

Product / system qualification and change evidence

Use one controlled dossier per product/system family and required customer/application boundary. These records support supplier quality assurance; they do not issue IAF product approval or replace the actual customer decision.

DOSSIER ID/VERSION, SUPPLIER, OPERATIONAL SITE, FAMILY AND CUSTOMER/PROGRAMME

ACTUAL RESPONSIBILITY, PRODUCT/SYSTEM IDENTITY, REVISIONS AND INTENDED USE

REQUIRED CUSTOMER DISPOSITION OR DOCUMENTED INTERNAL-RELEASE BASIS

EVIDENCE MANIFEST, CONFIDENTIALITY/ACCESS PLAN AND ORIGINAL SOURCE LOCATIONS

INCOMPLETE EVIDENCE, LIMITATIONS, CONCESSIONS AND EXPLICIT RELEASE HOLDS

ACCOUNTABLE OWNER, INDEPENDENT REVIEWER AND AUTHENTICATED AUTHORIZATION

Q01 Product, system and customer boundary

ENTITY / SCOPE / CASE REFERENCE

DOSSIER ID/VERSION, LEGAL SUPPLIER, OPERATIONAL SITE AND FAMILY/SCOPE IDS

CUSTOMER, APPLICATION, ORDER/PROGRAMME AND EXACT PRODUCT/SYSTEM IDENTITY

PART, HARDWARE, SOFTWARE, MATERIAL, VARIANT AND CONFIGURATION REVISIONS

SUPPLIER RESPONSIBILITY, SOURCE MANUFACTURER AND INCLUDED RELATED SERVICES

APPROVAL BASIS, REQUIRED CUSTOMER AUTHORITY, INTENDED USE AND EXCLUSIONS

Q02 Requirements and feasibility baseline

ENTITY / SCOPE / CASE REFERENCE

CUSTOMER SPECIFICATION/DRAWING/DATA VERSIONS AND ACCEPTANCE CRITERIA

FUNCTIONAL, SAFETY, LIFETIME, INTERFACE, ENVIRONMENTAL AND MARKET REQUIREMENTS

PACKAGING, DELIVERY, SERVICE, SUPPORT AND NOTIFICATION REQUIREMENTS

UNRESOLVED REQUIREMENTS, CONFLICTING INPUTS AND ACCEPTED TECHNICAL RESOLUTIONS

FEASIBILITY REVIEW, OWNERS, CAPACITY ASSUMPTIONS AND AUTHORIZED COMMITMENT

Q03 Responsibility and interface agreement

ENTITY / SCOPE / CASE REFERENCE

DESIGN, PROCESS, INTEGRATION, TEST, RELEASE AND FIELD-ACTION ACCOUNTABLE PARTIES

CUSTOMER-NOMINATED SOURCES, SUPPLIED DESIGN AND RETAINED SUPPLIER DUTIES

SYSTEM INTERFACES, ALLOCATED REQUIREMENTS AND UNVERIFIED CUSTOMER ASSUMPTIONS

CUSTOMER PROPERTY, DATA/IP RIGHTS, EVIDENCE ACCESS AND SUPPORT DEPENDENCIES

AGREED RESPONSIBILITY DECISIONS, DATES, AUTHORITY AND UNRESOLVED BOUNDARIES

Q04 Risk, safety and critical-characteristic map

ENTITY / SCOPE / CASE REFERENCE

HAZARDS/FAILURES, INTENDED CONDITIONS, FORESEEABLE MISUSE AND CONSEQUENCES

CRITICAL CHARACTERISTICS AND LINKS TO CUSTOMER/SYSTEM SAFETY REQUIREMENTS

PREVENTION, DETECTION, REACTION, ACCEPTANCE AND RESPONSIBLE OWNER PER RISK

SUB-TIER/PROCESS/SOFTWARE CONTRIBUTIONS AND COMMON-CAUSE DEPENDENCIES

RESIDUAL UNCERTAINTY, COMPETENT ACCEPTANCE AND UNRESOLVED RELEASE HOLDS

Q05 Verification and application validation

ENTITY / SCOPE / CASE REFERENCE

REQUIREMENT-TO-METHOD MAPPING, SAMPLE/CONFIGURATION AND ACCEPTANCE RULES

ORIGINAL RESULTS, FAILURES, RETESTS, DEVIATIONS AND REPORT/SOURCE REFERENCES

REPRESENTATIVE/WORST-CASE SELECTION, LIFE/ENVIRONMENT/INTERFACE COVERAGE

VIRTUAL/AI EVIDENCE VALIDATION, UNCERTAINTY AND PHYSICAL CORRELATION IF USED

TECHNICAL CONCLUSION, UNTESTED COMBINATIONS, CUSTOMER INTEGRATION AND AUTHORITY

Q06 Process qualification and launch control

ENTITY / SCOPE / CASE REFERENCE

ACTUAL PROCESS FLOW, SITE, TOOLS/CAVITIES, EQUIPMENT, SOFTWARE AND SUB-TIERS

CONTROL PLAN, PROCESS-RISK LINKS, SETTINGS/WINDOWS AND REACTION RULES

REPRESENTATIVE RUN/LOAD/RELEASE IDENTITY AND ORIGINAL QUALIFICATION RESULTS

SPECIAL-PROCESS VALIDATION, HIDDEN FEATURES AND POST-CHANGE CHECKS

ENHANCED LAUNCH CONTROLS, OBJECTIVE EXIT CRITERIA AND AUTHORIZED DISPOSITION

Q07 Measurement and acceptance capability

ENTITY / SCOPE / CASE REFERENCE

CHARACTERISTIC, METHOD, RANGE, EQUIPMENT/SOFTWARE AND DECISION RULE

CALIBRATION/VERIFICATION, REPEATABILITY, REPRODUCIBILITY AND RELEVANT UNCERTAINTY

SAMPLING RATIONALE, ENVIRONMENT, FIXTURE, OPERATOR AND REPRESENTATIVE EVIDENCE

EXTERNAL PROVIDER COMPETENCE, SAMPLE CHAIN AND REPORT AUTHENTICITY

ACCEPTANCE AUTHORITY, INCONCLUSIVE RESULTS, RETESTS AND LIMITATIONS

Q08 Materials, provenance and substances

ENTITY / SCOPE / CASE REFERENCE

COMPOSITION/GRADE/FORMULATION, SUPPLIER, ACTUAL SOURCE AND LOT BOUNDARIES

DECLARATIONS, ORIGINAL BATCH/LOT EVIDENCE, SAMPLING AND SOURCE AUTHENTICITY

RESTRICTED-SUBSTANCE, HAZARD, HANDLING, STORAGE AND SHELF-LIFE CONTROLS

RECOVERED/REUSED CONTENT, PERFORMANCE EVIDENCE AND CLAIM CALCULATION LIMITS

MATERIAL/SOURCE CHANGES, CUSTOMER DISPOSITION AND FIRST AFFECTED BATCH

Q09 Software, data and digital release

ENTITY / SCOPE / CASE REFERENCE

ARTIFACT/FUNCTION/VERSION, SUPPORTED CONFIGURATION AND CUSTOMER DEPLOYMENT

COMPONENT/DEPENDENCY INVENTORY, PROVENANCE, LICENCES AND SUPPORT OWNER

TOOLCHAIN/BUILD, REVIEW/TEST EVIDENCE, INTEGRITY AND SIGNING AUTHORIZATION

VULNERABILITY DECISIONS, KNOWN LIMITATIONS AND SAFETY/SECURITY ESCALATION

DEPLOYMENT, UPDATE, RECOVERY AND END-OF-SUPPORT EVIDENCE AND RIGHTS

Q10 Genealogy and completed-case population

ENTITY / SCOPE / CASE REFERENCE

FAMILY/SITE/RESPONSIBILITY, SIX-MONTH OPERATING PERIOD AND FULL CASE POPULATION

CASE 1: ACTUAL IDENTITY/DATE, EXECUTION, ACCEPTANCE, RELEASE AND RECIPIENT TRACE

CASE 2: ACTUAL IDENTITY/DATE, EXECUTION, ACCEPTANCE, RELEASE AND RECIPIENT TRACE

CASE 3: ACTUAL IDENTITY/DATE, EXECUTION, ACCEPTANCE, RELEASE AND RECIPIENT TRACE

SUB-TIER-TO-CUSTOMER TRACE, SPLIT/MERGE/REWORK QUANTITIES AND SOFTWARE VERSIONS

ADVERSE/CHANGED CASES, RETRIEVAL EXERCISE AND UNRESOLVED POPULATION LIMITS

Q11 Capacity and supply continuity

ENTITY / SCOPE / CASE REFERENCE

CUSTOMER DEMAND, PROGRAMME MIX, SERVICE OBLIGATION AND AGREED DELIVERY BASIS

CONSTRAINT OPERATION, AVAILABLE TIME, LOSSES, CYCLE AND ACCEPTED OUTPUT

REPRESENTATIVE RUN, STAFFING, SUB-TIER CONSTRAINTS AND ASSUMPTIONS VERIFIED

RECOVERY, QUALIFIED ALTERNATIVES, SOURCE CONCENTRATION AND TEST RESULTS

OBSOLESCENCE, SUPPORT EXIT, LAST-TIME BUY AND HONEST COMMITMENT DECISION

Q12 Customer disposition and internal release

ENTITY / SCOPE / CASE REFERENCE

REQUIRED CUSTOMER APPROVAL OR DOCUMENTED BASIS FOR INTERNAL-ONLY RELEASE

ACTUAL DISPOSITION, EXACT CONFIGURATION/SITE/SOURCE AND AUTHORITY/DATE/REFERENCE

QUANTITY/TIME/USE LIMITS, CONDITIONS, CONCESSION EXPIRY AND PROHIBITED USES

SUPPLIER INDEPENDENT RELEASE CHECKS, AUTHORITY AND SHIPMENT/DELIVERY LOCK

OPEN ISSUES, MISSING APPROVALS AND EVIDENCE OF STOPPED UNSUPPORTED SUPPLY

Q13 Change impact and reapproval

ENTITY / SCOPE / CASE REFERENCE

CHANGE ID, OLD/NEW BASELINE, REASON, AFFECTED CUSTOMERS AND SCOPE ROWS

SAFETY, PERFORMANCE, SOURCE, PROCESS, SOFTWARE, SUPPORT AND RIGHTS IMPACT

QUALIFICATION, REQUIRED CUSTOMER NOTICES/APPROVALS AND IAF SCOPE NOTIFICATION

STOCK SEGREGATION, OLD/NEW TRACE, FIRST AFFECTED LOT/RELEASE AND IMPLEMENTATION

POST-CHANGE RESULTS, ADVERSE EFFECTS, EFFECTIVENESS AND FINAL AUTHORIZATION

Q14 Production/service handover and dossier review

ENTITY / SCOPE / CASE REFERENCE

APPROVED REQUIREMENTS TRANSLATED TO PURCHASE, WORK, RELEASE AND SERVICE CONTROLS

TRAINING, TECHNICAL OWNERS, SUB-TIER COMMITMENTS AND CUSTOMER INFORMATION

COMPLETE ORIGINAL EVIDENCE MANIFEST, ACCESS RESTRICTIONS AND RETAINED FAILURES

ONGOING CHECKS, REQUALIFICATION TRIGGERS, PERFORMANCE AND SUPPORT MONITORING

INDEPENDENT TECHNICAL REVIEW, OPEN MATTERS, DISPOSITION AND AUTHENTICATED AUTHORITY

Continuation and supporting detail

ENTITY / SCOPE / CASE REFERENCE

PARENT FIELD, REQUIREMENT OR RECORD ID / CONTINUATION NUMBER

FULL RESPONSE, SOURCE REFERENCES, RATIONALE AND LIMITATIONS

PREPARED BY / ROLE / DATE / AUTHORIZATION