SoftComply

- compliance made easy -

REGULATED INDUSTRIES

THREAT TO HUMAN LIVES

50'000 MEDTECH CO-s
90% SMEs
$60bn spent on Compliance a year

REGULATIONS & AGILE

REGULATORY COMPLIANCE

- FDA 21 CFR Part 820
- Medical Device Regulations
- ISO 13485
- ISO 14971
- IEC 62304

COMPLEX

TIME-CONSUMING

EXPENSIVE

SOFTCOMPLY TOOLS HELP AUTOMATE REGULATORY COMPLIANCE

SOFTWARE TRENDS

- Increasing amount of software in medical devices
- Increasingly open enterprise software platforms

MORE SOFTWARE

OPEN PLATFORMS

AIM: CUTTING REGULATORY COSTS 10X

OUR MAIN CONSIDERATION:

INTEGRATION

COST

TIME

- Building regulatory compliance into software development lifecycle
- Integrated to Atlassian tools Jira and Confluence
- Low entry price for SMEs
- Cutting regulatory cost 10x
- Faster time to market

SoftComply   ATLASSIAN

AUTOMATING COMPLIANCE

DOCUMENT MANAGEMENT APPS

Document Manager — DOCUMENT MANAGEMENT APP WITH COMPLIANT WORKFLOWS & E-SIGNATURES

Validation — AUTOMATED VALIDATION APP FOR CONFLUENCE CLOUD

Validation — AUTOMATED VALIDATION APP FOR THE RISK MANAGER PLUS

Static Snapshots — FREEZING THE DYNAMIC CONTENT ON CONFLUENCE PAGES

RISK MANAGEMENT APPS

Information Security Risk Manager — THE INFORMATION SECURITY RISK MANAGEMENT APP FOR ISO/IEC 27001 COMPLIANCE

Risk Manager PLUS — THE MOST ADVANCED RISK MANAGEMENT APP ON JIRA CLOUD

Risk Manager for Confluence — RISK REPORTING ON CONFLUENCE CLOUD FOR OUR RISK APPS on JIRA

Risk Manager — THE RISK MANAGEMENT APP FOR SIMPLE PROJECT RISKS

OVER 1000 CLIENTS

COMPLIANCE MADE EASY

Automating Regulatory Compliance on Atlassian Jira & Confluence

Jira

Risk Manager PLUS

The **Most Powerful Risk Management Solution**

Information Security Risk Manager

The only **Information Security Risk Management Solution** for **ISO 27001 compliance**

Confluence

Risk Manager for Confluence

Report Risks in Confluence Cloud

Validation

Automated Integrity Checks of your Confluence Cloud

Document Manager

The **Document Management solution on Confluence Cloud**

Static Snapshots

Freeze the Dynamic Content on Confluence Pages

eQMS

Compliant medical device **Quality System Documentation**
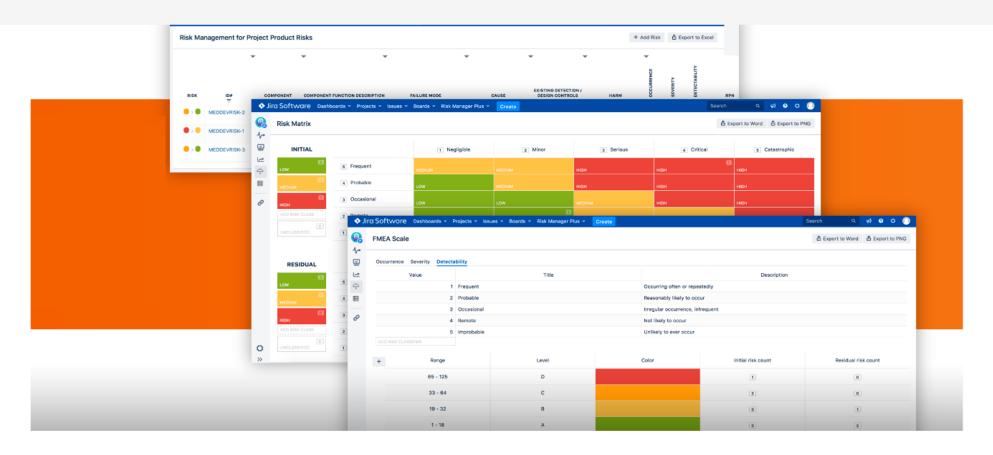
SOFTCOMPLY DOCUMENT MANAGER

Compliant **Document Management Solution** on Confluence Cloud
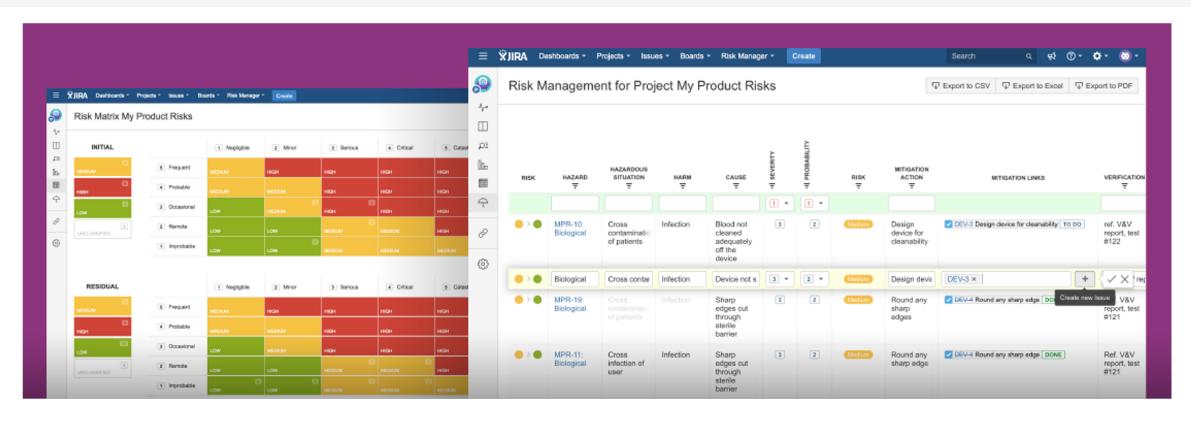
SOFTCOMPLY INFORMATION SECURITY MANAGER

The only **Information Security Risk Management Solution** on Jira
Cloud supporting compliance with ISO/IEC 27001

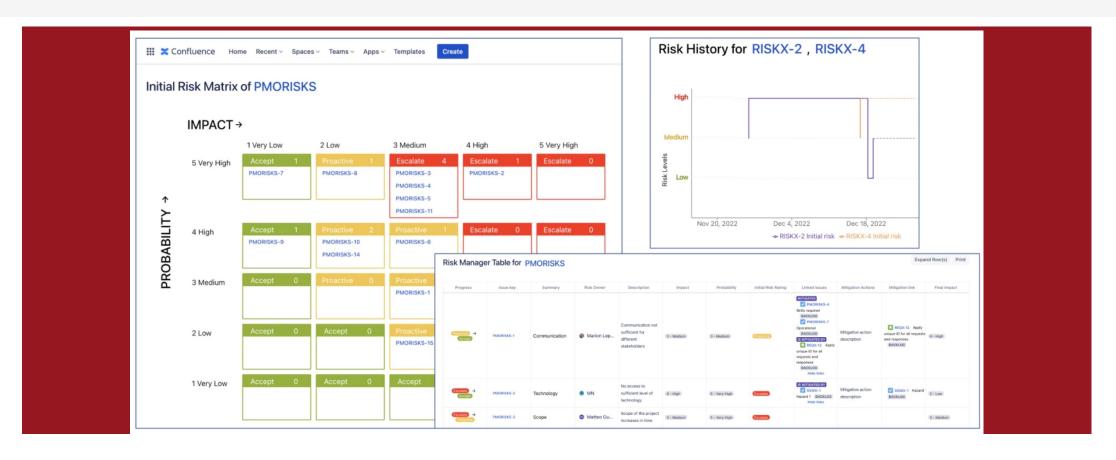SoftComply   info@softcomply.com

SOFTCOMPLY RISK MANAGER PLUS

The Most Advanced **Risk Management Solution** on Jira Cloud **for any Risk Management Method**

SoftComply   info@softcomply.com
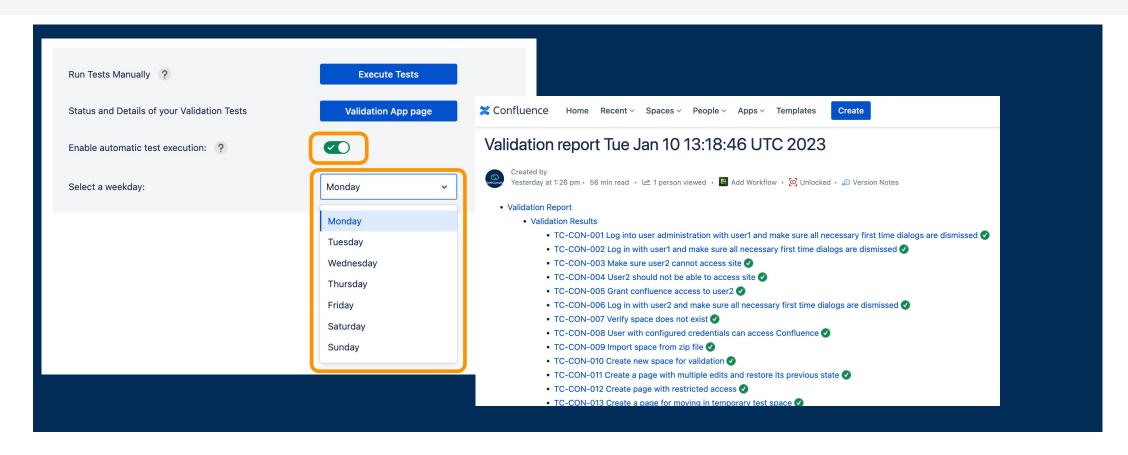
SOFTCOMPLY RISK MANAGER

Fully customizable **Product Risk Management Solution** on Jira (Cloud & Server/DC) for software system safety or security risk management

SOFTCOMPLY RISK REPORTING

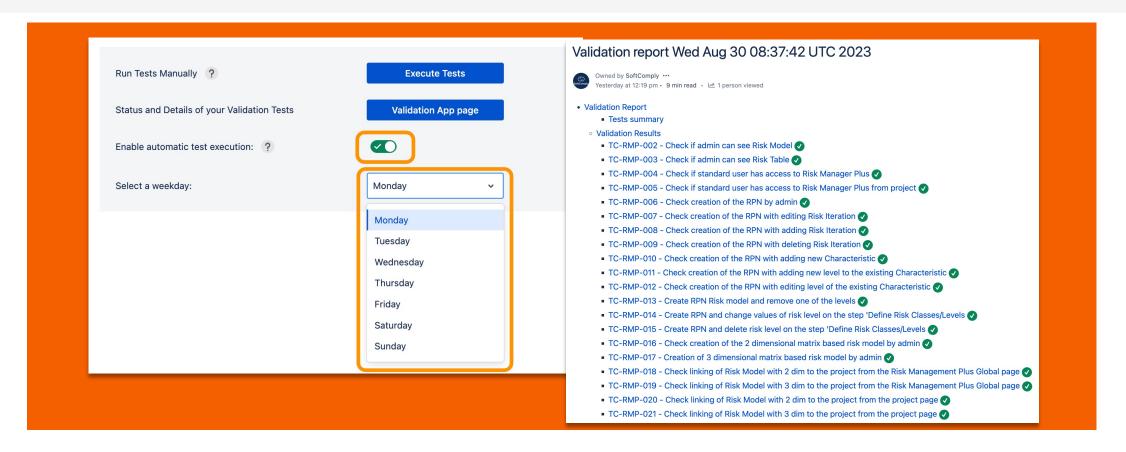The **Risk Reporting extension on Confluence Cloud** for SoftComply Risk Manager & Risk Manager Plus

VALIDATION FOR CONFLUENCE

Run **Regular Integrity Checks of your Confluence Cloud instance** with the SoftComply Validation app for Confluence
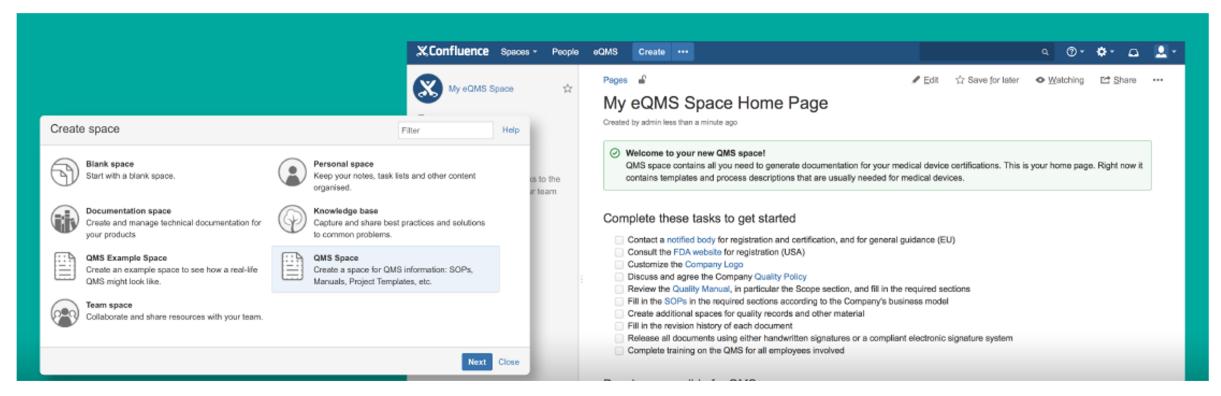
SoftComply   info@softcomply.com

VALIDATION FOR RISK MANAGER PLUS

Run **Regular Integrity Checks of your Risk Manager Plus on your Jira Cloud instance**
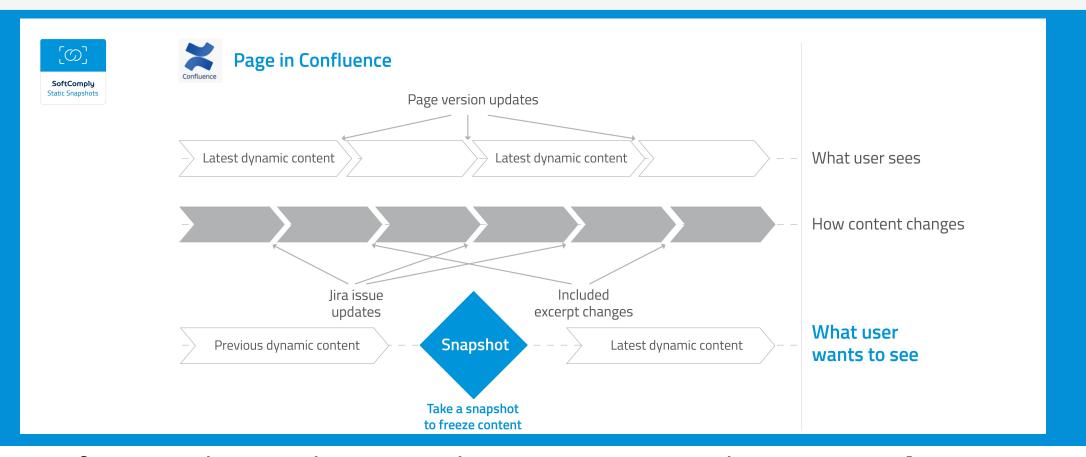
SOFTCOMPLY eQMS

Full **medical device Quality System on Confluence** with embedded instructions and guidance to customization, **fully compliant with EU and US regulations**
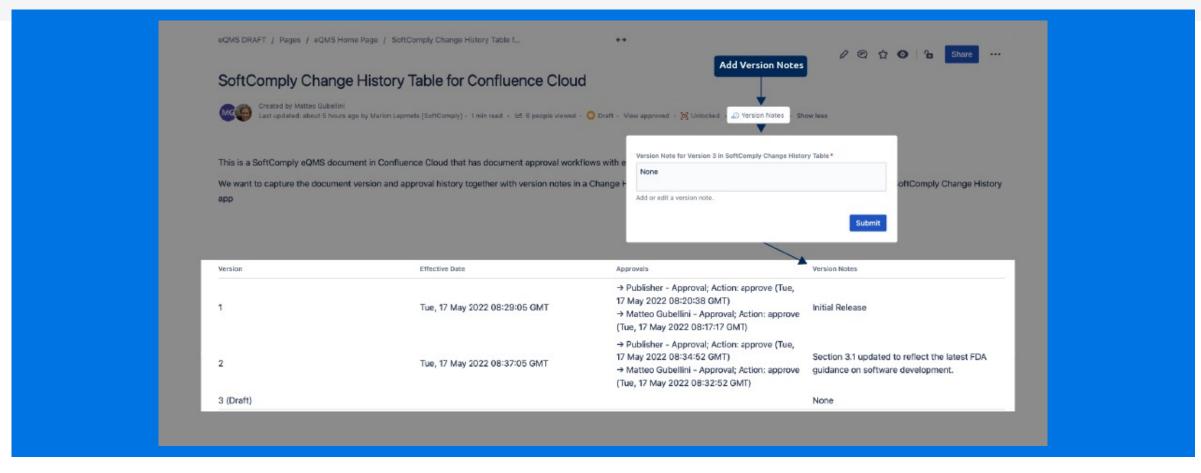
SOFTCOMPLY STATIC SNAPSHOTS

The SoftComply Static Snapshots to Freeze the **Dynamic Content** **on Confluence Pages**

CHANGE HISTORY

Add **Approval History** to your **Confluence Page** with the SoftComply Change History app

HOW TO REACH US

SoftComply

🌐 www.softcomply.com

✉️ info@softcomply.com

🐦 @SoftComply

💼 /company/softcomply/

📘 facebook.com/softcomply

▶️ SoftComply channel