ComplianceWire® 2025R2 Major Release Risk Assessment

In accordance with all applicable UL Verification Services Inc. ("UL") SOPs, UL has performed a risk assessment of the enhancements included within the ComplianceWire® 2025R2 Major Release. Please refer to the next page for more information on how this risk is assessed.

	Risk Ratings			
Enhancement	**Severity of Impact**	**Probability of Occurrence**	**Likelihood of Detection**	**OVERALL RISK**
	Low=1, Medium=2, High=3	Low=1, Medium=2, High=3	Low=3, Medium=2, High=1	1-5=Low, 6-17=Medium, 18-27=High
Segmented Form and Form Improvements	Medium (2)	Medium (2)	Medium (2)	(8) **Medium**
Due Dates Adjustments: New Manage Reasons Page with Due Date Adjustment, New Assignment Information Page with Due Date Adjustments Enhancements	Low (1)	Medium (2)	Medium (2)	(4) **Low**
Handling of Minimum Passing Score (MPS) for Course Create content published to ComplianceWire	Medium (2)	Low (1)	Medium (2)	(4) **Low**
API Request Details Report	Low (1)	Low (1)	Low (3)	(3) **Low**
Company preference to include disabled users by default in users search results	Low (1)	Low (1)	Medium (2)	(2) **Low**
Upload Tools Encoding	High (3)	Medium (2)	Medium (2)	(12) **Medium**
Add VOC Feedback for UL ComplianceWire	Low (1)	Low (1)	Medium (2)	(2) **Low**
Remove Login Again button on Session Disconnect Page	Low (1)	Low (1)	Medium (2)	(2) **Low**
Technical Debt: To-Do List/Curriculum Performance Improvements, Database Maintenance for Assignments	Low (1)	Low (1)	Medium (2)	(2) **Low**

The risk for the enhanced areas was assessed against a series of criteria including but not limited to:

- How visible is the Enhancement to the user?
- How important is the Enhancement to the user?
- How complex, and thus most subject to error, is the code to implement/resolve the Enhancement?
- Does the Enhancement impact 21 CFR Part 11 in anyway?

The risk is then quantified using the following indicators:

Severity of Impact

Evaluation of the immediate, long term and widespread effects of the risk.

1	Low	Little to no impact on 21 CFR Part 11 and/or the business. The impact would not be expected to have a long-term effect.
2	Medium	Moderate impact on 21 CFR Part 11 and/or the business. The impact could be expected to have short-to-medium term effects.
3	High	Significant Impact on 21 CFR Part 11 and/or the business. The impact could be expected to have significant long-term effects and potentially catastrophic short-term effects.

The severity of (negative) impact is categorized as high impact = 3, medium impact = 2, and low impact = 1. Higher Impact increases the overall risk score for the enhancement.

Probability of Occurrence

Evaluation of the chance or likelihood that an adverse event will occur due to the enhancement (prior to additional risk mitigation).

1	Low	The probability of the event occurring is perceived to be low (less than 10% of the time).
2	Medium	The probability of the event occurring is perceived to be medium (between 10-25% of the time).
3	High	The probability of the event occurring is perceived to be high (greater than 25% of the time).

The probability that a risk will occur is categorized as high probability = 3, medium probability = 2 or low probability = 1. Higher probability of occurrence increases the overall risk score for the enhancement.

Likelihood of Detection

Evaluation of the Likelihood of Detection by whether the risk effects can be recognized or detected by other means.

3	Low	Detection is perceived to be somewhat unlikely. The effects will most likely not be detected via normal work processes (less than 20% of the time).
2	Medium	Detection is perceived to be reasonably likely (50/50 chance). The effects may or may not be detected via normal work processes (20% - 50% of the time).
1	High	Detection is perceived to be highly likely. The effects are highly likely to be detected via normal work processes (greater than 50% of the time).

The likelihood of detection is the last factor in the risk score. This factor is categorized as high likelihood of detection = 1, medium = 2, and low = 3. Lower Likelihood of Detection increases the overall risk score for the enhancement.

Overall Risk Rating

Weighted numbers that were assigned to each risk indicator above (severity, likelihood, detectability) are then multiplied together to obtain the Risk Rating.

Severity of Impact X Probability of Occurrence X Likelihood of Detection = Risk Rating

The numerical rating is then converted to an overall risk rating of High, Medium or Low using the following scale:

1-5	=	Low
6-17	=	Medium
18-27	=	High

The overall risk rating helps determine the risk mitigation strategy and focus of the validation effort. Concentrating on areas of vulnerability (e.g., High risk) allows us to achieve our overall goal to reduce the probability of failure and build quality into the product.