

A WhitePaper

# 10 MUST-HAVE SOFTWARE FEATURES

For Quality And  
Regulatory Compliance

**SpiraPlan: Making Mission-Critical Systems  
Deliver Every Day**

May 2021

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We all live in a society governed by regulations; whether we know it or not, we interact with and are affected by regulations almost daily. Regulations are a set all-caps rules in the playbooks of the healthcare, motor vehicle manufacturing, aviation, telecommunication, financial industries, etc. Each of these is tightly regulated and faces a concrete set of constraints.

Regulation may limit the speed and extent of "disruption" but companies that embrace regulation and still manage to innovate outperform those that view it simply as a limitation.

In heavily regulated industries, the testing and validation of processes, software and hardware, and management and proper maintenance of data can be overwhelming. Keeping track of international standards, industry-specific rules and regulations, documents and reporting requirements is an enormous task. Regulation and compliance turn to risks only if they are not adhered to and maintained.

Heavily regulated companies still can create agile processes that comply with regulations while bringing to the market innovative products that are valued by customers, stakeholders, and regulators.

**Here are 10 critical software capabilities that companies need to invest in to deliver, innovate and succeed in regulated industries:**

# 10 Must-Have Software Features For Quality & Compliance in Regulated Industries

## 1. Project & Portfolio Management

Integrated project and program management that let you manage your programs, projects and portfolios.

## 2. Risk Management & Mitigation

Fully integrated enterprise risk management capabilities that let you manage risks across the organization.

## 3. Security & Data Privacy

Powerful security and privacy support to ensure your data is secure, whether you choose to deploy on-premise, air-gapped or on the secure cloud.

## 4. Requirements Verification

Integrated requirements and test management platform lets you manage and test all of your requirements, policies and regulations.

## 5. Test Step Traceability & Compliance

End-to-end traceability from the requirements, to test steps, test cases, defects, development work items, source-code and resources.

## 6. Validation & Testing

Streamlined workflows and testing for integrated validation of the whole system.

## 7. Electronic Signatures

A facility for CFR 21, Part 11 electronic signatures that is tightly integrated with customizable workflows to ensure compliance.

## 8. Audit Trails & Reporting

Automatic maintenance of secure audit logs of all actions in the system, with customizable reporting on all activities for regulators and management.

## 9. Automated Testing

Automation to manage test scenarios and scripts directly from your running applications.

## 10. Robotic Process Automation

Automation of common business processes using a mixture of traditional workflow automation API calls and user interface robotic process automation (RPA).

## What Is SpiraPlan?

**SpiraPlan** by Inflectra is an Agile Program Portfolio Management system with baked-in modules for QA, Agile project management and DevOps for teams. Available both on-premise and cloud-hosted, SpiraPlan is the most feature-complete solution for managing **mission-, safety- and business-critical applications and embedded systems** in regulated industries.

## SpiraPlan: Out-Of-The-Box Functionality

- Enterprise-level agile software development, planning and management
- A complete QA suite with bug, issue and task tracking
- Program, Portfolio and Enterprise Management
- Project Risk management
- Management of project requirements, user stories and use cases
- Baselining with robust configuration management and version control
- [Resource Management](#)
- Management of Source Code and [IDE Integration](#) with native code difference viewing
- Instant messaging and work collaboration

# SpiraPlan: A Solution Designed For Your Industry

## Energy & Industrial

SpiraPlan helps you test and validate critical systems for operational and regulatory compliance and public safety. Whether is it Energy, Manufacturing or Utilities, SpiraPlan will help to harness remote data collection, test your systems and ensure compliance with ISO, NIST, ICS [NERC-CIP](#) regulations.

## Aviation & Aerospace

SpiraPlan helps you develop quality airborne systems and manage testing and compliance activities to perform reliably in an airborne environment. In the strictly regulated aviation industry in the USA, [SpiraPlan makes mission-critical systems deliver in accordance with FAA's guidelines \(DO-178C\) for software reliability in an airborne environment.](#)

## Financial Services

SpiraPlan helps you develop, test and manage business-critical systems, ensuring security across development, regulatory compliance, and risk mitigation. In [Financial Services systems' regulators want to ensure that controls, processes and technologies](#) for managing changes to the system are developed, tested and documented which is where SpiraPlan performs well.

## Healthcare

SpiraPlan helps you manage safety-critical systems and medical devices, validate patient systems, with approval workflows and electronic signatures. When developing medical devices or information systems, SpiraPlan helps you ensure that the testing and validation procedures meet the requirements of the [FDA / EMA and specifically 21 CFR Part 11](#).

## Government & Defense

SpiraPlan helps you test and build quality critical systems, guaranteeing reliability with secure code, end-to-end traceability, reporting and data security. Explore how SpiraPlan can help advance IT Management and compliance with government regulations, including with [OMB exhibit 300](#) as well as [DOD 500](#).

## Telecommunications

SpiraPlan helps manage, plan and test networks and systems to ensure reliability, performance and compliance with ITU/ITRs. The rollout of ever-faster 5G networks is changing the mobile landscape and global networks. With wireless networks increasingly replacing fixed broadband, and the adoption of the Internet of Things (IoT), organizations using SpiraPlan will be able to reliably innovate.



# SpiraPlan Differentiators

## General:

- **Deployment:** AWS or private cloud; Air-gapped on-premise
- **Licensing:** concurrent licensing model
- **Contracts:** monthly, annual and multi-year contracts
- **Payment:** multiple payments methods (incl., gov't procurement)
- **Access:** Unlimited storage, API calls, projects, programs,
- **Random:** Dark Mode, OAuth & Odata

## Free With SpiraPlan Purchase:

- **Support:** 1 year unlimited support (incl., phone, email)
- **Environment:** Over 60 plugins and integrations; Migration paths from legacy and modern tools
- **Adoption:** Limited in-person training; Getting Started Videos, Documentation; Dedicated account manager
- **Add-on:** Source Code Management Tool - TaraVault

## Additional Inflectra Services:

- **Migration:** Quick and easy migration from on-premise installation to Inflectra's secure cloud and vice-versa
- **Implementation Services:** migration assistance, workflow setup, platform customizations, consulting help, etc
- **Training:** Live (in-person, virtual); on-demand/pre-recorded.

## SpiraPlan: A Deep Dive

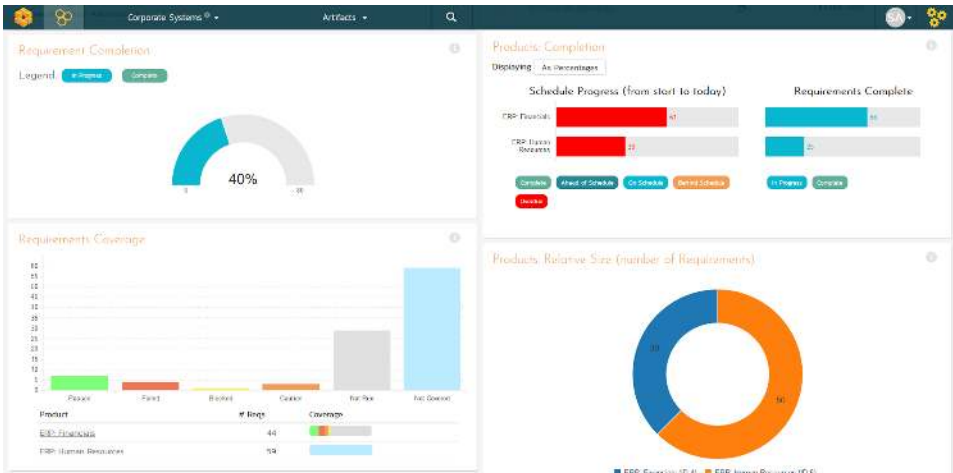
### Project Management Capabilities of SpiraPlan

#### Project Management

SpiraPlan projects come with dashboard home-pages that summarize the information into a comprehensive, easily digestible form with a “one-stop-shop” view of the overall status of the project at a glance. It contains summary-level information for all types of artifact (requirements, test cases, incidents, etc.) that you can use to drill-down into the appropriate section of the application.

#### Program Management

SpiraPlan recognizes that projects are usually part of larger initiatives. SpiraPlan includes program management and program planning features that let you plan and execute multiple projects in parallel, with tools to help you keep track of the progress, milestones, and inter-project dependencies.



## Portfolio Management

SpiraPlan includes rich Project Portfolio Management (PPM) functionality that lets you analyze and collectively manage your projects and programs in a centralized place. SpiraPlan lets you identify the fastest, cheapest, and most suitable approach to deliver your projects and programs.

## Risk Management

SpiraPlan includes an enterprise risk management system that is fully integrated with the requirements and project management features. The risk management module lets you identify, analyze, treat, and monitor risks with support for risks, mitigations, tasks and risk cubes.

Library Information System (Sample) - Risks - Reporting

Displaying 1 - 6 out of 6 risk(s) for this project.

Name	Probability	Impact	Exposure	Type	Status	Owner	Last Updated	ID	Edit
The UML release may not be ready in time	Critical	Critical	36	Schedule	Open	Fred Bloggs	22-Jan-2019	RK.1	Edit
We may not get enough authors to sign up	Unlikely	Significant	11	Business	Open	Fred Bloggs	22-Jan-2019	RK.2	Edit
The database may not support the volume	Unlikely	Critical	8	Technical	Analyzed	Joe P Smith	22-Jan-2019	RK.3	Edit
The book pages may not be easy enough to use	Possible	Marginal	3	Business	Analyzed	Joe P Smith	22-Jan-2019	RK.4	Edit
The software licenses may be too expensive	Unlikely	Marginal	4	Financial	Evaluated	Fred Bloggs	22-Jan-2019	RK.5	Edit
The client team may not be ready for UAT	Rare	Critical	3	Schedule	Evaluated	Fred Bloggs	18-Jan-2019	RK.6	Edit

## Document Collaboration

SpiraPlan includes an integrated web-based document management system to upload documents in a secure, centralized location, with support for folder organization, documentation taxonomies and meta-tagging as well as built-in version control. These documents can be connected to SpiraPlan artifacts (requirements, tasks, incidents) to provide the complete picture to users.

Library Information System (Sample) - Documents - Reporting

Displaying 1 - 5 out of 5 document(s) in the current folder.

Name	Type	Size	Edited By	Edited On	Author	Status	ID
Author_Management_Screens_Website.png	Screen Layout	513 KB	Fred Bloggs	19-Mar-2019	Joe P Smith	Completed	DC.8
Book_Management_Screen_Website.html	Screen Layout	302 KB	Fred Bloggs	19-Mar-2019	Joe P Smith	Draft	DC.9
Sequence Diagram for Book Mgmt.pdf	UML Diagram	35 KB	Joe P Smith	17-Feb-2019	Fred Bloggs	Completed	DC.7
Website Design Mockups.pdf	Screen Layout	1009 KB	Joe P Smith	15-Feb-2019	Joe P Smith	Completed	DC.10
User Flow Diagram.pdf	UML Diagram	48 KB	Fred Bloggs	19-Feb-2019	Fred Bloggs	Completed	DC.12

# Planning Scheduling

## Requirements Management

SpiraPlan lets you easily manage your requirements and user stories in an integrated requirements matrix. These requirements can be validated with the end customer and then elaborated into more detailed tasks that can be used as the basis for development.

The screenshot displays the SpiraPlan web application interface. The main content area shows a requirement titled "Ability to add new books to the system" with ID [RQ-4], type Feature, and status Developed. Below the title are tabs for Overview, Test Coverage, Tasks, Attachments, History, and Associations. The interface is divided into three main sections: Releases, Properties, and Dates and Times.

Releases		Properties		Dates and Times	
Release	10.0.0.0001 - Sprint 001	Importance	T - Critical	Creation Date	3/16/2018 9:58:05 PM
People		Component	Book Management	Last Updated	3/22/2018 9:58:05 PM
Author	<input type="radio"/> Fred Dieggs	URL	http://www.library.org	Estimate (points)	2.0
Owner	<input type="radio"/> Joe P Smith	Difficulty	Medium	Review Date	7/1/2012
Class		Classification	--- Please Select ---		
		Version	1		
		Decimal	1234		

Below the table, there is a section for "Detailed Information" with a description: "The ability to add new books into the system, complete with ISBN, publisher and other related information."

## Release Planning

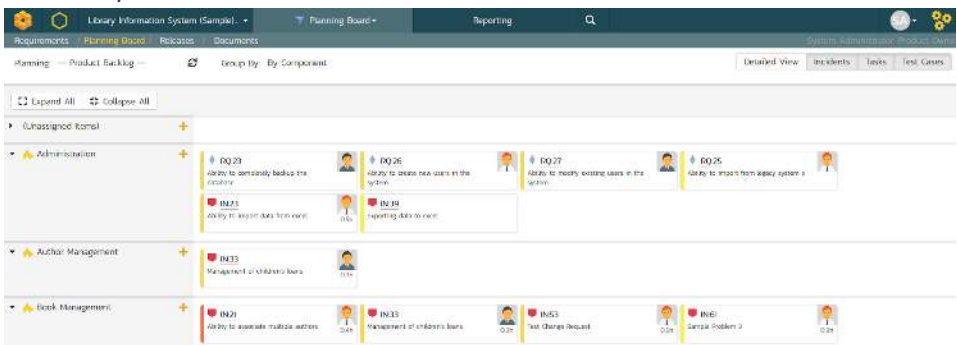
SpiraPlan provides the ability to manage the list of releases / versions of the software being developed. Each of the releases can be broken down into smaller units of work called Iterations or Sprints. SpiraPlan includes integrated resource estimation capabilities so that you can plan out the team size needed for each iteration.

## Iteration/Sprint Planning

SpiraPlan lets you plan the work to be accomplished in each Iteration/Sprint. You can include requirements, tasks and defects - allowing you to determine the schedule impact of addressing critical issues as well as pre-planned features.

## Planning Board

SpiraPlan helps business and technical teams work together to develop the sprint plan for the iterations, breaking up the features into discrete tasks and assigning the tasks to the individual team members. During development SpiraPlan will track changes in the actual effort to determine if the plan needs to be rebalanced to ensure on-time, on-budget delivery.



## Resource Management

SpiraPlan lets you schedule the team members and load balance the task resourcing allocations. As team members work on their assigned tasks they can update their progress in terms of actual and remaining effort. This provides project managers with real-time visibility on the progress of the iteration and early indications of schedule overrun.

# Tracking Reporting

## Bug Tracking

Looking for a better way to track bugs and issues? SpiraPlan offers a complete bug tracking solution that is fully integrated with your planning system. Bug tracking features include support for customizable workflows and fields, flexible reporting, configurable email notifications, and fully editable statuses, priorities, severities and bug types.

The screenshot displays the SpiraPlan web application interface for creating a new incident. The browser title is "Library Information System (Sample)". The page has a dark header with navigation tabs: "Incidents", "System Details", "Tasks", "Resources", and "Source Code". The "Incidents" tab is active, showing a "Back to Incidents List" link and a "Display: Current filter" dropdown.

The main content area is titled "Enter new incident name" and includes a form with the following fields:

- Title:** [IN.]
- Type:** Incident
- Status:** New
- Progress:** 0/100

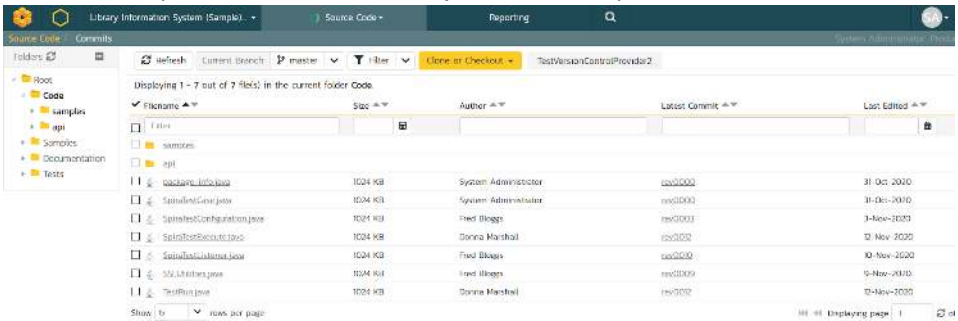
Below the form are several sections:

- Overview:** Contains a list of recent incidents with details like "Cannot log into the application", "Not able to add new author [N2]", "Clicking on link throws fatal error", "Database not backing up correctly", "Cannot install system on Oracle", "The book listing screen doesn't", "Cannot add a new book to the s", "Editing the date on a book is ck", "Editing the date on an author is", "I don't let me add a new category", "Validation on the edit book page", "Quote handling issues throughout", "The tables get cutoff on low-res", "Permissions not updating when", and "Session handling [N15]".
- Assignments:** Shows "Detected Release" as "None" and "Detected by" as "System Administrator".
- Properties:** A list of dropdown menus for "Priority" (None), "Severity" (None), "Component" (None), "Opening System" (Please Select), "Web Browser" (Please Select), "Internal?" (No), and "Difficulty" (Please Select).
- Attachments:** A section for adding files.
- Dates and Times:** A table with columns for "Creation Date" (7/8/2010 12:14:40 PM), "Last Updated" (7/8/2010 12:15:10 PM), "Start Date", "Project (Ref ID)", "Est. Effort (h)", "Actual Effort (h)", "Remaining Effort (h)", and "Review Date".
- Delayed information:** A section for "Description".



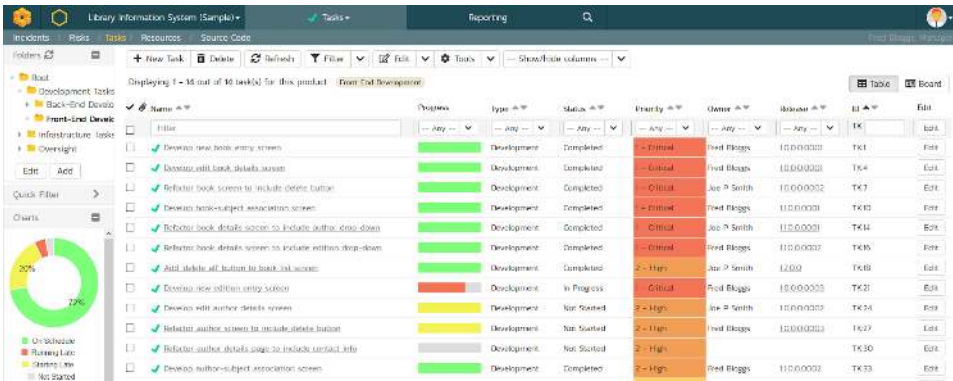
## Source Code Management

SpiraPlan includes powerful Software Configuration Management (SCM) module so that you can connect and browse source repositories within the platform. By linking commits in the code repositories to other artifacts, SpiraPlan can provide code-level traceability of changes. This gives unparalleled traceability across the development lifecycle.



## Task Management

SpiraPlan includes a robust task management system that lets users define tasks, categorize into types, organize by folder, assign to team members, and track the progress until completion.



## Build Management

SpiraPlan provides the ability to integrate with continuous integration build servers such as Hudson and CruiseControl so that the status of builds can be recorded in SpiraPlan and linked to source code revisions and incidents. This provides traceability for each build, so that you can see what was changed in each build, what was tested and what was fixed.

Recent Builds		
Name	Status	Creation Date
<a href="#">Build_0005</a>	Failed	2/22/2019 4:21:06 PM
<a href="#">Build_0004</a>	Succeeded	2/21/2019 4:21:06 PM
<a href="#">Build_0003</a>	Failed	2/19/2019 4:21:06 PM
<a href="#">Build_0002</a>	Succeeded	2/17/2019 4:21:06 PM
<a href="#">Build_0001</a>	Failed	2/15/2019 4:21:05 PM

## Pull Requests & Code Reviews

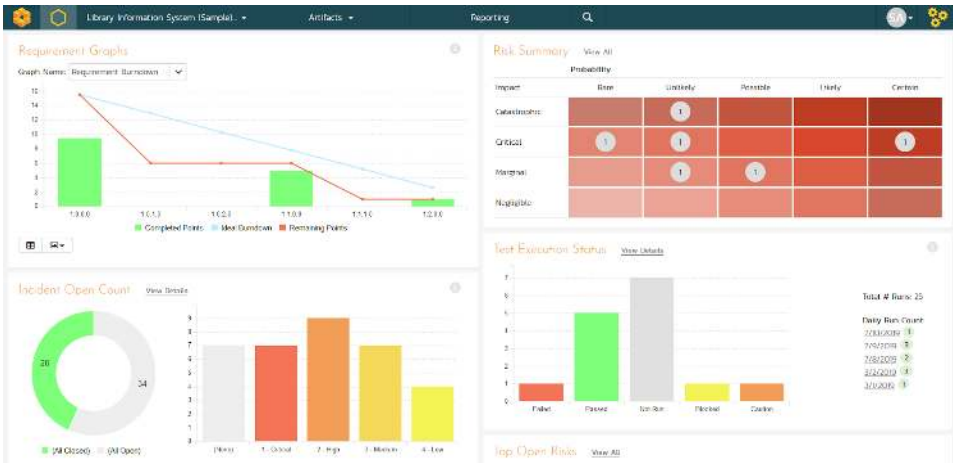
SpiraPlan lets you manage your software development activities and workflows with ease. You can create pull requests (also known as merge requests) to track code branches ready for review. Using the tracking and commenting features, developers can collaboratively review the code and approve the merge into the main development branches.

<input type="checkbox"/>	Name	Merge From	Merge To	Status
<input type="checkbox"/>	Filter	-- Any --	-- Any --	-- Any --
<input type="checkbox"/>	Merge 'feature/sprint-2' into 'develop'	feature/sprint-2	develop	Not Started

Show 15 rows per page

## Reporting

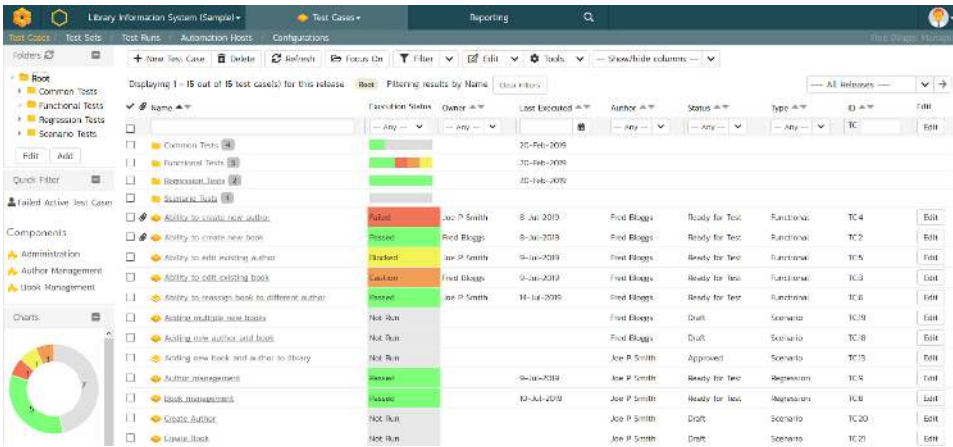
SpiraPlan includes an extensive library of printable reports and graphical charts. The reports can be customized through extensible XML based report templates. The supported report formats include: MS-Word, MS-Excel, HTML, Adobe Acrobat and MS-Project.



## Quality Assurance

### Test Case Management Tools & Software

Tired of managing your project requirements and test cases in documents and spreadsheets. Empower your testing team and throw off the shackles of outdated methods, SpiraPlan offers unparalleled functionality and usability combined with our award-winning technical support. Available as an on-premise installation or hosted service.



## Manual Testing

SpiraPlan provides the ability to execute groups of test cases using an easy-to-use test execution wizard that allows you to mark each step as pass/fail and optionally record a bug / defect. This provides complete traceability from a recorded defect to the underlying requirement.

## Automated Testing

With RemoteLaunch for SpiraPlan you can setup automated test cases in SpiraPlan and schedule them against a master list of automation hosts for execution on either the local computer or remote machines. Available Plug-ins include: QuickTest Pro, TestComplete, Squish, Selenium and Command-Line.

## Exploratory Testing

SpiraPlan includes a dedicated exploratory testing mode where you can create and edit your tests on the fly during testing. It also includes tools for tracking follow-up activities between the developers and testers.

## Baselining

SpiraPlan provides powerful baseline management features that allows you to have robust configuration management and version control of the artifacts in your projects and products. This makes SpiraPlan especially well suited for managing requirements, test cases and other artifacts on more complex systems and engineering projects.

## Other

### Customization

Customization and configuration are critical for ensuring that a system integrates seamlessly with your business processes. SpiraPlan can be configured and customized without any coding or scripting. You can create custom properties throughout the system, customize all the incident fields (status, priority, severity, etc.), create customized email templates, and configure custom workflows for managing your lifecycle.

## Administration

SpiraPlan has an extensive administration capability that can be accessed using just a web-browser. To reduce the burden on IT staff, you can delegate project administration to different users, allowing project managers to be self-sufficient.

## IDE Integration

SpiraPlan maximizes efficiency and improves productivity of developers by allowing them access their SpiraPlan information directly within their existing IDE.

## Email Integration

SpiraPlan has powerful email integration capabilities that ensure that all users are notified about changes in the system, and allows users to raise incidents and post comments directly from their email system.






















## Data Migration

Using our Add-Ins for Microsoft Word, Excel and Project you can easily import requirements, test cases, releases and incidents from your existing templates. In addition SpiraPlan comes with an import wizard for easily migrating from many legacy tools.

# SpiraPlan Integrations

SpiraPlan comes with over 60 integrations and more are added monthly. The inflectra Dev Team works regularly with our customers to build integrations and plugins that fit our customers' needs and make their lives easier.

Here is a sample of Inflectra's most popular integrations:

<b>Developer IDEs</b>   	<b>Unit Test Frameworks</b>     
<b>CI / Build Servers</b>   	<b>Bug-Tracking Tools</b>    
<b>Modelling Tools</b>   	<b>Functional Testing Tools</b>     
<b>CRM &amp; Service Management</b>   	<b>Performance Testing Tools</b>   



## The Inflectra Promise

### Easy To Migrate

It's super easy to switch to the Inflectra Platform. Migrate your legacy data, documents, spreadsheets, date exports, and more.

### Free Trials

No credit cards, no contracts, no hassles. You can trial all of Inflectra products in the cloud or on your own servers, and all for 30 days.

### Service You'll Love

Best practices are baked into every product, dozens of integrations, common sense options, first-class support every time.

This is why our customers love about working with Inflectra.

**Take SpiraPlan for A Spin Now!**

## About Inflectra

Founded in 2006, Inflectra is a market leader in software test management, test automation, application lifecycle management, and enterprise portfolio management space. The company is headquartered in the USA but has offices in 12 countries. Known globally for its legendary customer support, Inflectra makes turn-key solutions that address many challenges in software testing and QA, test automation, and product lifecycle management. Its methodology agnostic software tools are used in regulated industries where portfolio management, requirements traceability, release planning, resource management, document workflow, baselining, and enterprise risk analysis are required.

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