

**Manual 038**

**Figure: Cleaning Validation Requirements**

<b>Plant Use/ Risk Level</b>	<b>Risk Considerations</b>	<b>Minimum Requirements</b>
Dedicated Plant- no changeovers	No risk of cross contamination. Campaign length and any engineering cleaning should be assessed (see sections 5.2.6 and 5.2.7)	No formal validation required. Verify removal of gross contamination at justified periodic intervals
Level 0	No technical restrictions limiting carry over. If sequence of stages or products change then the risk should be revisited.	Verify removal of gross contamination at changeover.
	Technical restrictions limiting carryover.	Demonstrate plant/equipment is visibly clean (or cleaned to technically justified level) for three changeovers
Level 1	Risk of cross contamination between product families at stages prior to finale purification.	ACQ maximum 100ppm demonstrated for three changeovers.
Level 2	Risk of cross contamination into finale	Level of carryover at or below (see section 5.2.4) demonstrated for three changeovers.