to assess the internal controls of a service organization and issue a service auditor's report. A Type II service auditor's report includes the service auditor's opinion on the fairness of the presentation of the service organization's description of controls that have been placed in operation and the suitability of the design of the controls along with the auditor's opinion on whether the specific controls were operating effectively during the period under review.

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