7. CONVERTED P2 VALUES

Table 1 – Therapy Occurrence Conversions

Therapy Occurrences (HSHA)		
Qualitative		**Quantitative (OPM)**
Expected	7	> 500,000
Likely	6	>240,000 to <= 500,000
Often	5	> 100,000 to <= 240,000
Periodic	4	> 10,000 to <= 100,000
Occasional	3	> 100 to <= 10,000
Rare	2	> 1 to <= 100
Exceptional	1	> 0 to <= 1

The probability of the Hazardous Situation (P1) occurring will leverage occurrence rankings based on information from multiple sources, including but not limited to: SME expertise, UEA, and pFMEAs. For each Hazardous Situation, the probability of occurrence of harm for this product family will be evaluated based on the consideration of both P1 and P2 (P1 x P2). See next section for P1 methodology.

a. Data Roll Up of the 'STDA End Effect' and maximum Probability Rating are provided in the "End Effects Max Probability" tab of Attachment 1_Vial and Bottle UEA BXU571529.

3. For pFMEAs:
Comparable pFMEAs, found in Attachment 34, were utilized in circumstances where a specific mixing pFMEA was not available.

For Process related End Effects, map in the 'STDA End Effect' column in the pFMEAs to the appropriate End Effect on Product from STDA-PHARMACEUTICALS.

a. Calculate the Occurrence x Detection (O x D) value using the chart below to determine the predicted failure rate for each row in the pFMEA.

Qualitative Detection		
Category	**Rank**	**Definition**
Improbable	5	It is unlikely that the detection control will detect the defect
Low	4	There is low probability the detection control will detect the defect
Moderate	3	The detection control will detect about half of the defects in the population
High	2	The detection control will detect a significant portion of the defects
Almost Certain	1	The detection control will detect almost all defects

O X D		Detection				
		1	**2**	**3**	**4**	**5**
Occurrence	**1**	1	1	1	1	1
	2	1	1	1	1	2
	3	1	2	2	2	3
	4	1	3	3	3	4
	5	2	4	4	4	5

b. Data Roll Up of the End Effect and maximum O x D for each pFMEA is provided in the "P1 Pivot" tab of Attachments 2-33.

c. Document the relationship between the 'STDA End Effect' for each pFMEA to the applicable Hazardous Situations in 'Appendix D - Data Summary' of the RACT as each respective "Process" pFMEA source column.

4. Then populate the worst-case failure rate (WC failure rate) with the highest value between the pFMEA and the UEA for each Hazardous Situation.

5. Use the following table to determine the predicted P1 for each End Effect – Hazardous Situation combination by comparing the worst-case failure rate determined in Step 4 and the allocation factor (1-3-5) determined in STDA-PHARMACEUTICALS:

Table 5 – P1 Calculations

FR x AF		Allocation Factor		
		1	**3**	**5**
Failure Rate	**1**	1	1	1
	2	1	1	2
	3	1	3	3

	4	1	3	4
	5	1	5	5

Then record the worst case P1 for each hazardous situation in "Data Summary Derived P1" column of 'Appendix C – P1 Table.'

6. Convert the UCLs (Upper Control Limits) from Complaint Data (seen in Attachment 36) to qualitative according to GG-10-01 Appendix 1 Table A1--5, provided below.

Qualitative		Quantitative
Frequent	5	X >1000 OPM
Probable	4	1000 ≥ X > 100 OPM
Occasional	3	100 ≥ X > 10 OPM
Remote	2	10 ≥ X >1 OPM
Improbable	1	< 1 OPM

   Then record qualitative values in the "UCL" column of 'Appendix C – P1 Table' for all applicable Hazardous Situations. Note: UCLs were calculated using the upper limit of the Allocation Factor Range, to be conservative. An allocation of 1 was represented as 10%, an allocation of 3 was represented as 79%, and an allocation of 5 was represented as 100%.
7. Evaluate the worst case P1 between the "Data Summary Derived P1" and "UCL" data to record in the P1 column of 'Appendix C – P1 Table' the final P1 value.
   Note: SME establishes P1 value with Rationale, if appropriate, in 'Appendix C – P1 Table' in the P1 Predicted by Subject Matter Expertise and Selected P1 Rationale columns.
8. Next, record the P2 Conversion and P1 values for each Hazardous Situation in 'Appendix E – PHarm Table'. Calculate PHarm for each Hazardous Situation by multiplying P1 x P2 at each severity level. Convert the PHarm values to Qualitative using Table 6 below:

Table 6 – PHarm Conversions

Individual Residual Risk		Severity (Qualitative)		
		Critical	Moderate	Minor
P1 x P2	0	N/A	N/A	N/A
	1-7	Medium	Low	Low
	8 – 18	High	Medium	Low
	19 – 35	High	High	Medium

9. Record the P1 values and PHarm Qualitative values, per each severity level, for all Hazardous Situations in ‘Appendix A – Global RACT’.