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| **Area of Risk** | **Process***What is the function?* | **Failure Mode***What could go wrong?* | **Failure Effect***How does this affect the process function?* | **Severity** | **Causes***Root cause or reason for potential system failure?* | **Occurrence** | **Control***What controls are in place to prevent failure?* | **Detection** | **Score***(S x O x D)* |
| **Appropriate change facilities** | To allow suitable change into room – grade appropriate clothing | Introduction of contamination to higher grade areas due to lack of second change | Can introduce into Grade A zones | 3 | Lack of second change area provides lack of segregated changing from dirty to clean areas | 4 | None at present meaning there is a continuous failure to adhere to best gowning practice | 1 | 12 |
| **Facility Layout** | To provide logical direction of staff from ungraded to Grade C areas. Similar for products there is a designated pathway form unclassified storage areas to Grade A isolator zones | Lack of suitable disinfection of products into and out of unit areas.Entry of staff from ungraded areas to Grade C rooms | Inappropriate movement of staff without associated procedural adherence can cause cross contamination | 3 | No process of unidirectional work flow, therefore may cause product mix up into and out of clean room | 2 | Procedures for gowning and line clearance into and out of rooms and isolators | 2 | 12 |
| **Support Rooms****(Grade D)** | Preparation room provides area for set up and disinfection of products into the clean room, and also product release of prepared items | Product mix upCross contamination of cytotoxic residues | Can results in product mix up of assembled ingredients, product damage with release of cytotoxic residues | 3 | Area is very cramped with a number of un-associated tasks undertaken without segregated areas | 2 | Dedicated benches for each type of product stage, however unsuitable due to room size. | 3 | 12 |
| Room kept at environmental and physical levels to meet de D environment | Loss of physical or environmental control | Introduces and increased risk of microbiological or particulate contamination | 2 | AHU failureIncreased environmental stress due to workload.Poor cleaning | 2 | Continuous physical monitoring plus a daily/weekly/monthly environmental monitoringPPM for AHU | 3 | 12 |