

Loftware Prisym 360 streamlines clinical supply labeling – it's built into our software's DNA

We simplify complexities and shorten timelines in clinical supply labeling

Loftware
Prisym 360

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Industry challenges answered

Across the life science industry worldwide, the way in which organizations approach the design, creation, and printing of labels has historically been both inconsistent and fragmented. Often regarded as static pieces of content, labeling processes have typically resided in operational silos, separate from product production.





The reality is that in today's increasingly competitive and regulated global marketplace, such approaches leave organizations even more vulnerable to mislabeling, voluntary recall, non-compliance, and non-adherence.

In addition, any need to implement changes on a global or local level to label content - such as expiry or warning statements - quickly becomes a complex, costly, and high-risk project.

Developed over a five-year period, Loftware's Prisym 360 software was created in collaboration with many of the industry's leading clinical and pharmaceutical companies. The solution is designed to simplify complexities and shorten timelines specific to clinical supply labeling.

Streamlining clinical supply labeling

Prisym 360 provides organizations with complete label integrity to meet the strictest compliance requirements for FDA & EU regulations, specifically FDA 21 CFR Parts 11, 810, and 820.

By focusing on the data, rather than the label, Prisym 360 provides a revolutionary 360° outlook of your master data assets and gives the ability to control and optimize them to create a fully integrated approach across the full label lifecycle.

Our dynamic label generation methodology (that label templates are designed using placeholder variables populated with the necessary content or values dynamically, at the time of print) offers two significant advantages over traditional label design software:

- Firstly, a single label template can be used to produce many different labels, as the label content can vary. This allows for the number of label designs to be reduced significantly, as a single template may be used for many products.
- Secondly, as the label content is retrieved at the time of print, only the most up-to-date data is used in the required local language - be that expiry dates, company logos, or usage or dosage instructions.

Utilizing the latest technologies and standards, Prisym 360 is offered as a cloud-based solution, ensuring it can integrate fully with enterprise IT strategies and policies.

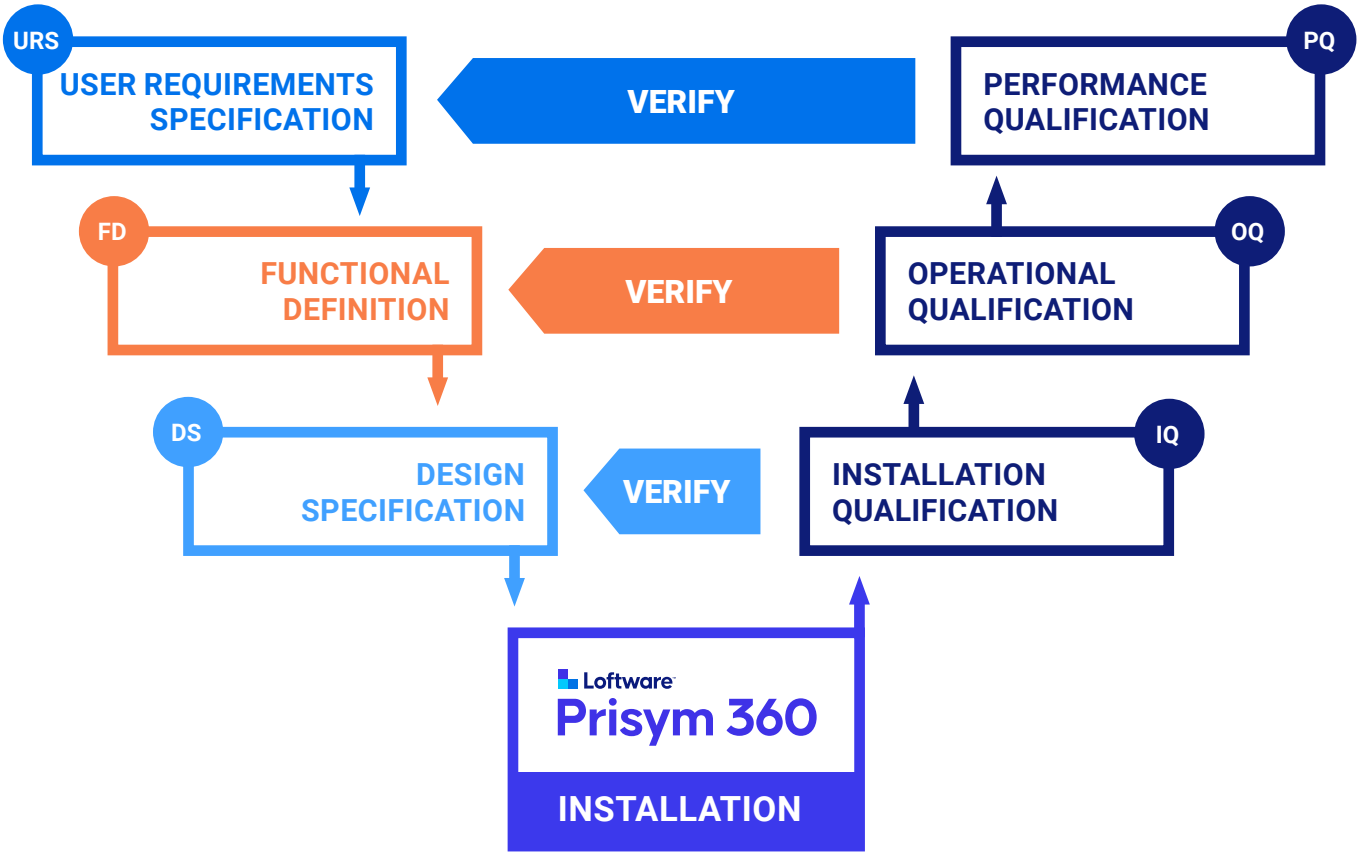
Why Prisym 360?

When it comes to clinical trial labeling, Prisym 360 gives companies a complete view of the full production process. With the correct data structure and management processes in place, all the downstream benefits will emerge for free: label designs, workflow processes, inspection capabilities and audit control all flow from ensuring the right data is available to the right people, at the right time. The efficiency gains are a natural and welcome by-product.



Validation – ready

Appreciating the significant effort required by life sciences organizations to validate software systems, Prisym 360 is provided with industry-leading documentation, guidance, and support to aid the validation process.



Each release of Prisym 360 is designed, tested, and delivered with a full validation documentation pack, comprising auditable security protocols and lifecycle documentation based on ISPE's GAMP V (Good Automated Manufacturing Practice): A Risk-Based Approach to Compliant GxP Computerized Systems guidelines.

Significantly, GAMP V advises regulated organizations to leverage their system supplier's knowledge, experience, and documentation to perform validation. It is this approach that Loftware encourages to avoid duplication of effort.

Prisym 360 is developed using definitive and structured testing practices, based on standard software development lifecycle models, which result in a significant amount of evidence-based documentation. This includes Installation Qualification (IQ) and Operational Qualification (OQ) documents, which can be leveraged to assist in the creation of Performance Qualification (PQ) documentation, to facilitate a more rapid deployment while minimizing risk to project delivery.

Loftware has a team of in-house compliance and validation subject matter experts, with many years of experience working in partnership with organizations to deliver validated solutions. For each deployment, these experts are available to support project planning, risk assessment, and testing of Prisym 360 implementations to streamline the task of validation.

Loftware has an international professional services and support organization to help design, deliver, and maintain global label and artwork management solutions. The teams comprise experts with extensive, first-hand experience of the delivery and support of successful label and artwork projects specifically within the highly regulated life sciences sector.

Business controls

Built specifically for the life sciences industry, Prisym 360 has sophisticated features that are integral in its design to provide the operational visibility and control that are critical in complying with global regulations.



Security and administration

The software provides extensive support for user and password administration, group management, and security tags. Username and password policies can be configured to align with corporate standards or can be integrated with an organization's LDAP or Active Directory for user and group management.



Electronic records and electronic signatures

To comply with regulatory requirements, Prisym 360 stores all data and actions as electronic records, and these cannot be subsequently changed or deleted. These records can generate human readable copies or be exported in electronic format. The use of full electronic signature captures username, date and time and signature reason for all activities requiring e-signature verification.



Version and revision control

The software enforces comprehensive version and revision control on every data entity. If approved entities are changed, their version number is incremented automatically, changes are subject to approval, and are audit logged.



Audit log

Designed to provide human-readable evidence, the audit log automatically records all operations when they occur in the system, with full electronic signatures of who performed the action and from which computer. The audit log has extensive search and filter options to aid in fast and accurate reporting.



Notifications

Users can be notified of a wide range of information, tasks, and error events. Personal notification settings are highly configurable, ensuring applicable users are quickly made aware when they are required to act.



Search

Every label, content, and system component are allowed to be searched for, using single words or phrases with wildcards and Boolean operators with the search results being easily filtered into result types.



Regulatory rules

This engine allows rules to be defined specifying the content required to be on labels, dependent upon conditions such as packaging, destination country, or product type. These rules could stipulate local country regulatory requirements such as sponsor's name and address, the UDCT number, use of regulatory symbols and expiry dates. Conformance to these rules is clearly indicated at both label design and label approval phases, with visual warnings if these rules are not being met.



Reprint/reconcile

Users can select previous print jobs to perform a reprint to produce an exact copy of a previously printed label, using the same data input at time of the original print. Users can also perform a re-label. Reconciliation of every label in a print job is supported, to allow for the accounting of labels that are damaged or failed to print correctly.

Content management

Sophisticated content management is central to Prisym 360's architecture; it comprises of features to structure, store, and manage content (or digital assets) effectively at a component level, such as label text, numbers, images, and variables.



Content

Content components are stored within a secure database, along with additional data that affects the printed label or artwork, such as fonts, printer types, and label stock information. These content 'entities' are subject to version control and design status control, with Prisym 360 also managing each content's ownership, availability status, and links to other content entities. This ensures that any label can be reproduced at any time, while changes to labels are tracked, versioned, approved, and audit logged.



Data integration

Prisym 360 seamlessly integrates with Clinical Supply Management (CSM), Enterprise Resource Planning (ERP), Product Lifecycle Management (PLM) systems, and other data repository systems to retrieve the most up-to-date label data at the point of printing, providing accuracy and consistency. The software offers a wide range of configurable system interface options, including web services, file-drop, and staging tables, and where automated integration is not required, a data record upload add-in enables manual data import.

The solution has been integrated and certified with a range of ERP systems, including Oracle and SAP, to ensure production operations can be streamlined and managed effectively.



Clinical trial management

This functionality is designed to simplify the complex process of designing and printing clinical trial labels. These pre-defined clinical trial data structures and print logic aid in streamlining the process of producing accurate and compliant clinical pack labeling. The flexible clinical trial data import functionality, blueprint print processes, and reporting capabilities all make Prisym 360 ideal for sponsors, clinical manufacturing organizations, contract research organizations and clinical supplies organizations involved in labeling clinical supplies and the overall supply chain.



Language and phrase management

The solution supports multi-language labels and multi-page booklet labels. The languages and phrases printed can be determined automatically based on the country data. Managing language phrases and translations is a complex task. Prisym 360 can manage translations for over 150 ISO languages and regional variations, following the Unicode standard, as well as phrases and pluralization. Missing translations for label data can be quickly and easily identified, and translation request functionality can ensure these are completed without impacting production.



MLT/CLT

Prisym 360 offers Master Label Text/Country Label Text (MLT/CLT) functionality, designed to streamline the process of defining the content, design, and production of clinical supplies labels and booklets.

Clinical labeling teams often specify English MLT content to define the governing label content. Once collated and approved within Prisym 360, this MLT content is then used to create variations for each country and region to be included in the study, commonly referred to as CLT. These variations typically include country-specific phrase translations, regulatory statements, and symbols.

PDFs can then be swiftly generated by applying this resulting content to label or booklet layout designs.

Additionally, with support for electronic records and electronic signatures, all activities are recorded in the software's audit log, helping to ensure GxP-compliance.

Images

The platform supports a wide range of image formats for use on labels and artwork, including .bmp, .gif, .jpeg, .png, and pdf formats. As with other types of content, images are subject to version and design status control within Prisym 360.

Randomization

The Prisym 360 randomization module offers comprehensive functionality for generating randomized clinical label data. The module enables a step-by-step definition of the structure, parameters and data required to generate each randomization. These are managed as randomization definitions within the software, with each being state and version controlled.

The randomization definition comprises the structure of the data, including the study type (patient or kit), number of visits, treatment, and treatment groups. For patient-based study types, definition properties include patient code format, single or double-blind, study centers and stratification type and for kit-based study types, definition properties include sequenced or scrambled and pack code format. The resulting randomized data can be used within Prisym 360 clinical label print processes to produce production labels.

Design management

Prisym 360's label and artwork design functionality comprise of the editors and plug-ins which facilitate the layout and formatting of labels, multi-page documents, and artwork.



Label designer

Prisym 360's label designer is for the design and editing of label templates (label formats) and multi-page document templates for use with variable, dynamic data. There is support for rich text, images, barcodes, lines, shapes, and tables as well as sub-labels, while a graphical 'drag and drop' interface allows available content to be easily selected and placed on the label design. Multi-language phrase texts can be selected, and the contextual language of the label format can be easily changed to see the resulting effect within the label design using pinned data. Label format comments, such as design decisions, can be recorded for future reference. Prisym 360 also supports machine readable data. A wide range of barcode symbologies can be easily generated and placed on label designs, while an Application Identifier (AI) wizard simplifies the creation of compliant 1D and 2D GS1 barcodes. Finally, RFID support allows labels comprising RFID tags to be programed.

Multi-page document support

Prisym 360 supports the design and print of multi-page documents and booklet labels, and other supporting documentation.

Different templates can be applied to different pages within a booklet, while the number of pages printed can vary dynamically depending on the data. For example, a booklet template may be designed with a different page for each language, and the number of languages, and therefore the number of pages is determined at time of print.

Indesign artwork management

To extend functionality to artwork teams using Adobe Creative Cloud, Prisym 360 is enhanced with an InDesign plugin available to make content accessible. In addition, Adobe InDesign files can be uploaded to Prisym 360, along with pdf versions, to be managed, approved, version controlled, and searched.

Fonts

A wide range of fonts are supported, with each being subject to approval and version control. System fonts can be standardized, controlled, and referenced, and specific fonts can be uploaded for use by all users.

Workflow management

Prisym 360 incorporates a range of workflow features to control how content is created, changed, and approved by users.

Change requests

Users can raise requests for changes to label designs or content, which can be routed to specific individuals or groups for approval, and then for action.

They include descriptions of the change, the content that requires the changes, and links to any related content. Once a change request has been completed, an approval request can be automatically generated to route this changed content for approval. A change request dashboard offers a simple, clear view of the number and status of all active change requests.

Approval requests

Approval workflows define the steps and groups through which approval requests are routed. A workflow step can comprise individual users that are either required to make decisions or act as optional reviewers. Additionally, workflow steps may comprise groups of users for voting; quorums can be set to specify the minimum number of positive votes required to pass the approval step.

Once defined, approval workflows can be saved as templates for easy use or amendments, with each workflow template subject to approval and version control.

Approval step milestones can be set to aid tracking of approval workflow progression, with clear display through an approvals workflow dashboard.

Red marking

Allows the visual highlighting of areas of interest within label designs through a graphical indication and accompanying text. This can be used to highlight areas of existing labels requiring changes as part of a change request, or when indicating reasons for rejection within approval requests.

Impact analysis

As Prisym 360 keeps track of the usage links between content, it can quickly provide details of the labels or multi-page documents that make use of certain content, such as specific images or phrases. This is often referred to as 'where used.'

Searching on content entities will provide results in either a detailed table which can be exported, or in a graphical relationship view that enables the navigation of content links visually. This proves invaluable when a logo, product name or compliance statement needs to be changed for example, and finding all the places where it is used would otherwise prove a significant administrative activity.

Version comparison

This capability allows variances between versions of label formats or data to be analyzed. Differences on labels are shown graphically in addition to a text explanation and differences in data variables are also included in the comparison.



Label and artwork output

Prisym 360's label output features include a print management system, as well as 'print processes', which control the logic for determining which content to use to generate labels dynamically.



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Blueprint print processes

There are several standard pre-configured print processes for use in the most common production print environments. These 'blueprints' comprise standard user interfaces and content 'logic' for generating labels to print. Each blueprint print process is designed for a particular production model while a straightforward user interface allows the input of variables and parameters specific to the print job at time of print, such as expiry dates.

Production print execution

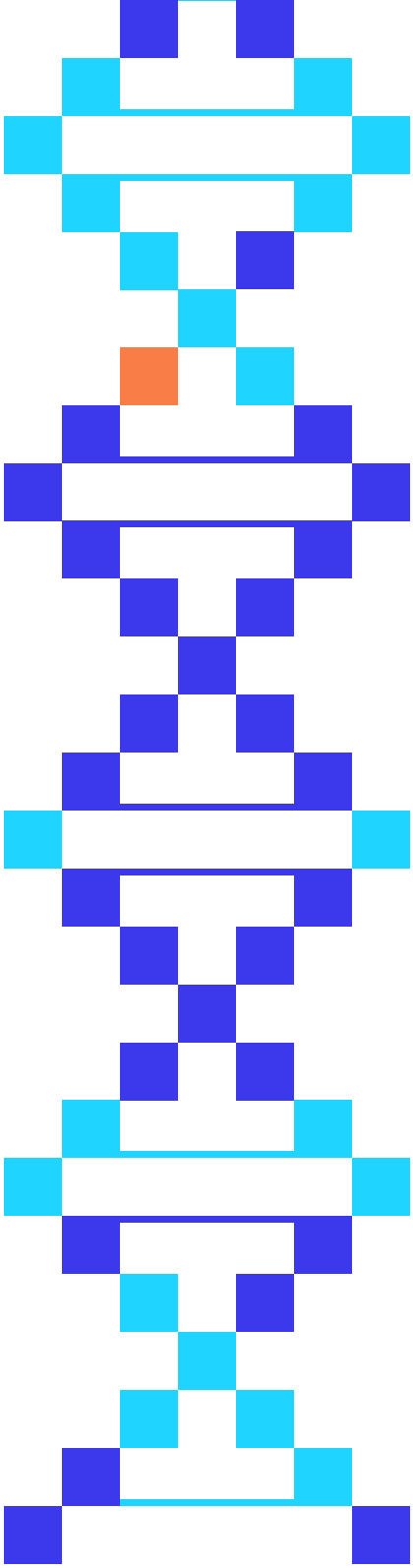
Prisym 360 incorporates extensive capabilities for managing production printing to a range of printing and coding technologies, using either Microsoft Windows drivers or native printer drivers. It controls management of printer settings, print jobs, printer queues and print notifications.

Automated/unattended print support

Print Processes can be configured to print automatically on receiving instruction and data from another system, such as CSMs, SAP, Oracle JDE and other ERP systems. This avoids unnecessary user involvement, helping streamline production efficiency while reducing the risk of errors.

Electronic output

In addition to producing printed labels and documents, Prisym 360 will generate electronic versions of documents and labels. These may be required for records and audits or may be utilized for e-labeling applications.



Prisym 360 platform technology and architecture

Prisym 360 is a modern enterprise-class cloud-based application which uses the latest, standards-based technologies and programming frameworks including JavaScript, Node.js, and Microsoft .NET. This helps ensure its reliability and flexibility as a platform. It is developed and supported entirely by Loftware's own in-house development team.

Prisym 360 has been architected using the latest enterprise application design principles, enabling it to scale from small, single site implementations through to global deployments, supporting multiple organizational business units spanning any number of countries.

It adopts a centralized architecture to align with the growth in enterprise IT data centers. As a result, Prisym 360 can scale in terms of performance and capacity simply by increasing server resources.

Prisym 360 supports the operating systems, server, and database platforms from Microsoft and Oracle, enabling life sciences organizations to leverage existing expertise, tools, and licenses.

Finally, the user interface is fully browser-based, utilizing the latest HTML5 and CSS3 technologies. This helps simplify application deployment and support, while ensuring a great user experience.

For more information on Loftware's clinical trial offerings, please go to

https://www.loftware.com/solutions/industries/clinical-trials

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