



THE CLEANING VALIDATION

| CHAPTER 19 |

May 21, 2024

Reference Guidelines: ISPE | APIC | PDA | EMA

POINTS TO CONSIDER WHEN USING QRM TOOLS FOR CLEANING PROGRAMS

RISK PRIORITIZATION

Risk Priority Numbers (RPN) can be derived from a matrix that take inion, and to consideration the likeliness, detection, & impact of risks to produce a scalable value.

Once the risks are prioritized, a mitigation strategy can be agreed to.

RPN Value	Severity	Occurrence	Detection
10	Injury to a patient or employee; ADE < 1 µg/day	More than once per batch	Not detectable by current methods
7	Cause extreme customer dissatisfaction; ADE = 1 > 10 µg/day	Once per batch	All manually inspected
5	Something likely to result in a complaint; ADE = 10 > 100 µg/day	Once per six months	Statistical Sampling
3	Minor nuisance resulting in no loss; ADE = 100 > 1000 µg/day	Once every one to three years	100% Inspection
1	Be unnoticed and not affect performance ; ADE ≥ 1000 µg/day	One occurrence in greater than five years	Obvious or controlled and monitored & alarmed by control system

FMEA Scoring

Points To Consider For Cleaning Validation

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