

Validation Risk Assessment Document

1. Document Information

Title	
Document Number	
Version	
Date	
Author	
Department	

2. Purpose

3. Scope

4. System/Process Description

5. Validation Risk Assessment Summary

Assessment Area	Description	Risk Type	Potential Impact	Probability	Severity	Risk Level	Control/Mitigation	Residual Risk	Remarks

6. Risk Assessment Methodology

7. Conclusions & Recommendations

8. Approval

Name	Position	Signature	Date