# EDQM Blood Conference
## Innovation in Blood Establishment Processes

14-15 January 2025
Strasbourg, France

## Workshop:
# Blood Quality Management
(13:30 – 15:00)

Moderator: **Vanja Nikolac-Markić**, Head of SoHO Quality Section, EDQM

Hosts: **Ína Björg Hjálmarsdóttir**, The Blood Bank, Landspitali University Hospital, Iceland
**Stephen Vardy**, NHS Blood and Transplant, England
**Nigar Ertuğrul Örüç**, Blood Transfusion Center, University of Health Sciences Diskapı Yildirim Beyazit Training and Research Hospital, Türkiye

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# Blood Quality Management –

# Application in implementing innovation in a Blood Establishment

**Stephen Vardy**
NHS Blood and Transplant

**Ína Björg Hjálmarsdóttir**
The Blood Bank Iceland

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# Quality Management System – Good Practice Guidelines

1.2.1. Quality management is a wide-ranging concept covering all matters that individually or collectively influence the quality of blood and blood components. It is the sum total of the organised arrangements made with the objective of ensuring that blood components are of the quality required for their intended use. Quality management therefore incorporates good practice.

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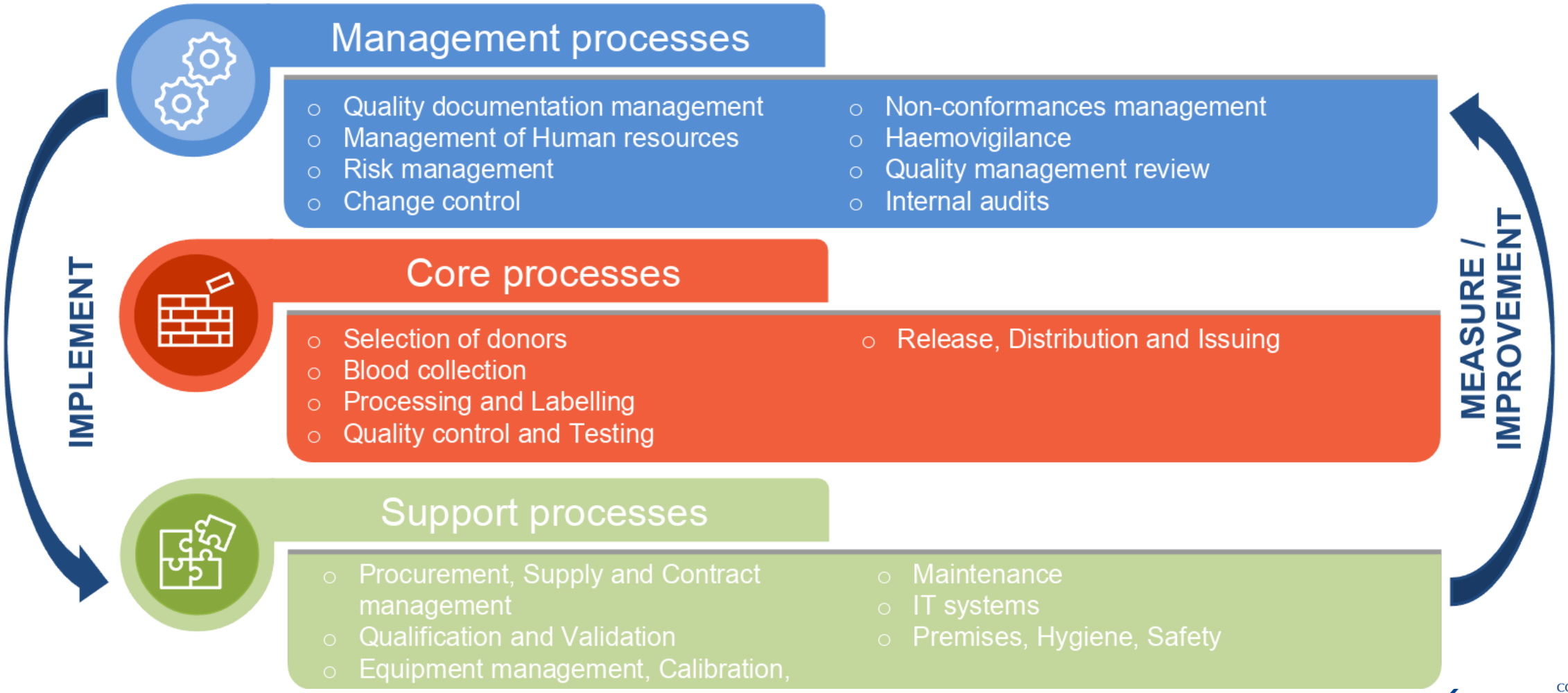
# Quality Management System in BEs

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# Implementing innovation in a BE

The example:
Request from a customer to supply a dried plasma product

- Change control
- Risk assessment
- Qualification and validation

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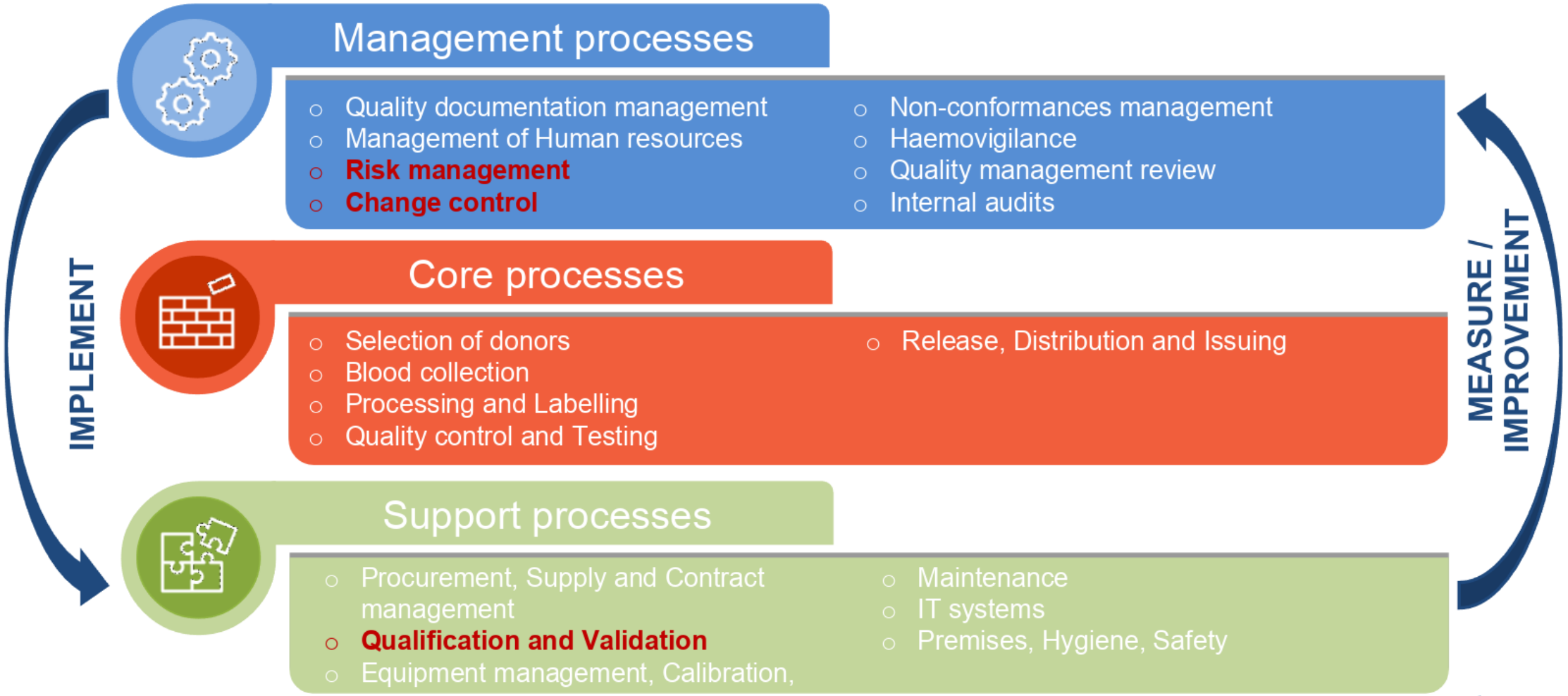
# Focus on:

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# Customer product requirements for the dried plasma product

| | |
|---|---|
| Units per annum | 1,000 |
| Source of plasma/Site of manufacturing | UK non-remunerated blood donors |
| Blood group | Group A low titre or AB |
| Leucocyte depleted | Yes, to meet UK spec for LD |
| Viral risk | No worse than current UK FFP |
| Single donor or mini-pool | Either as long as micro risk acceptable |
| Product quality | Meets agreed Red Book Spec for new component |
| Storage container of final product | **Plastic** not glass bottle |
| Shelf-life – minimum of | 24 months at 2-8°C<br>18 months at 2-24°C<br>12 months at 50°C |
| Likely acceptable cost per unit in routine use | xxxxxx |

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# Project Established - Objectives

- Develop a product suitable to manufacture long term in UK, within the timeframe required by funder, that is commercially viable & meets needs of funder
- Assess operational feasibility/cost
- Develop product specification & conduct laboratory studies to show product conforms
- Agree regulatory classification and route to approval in UK
- Design and conduct any clinical study needed
- Understand civilian benefits and demand
- Gain all approvals to manufacture in UK (subject to nature of clinical data)

**Y1-2 (2022/23)**
- Collaboration agreement
- Site works to accommodate equipment
- Install and qualify equipment

**Y3 (2024)**
- Laboratory validation
- Design clinical study & trial authorisation

**Y4 (2025+)**
- Clinical study
- Regulatory submission for UKCA/CE marking of medical device

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# Change control

**Good Practice Guidelines 1.2.12:**

"A formal change control system should be in place to plan, evaluate and document all changes that may affect the quality, traceability, availability or effect of components, or the safety of components, donors or patients. The potential impact of the proposed change must be evaluated, and the degree of revalidation or additional testing, qualification and validation needed must be determined."

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# Why change control?

- Guarantee that all changes are evaluated for their effect on product quality and validation status
- To ensure that changes are introduced in a controlled and coordinated manner
- To identify and reduce risks
- Uncontrolled changes carry significant risks and may impact the validated status

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# Change control procedure step by step

1) Change Request

2) Assessment

3) Change Plan

4) Change plan approval

5) Execution of action items

6) Change implementation approval

7) Change closure

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# Change control procedure step by step

1) Change Request

- Formal request (standardised form)
- Description of old versus new situation
- Reason for change, rationale
- Planned implementation date
- Request approved by manager/person responsible

2) Assessment

3) Change Plan

4) Change plan approval

5) Execution of action items

6) Change implementation approval

7) Change closure

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# Change control procedure step by step

1) Change Request

2) Assessment

- Which departments are involved?
- What is the impact of the change?
- What are the risks if the change is not implemented?
- What are the risks if the change is implemented?
- What can you do to eliminate or reduce the risk?
- Review assessment

3) Change Plan

4) Change plan approval

5) Execution of action items

6) Change implementation approval

7) Change closure

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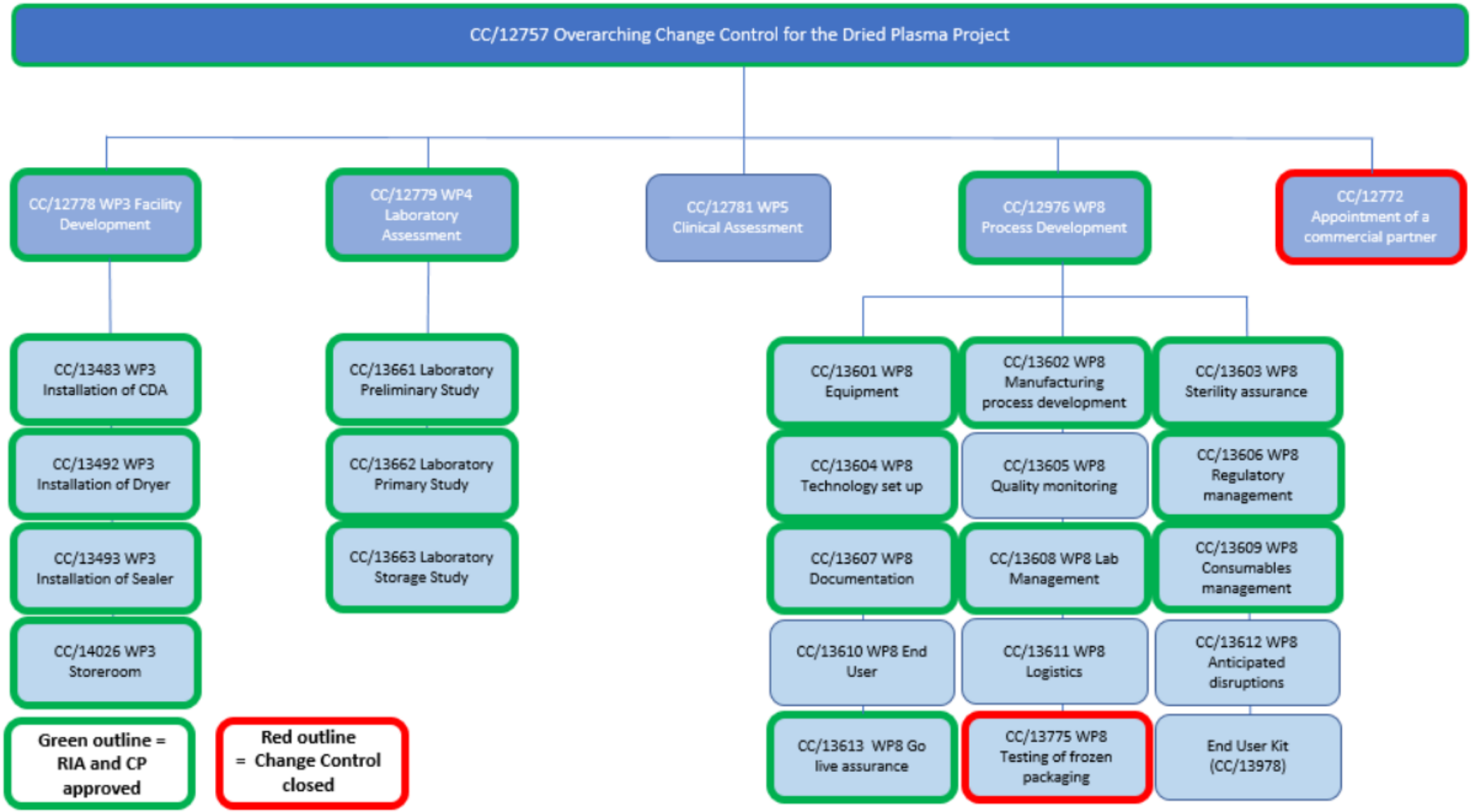
# Dried plasma change control structure



# Risk assessment matrix

FRM4889/8 – Quality Risk Assessment Record

[CC/INC/QI/ ]

NHS Blood and Transplant

Effective date: 19/04/2022

**Appendix 1 – Risk management tool**

| | Step 1 – Risk Impact Criteria (I) | | | Step 2 – Likelihood Scoring (L) | | |
|---|---|---|---|---|---|---|
| **Impact Level Score** | **On individuals (Patient/donor)** | **On System** | **On supply Product/service** | **Score** | **Classification** | **Description** |
| **Negligible 1** | Nil<br>No apparent adverse effect on donor or patient health | No effect | Insignificant.<br>Product loss but no impact on supply | **1** | **Rare** | **Practically impossible**<br>e.g. < 1 in 10,000. Not expected to occur for years |
| **Minor 2** | Non Serious.<br>Non-permanent adverse effect | Minor damage | Temporary delays | **2** | **Unlikely** | **Not expected to occur**<br>e.g. 1 in 10,000 to 1 in1000.<br>Expected to occur at least annually |
| **Moderate 3** | Serious.<br>Semi-permanent adverse effect<br>Adverse effect on several (2-15) donor's/patient's health | Damage for a short period | Cannot meet demand for short period of time.<br>Hospital procedures cancelled or postponed | **3** | **Possible** | **May occur occasionally**<br>e.g. 1 in 1000 to 1 in 100. Expected to occur monthly |
| **Major 4** | Life Threatening<br>Permanent adverse effect<br>Adverse effect on several15-50 donor's/patient's health | Major damage.<br>Significant delay to repair | Unable to meet demand for more than 1 day<br>Significant number of hospital procedures cancelled | **4** | **Likely** | **Expected to occur, but not persistent**<br>e.g. 1 in 100 to 1 in 10. Expected to occur at least weekly |
| **Catastrophic 5** | Death of ≥1 or<br>Harm to many (>50) patients/donors | System destroyed – Need to rebuild | Total inability to meet demand | **5** | **Almost Certain** | **Expected to occur on many occasions**<br>e.g. 1 in 10 or more frequent.<br>Expected to occur daily |

**Applying the Risk/Impact Matrix**

| | 1<br>Rare | 2<br>Unlikely | 3<br>Possible | 4<br>Likely | 5<br>Almost Certain |
|---|---|---|---|---|---|
| 1<br>Negligible | 1 | 2 | 3 | 4 | 5 |
| 2<br>Minor | 2 | 4 | 6 | 8 | 10 |
| 3<br>Moderate | 3 | 6 | 9 | 12 | 15 |
| 4<br>Major | 4 | 8 | 12 | 16 | 20 |
| 5<br>Catastrophic | 5 | 10 | 15 | 20 | 25 |

| | **Risk Level** |
|---|---|
| 1 - 3 | Low / Acceptable |
| 4 - 8 | Manageable |
| 9 - 14 | Medium/Significant |
| 15 - 25 | HIGH |

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# How is the matrix used? An example:

**FRM4889/8 – Quality Risk Assessment Record**

CC/12757

NHS
Blood and Transplant
Effective date: 19/04/2022

| | |
|---|---|
| **Description/Summary of CC/ Event** | Overarching change control for the Dried Plasma (DP) project.<br>To develop a dried plasma product suitable to manufacture long term in UK, within the timeframe required by funder (MoD), that is commercially viable & meets needs of military.<br>The project is initially scheduled for 3 years, with the following key activities:<br>Year 1 - Collaboration agreement with commercial partner, site works at NHSBT Cambridge to accommodate equipment, Install and quality equipment.<br>Year 2 - Laboratory studies, Sterility assurance, Design clinical study and trial authorisation.<br>Year 3 - Clinical study, Regulatory submission for UKCA marking of equipment.<br><br>This risk assessment will assess risks to the patient and/or product safety. Project risks will be captured in the project risk register using standard PM governance. |

| Hazard with Potential Consequences | Controls<br>What are the current controls in place to mitigate the risk | Residual After controls<br>I | L | Risk | Actions<br>What further action is required to reduce the risk further (if deemed necessary) | Final Post actions<br>I | L | Risk | Risk assessment Action Ref. |
|---|---|---|---|---|---|---|---|---|---|
| **People** | **Consider:**<br>• Risks to donors, patients, staff, Medical Device users and donor relatives (including capacity planning).<br>• Human Factors implications<br>• Any other hazards related to People. | | | | | | | | |
| Hazard:<br>Poor governance arrangements. Insufficient definitions of roles and responsibilities (R&Rs)<br>Potential Consequence:<br>Poor decision making.<br>Unable to identify project issues and report on these leading to an inferior or harmful product | Governance structure in place with Work Packages with assigned leads, project team, Accountable Exec and Project board for decision making | 5 | 2 | 10 | Action:<br>• Ensure R&Rs are in place<br>• Implement and use a RAPID project management decision tool<br>Evidence Required:<br>• Link to where R&R documents held<br>• Link to where RAPID matrix held | 5 | 1 | 5 | 6<br>7 |
| Hazard:<br>Key stakeholders unable to work on the project for unforeseen circumstances (e.g. long-term sickness, emerging urgent NHSBT duties) without designated deputies. Project continues with a less experienced team.<br>Potential Consequence:<br>Delays, inefficient working, miss something leading to an inferior or harmful product | • Overlap of some key project roles (e.g. Facility lead and Lab Assessment lead)<br>• Briefing of wider QA team on regulatory issues<br>• Ability to work remotely | 5 | 2 | 10 | Action:<br>• Appoint to support roles (deputies) to increase resilience – resilience plan and R&Rs<br>• Ensure training and work shadowing arrangements are in place<br>• Document any required work instructions in SOPs<br>Evidence Required:<br>• Document all in Q-Pulse stage actions | 5 | 1 | 5 | 8<br>9<br>10 |



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| Hazard with Potential Consequences | Controls | Residual | | | Actions | Final | | | Risk assessment Action Ref. |
|---|---|---|---|---|---|---|---|---|---|
| | | I | L | Risk | | I | L | Risk | |
| **Process** | **Consider:**<br>• Documentation that may need to be created or revised. Validation needs to ensure correct qualification phases are added to the validation protocol and Q-Pulse record.<br>• Ethical/Medical approvals.<br>• Any other hazards related to Process | | | | | | | | |
| Hazard:<br>Process for manufacturing DP not adequately defined or documented.<br>For example, process doesn't allow for sufficient donation number audit trail on PULSE/through labelling for the end-to-end process.<br>Potential Consequence:<br>Insufficient controls to ensure final product is linked to donation, with the potential for mix up and patient harm/loss of traceability | Blood component manufacturing processes in place with appropriate controls within NHSBT that includes the transfer of blood product from original donation pack to unattached packs | 5 | 3 | 15 | Action:<br>• Set up a new specific work package (WP) for developing the process of manufacturing DP including mapping out the end-to-end process<br>• Raise a change control for process design<br>Evidence Required:<br>• New WP established<br>• Reference to change control number | 5 | 1 | 5 | 11<br>12 |



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# Change control procedure step by step

1) Change Request

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7) Change closure

- Analysis of the impacts of the change and associated risks
- Identification of action items (risk mitigation measures: avoidance, reduction, transference, acceptance)
- Time-schedule: planning **WHEN** to do **WHAT**
- Assign action items/tasks

Tasks may include:

- Qualification / validation
- Staff training
- Creation / update of procedures / SOPs
- Contract update (suppliers)
- Creation / update of a maintenance plan
- Information of impacted third parties (e.g. donors)
- Information of competent authority

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# Change plan example (1)

CHANGE CONTROL PLAN – OVERARCHING CHANGE CONTROL FOR THE DRIED PLASMA PROJECT (CC/12757)

**Change Team:**

**Accountable Exec**
Rebecca Cardigan, Head of Component Development

**CDL Programme Team**
Melanie Munro, Component Development Laboratory (CDL) Translational Research Programme Lead
Sian Huish, CDL Translational Research Programme Lead
Gillian Eastwood, Translational Research Project Support Officer

**Clinical Lead**
Laura Green, Consultant Haematologist

**CDL Operations**
Mike Wiltshire, CDL Manager & Head of Centre Cambridge
Lucy Bower, CDL Lead Specialist

**Blood Supply Technical and Scientific Development**
Michelle Ray, Assistant Head of Manufacturing Development

**Quality**
Steve Vardy, Lead Quality Specialist – Component Development

| Action | Risk Action Ref | Actions | Target | Owner | Required Evidence *(to be recorded and/or attached to CC record in Q-Pulse)* |
|---|---|---|---|---|---|
| 1. | 1 | Recruit a Project Support Officer to support the project, including with delivering comms | 31/01/23 | MM | Confirmation of appointment |
| 2. | 2 | Develop SharePoint site for project documentation with access for all relevant stakeholders | 01/03/23 | MM | Document link to the SharePoint site |

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# Change plan example (2)

CHANGE CONTROL PLAN – OVERARCHING CHANGE CONTROL FOR THE DRIED PLASMA PROJECT (CC/12757)

| | | | | | |
|---|---|---|---|---|---|
| 3. | 3 | Ensure Regular meetings/ updates are held and minuted | Throughout project | SH | Document link to where agendas/minutes are held |
| 4. | 4 | Have dashboards on project progress and share with relevant stakeholders | Throughout project | SH | Document link to where dashboards are held |
| 5. | 5 | Build relationship with chosen Commercial Partner to ensure open communication with chosen supplier | 31/01/24 | SH | Document how this is established and maintained |
| 6. | 6 | Ensure Roles & Responsibilities are in place and documented for governance arrangements | 13/03/23 | SH | Link to where R&R documents are held |
| 7. | 7 | Implement and use a RAPID project management decision tool | 13/03/23 | SH | Link to where RAPID matrix is held |
| 8. | 8,9,10 | Appoint to support roles (deputies) to increase resilience –<br>• Document this in a resilience plan and R&Rs<br>• Ensure training and work shadowing arrangements are in place<br>• Document any required work instructions in SOPs | 01/09/23 | SH | Document in Q-Pulse action |

# Qualification and validation

## Good Practice Guidelines 4.3:

- Qualification of facilities and equipment
  - *Qualification is a part of validation and the act of verifying that any personnel, premises, equipment or material works correctly and delivers the expected results.*
- Validation of systems, manufacturing processes and tests
  - *Validation refers to the establishment of documented and objective evidence that the predefined requirements for a specific procedure or process can be fulfilled consistently.*
  - *Validation plan is a description of validation activities, responsibilities and procedures. It describes specifically how a certain validation is to be done.*
- Requirement to control the critical aspects of the operations

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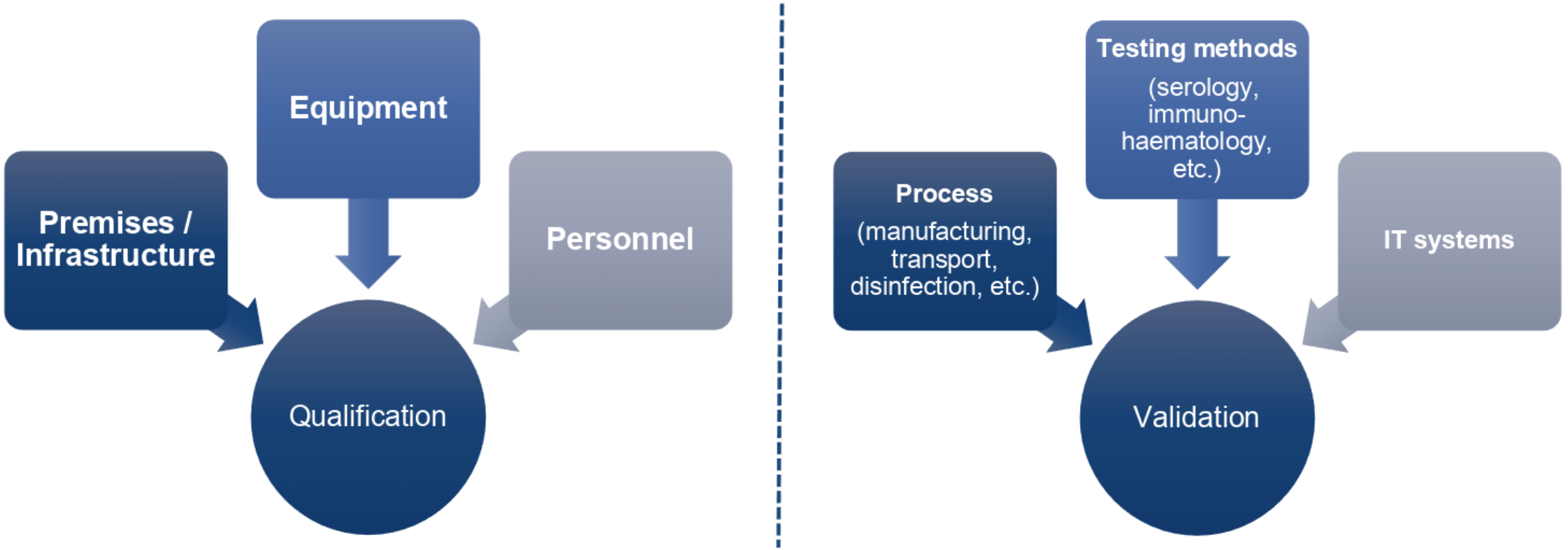
# Qualification vs validation




Qualification (premises, equipment) is conducted prior to method/process validation

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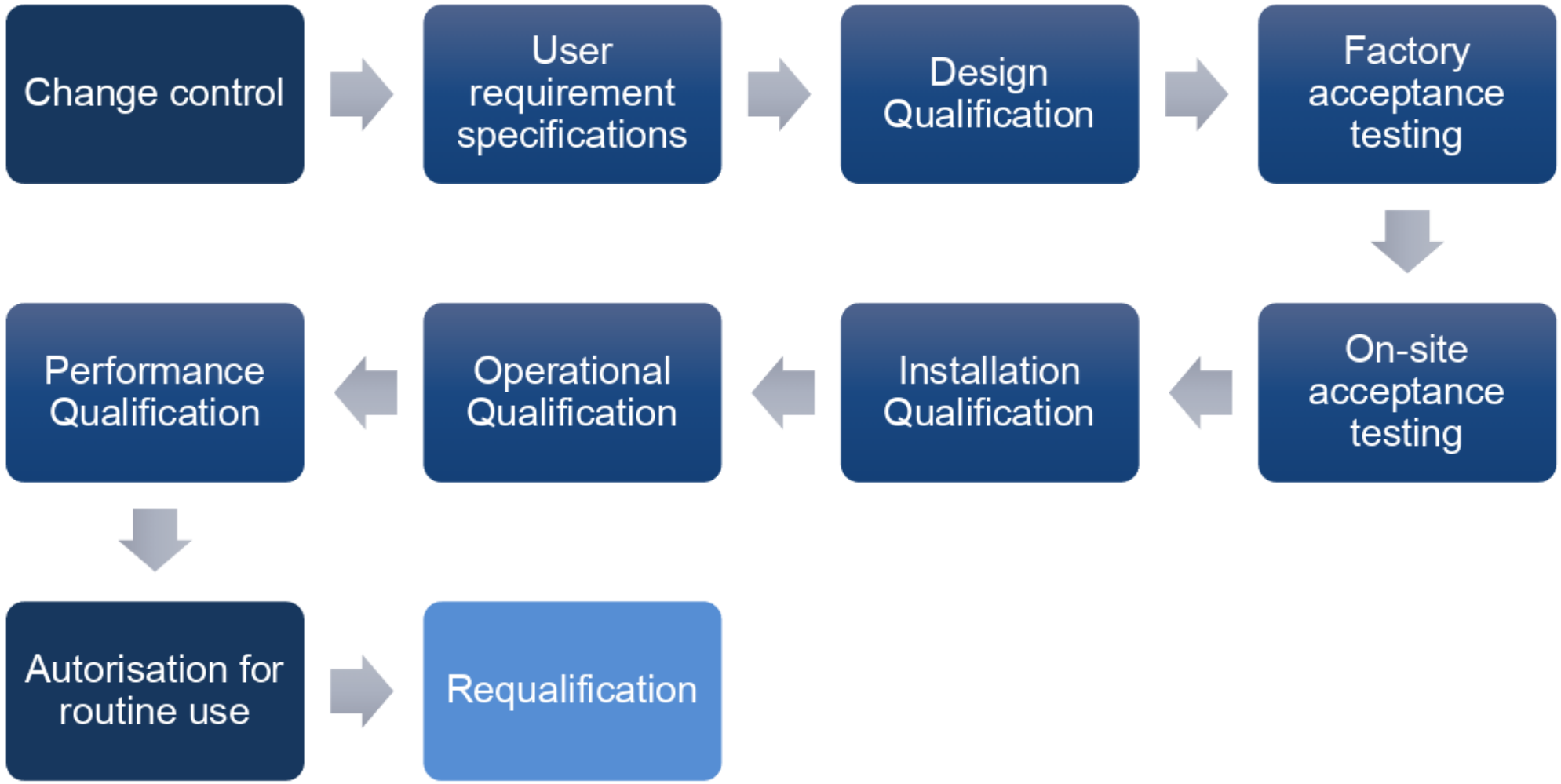
# Qualification process steps

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# Process validation

- All critical manufacturing process should be validated:
  - Before implementation
  - Based on a documented test protocol and predefined acceptance criteria

- Objectives:
  - Ensure blood components are produced with consistent quality and meet specifications
  - Demonstrate that the process is robust and reliable

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# Change control procedure step by step

1) Change Request

2) Assessment

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4) Change plan approval

5) Execution of action items

6) Change implementation approval

7) Change closure

- Who should evaluate and approve the plan?
  - Change Control Board
  - Process owner/manager
  - Other relevant managers
  - Responsible Person
  - Quality Manager

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# Change control procedure step by step

1) Change Request

2) Assessment

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6) Change implementation approval

7) Change closure

- Execution of tasks (qualification/validation, documentation, training, communication)
- Regular update on status
- Project leader verifies completion of actions described.

**IMPORTANT:** Modification of the action plan requires prior approval by the person responsible for this process (project leader / quality manager)

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# Validation planning for dried plasma

**SPN2244/1 – Dried Plasma - Validation Master Plan**

NHS Blood and Transplant

Copy No:

Effective date: 28/03/2023

## Objective

The purpose of this Validation Master Plan is to outline the key elements for the prospective qualification and validation requirements of the new dedicated Dried Plasma Manufacturing facility and process to be located at NHSBT Cambridge site. Due to the size and complexity of the project this Validation Master Plan has been developed in accordance with the guidance given in the EDQM Good Practice Guidelines:4.3: Qualification and Validation.

The qualification requirements will encompass the new facility and the equipment used in the manufacture of a dried plasma product, followed by laboratory studies to assess the quality of the reconstituted product ahead of clinical trials.

The new facility will be licensed for the manufacture of Blood Products including Dried Plasma by the MHRA as part of NHSBT's Blood Establishment Authorisation (BEA 25224) for NHSBT's Cambridge site.

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**4. Scope**

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5.2 Requirements and Planning
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**6. Document format and control**
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**11. Revalidation**

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Appendix 2 - Change Control Strategy





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# User requirements – Facility



## Layout

Ambient temperature-controlled areas, equipment and new storage facilities must be temperature mapped. EMS probe type e.g. air or core and location should be positioned in areas of operational risk in accordance with MPD77.

Laboratory facilities are based on H&I and RCI specifications (SPN1271 & SPN1278), in addition to "Requirements and principals for NHSBT manufacturing premises" (SPN372 and DAT1766). The layout and configuration of space needs to be considered on a site-by-site basis using regulatory requirements and the diagrams below.

### *Functional Design Qualification*

Scale drawing of an example layout of a DPMF with an activity of 1-2000 units of DP per year.

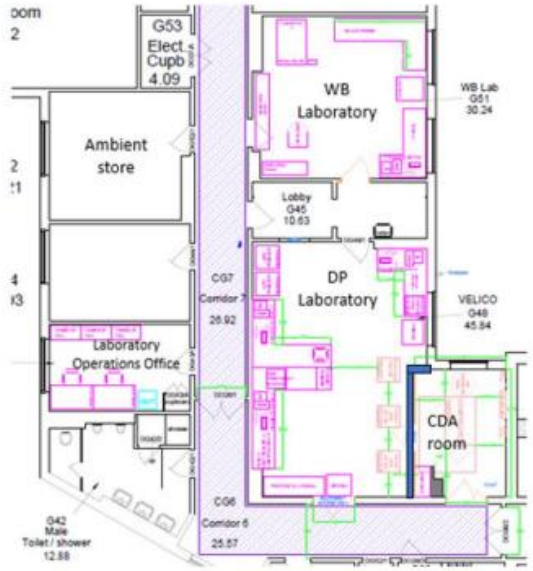


**Figure 3. Velico DPMF example layout**
Example layout of a DPMF with an activity of 1-2000 units of DP per year.

Note: The room specification is for two ODP frontline driers (spray driers) to future proof the facility in case there is a requirement to increase manufacture of DP - only one will be purchased in the first instance.



**SPN2174/2 – Dried Plasma Manufacturing Facility (Velico) Specification**

NHS Blood and Transplant
Copy No:
Effective date: 14/10/2024

## Technical Specification for Construction

| Dried Plasma Manufacturing Facility – Dried Plasma (DP) Laboratory | |
|---|---|
| **Details** | **Comments** |
| **Area m2:** Variable<br>Size is dependent on projected workload. Suggested minimum size 25-30 m2 | Location in Cambridge – G48 (approx. 45 m2) |
| **Occupancy:**<br>Typically to accommodate 2-3 people | N/A |
| **Floor to ceiling height:**<br>Should equal or exceed 2700mm | Largest item in the room has a height of 2030 mm (H) |
| **Doors:**<br>Staff access door from the DP Laboratory to the Staff Lobby.<br>Equipment access door from the DP Laboratory to the Corridor<br>Access door from the DP Laboratory to the CDA Room | PVC Encapsulated hygienic door panels and architraves<br>All doors to have a vision panel<br>Staff access door to be automatic (motorised) opening when badge is swiped (G4S)<br>Equipment access door must be lockable and be able to accommodate Equipment size: 940 mm(L) × 1170 mm (W) × 2030 mm (H) without tilting. Propose a double door or door and a half?<br>Staff access door from the DP Laboratory to the CDA Room must be lockable |
| **Windows:**<br>Internal windows to staff lobby<br>Window to outside to be UPVC or Aluminium | Windows must be non-opening<br>Tinted / reflected to minimise solar gain, sealed / non openable, easy clean, no dust traps |
| **Electrical requirements:**<br>Max power requirements (single item) – 220 VAC, 30 A, 50Hz<br>Sockets required for all listed equipment (see Equipment Data Template: Dried Plasma Manufacturing Facility – DP Laboratory)<br>Additional sockets required for cleaners and spares | Room requires single phase power only<br>3 x 30 Amp sockets required<br>Frontline Freezer – maximum 2 required<br>Emergency shut off switch for Frontline driers and sealer circuits<br>Twin 10/13 A sockets: 24 required (est.)<br>All cabling and sockets to be housed in appropriate trunking |
| **Lighting:**<br>LED/emergency lighting range, artificial natural lighting, sensor activated light switches | Illuminance should be at an appropriate level for the work to be performed – ideally lux levels on the lights installed should be adjustable.<br>Flush / recessed, sealed, no dust traps, easily accessible, anti-reflective. 'no hands' operation (Automated lighting, either absence or presence detection). |
| **Heating/Cooling/ventilation:**<br>Must be able to maintain a room temperature of 18 – 26 °C<br><br>Passive ventilation required for each ODP Frontline drier (2 required) | Essential high specification, must hold required temperature 18 – 26°C)<br>Humidity range of the room must be maintained between 10 – 80%<br>Exhaust per drier approx.: 50°C, TBD humidity, 800 L/min (see appendix 3)<br>*Propose n+1 needed for HVAC for this room – cost dependent* |
| **Fire Alarms and Detection:**<br>Smoke detection and alarms | Equipment must meet to BS5839 |
| **Data/telephone:**<br>Data/electrical trunking to be fitted around the room<br>Phones attached via WBTs<br>Wi-fi router if required | Where possible data points should accompany electric sockets<br><br>Wi-fi to cover the laboratory |
| **Room monitoring:**<br>Contronics points required<br>Humidity monitoring | 2x fridge – Location as shown on the plan<br>2x freezer – Location as shown on the plan<br>4 room monitoring probes – location to be agreed on detailed plan<br>Humidity monitoring required |
| **Security/Entry System/Intercom:**<br>Corridor to Lab intercom<br>Windows secured – non opening<br>G4S security and locking doors as above | Intercom required so that colleagues in the Corridor can communicate with staff in the DP laboratory |
| **Music/Speakers:**<br>Tannoy speakers to be fitted here | N/A |
| **Water:**<br>1 lab grade sink | No swan necks or overflows, taps offset from traps, 'no hands' operation, large / curved to contain splashes, sealed to backsplash, hot and cold running water, drain plug.<br>Sink tap will need a device to air gap from main system<br>Minimise bends, dead legs and blind ends, accessible for maintenance. |



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# User requirements – Dried plasma

**SPN2183/2 – Dried Plasma Equipment/Commercial Partner for Feasibility Studies**

NHS Blood and Transplant
Copy No:
Effective date: 04/11/2022

## Objective

To define the requirements for the equipment to manufacture dried plasma as part of the project for the feasibility of this product. The supplier of this equipment will become a commercial partner for the project.

## Changes in this version

Numerous changes from previous version and moved from an Excel format to Word

### Requirements

| Heading | Ref | Requirement |
|---|---|---|
| Equipment | EQ1 | The Supplier MUST provide Equipment (required to manufacture and package the final dried plasma product) to, as a minimum, have sufficient capacity to handle the manufacture of 1,000 dried plasma units per annum, using a single device, at a single Authority site, based on routine Authority working hours of 0900hrs to 1700hrs, Monday to Friday. |
| Equipment | EQ1 evidence | The Supplier MUST confirm what the expected throughput (expressed in dried plasma units per 8-hour day) of the Equipment. |
| Equipment | EQ2 | The Equipment MUST be designed for use in a routine blood manufacturing laboratory without the need for laminar flow hoods or clean rooms to prevent microbial contamination. |
| Equipment | EQ2 evidence | The Supplier MUST:<br>(A) Confirm how the system prevents microbial contamination of the final dried plasma product.<br>(B) Provide data on microbial contamination performance submissions/ responses to regulatory bodies. NOTE: This will be assessed against the requirements of euGMP Annex 1. |
| Equipment | EQ3 | The Equipment MUST have a minimum working life of 3 years, based on throughput of 1,000 dried plasma units per annum. |
| Equipment | EQ3 evidence | The Supplier MUST confirm the:<br>(A) Recommended working life of the Equipment, based on throughput of 1,000 dried plasma units per annum.<br>(B) Rationale for arriving at the figure in (A) above. |
| Consumables | CON1 | The Supplier MUST provide all Consumables required to manufacture the final dried plasma product. |
| Consumables | CON2 | All Consumables that come into contact with the plasma during the stages of processing and storage MUST be provided as sterile. |
| Consumables | CON2 evidence | The Supplier MUST provide certificate(s) of sterility. |
| Consumables | CON3 | All Consumables MUST be labelled with a clear indication of product code, batch/ lot number, expiry date and storage conditions. |
| Consumables | CON3 evidence | The Supplier MUST provide details of the environmental storage conditions for each Consumable |
| Consumables | CON4 | All Consumables that come into contact with the plasma during the stages of processing and storage MUST be designed to comply with ISO3826-1, ISO3826-2 & ISO3826-3, Plastics collapsible containers for human blood and blood components, where applicable. |
| Consumables | CON4 evidence | The Supplier MUST provide evidence which illustrates and/ or explains how the relevant Consumables are compliant with this requirement. |
| Consumables | CON5 | Inlet ports on the Consumables which store the final dried plasma product MUST be designed to be compatible with the Consumable used for reconstitution. |
| Consumables | CON5 evidence | The Supplier MUST provide evidence which illustrates and/ or explains how the relevant Consumables are compliant with this requirement. |
| Consumables | CON6 | Over-wrap packaging MUST be designed to:<br>- Prevent inadvertent damage to the Consumable during its opening by Authority staff.<br>- Open without the use of scissors, knife or any other type of cutting utensil. |
| Consumables | CON6 evidence | The Supplier MUST provide:<br>(A) Evidence which illustrates and/ or explains how the relevant Consumables are compliant with this requirement (e.g. laminate peel, tear open pouch etc...).<br>(B) A copy of the instructions for use. |
| Consumables | CON7 | Base labels SHOULD comply with the Guidelines for the Blood Transfusion Services (UK) specification for base labels. NOTE: The Supplier MUST work with the Authority to successfully address any labelling specification risks/ issues. |

# Qualification traceability matrix

Requirements in SPN2183/2

| Ref | Requirement | Supporting documentation/qualification stage | CC or WP |
|---|---|---|---|
| EQ1 | The Supplier MUST provide Equipment (required to manufacture and package the final dried plasma product) to, as a minimum, have sufficient capacity to handle the manufacture of 1,000 dried plasma units per annum, using a single device, at a single Authority site, based on routine Authority working hours of 0900hrs to 1700hrs, Monday to Friday. | Covered in tender response | CC/12772 Appointment of a commercial partner |
| EQ2 | The Equipment MUST be designed for use in a routine blood manufacturing laboratory without the need for laminar flow hoods or clean rooms to prevent microbial contamination. | Covered in tender response | CC/12772 Appointment of a commercial partner |
| EQ3 | The Equipment MUST have a minimum working life of 3 years, based on throughput of 1,000 dried plasma units per annum. | Covered in tender response | CC/12772 Appointment of a commercial partner |
| EQ4 | The Equipment MUST work with UK power supply or modified UK power. If modified UK power supply is required the Supplier MUST provide a plan to design, procure and install this, when requested by the Authority. | IQ step 8<br>VAL1616 | CC/13483 WP3 Installation of CDA |
| EQ5 | All electrical Equipment MUST comply with the Low Voltage Directive version 2014/35/EU or equivalent as evidence of compliance with current UK and EC regulations. | IQ step 1<br>VAL1616 | CC/13483 WP3 Installation of CDA |
| EQ6 | The Equipment SHOULD simply plug into standard power sockets. If the Equipment needs to be physically connected or wired into building circuitry, this is possible. | N/A | N/A |
| EQ7 | The Equipment MUST be capable of being accommodated in the allocated space (approximately 59 square meters) as detailed in the Authority's Cambridge site plan. | Covered in tender response | CC/12772 Appointment of a commercial partner |
| EQ8 | The Equipment SHOULD function within the laboratory temperature range of 20 to 24 degrees centigrade. | OQ step 1<br>PQ step 1<br>VAL1556 | CC/12778<br>WP3 Facility Development |
| EQ9 | Material Safety Data Sheets (MSDS) MUST be provided (when requested) for any consumables, waste materials and cleaning compounds which relate to the Equipment. This includes all solids, liquids, and gases. | IQ step 4<br>VAL1616 | CC/13483 WP3 Installation of CDA |



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# Execute qualification/validation

**VAL1616/1 – Validation of the Clean Dry Air (CDA) system for use with the Velico plasma dryer IQ/OQ**

NHS Blood and Transplant

Copy No:

Effective date: 30/11/2023

cc/ 13483

| | | | | | | |
|---|---|---|---|---|---|---|
| 6. | Installation of compressor, desiccant air drier and receiver tank (supplier IQ) | Compressor, desiccant air drier and receiver tank is installed, and supplier qualification completed.<br><br>Receive IQ documentation from the supplier, including:<br>• CDA system installation checklist (section 4 of IQ protocol for CDA system document)<br>• Pipework inspection checklist<br>• HVAC checklist<br>• Confirmation that the system / equipment has been commissioned by the manufacturer | CDA system IQ record received by Velico | Pass | See attached | UB 20/11/24 |
| 7. | IQ by supplier completed successfully | NHSBT confirm that all documentation received from the supplier is acceptable and understood | Yes | Pass | | UB 20/11/24 |
| 8. | Post supplier IQ equipment checks (NHSBT) | NHSBT ensure:<br>• The system is suitably accommodated in the plant room<br>• CDA equipment (x3) is successfully connected to UK power supply<br>• System turns on successfully<br>• Plumbing / Drainage is suitable<br>• Requirements for UPS have been considered | • Yes<br>• Yes<br>• Yes<br>• Yes<br>• Not required | Pass | | UB 20/11/24 |



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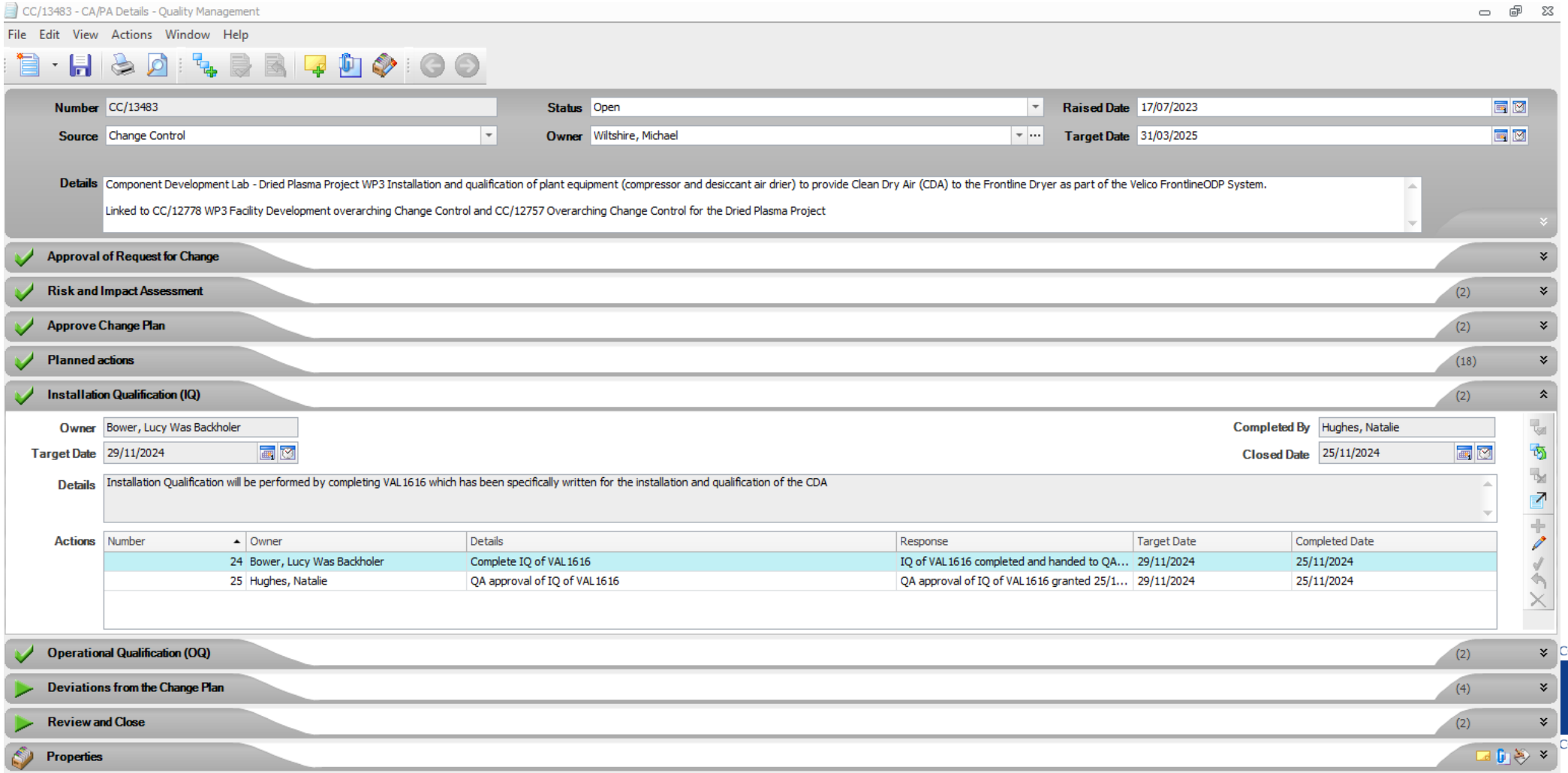
# Quality approval / tracking

| | | | | | | |
|---|---|---|---|---|---|---|
| 11. | Completion of IQ | IQ approved by quality<br><br>Evidence: QA sign off approved<br>IQ completion recorded in Qpulse | | PASS | SATISFACTORY | N.Hughes 25/11/2024 |

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# Change control procedure step by step

1) Change Request

2) Assessment

3) Change Plan

4) Change plan approval

5) Execution of action items

6) Change implementation approval

7) Change closure

- Evaluation and approval for implementation by CCB
  - All planned actions have been successfully performed
  - There are no unresolved nonconformities / risks / deviations
- Determine a person responsible for approval of CHANGE

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# Change control procedure step by step

1) Change Request

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5) Execution of action items

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7) Change closure

Effectiveness check after agreed time period:

- Was the change beneficial? Expected results achieved?
- No problem / unknown risks generated by the change implementation?
- Any impact on other processes ?
- Lessons learnt documented?

- Document effective date
- Document effectiveness check
- Closure by named person
- Archive records

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# PDCA – Deming Wheel

**PLAN**

**Establish policies, objectives and processes** (process mapping, procedures, forms) necessary to deliver results in accordance with the specifications

**DO**

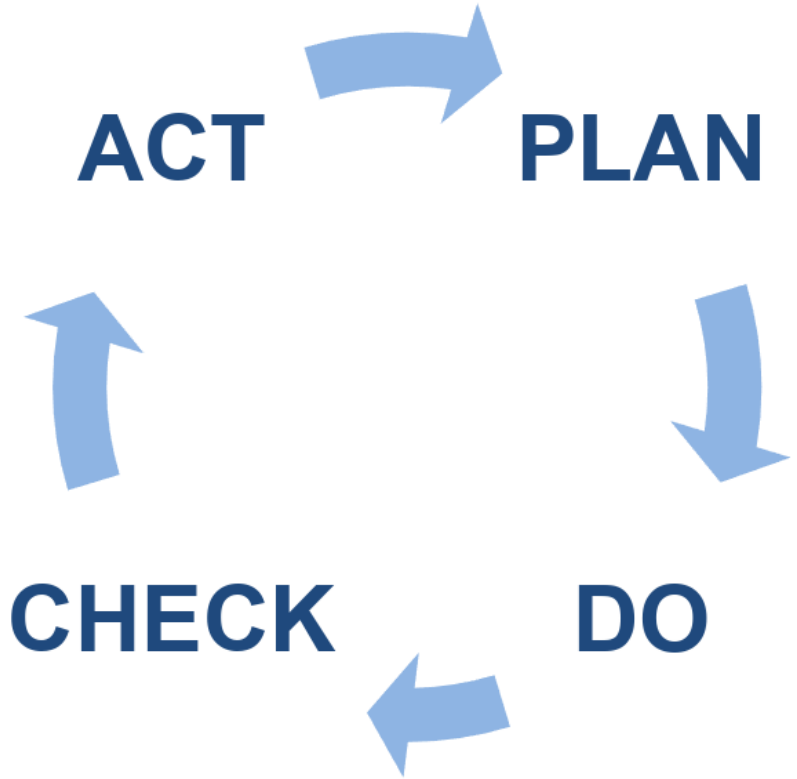
Implement the process, perform the process **described in the SOP.** Collect Data.

**CHECK**

**Monitor** and **evaluate** the process and results against objectives and specifications and report the outcome into **RECORDS**

**ACT**

Apply actions for **improvement**. Review all steps (Plan, Do, Check, Act) and modify the processes to **improve** it before its next implementation



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# Takk fyrir
# Thank you

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