

ECA Task Force on Contamination Control Strategy



Attachment 1: Example of a gap assessment (non-exhaustive)

| Key Areas | Key Elements | Detailed CCS Elements | | Annex 1 rev12 draft reference | Identified potential gaps (or documentation improvement need) versus Annex 1 draft expectations | Key supporting Site Strategies, Rationales, Risk assessments | Key Site Procedures |
|--|--------------|---|--|---|--|--|--|
| | | | | | | Include Reference, title and if possible hyperlink to the | Include Reference, title and hyperlink to the document |
| Facilities, equipment, Utilities and Infrastructure Design, Qualification, Maintenance and Control | Facilities | Facilities Design | Facility design requirements (plant layout, air filtration, material of construction, cleanability, airlock design, logical and chronological activities flows) | 4.1, 4.2, 4.3, 4.5, 4.6, 4.7, 4.8, 4.9 4.10, 4.11, 4.12, 4.13, 4.17 6.6 6.21 | 4.1 explain how controls and monitoring are "scientifically justified and capable of evaluating the state of environmental conditions for cleanrooms, airlocks and pass-throughs used for material and equipment transfer" 4.3 Barriers should be considered in the CCS. " Any alternative approaches to the use of RABS and Isolators should be justified" Develop the current material transfer and airlocks sections using wording of 4.10, 4.11, 4.12, 4.13 | To be filled out accordingly | To be filled out accordingly |
| | | | HVAC system design requirements (Air Filtration/HEPA Filters, Pressure cascades, Temperature, RH, locations of air inlets & outlets, ducts cleanability, air exchanges rates, alarms settings and controls ..) | 4.13, 4.14, 4.15, 4.16 4.35 | Develop an adequate section to cover 4.16 "Setpoints and the criticality of pressure differentials should be documented within the CCS" / "where alarm delays are set, these should be assessed and justified within the CCS" | To be filled out accordingly | To be filled out accordingly |
| | | | Area Classification / Grade cascading | 4.1, 4.4, 4.12, 4.13, 4.20 8.14 | No gap identified | | |
| | | | Physical segregation of activities (dedicated facility/area, use of closed systems, other containment systems, ...) / Barriers | 4.2, 4.3, 4.4 4.18, 4.19, 4.20, 4.21, 4.22, 4.23 8.10, 8.14, 8.15, 8.16 | 4.3 Use of barriers should be considered in the CCS : any alternative approaches to the use of RABS or isolators should be justified | To be filled out accordingly | To be filled out accordingly |
| | | | Localized Unidirectional Air Flow application/protection, dust control systems | 4.2, 4.25 4.6 | No gap identified | | |
| | | Classification & Qualification of Facilities / Barriers | Qualification Program and control (AFPT, Air velocity...) | 4.15, 4.21, 4.26, 4.27, 4.28, 4.29, 4.30, 4.31, 4.32, 4.33, 4.34 | 4.30 & 4.33 develop the current section to explain how current strategy fulfills the requirement for the sampling locations and their positioning during classification " critical processing locations should be based on a documented risks assessment and knowledge of the process and operations" and during qualification "the number of sampling locations s hould be based on a documented risk assessment, including the results of the classification, air visualization and knowledge of the process and operations" | To be filled out accordingly | To be filled out accordingly |
| | | Facility Cleaning and Disinfection | Cleaning Programs (agents selection, frequency, materials...) / Practices | 4.22, 4.36, 4.37 | No gap identified | To be filled out accordingly | To be filled out accordingly |
| | | | Sanitization agents validation (including verification against local flora) | 4.24, 4.37, 4.38 | No gap identified | To be filled out accordingly | To be filled out accordingly |
| | | Pest Control | Pest control Program / Traps location maps | Identified as additional risk beyond Annex 1 requirements | No gap identified | To be filled out accordingly | To be filled out accordingly |
| | | Maintenance | Program for facilities (including Fit and Finish program) | 5.3, 5.6 | No gap identified | To be filled out accordingly | To be filled out accordingly |
| | | | Periodic HEPA filters integrity testing | 4.34 | No gap identified | To be filled out accordingly | To be filled out accordingly |
| | | | Maintenance practices for product protection | 5.6 | No gap identified | To be filled out accordingly | To be filled out accordingly |
| | | Waste Management | Return to service after maintenance | 5.6, 5.7 | No gap identified | To be filled out accordingly | To be filled out accordingly |
| Waste flow and segregation | | | No gap identified | To be filled out accordingly | To be filled out accordingly+82:H17 | | |

ECA Task Force on Contamination Control Strategy



Foundation
Fostering harmonisation
of GMP/GDP regulations

| Key Areas | Key Elements | Detailed CCS Elements | | Annex 1 rev12 draft reference | Identified potential gaps (or documentation improvement need) versus Annex 1 draft expectations | Key supporting Site Strategies, Rationales, Risk assessments <i>Include Reference, title and if possible hyperlink to the</i> | Key Site Procedures <i>Include Reference, title and hyperlink to the document</i> |
|--|---|--|---|---|--|--|--|
| Facilities, equipment, Utilities and Infrastructure Design, Qualification, Maintenance and Control | Equipment | Equipment Design | Equipment design requirements /capability /cleanability | 5.1, 5.2, 5.3, 5.8 5.9 8.34 | 5.9 Include in the CCS the more precise requirement for particles counters maximum tubing length and minimum bend radius | To be filled out accordingly | To be filled out accordingly |
| | | | Operational practices (out of place or in place cleaning of pieces of equipment, draining, drying, steaming, sterilization,...) | 5.6 | No gap identified | To be filled out accordingly | To be filled out accordingly |
| | | | Equipment integrity and storage conditions after cleaning and sterilization (system integrity , storage under positive pressure prior to use..) | 4.11 8.45, 8.46, 8.47, 8.48 | No gap identified | To be filled out accordingly | To be filled out accordingly |
| | | Preventive and Corrective Maintenance | Maintenance Program for equipment | 5.6 | No gap identified | To be filled out accordingly | To be filled out accordingly |
| | | | Maintenance practices for product protection | 5.6 | No gap identified | To be filled out accordingly | To be filled out accordingly |
| | Qualification and Validation of Equipment | Return to service after maintenance | 5.6, 5.7 | No gap identified | To be filled out accordingly | To be filled out accordingly | |
| | Utilities | Utilities Design (Water systems, Clean steam, Compressed gases) | Utilities generation and distribution systems design (materials of construction, loops, recirculation conditions, heat exchangers design, process control limits, on-line control systems, sanitization capabilities, ...). Quality levels and applications | 6.1, 6.2, 6.3, 6.4, 6.5, 6.6 6.7, 6.8, 6.9, 6.10, 6.11 6.16, 6.17 6.18, 6.19 | 6.19 add to existing chapter for gases that "any transfer pipework or tubing that is located after the final sterilizing filter" is sterilized | To be filled out accordingly | To be filled out accordingly |
| | | | Sanitization | Sanitization Program (method, frequency...) | 6.10, 6.12 | No gap identified | To be filled out accordingly |
| | | Preventive and Corrective Maintenance | Maintenance Program for utilities | 6.11 | No gap identified | To be filled out accordingly | To be filled out accordingly |
| | | | Maintenance practices for product protection | 6.12, 6.20 6.22, 6.23 | 6.22, 6.23 Create adequate section to document the contamination control of heating, cooling and hydraulic systems | To be filled out accordingly | To be filled out accordingly |
| Return to service after maintenance | | 6.12 | No gap identified | To be filled out accordingly | To be filled out accordingly | | |
| Qualification and Validation of Utilities | | Utilities Qualification Strategy and control | 6.13 6.15 | 6.13 iii explain how current risk based strategy (including the frequency) fulfills the requirement "a sample from the point at the end of the distribution loop each day that the water is used" | To be filled out accordingly | To be filled out accordingly | |
| Process Design, Validation and Control | Process | Process Design | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | | | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | | | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | | | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | | Aseptic Intervention Management | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | | Glove Control Strategy (RABS, Isolator) | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | | Sterilization Validation | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | | Sterilization Validation | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | | Sterilizing Filtration Validation and integrity testing strategy | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | | Sterile hold times validation | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| Product, Container Closures Design, validation and Control | Materials and Components | Product properties, CQAs | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | | | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | | | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | | Selection of Material and Components (native, RTU, RTS) | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | | Material / Component Flow and Storage | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | | Supplier Management | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | Container / Closure systems | Qualification of Material and Components | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | | Lab Equipment and Methods | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | | Selection of Container / Closure System | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |
| | | Qualification of Container / Closure System | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly | To be filled out accordingly |