



Content Management for Regulated Industries

Push your life sciences business to new success with a content management for regulated industries solution

How do you continue to innovate, bringing new products and processes to the \$1.5 trillion life sciences industry, while maintaining tight regulatory compliance with governmental guidelines such as the FDA's 21 CFR Part 11 and the EU's Annex 11? That's the major question facing life science businesses around the world. As their organizations become ever more data and document intensive, CIOs are tasked with meeting increasingly complex demands.

Against a backdrop of growing regulatory pressure and competition, decreasing product pipelines, and the rising costs associated with drug development and commercialization, life science companies – such as those in the pharmaceutical, biotech, and cosmetic sectors – are under strain like never before.

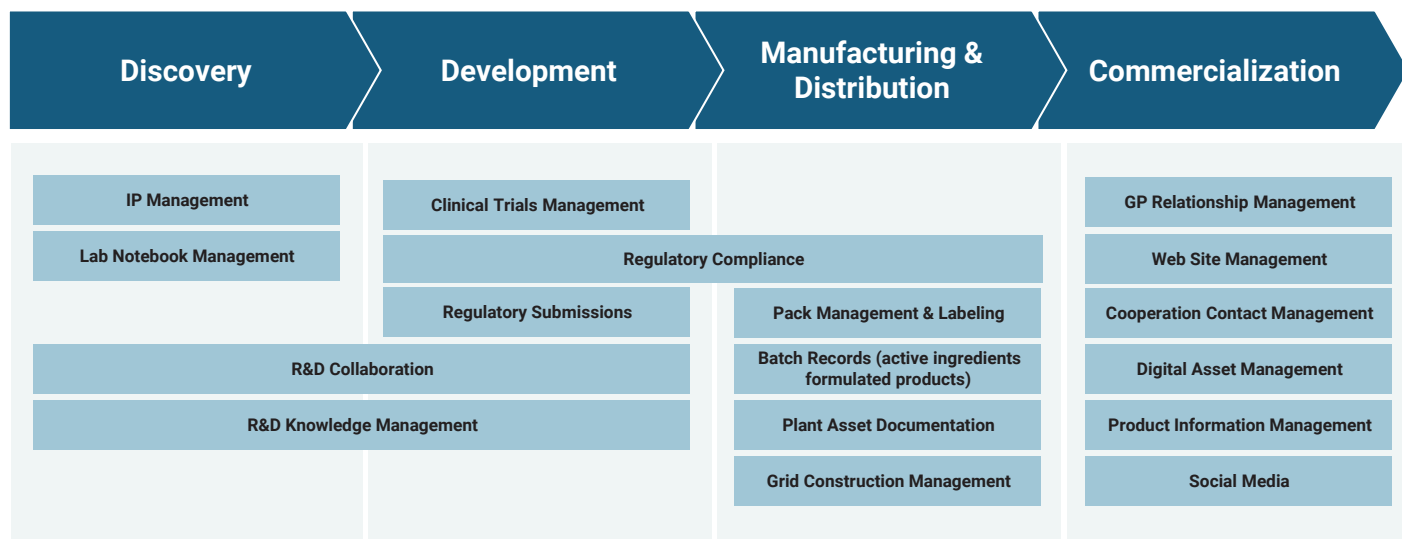
Improving product pipelines and reducing time-to-market are key to long-term success. But achieving this, and making the best possible

decisions, requires disparate teams and departments to have access to the same information at exactly the same time. Huge quantities of information stored on legacy systems also need to be made available to all stakeholders.

TerraLink's content management for regulated industries solution, which is based on OpenText™ Regulated Information Management, provides convenient access to all documents within a controlled environment.

Actual customer results

- Document approval process costs reduced by 60% in one year
- Manual document processing time reduced by 66%
- 100% regulatory compliance achieved



Regulated Information Management across the Life Science value chain

Installing TerraLink's content management for regulated industries solution enables life science companies to accelerate time-to-market while complying with federal and international regulations. And its extensive collaboration features, electronic signature capabilities, and content categorization via metadata and taxonomic classifications, make managing and controlling key documents throughout their lifecycle easier than ever.

Selected solution highlights

- Store content in a powerful, highly scalable repository capable of managing millions of documents – including text, spreadsheets and drawings.
- Enjoy ultimate control with a nine-level permission model so only appropriate users can conduct the actions you choose.
- Meet compliance obligations with extensive version control features, including change histories and audit trails that reveal when, what and why changes were made to documents.
- Work across all document lifecycle phases, from authoring, review and approval through to release, change, retirement, and archiving.
- Connect directly via Microsoft Word or Adobe Acrobat by using the desktop integration features.

How can TerraLink help your business?

- Enhance competitive advantage and accelerate time-to-market by providing an efficient system in which documents are managed and automatically comply with FDA 21 CFR Part 11 and EU Annex 11.
- Increase productivity and efficiency by providing a single repository for securely organizing, controlling, and sharing enterprise content.
- Minimize change management and training costs by providing access to content via familiar desktop applications.
- Create business value and achieve strategic success with an intuitive workflow designed to provide security, control and appropriate accessibility for all content throughout its entire lifecycle.

Experts trusted around the world

- More than 200,000 global users benefit from TerraLink ECM solutions
- A team of 200+ skilled professionals are ready to implement your solution
- The average TerraLink team member has 11.4 years' experience
- TerraLink has been an OpenText Platinum partner since 2009
- Guaranteed stability, scalability and innovation

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Our solutions



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