

Entry #	Category	Knowledge Input to QRM	(1) Tacit or Explicit	(2) <i>FLOW</i> of knowledge - Available, accessible, on demand? - Are heroics needed? - A newcomer figure it out quickly?	(3) <i>QUALITY</i> of knowledge - Reliable (for intended use)? - Sufficient Context & Rationale ? - Is it Complete & Accurate ?	(4) Comment
example	Process Knowledge	History of Problems with process/outputs	Explicit	Marginal	Marginal	No standard repository in use across multiple sites using the same equipment makes it difficult to find documents
			Tacit	Poor	Excellent	Very difficult to know who SMEs are at various sites - and the SME at the vendor is always traveling so is difficult to talk to - but once we find the right people we get what we need
Entry #1						
1	Process Knowledge	Design / Validation Documents - Facility & Utilities	Explicit	Marginal	Marginal	
			Tacit			
Entry #2						
2	Process Knowledge	Prior Knowledge/Lessons Learnt - current or other locations	Explicit			
			Tacit	Poor	Marginal	
Entry #3						
3	Process Knowledge	Routes for Contamination/Cross Contamination	Explicit	Excellent	Excellent	
			Tacit	Marginal	Poor	
Entry #4						
4	Process Knowledge	QRM Documents from design/previous stages	Explicit	Marginal	Excellent	
			Tacit	Poor	Excellent	
Entry #5						
5	Process Knowledge	System Integration Requirements (e.g., MES, EBR, BMS, etc.)	Explicit	Marginal	Marginal	
			Tacit	Excellent	Marginal	
Entry #6						
6	Regulatory Requirements	Applicable Legislation, Laws, EHS, etc.	Explicit			
			Tacit			