HP TRIM software: document and records management for the life sciences industry

Solution brief

HP TRIM software is a proven enterprise records management solution that helps you manage your life sciences information and comply with regulations and legislation.

Challenges in the life sciences industry

Today the life sciences industry has blurred the lines that once separated pharmacology, biotechnology, and other healthcare disciplines. Your organization may be involved in one of these traditional areas or in research that extends across all elements of life sciences.

In addition to the challenges you face in your scientific work, you may be confronting increasing financial constraints. Life sciences is a very highly regulated industry that is facing rising research and development costs, shorter time to production cycles, and fierce competition.

Bringing new products to market

To deliver treatments for human use requires a license that is issued by the appropriate regulatory authority. For example, the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA)—an executive agency of the Department of Health—works closely with the European regulator, the European Medicines Agency (EMEA), to issue licenses. In the United States, the U.S. Food and Drug Authority (FDA) applies close scrutiny to a new drug before it can be released to the market. To obtain a license for a drug, a manufacturer must prove its quality, safety, and efficacy.

In general, you need to complete several phases before getting a license for a new product, including discovery, research, and development. The failure rate during these phases is usually high, and some products never reach the market.

Each phase in the development of a new product contributes to the cost of production and the final product. During each phase, you need to carefully gather, collate, and analyze data before deciding to move to the next phase and at the same time maintain this information for subsequent quality control, audit, and discovery. Maintaining control over each stage of the research and developmental process is essential regardless of whether a product or service finally reaches the market.

Managing the data explosion

You are required to demonstrate to regulatory authorities that a product meets the required standards of quality, safety, and efficacy for accreditation. Forty years ago a clinical study may have been documented in 350 pages; today it is closer to 25,000 pages!

Your staff collaborate and document everything they do during the research, development, and production processes. The communications created during this collaborative process need to be retained for quality control, audit, and discovery purposes. Increasingly, you may be using newer technologies during this collaboration process such as emails, wikis, discussions, and blogs. Each of these types of content needs to be managed in context with the project at hand. What is important is not the technology but the processes and systems you have to manage this information for its various users, be it for project management, financial, or legal purposes.

To meet product, market, and regulatory challenges, you need to electronically store the large amounts of data you generate. You need to manage this information seamlessly, efficiently, and securely across your organization, from development to manufacturing, as well as sales and marketing. Effective and structured management of this information is critical to reducing your regulatory or legal risk and decreasing the time to market.

You also need to consider the legal discovery implications for all information. You must define retention schedules for electronic records (including email, discussion forums, and other new technologies) so that they can be used as evidence to support (or defend) an alleged civil, criminal, or legislative infringement. The statute of limitations for civil and criminal proceedings can occur years after an alleged incident, and physical and electronic records may be required as evidence.

If electronic records are likely to be called as evidence, then you should also address their legal admissibility. By implementing the necessary security and policy controls, you can prove that an electronic record is authentic and unchanged from its time of archival.

Having a records management system in place makes it easy to demonstrate to any investigative or auditing authority that you can capture and produce all information in accordance with your legislative obligations.

Life sciences and HP TRIM

To address the stringent information management needs of the life sciences industry, many forward-thinking organizations are turning to enterprise records management systems, such as HP TRIM software, to manage the documents and records generated across a product's lifecycle.

HP TRIM software provides a scalable, policy-driven foundation to your information governance strategy, driving business efficiency and records integrity. A proven enterprise records management system, HP TRIM can capture all the business decisions and records that your organization generates regardless of source—including email, messages, documents, forum discussions, blogs, wikis, images, audio, and video—along with the context in which they were made and manage these records for their life. It helps life sciences organizations such as yours to realize best practices information management. It also helps you to achieve the regulatory compliance obligations you have and make you prepare for legal discovery, investigation, or audit.

In an effort to achieve new economies of scale and to reach new markets, the life sciences industry is undergoing considerable consolidation: Major global mergers and acquisitions have led to vast research and development organizations where information management scalability and ease of integration with legacy systems are paramount.

HP TRIM is low risk and has a proven track record of implementations that demonstrate its adaptability and scalability. For example, some HP TRIM installations have more than 350,000 users. HP TRIM, with an ability to support very large global enterprises in the life sciences industry, can also help you capture the dramatic increase of electronic information in your organization.

HP Services

Get the most from your software investment. With HP, you have access to standards-based, modular, multi-platform software coupled with global services and support for all aspects of your application lifecycle needs. The wide range of HP service offerings—from online self-solve support to proactive mission-critical services—enables you to choose the services that best match your business needs.

For an overview of HP Software Professional Services for HP Information Management software, visit **www.hp.com/go/imservices**

To access technical interactive support, visit Software Support Online at **www.hp.com/managementsoftware/services**

To learn more about HP Software Customer Connection, a one-stop information and learning portal for software products and services, visit **www.hp.com/go/swcustomerconnection**

To understand how HP TRIM can help you manage your life sciences information and comply with regulations, please visit www.hp.com/go/hptrim

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