**Objective**

The purpose of this specification is to define the NHSBT’s Clinical Biotechnology Centre user requirements for the provision of commercially available sterile, pharmaceutical grade plastic vials and consumables compatible with an Aseptic Technologies Filling Line for the Fill and Finish of GMP grade Investigational Medicinal Products.

**Changes in this version**

New document

**Requirements**

1. **Introduction**

This document was generated by the NHSBT’s Clinical Biotechnology Centre (CBC) for the purpose of specifying the user requirements for sterile, pharmaceutical grade plastic vials and consumables compatible with an Aseptic Technologies Filling Line located within the classified clean rooms. The CBC has an MHRA licence for the manufacture of sterile investigational medicinal gene therapy, recombinant protein products and recombinant viral vectors for clinical trials. The intended use of the consumables is for the GMP Fill and Finish GMP of these types of products.

1. **Technical Specification**

***Pharmaceutical Grade Vial***

* 1. MUST be available as a Closed Plastic Vial Ready-to-Fill container format with stopper.
  2. MUST be available over a range of fill volumes such as 1 mL, 2 mL, 10 mL, 20 mL to 50 mL fill Volumes.
  3. MUST be available as clear vials.
  4. MUST be available with a sterile cap for capping post-filling.
  5. Stopper MUST be capable of being resealed using a laser for integrity post-filling.
  6. Materials selected for the product contact parts MUST meet United States Pharmacopoeia and European Pharmacopoeia requirements for the pharmaceutical industry primary container.
  7. MUST be able to tolerate low temperature storage of below – 65 °C.
  8. The Packaged vials MUST be double bagged.
  9. MUST be Certified as sterile by gamma irradiation.

***Filling Kit (Needle and assembly)***

* 1. Needle MUST be designed and compatible with the Aseptic Technologies Filling Line
  2. Needle MUST be stainless steel 316L, pencil tip with a diameter of 2.0 to 3.1 mm.
  3. Needle MUST be non-coring
  4. Needle MUST allow the lateral injection of the liquid
  5. Needle MUST have side grooves to avoid over-pressure during filling
  6. Assembly MUST be customisable to allow connection of various elements such as filters, connection and tubing etc.
  7. The Filling Kit MUST be double bagged and sterilised by gamma irradiation.
  8. MUST be supplied with a Certificate of Conformity and approved by a Qualified Person.

1. **Manufacturing Specification** 
   1. MUST be manufactured in a clean environment such as a clean room.
   2. All materials MUST be fully traceable to the manufacturer and product code.
   3. SHOULD have a shelf-life of at least 12 months when stored at room temperature under the appropriate conditions.

**Labelling & Packaging**

* 1. All goods MUST be labelled in English using British nomenclature.
  2. The Supplier MUST ensure product details are indelibly printed on each package including the batch/lot number and expiry date.
  3. The Supplier MUST ensure that the name and address of the supplier appears clearly on the packaging of all consignments of the goods.
  4. The Supplier MUST package supplies for transport in a safe and secure way minimising any risk of damage to the goods.

1. **Quality** **Requirements**
   1. The Supplier MUST be ISO 9001 accredited with a defined and documented quality system.
   2. MUST have a Validation Master Plan (Regulatory Support File) available from the Supplier for the goods.
   3. MUST have a Product Certification e.g., Certificate of Analysis, Quality Certificate, Certificate of Conformity for released manufacturing lots.
   4. The Supplier MUST provide a Certificate of Sterility Assurance or appropriate evidence of sterility.
2. **Business Requirements** 
   1. Products MUST be available in volumes requested, up to 4000 vials and 40 Filling Kits per calendar year.
   2. The service MUST be able to provide prototypes to allow evaluation and validation by NHSBT at a reasonable cost if required.
   3. The Supplier MUST ensure the accessibility of key personnel for customer support with regards to a help desk, routine quality, delivery and production, Monday through Friday from 0900hrs to 1700hrs.
   4. The supplier MUST have a documented system for dealing with safety alerts and recalls.
   5. The Supplier MUST notify NHSBT of any changes to the goods within a reasonable timeframe in advance of the change e.g., at least 3 months.
   6. The supplier must respond to Complaints raised by NHSBT regarding the supply or performance of the material. An acknowledgement of receipt of the Complaint is required within 7 days and a response time within 20 working days of receipt.
   7. A supplier evaluation will be required as part of the evaluation of tender offers (unless already undertaken). This will be based upon responses received against NHSBT Supplier evaluation process (NHSBT National Process as MPD556). Any information requested as part of the tender will be treated as confidential.
   8. Delivery times and conditions from supplier to customer MUST fall within the parameters determined by supplier.

**Business Continuity**

* 1. The Supplier MUST be able to provide a Business Continuity Plan covering all aspects and locations of their business which impact on supply of the goods or services, and this plan should be reviewed, updated, and tested or exercised at least every two years.

**Equality and Diversity**

* 1. Contractors are required to comply with all UK and European statute law relating to Equality and Diversity. This covers all discriminatory issues due to race, religion, age, sex, sexual orientation, and disability. Failure to comply in any area will result in exclusion from tendering.

**Customer Service / Account Management:**

* 1. The Contractor must provide a dedicated Strategic Account Manager to act as a single point of contact for the purposes of the operation of the framework. The Contractor shall also appoint a reserve contact in the event of the nominated contact not being available. If required a named account team on the help desk will be provided. Regional and/or sector account management contacts will also be appointed where appropriate.
  2. The Contractor must provide a nominated Account Manager, who shall take responsibility for the overall relationship with the NHSBT, including agreeing any individual requirements relating to invoicing, management information and preferred methods of communication. The Account Manager shall also act as a primary point of contact for the Member on issues relating to the arrangement.

**Environmental Considerations**

* 1. NHSBT requires Contractors to take responsibility for their impact on the Environment and where relevant society. Contractors are required to demonstrate an Environmental Management System e.g.ISO14001 or an equivalent EMS. NHSBT may require the auditing of this system. Where an EMS does not exist Contractors will be required to demonstrate adequate management of their impact and where suitable may be required to develop an EMS system.

**Contract Management**

* 1. The Contractor MUST attend meetings to review performance of the Contractor and services provided. Frequency of the meetings will be every 6 six (6) months unless agreed otherwise and at a nominated NHSBT premises or by telecom.

Meeting agendas will include

•   review of key performance indicators

•   agree and monitor status of actions to resolve and quality

•   technical or contractual issues

•   identify topics/areas to feed into the continuous improvement programme

**Definitions**

* CBC – Clinical Biotechnology Centre
* EU – European Union
* GMP – Good Manufacturing Practice as defined by EU GMP EudraLex Volume 4
* IMP – Investigational Medicinal Product
* ISO – International Organisation for Standardisation
* MHRA – Medicine and Healthcare products Regulatory Authority
* NHS – National Health Service
* NHSBT – NHS Blood and Transplant
* URS – User Requirement Specification
* SHOULD or SHOULD NOT - means an optional or non-mandatory / Desirable requirement. Note: Any Supplier failing to meet a non-mandatory requirement will not be disqualified from the tender process.
* MUST or MUST NOT - means a mandatory/Essential requirement Note: Any Supplier failing to meet a mandatory requirement will be disqualified from the tender process.

**Related Documents / References**

* MPD556 Supplier Management
* ISO 9001 Quality Management Systems

**Appendices**

* N/A