# ComplianceWire® 2025R1 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® 2025R1 Major Release. Please refer to the next page for more information on how this risk is assessed.

| Enhancement | Risk Ratings | | | |
| --- | --- | --- | --- | --- |
| | 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 |
| New Form Builder and Form Enhancements | High   (3) | High   (3) | Medium   (2) | (18)  **High** |
| Non-GxP/Custom Attributes: Preference Settings for Custom Attributes, Configure Custom Attributes, Assign Custom Attributes, Reports - Custom Attributes | High   (3) | Medium   (2) | Medium   (2) | (12)  **Medium** |
| Home Page - Translation | Low   (1) | Low   (1) | High   (1) | (1)  **Low** |
| E-mail Notification upon New Class Added in ILC | Low   (1) | Low   (1) | High   (1) | (1)  **Low** |
| E-mail Notification for Scheduled Report without Record Found | Low   (1) | Low   (1) | High   (1) | (1)  **Low** |
| User Group Membership Quick Report | Medium   (2) | Medium   (2) | Medium   (2) | (8)  **Medium** |
| Class Management Improvements | Low   (1) | Low   (1) | Medium   (2) | (2)  **Low** |
| My Curriculum Report should not allow launching training if learner doesn't have access | Low   (1) | Low   (1) | High   (1) | (1)  **Low** |
| Rename Report Type to Base Report Name in Knowledge Center | Low   (1) | Low   (1) | High   (1) | (1)  **Low** |
| Login Migration | High   (3) | High   (3) | Medium   (2) | (18)  **High** |
| Optimize Matrix Membership Processing | High   (3) | High   (3) | Medium   (2) | (18)  **High** |

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 | PROBABILITY OF OCCURRENCE | LIKELIHOOD OF DETECTION |
|---|---|---|

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.

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.

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.

$$\text{Severity of Impact} \times \text{Probability of Occurrence} \times \text{Likelihood of Detection} = \text{Risk Rating}$$

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.