

Debenu PDF Aerialist Pharma Edition Whitepaper 2014 v1.2

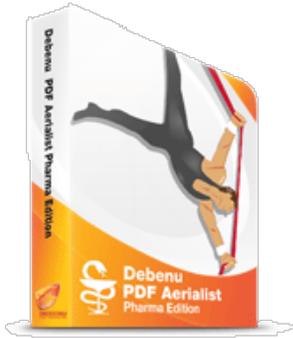


Table of Contents

[Background](#)

[User Requirement Specification](#)

[Total Solution Offering](#)

[Deployment and Training](#)

[Support Resources](#)

[Technology and Quality integrated - Software Validation](#)

Background

The pharmaceutical industry strives to satisfy both the urgency of speed-to-market and the high standards set by global regulators and other key stakeholders. Driven by these dual pressures, effective automation solutions facilitate swift approval processes by saving time and minimizing the risk of manual handling errors.

Optimizing total quality management while saving time and resources is a key goal in an industry where, in a very real sense, time *is* money. This is especially true in the current economic climate and navigating this process requires pharmaceutical grade software that facilitates this process.

Recognition of the needs of business level clients spurred the development of numerous offerings, from self-contained software applications to enterprise-level, managed solutions. While the latter offer a high-end, customized approach, this flexibility comes with a similarly high-end price tag, and involves lengthy periods of implementation and training. Meanwhile, what applications may lack in personalization, they make up in well-tested and standardized functionality.

This distinction can be significant in highly regulated sectors such as healthcare and pharmaceutical industries. There, consistency and compliance with relevant standards are crucial. That being the case, it can be argued that custom solutions pose greater risks than desktop products. Reliable software is strongest when the product is based on robust, mature technology, and built according to industry standards by experts. One desktop product that fulfills all of these criteria is Debenu PDF Aerialist Pharma.

The core technology behind Debenu PDF Aerialist Pharma drove the very first Acrobat Acrobat plug-ins for working with PDF. In this sense, Aerialist and its predecessors have empowered Acrobat and its users for more than 15 years.

Used in government (e.g., FDA), pharmaceutical, legal, finance, IT and publishing industries, Aerialist remains a popular, fully-featured plug-in for working with PDF documents.

Developed in response to the sheer demand for a validated solution to eCTDs, Debenu PDF Aerialist Pharma Edition was released in 2014. Designed specifically for our customers in the healthcare and pharmaceutical industry.

With a custom designed feature set purpose-built to comply with requirements set out by local and global regulatory authorities. Debenu PDF Aerialist Pharma serves to speed up report compilation, maximize total quality management, and reduce the margin of error.

User Requirement Specification

Specialized functionality of Debenu PDF Aerialist Pharma Edition supplements that of Adobe Acrobat to meet the high standard expected in the Pharmaceutical Industry.

In the process of developing Debenu PDF Aerialist Pharma a number of needs were identified that were unique to the pharmaceutical industry. Below is a list of selected Debenu PDF Aerialist Pharma functionality based on user specifications.

Features Included in Debenu PDF Aerialist Pharma

Debenu PDF Aerialist has been engineered to complement the power of Acrobat. It is continuously updated by the Debenu development team to ensure that this partnership delivers optimal results. Many Pharma solutions for Acrobat include features that overlap with those of Acrobat. As such, clients may unknowingly pay for this duplication. Debenu actively connects Acrobat and Aerialist Pharma to offer maximal intelligence from within a unified system. Key needs and functionality of Aerialist and Acrobat are outlined below in Table 1.

Table 1.

URS	Description	Function Group
4.1	<p>Need: Quickly linking a set of related documents to make it easy for regulatory bodies to navigate complex submissions.</p> <p>Solution: Generate roadmap bookmarks in multiple files at once.</p> <p>With its Bind Documents feature, Debenu PDF Aerialist Pharma can generate bookmarks across multiple documents based on folder</p>	Bookmarks

	<p>structure and file name, and/or create a “master” table of contents, where each entry links to an external document.</p>	
4.2	<p>Need: Automating standard document preparation tasks can prevent costly and time-consuming manual processing.</p> <p>Solution: Apply multiple tools to thousands of files at once. Save, reuse and share workflows.</p> <p>Adobe Acrobat’s Action Wizard can administer tools in order, using pre-defined settings across thousands of documents. These actions can be saved for sharing and re-use.</p>	Acrobat
4.3	<p>Need: Validating that bookmarks and links function correctly is crucial to ensure that submissions meet key standards and can be easily navigated to streamline approval processes.</p> <p>Solution: Audit, modify and spell check bookmarks and links.</p> <p>A range of features (Audit Links (or bookmarks), Bookmarks > Edit All Properties and Links > Edit All Properties) allow Debenu PDF Aerialist Pharma to audit and fix dead bookmarks and links, and to systematically modify links and bookmarks within documents.</p>	Bookmarks Links
4.4	<p>Need: Ensuring standard properties for bookmarks contributes to a consistent reader experience (i.e., look-and-feel) within and between documents.</p> <p>Solution: Modify bookmark attributes and save settings as reusable styles.</p> <p>Using the “Bookmarks > Edit All Properties” feature, Debenu PDF Aerialist Pharma can modify bookmark and link properties within a PDF individually or in bulk.</p>	Bookmarks
4.5	<p>Need: Intelligently adding bookmarks based on standard formatting elements saves time and money, and ensures simple navigation for regulatory evaluation.</p> <p>Solution: Create bookmarks based on font information, location, keyword or created links automatically.</p> <p>The Build Bookmarks and Add Bookmarks features allow Debenu PDF Aerialist Pharma to easily create bookmarks based on font information, selected text samples, keywords (with user-defined inclusions and exclusions), and text location (e.g., tables of contents), along with file names and locations (including hierarchical folder structure).</p>	Bookmarks
4.6	<p>Need: Intelligently editing bookmarks based on standard formatting elements saves time and money, and ensures simple navigability for regulatory evaluation.</p> <p>Solution: Create bookmarks based on font information, location, keyword or created link automatically.</p>	Bookmarks

	<p>The Build Bookmarks and Add Bookmarks features allow Debenu PDF Aerialist Pharma to easily create bookmarks based on font information, selected text samples, keywords (with user-defined inclusions and exclusions), and text location (e.g., tables of contents), along with file names and locations (including hierarchical folder structure).</p>	
4.7	<p>Need: Maintain navigational functionality when splitting or merging documents. This avoids breaking links and bookmarks, which makes it more difficult to evaluate documents.</p> <p>Solution: Delete bookmarks and hyperlinks to prepare for importing, or delete all broken links in a document.</p> <p>Using the Delete Bookmarks and Delete Links features, Debenu PDF Aerialist Pharma can delete bookmarks or links that are not needed. With options to determine the type and location of links/bookmarks deleted or saved.</p>	<p>Bookmarks</p> <p>Links</p>
4.8	<p>Need: Converting forms and documents to standardised PDF format as they are received to ensure they can be accepted by regulatory bodies.</p> <p>Solution: Convert multiple files of varying types into a single PDF or individual documents.</p> <p>Adobe Acrobat can convert files in almost any format into either separate PDFs or a single PDF that combines all of the original documents.</p>	<p>Acrobat</p>
4.9	<p>Need: Create scanned documents that are easy to navigate by using Optical Character Recognition (OCR) and then adding interactive bookmarks.</p> <p>Solution: Create bookmarks for image-based PDFs using OCR.</p> <p>Acrobat can perform OCR on PDF files either individually or in batch. Once text has been recognized, Debenu Aerialist Pharma offers numerous options for creating bookmarks via its Bookmarks functions, including Add Bookmarks and Build Bookmarks.</p>	<p>Acrobat</p> <p>Bookmarks</p>
4.10	<p>Need: Automatically generating consistent links based on PDF text content saves time and removes errors involved in manually creating what can be thousands of links.</p> <p>Solution: Generate internal or external hyperlinks dynamically based on PDF text.</p> <p>Acrobat and Adobe Reader (the most popular free PDF viewer) automatically recognize text in the format of web locations and treats these as hyperlinks. Using its Create Keyword Links feature, Debenu PDF Aerialist Pharma can create external links by based on keywords (including phrases) located anywhere within a PDF. The Create Page Links can search through pages or page ranges to locate and automatically link page numbers.</p>	<p>Acrobat/Reader</p> <p>Links</p>

4.11	<p>Need: Deliver a consistent reading experience across documents to facilitate the approval processes by ensuring that all submissions conform to appropriate standards.</p> <p>Solution: Convert documents to a specified PDF version ensuring consistency by optimizing and converting thousands of PDF documents to one specified version.</p> <p>Acrobat can optimize and convert PDF documents individually or in bulk, via its Action Wizard feature.</p>	Acrobat
4.12	<p>Need: Ensuring standard properties for links contributes to a consistent reader experience within and between documents.</p> <p>Solution: Modify all hyperlink attributes (border and text color, magnification, etc.) and save settings as reusable styles.</p> <p>With its Set Link(s) Properties feature, Debenu PDF Aerialist Pharma can modify link attributes across an entire document, selected pages or ranges, and can be set to change only visible links.</p>	Links
4.13	<p>Need: Combining all documents related to a particular submission ensures that no crucial files can be lost in transit.</p> <p>Solution: Join multiple PDF files into a single document while maintaining accurate navigation.</p> <p>Debenu PDF Aerialist Pharma can easily merge numerous PDF files while preserving navigational elements, using its Merge feature.</p>	Content Assembly
4.14	<p>Need: Good information about the nature of document output is necessary to refine document preparation processes.</p> <p>Solution: Generate comprehensive reports about your PDFs (number of hyperlinks, bookmarks, etc.).</p> <p>With its Audit Reports feature, Debenu PDF Aerialist Pharma can generate reports on the numbers and validity of actions, links, bookmarks, and external dependencies.</p>	Links
4.15	<p>Need: Delivering a consistent reader experience is important when working in a highly regulated industry.</p> <p>Solution: Modify document information fields, file option options and security settings within several PDF documents simultaneously</p> <p>Using the Action Wizard, Acrobat can simultaneously modify document metadata (AKA document information), initial viewing settings and encryption across many PDF files.</p>	Acrobat
4.16	<p>Need: In order to ensure consistent and compliant document output, it may be necessary to apply logos, headers, footers or even interactive content</p>	Stamps

	<p>across pages or documents.</p> <p>Solution: Apply custom headers, footers, page numbers, and/or master pages across PDFs.</p> <p>Acrobat can apply a variety of stamps, watermarks headers and footers individually or in bulk, via the Action Wizard. Debenu PDF Aerialist's Stamp feature can apply letterhead, headers, footers, Bates numbers, letterhead, or even interactive elements.</p>	
4.17	<p>Need: Ensuring that bookmarks and links function correctly facilitates easy navigation of documents, which in turn allows faster review and approval. Dead links and bookmarks can slow this process.</p> <p>Solution: QC document(s) on link and bookmark validity.</p> <p>Using the Audit Links (and bookmarks) feature or the Dead Link Toolbar, Debenu PDF Aerialist Pharma can locate and fix broken links and bookmarks, either manually or automatically. Invisible links can also be easily located using the Link Selection Tool.</p>	<p>Bookmarks</p> <p>Links</p>
4.18	<p>Need: Creating links of an appropriate size so that they are not too small and cannot be found or too large and interfere with other content.</p> <p>Solution: Create perfectly sized text links by selecting text.</p> <p>Acrobat can easily create links from selected text using a context menu.</p>	<p>Acrobat</p>
4.19	<p>Need: Create tables of contents quickly and easily to there is a built-in roadmap for paper documents, and to make them directly interactive in PDF files for easy navigation.</p> <p>Solution: Generate bookmarks and links from tables of contents.</p> <p>Starting with a table of contents (TOC), Debenu PDF Aerialist Pharma can generate bookmarks (via Add Bookmarks feature), page links (via Create Page Links). Debenu PDF Aerialist Pharma can even create linked PDF TOCs from bookmarks, heading/font information, or folder structure and filenames. It can do this either for a single document or in batch, when combined with Acrobat's Action Wizard.</p>	<p>Bookmarks</p> <p>Acrobat</p>

Total Solution Offering

Debenu PDF Aerialist Pharma is purpose-built to achieve compliance, maintain consistency and remove tedium from the process of document creation in the healthcare and pharmaceutical sectors. It constitutes the processing power behind regulatory electronic submissions, with features that produce faster approvals.

As desktop software, Debenu PDF Aerialist Pharma features competitive pricing that scales sensibly from individual licenses to department-wide installations. The volume pricing scheme also accommodates workforce growth, allowing for scalability within organizations.

This is driven by the Debenu company creed, which holds that quality makes good business sense.

Premium Upgrade Protection can also be added to any license pack. This provides clients with major version upgrade protection for 12 months. Minor upgrades are always free.

Deployment and Training

Debenu PDF Aerialist Pharma Edition works hand-in-hand with Acrobat, and is simple to deploy and use. It is intuitive and guides the user through the process of installation so that he or she can get to work immediately. Additional support is available via instructor-led online courses. These classes demonstrate how to Acrobat and Aerialist in concert to ensure the best, most consistent results.

Support Resources

The Debenu team has more than 20 years of experience in PDF, and has actively contributed to the approval of PDF standards and specifications in the community. The core technology behind Aerialist Pharma has stood the test of time and counts the largest Pharmaceutical giants among its customers.

Within Debenu are industry experienced subject matter experts in global regulatory compliance to further assist with application approvals if required.

Debenu has a 24-hour customer service team that is available any time of the day or night to respond to client needs. There are no after sales costs, as Debenu offers all technical support free-of-charge.

Technology and Quality integrated - Software Validation

The purpose of the software validation process is to provide a high degree of assurance that a

specific process will consistently produce a product which meets predetermined specifications in a reproducible, repetitive and robust manner.

This is a regulatory requirement in most countries and as a contracted resource of software and services to Pharmaceutical and other life sciences companies, Debenu is responsible for ensuring that its software is compliant.

This is the responsibility of Debenu's corporate management and any personnel directly or indirectly involved in the design, development, testing and validation of Debenu PDF Aerialist Pharma.

Debenu PDF Aerialist Pharma is governed by the following Validation Documentation:

- *Product Development Lifecycle Project*
- *Debenu Validation Master Plan (DVMP)*
- *Validation of products for regulatory environments (Debenu PDF Aerialist Pharma Edition) SOP DER055*
- *Validation Sampling and Testing Regime in Different Environments SOP DER056*