**Unlicensed Parenteral Nutrition (PN) Specification**

**(PART A)**

**Document 8**

**Invitation to Offer for a Framework Agreement for the Supply of** **Unlicensed Parenteral Nutrition (PN) to Trusts within the Yorkshire and Humber NHS Pharmaceutical Purchasing Consortium direct awards.**

**Period of Framework: 1st March 2024 to 28th February 2027 with an option to extend for up to a further 12-month extension**

**Atamis Project Reference: C173941**

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1. **INSTRUCTIONS**
	1. This is the specification and it’s made up of the following:
* Description of Service
* Specification for Technical & Quality
* Specification for Social Value Model
* Appendix 1 Abbreviations
* Appendix 2 Definitions

**1.2** This document should be read and completed in conjunction with Document 6a Parenteral Nutrition (PN) Award Criteria Methodology. This includes the Assessment Methodology that the Authority will be using to assess the Suppliers (Offerors) responses.

Further responses are required in Document 8 Parenteral Nutrition (PN) Tender response PART B.

**1.3** This document covers all specification points which are mandated, adjudicated, compliance and for information. Where the point states Mandated or Adjudicated and where applicable Compliance points a response is required in Document 8 Parenteral Nutrition (PN) Tender Response (PARTS A & B)

**1.4** Within this document confirm that you have read and understood and will comply against the specification points by ticking “Yes” in the box provided. Where your answer is “No” please provide further information.

**1.5** Please note that some adjudication questions require a supporting statement from the Head of Quality as named on the manufacturer's MS Licence. Such statements must be provided as a signed and dated, headed document following the naming protocol as outlined in the instructions for Document 8 Parenteral Nutrition (PN) Tender Response (PART B)

**1.6** Suppliers (Offerors) shall comply with all points in this section to meet the requirements outlined below.

Should any documentation be missing, or any clarifications be required, in the first instance advise via the question section on the Atamis e-tendering system <https://health-family.force.com/s/Welcome> .

Tender clarification questions should be submitted by no later than the **18th August 2023.**

**2. Description of Service**

* 1. Suppliers (Offerors) will supply a range of aseptically prepared; batch manufactured products (and where applicable patient specific doses) in ready-to-administer presentations, ordered by and delivered in varying quantities (direct award; mini competition or a combination) to Participating Authorities.
	2. The Suppliers (Offerors) must hold relevant manufacturers licence(s) approved by the MHRA with the relevant scope to provide the products required in this tender.
	3. The Supplier (Offerors) must work with the Participating Authority (PA) towards electronic transmission of ordering and invoicing information through e-procurement technologies.
	4. Notification of any proposed changes shall ideally be made three months prior to the implementation date of proposed changes. The Supplier (Offeror) will ensure that they follow the change control process. Outlined in Document 5 NHS Framework Agreement for The Supply of Goods and Provision Services.
	5. Approved products supplied against purchase orders must continue to meet the requirements of the specification throughout the contract duration.
	6. The Supplier (Offeror) will not substitute any product ordered unless agreed by the Participating Authority (PA) and the Authority using the agreed change control process.
	7. All products should have at least 75% of the shelf life remaining at the time of receipt unless a lower shelf life is agreed with the Participating Authority. For any products carrying less than the agreed shelf life the Participating Authority reserves the right to return the products for a full refund or replacement.
	8. Products within the expiry date which have been damaged as a consequence of delivery or poor packaging will be replaced or refunded in an agreed timeframe at no cost to the Participating Authority.
	9. The Supplier (Offeror) must have a returns policy which, as a minimum, complies with the current guidelines on Good Distribution Practice (cGDP) of medicinal products for human use.
	10. The Supplier will take an active part in the management and distribution of stock in critical shortage situations and work collaboratively with the NHS, the Department of Health and Social Care (DHSC), the Commercial Medicines Unit (CMU), manufacturers and other wholesalers to manage supply or the re-introduction of product into the supply chain in a safe and effective manner.
	11. The Participating Authority (PA) reserves the right to return / reject goods, which, upon inspection after delivery, are found to be in an unusable / unacceptable condition and will be withdrawn and uplifted by the Supplier (Offeror) at the Suppliers (Offerors) own expense in compliance with Good Distribution Practice (cGDP).
	12. In the event of a product recall the Supplier (Offeror) shall inform the Participating Authority (PA) in a timely manner. The Supplier (Offeror) shall, at its own expense, arrange for the collection of any products delivered but unused. Any affected stock held by the Supplier (Offeror) will be quarantined and prohibited from onward supply.
	13. A customer services helpline will be provided from 9:00am to 5:00pm, Monday to Friday.
	14. In the event of a planned or unplanned shutdown involving a Pharmacy Aseptic Unit based in one and/or more of the Participating Authorities, the Supplier (Offeror) will agree to provide support in the form of the aseptically prepared, batch manufactured drugs in ready-to-administer presentations. Participating Authorities that require this service will agree to liaise with the relevant Supplier (Offeror) to agree service requirements and complete a Technical Agreement (guide sample in Appendix B).

**(This is only applicable to those Suppliers (Offerors) that accept the specification point (L1).**

**3. Specification (Technical & Quality)**

**A: Scope**

1. Suppliers (Offerors) will confirm they can supply a range of aseptically prepared; batch manufactured products (and where applicable patient specific doses) in ready-to-administer presentations ordered by and delivered in varying quantities to Participating Authorities. Product ranges are provided within the Commercial Schedule (Document No.6).

Suppliers (Offerors) must confirm that they hold a Manufacturer's Specials licence, please detail the site name and MS licence number, and submit a copy of the license in specification point C6 (Document 8 Part B, Tab 1). Where you are utilising multiple sites complete specification point C6 (Document 8 Part B, Tab 2).

Suppliers (Offerors) shall provide their Wholesale Distribution Authorisation - Human (WDA H) licence number **where applicable**, please detail the site name and WDA(H) license number (Document 8 Part B, Tab 1) and submit a copy of the license in specification point C6 (Document 8 Part B, Tab 1). Where you are utilising multiple sites complete specification point C6 (Document 8 Part B, Tab 2).

**MANDATED Point (Evaluated & Scored) please provide a response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**A2** Document No.7 lists the Participating Authorities with access to the framework pricing. Please note: - Deliveries will be made to Participating Authorities or Stores and not directly to patients. Details of annual historic contract product volumes are provided within the offer documentation although please note that these volumes are indicative and are not guaranteed or a prediction of uptake.

Estimated quantities shall indicate only the probable requirements and the Authority shall not be bound by these figures (unless otherwise agreed). This may differ from future usage as forecasting methods have not been used. Supplier (Offeror) are requested to base their prices on these indicative volumes.

It is envisaged that Participating Authorities will join the agreement on a phased basis. This phasing programme will be agreed between the supplier and the Participating Authority directly. Participating Authorities must provide the supplier (Offeror) with three months’ notice unless a shorter timeframe is agreed in writing.

On award of the contract, Suppliers (Offerors) must agree to work with Participating Authorities to complete and sign a Quality Technical Agreement - Document No.8 - Tender Response PART B (**Appendix B** - Sample Quality Technical Agreement).

**COMPLIANCE Point (Evaluated & Scored) please provide a response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

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| **All specification points listed above in “A Scope”** |
| **I confirm I have read and understood and will comply with all the above specification points and where applicable have completed Document 8 Parenteral Nutrition (PN) Tender Response (PART B)** **If NO, please provide further details here………………………………………** |

**B: Capacity and Contingency**

**B1** Supplier(s) (Offerors) must provide details of their Contingency / Business Continuity arrangements, and most recent test results in accordance with NHS Terms and Conditions Schedule 2 (point 6). This must include details of their contingency arrangements for managing an unexpected interruption to one or more of their manufacturing facilities or logistics partner.

The Supplier(s) (Offerors) shall test its Business Continuity Plan at reasonable intervals, at least once every twelve (12) months and provide a summary of the results to The Authority.

Supplier(s) (Offerors) must provide their Contingency / Business Continuity plan and most recent test results including details of all contingency partners that will be used or potentially used under this agreement. Detail is to be provided and relevant document(s) attached using the naming protocol.

If a supplier (Offeror) has ISO 22301 accreditation certificate, then please provide a copy.

Please include details of all contingency partners that will be used or potentially used under this agreement. Detail is to be provided and relevant document(s) attached using the naming protocol

**ADJUDICATED Point (Evaluated & Scored) please provide a response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**B2** Supplier(s) (Offerors) are required to provide total available capacity (in terms of number of total doses per year) for each manufacturing site in operation currently.

**For Information only (Not Evaluated & Not Scored)**

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| **Please provide a response below** |
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**B3** Suppliers (Offerors) are required to provide detail of the number and location of any additional manufacturing units currently being constructed or planned. Details should also be included of the anticipated manufacturing capacity of these facilities (including any details of ramp up volumes), the planned date of completion for the site, and the anticipated commencement of production at these location(s).

**For Information only (Not Evaluated & Not Scored)**

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| **Please provide a response below** |
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| **All specification points listed above in “B Capacity & Contingency”** |
| **I confirm I have read and understood and will comply with all the above specification points and where applicable have completed Document 8 Parenteral Nutrition (PN) Tender Response (PART B)** **If NO, please provide further details here………………………………………** |

**C: Manufacturing Process & Quality Culture**

**C1** Suppliers (Offerors) are required to describe the supply chain for the manufacturing and distribution of aseptically compounded Parenteral Nutrition products, (from starting materials to delivery to Participating Authority premises). Interrelationships between the contractor, the compounding unit(s) (if different) and any transport and distribution partners should also be included in the description.

Please only provide a statement for this specification point

**ADJUDICATED Point (Evaluated & Scored) please provide a response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**C2** Suppliers (Offerors) must provide a list detailing the names and addresses of all compounding subcontractors and delivery sub-Suppliers and contingency partners that will be used or potentially used under this framework agreement.

Where a supplier does not subcontract manufacturing or distribution services, please select the Not Applicable option.

Please also ensure compliance with the Standard Selection Questionnaire (SSQ) for this point.

**MANDATED Point (Evaluated & Scored) please provide a response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**C3** Where compounding or delivery are sub-contracted, Quality/Technical Agreements must be in place between the contractor and all sub-suppliers or contingency partners for:

- manufacturing

- distribution

Suppliers must provide a copy of the Quality/Technical Agreement between all relevant parties and their supplier/sub-contractor approval policy.

Where a supplier does not subcontract manufacturing or distribution services, please select the Not Applicable option.

**ADJUDICATED Point (Evaluated & Scored) please provide a response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**C4** If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor (Tab 2 - Response Per Site).

Where a supplier does not have an additional site(s), please select the Not Applicable option.

**MANDATED Point (Evaluated & Scored) please provide a response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**C5** Aseptically Compounded (terminally sterilised where applicable) Parenteral Nutrition products must be manufactured to the product specifications as set out by the Participating Authority to provide consistent products, supported by stability data that complies with NHS PQAC Standard Protocol for Derivation and Assessment of Stability Part Four - Parenteral Nutrition (1st Edition - May 2016). Document 8 (PART B) in Appendix A for reference.

Suppliers (Offerors) must confirm that all products supplied under this framework will be manufactured (by themselves and / or by relevant sub-suppliers) in accordance with the product specifications set out by the Participating Authority.

**MANDATED Point (Evaluated & Scored) please provide a response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

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| **Please note that specification points C6 to C31** **are applicable to your primary site and any additional sites a Supplier (Offeror) may have.**  |

**C6** Provide the name, address, and MS number of the licence holder(s) as applicable.

Suppliers (Offerors) must demonstrate that they hold an MHRA Manufacturer's Specials licence with the relevant scope to provide the tendered products. A range of products are provided within the Document 6 Commercial Schedule.

 Provide a full copy of your valid current MS licence as an attachment following the naming protocol. This must cover the scope of the tendered activity.

 Suppliers (Offerors) shall provide a copy of their Wholesale Distribution Authorisation - Human (WDA H) licence where applicable, please detail the site name and WDA(H) license number and where you are utilising multiple sites.

 If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**MANDATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable**

**C7** Suppliers (Offerors) will state the date of the most recent MHRA inspection for this manufacturing site.

Suppliers (Offerors) will provide a statement from their Head of Quality summarising the main findings of their most recent MHRA inspection including:

- critical or major findings

- the overall risk rating and inspection frequency

- details of progress made to correct the identified deficiencies.

Suppliers (Offerors) also provide the closure letter unless this has not yet been received from the MHRA.

Suppliers (Offerors) will state if the licence holder is currently under the management by the Inspection Action Group (IAG) or Compliance Management Team (CMT) or has been referred to the IAG or CMT and provide evidence of progress having been made to correct the identified deficiencies.

Suppliers (Offerors) will state if there are any current MHRA restrictions on capacity for any products/medicines made under the MS licence (not restricted to those medicines offered for this tender).

Provide the documentary evidence as attachment(s) for this site following the naming protocol.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point** **(Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C8** From the point of tender submission and during the life of the contract, Suppliers (Offerors) agree to provide the Authority with:

* + - the dates of forthcoming MHRA inspections, as soon as they are known to the Supplier (Offeror)
		- a statement from their Head of Quality summarising the main findings of any subsequent MHRA inspections
		- details of any critical deficiencies
		- details of any referral to IAG or CMT including evidence of progress having been made to correct the identified deficiencies
		- evidence of closure of all MHRA inspections
		- the anticipated date of the next planed MHRA inspection.
		- Any further restrictions on capacity enforced by the MHRA

Suppliers (Offerors) will inform the Authority within 10 working days if the licence holders have been referred to either the IAG or CMT.

Suppliers (Offerors) will engage with stakeholders and will provide details of any identified issues, production restrictions applied and their turnaround plans.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**COMPLIANCE Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C9** Suppliers (Offerors) will provide a copy of the most recent NHS QA audit report for the licence holders who will manufacture the ready to administer Aseptically Compounded Parenteral Nutrition product(s).

**NB** Suppliers (Offerors) are not requested to provide a copy their quality assurance of aseptic preparation service standards audit (as performed by their Regional QA Pharmacist where applicable) report against this point.

Provide a copy of your most recent NHS QA audit report as an attachment for this site following the naming protocol.

If no audit has taken place, Suppliers (Offerors) will allow Regional QA auditors to conduct an audit as soon as it is practically possible for both parties.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**For Information only (Not Evaluated & Not Scored)**

**C10**  Suppliers (Offerors) must seek approval from The Authority and/or Participating Authority for any proposed changes (permanent or temporary) that may have impact on the product supplied (specifications, products, preparation processes, packaging, and labelling). This includes changes made by compounding and logistics sub-Suppliers.

N.B. In exceptional circumstances changes may need to be made to ensure continuity of supply. In this case The Authority must be notified without delay.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**COMPLIANCE Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable**

**C11** Suppliers (Offerors) will provide evidence that there are systems in place to ensure any proposed changes (permanent or temporary) that may have an impact on the product(s) supplied. This will be communicated to the Authority and/or Participating Authority for approval.

Provide documentary evidence as an attachment(s) for this site following the naming protocol

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**MANDATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable**

**C12** Suppliers will not make any changes to product specifications and will not change any manufacturing or logistics sub-Suppliers without the prior agreement of the Authority. All requests for change must be sent initially to the Participating Authority for approval. Failure to comply with this procedure may result in breach of contract and termination of business.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**MANDATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C13** Suppliers (Offerors) must be able to provide documentary evidence of a robust quality culture and the technical capability to provide Aseptically Compounded Parenteral Nutrition products. The evidence required is detailed in specification points **C14 to C31** below.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**COMPLIANCE Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable**

**C14** Provide your Site Master File and Quality Policy.

These should include organogram(s), and descriptions of:

* + the manufacturing site(s)
	+ core manufacturing processes
	+ critical equipment
	+ quality review meetings
	+ arrangements for quality management within the organisation

Provide documentary evidence as an attachment(s) for this site following the naming protocol.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C15** Provide a brief description of how quality incidents are investigated and managed. This should include

* + deviations (non-conformances) and errors
	+ complaints
	+ recalls
	+ investigations
	+ root cause analysis
	+ risk assessment
	+ CAPA
	+ trending of deviations and complaints

Please submit the SOPs and policies that provide evidence for all the above relevant to this site following the naming protocol.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C16** Provide your out of specification results procedure or describe how retrospective out of specification results (such as end of session media fills) are managed for products already released.

Please submit documentary evidence as an attachment following the naming protocol

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C17** Provide your policies and procedures for change management.

This must include reference to:

* + internal changes
	+ changes which may impact on customers and other stakeholders
	+ changes that may impact product specifications
	+ risk assessment of the impact of proposed changes
	+ how the change is managed
	+ review of the change once implemented

If the policies and procedures do not describe all the above, please provide other relevant documents or a supporting statement explaining how changes are managed.

Please submit the SOPs and policies that provide evidence for all the above relevant to this site following the naming protocol or a summary.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**MANDATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C18** Suppliers (Offerors) will provide a description of their arrangements regarding the order, receipt and approval process undertaken when an order is received from a Participating Authority. This must be supported with current, GMP compliant, approved documentary evidence such as order receipt policy or procedure.

Documentary evidence must be clearly cross referenced to the description and provide a sufficient level of detail to give a thorough overview of how orders are received and approved.

Please submit the SOPs and policies that provide evidence for all of the above relevant to this site following the naming protocol or a summary.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C19** Provide your policies and procedures for final checking and release for all products offered under this framework.

These must include reference to:

* + final production reconciliation, inspection, and checking
	+ policies and procedures for non-conforming products including any rework e.g., container transfer due to detection of particles
	+ quality control or quality assurance checks
	+ how releasing officers are assured of finished product quality
	+ arrangements for provision of certificates of conformity

If the policies and procedures do not describe all the above, please provide other relevant documents or a supporting statement explaining the final checking and release processes.

Please submit the SOPs and policies that provide evidence for all the above relevant to this site following the naming protocol or a summary.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C20** Provide your policies and procedures for assessment of:

* + pharmaceutical quality of unlicensed medicines
	+ suitability of medical devices

used in the preparation of products offered for this tender. This includes all materials, components and consumables that have direct product contact.

Please submit the SOPs and policies that provide evidence for all the above relevant to this site following the naming protocol.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C21** If any starting material is an unlicensed medicine the Supplier (Offeror) will provide a copy of their unlicensed medicines assessment on request.

**For Information only (Not Evaluated & Not Scored)**

**C22** With reference to the MHRA Guidance for Specials Manufacturers (updated 25th February 2021), provide a statement from your Head of Quality confirming compliance with the following sections:

* 3.5.17 Design of aseptic processes in a ‘Specials’ manufacturing facility
* 3.5.18 Specific requirements for the use of ampoules in ‘Specials’ manufacturing units
* 3.5.19 Control of pooling in a ‘Specials’ manufacturing facility
* 3.5.19a Compounded intermediates for use in further processes e.g., intermediates for parenteral nutrition (PN) production.

Please submit the documentary evidence for all the above relevant to this site following the naming protocol.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C23** With reference to the MHRA Guidance for Specials Manufacturers (updated 25th February 2021) section 3.5.19b Contamination control strategy, provide a copy of your Contamination Control Strategy.

Please submit the documentary evidence for all the above relevant to this site following the naming protocol.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C24** Where gas sanitisation is used, provide a summary covering **all sites** in the box provided that the process does not adversely affect the finished product in terms of:

* + patient safety
	+ product stability

If this is not applicable please state

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**For Information only (Not Evaluated & Not Scored)**

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| **Please provide a response below** |
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**C25** Please confirm you have training and competence policies for all levels of staff who work within pharmaceutical manufacturing sites. This should cover

* + the arrangements for ensuring that all activities are undertaken by staff members who are appropriately competent
	+ accreditation, where appropriate
	+ validation and re-validation of competence (this must include accuracy, behaviour, and comportment in addition to microbiological validation)

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C26** Confirmation that your Validation Master Plan and associated policies and procedures include all the following:

* + facility maintenance & validation
	+ equipment maintenance & validation
	+ computer systems
	+ validation of people
	+ validation of aseptic preparation processes
	+ validation of automated devices, including GAMP
	+ validation of cleaning of critical work zones and product contact equipment
	+ validation of transfer sanitisation (including gas sanitisation and where components are stored in "aseptic hold")

Please provide a statement from your Head of Quality confirming that you comply with all the above and that the associated documents are within the review dates.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C27** Provide details of your programme for:

* + physical environmental monitoring e.g., particle counts, room air change rates, DOP tests etc.
	+ microbiological monitoring e.g., contact and settle plates, finger dabs, end of session media fills etc.

This should include:

* + sampling plans
	+ use of maintenance and testing sub-Suppliers where applicable
	+ trending and review of results

Please submit documentary evidence as an attachment following the naming protocol or a summary.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C28** Provide your policies and procedures for on-going process verification to assure continuing compliance with relevant current BP Monographs and product specification

This should cover a programme of testing of samples representative of finished product, including at the end of the shelf life, for:

* + chemical content
	+ sterility

If the Supplier (Offeror) does not have such a programme they will confirm that they will work toward implementation of a programme which is compliant with the MHRA Guidance for Specials Manufacturers - Originally published 30th January 2015 & Last updated 25th February 2021 (e.g., Ref 3.6.13, 3.6.18 etc.).

Please submit documentary evidence as an attachment following the naming protocol or a summary.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C29** Provide policies, procedures, and reports for temperature-controlled storage (ambient & refrigerated) at the manufacturing site(s).

These must include

* + validation and temperature mapping of storage areas
	+ operating procedures for temperature monitoring
	+ Out of specification temperature mapping and monitoring results procedure

Please submit the SOPs and policies that provide evidence for all of the above relevant to this site following the naming protocol or a summary.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C30** Provide policies, procedures, and reports for temperature-controlled distribution (ambient & refrigerated) of finished product from the manufacturing site(s) to the Participating Authority's premises.

These must include

* + validation and temperature mapping of delivery vehicles
	+ validation and temperature mapping of insulated shippers (cool boxes)
	+ operating procedures for temperature monitoring during transport (if applicable)
	+ Out of specification results procedure

Provide documentary evidence as an attachment for this site following the naming protocol.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

**C31** Provide your internal audit policies and procedures.

These must include the current internal audit programme including dates of planned and completed audits that demonstrate adherence to the audit policies and procedures.

The Supplier will carry out self-inspections of their quality system at regular intervals and record the results and raise corrective and preventative actions for any non-conformances found.

Provide documentary evidence as an attachment for this site following the naming protocol.

If there are additional manufacturing site(s) or manufacturing sub-contractor(s) to be used under this agreement, specification points **C6 to C31** must be completed for each manufacturing site / manufacturing sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1 and Tab 2 for additional sites if applicable.**

|  |
| --- |
| **All specification points listed above in “C: Manufacturing Process & Quality Culture”** |
| **I confirm I have read and understood and will comply with all the above specification points and where applicable have completed Document 8 Parenteral Nutrition (PN) Tender Response (PART B)** **If NO, please provide further details here………………………………………** |

**D: Component Materials**

**D1** Syringes will be filled to no more than the volumes stated below:

|  |  |  |
| --- | --- | --- |
| **Syringe size (ml)**  | **Max fill volume (ml)**  | **Measurable graduations** |
| 1 | 0.85 | 0.01ml |
| 3 | 2.5 | 0.1ml |
| 5 | 4 | 0.2ml |
| 10 | 8 | 0.2ml |
| 20 | 17 | 1ml |
| 30 | 25 | 1ml |
| 50 (60ml nominal) | 50 | 1ml |

**MANDATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**D2** All individual Products in each range must be labelled with the following critical information:

* + - patient's name, date of birth and NHS number (where applicable)
		- total volume
		- volume of individual ingredients
		- content of mmol, g, kcal. For paediatrics, this should also be expressed per kg
		- maximum infusion rate
		- route of administration (central or peripheral)
		- storage conditions
		- batch number
		- expiry date, unambiguously expressed as use before date
		- total volume to be infused
		- name and MS licence number of the manufacturing unit
		- warnings

NB for small containers certain details may be omitted, but the label should contain, as a minimum, the following information:

* The common name of the product
* A statement of the active ingredients expressed qualitatively and quantitatively per dosage unit or for a given volume or weight
* Route of administration
* The contents of the container by weight, volume or by number of doses
* The expiry date expressed in unambiguous terms (dd/mm/yy)
* The batch number.

In such cases, the label for the outer packaging should contain all the relevant label information

Please provide a sample label for each product range offered as an attachment following the naming protocol. This may include primary and secondary labels where applicable.

**MANDATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**D3** The design of the label and its placement on the product should enable critical information to be read easily in one field of view and ensure good differentiation between similar products offered to be easily distinguished.

**MANDATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**D4** Suppliers (Offerors) will be prepared to work towards labelling which includes a machine-readable bar code, preferably one which conforms to the GS1 coding system - information can be obtained from the website [www.gs1uk.org](http://www.gs1uk.org) which covers the original barcode.

**COMPLIANCE Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

|  |
| --- |
| **All specification points listed above in “D: Component Materials”** |
| **I confirm I have read and understood and will comply with all the above specification points and where applicable have completed Document 8 Parenteral Nutrition (PN) Tender Response (PART B)** **If NO, please provide further details here………………………………………** |

**E: Shelf Life**

**E1** Products should have at least 75% of the shelf life remaining at the time of receipt unless a lower shelf life is agreed with the Participating Authority. For any products carrying less than the agreed shelf life the Participating Authority reserves the right to return the product for a full refund or replacement. This should be read in conjunction with specification point G1.

**COMPLIANCE Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**E2** The Supplier's approach to assigning shelf lives of aseptically compounded medicines should conform to the current relevant Standard Protocol for derivation and assessment of stability published by the NHS Pharmaceutical QA Committee.

Please provide policies and SOPs for assigning stability to aseptically compounded products.

These must include details of

* + source(s) of stability information e.g., published literature, manufacturers' stability matrices, in-house or commissioned studies, specialist opinion.
	+ details of how the data used is interpreted to reach the assigned shelf-life, including where data are conflicting or where extrapolation is required.
	+ how it is assured that all persons making professional judgements are suitably qualified and experienced.

If supporting evidence includes attachments, please follow the naming protocol

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

|  |
| --- |
| **All specification points listed above in “E: Shelf Life”** |
| **I confirm I have read and understood and will comply with all the above specification points and where applicable have completed Document 8 Parenteral Nutrition (PN) Tender Response (PART B)** **If NO, please provide further details here………………………………………** |

**F: Outer Packaging**

**F1** Each product (dose) will be individually labelled. Each labelled product will be sealed in a leak-proof wrap.

If the label on the product cannot be read through the leak-proof wrap e.g., if the wrap used is light protective, a label identical to the product label will be applied to the wrap. It is acceptable for product requiring light protection to be sealed in transparent leak-proof wrap. However, each product (dose) will be supplied with an opaque light protective cover where required.

Please provide images for each product range offered as an attachment following the naming protocol.

**MANDATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**F2** If product is supplied in ‘multiples’ the individually labelled/wrapped product will be sealed in outer packaging containing no more than 10 products where applicable.

Please provide images for each product range offered as an attachment following the naming protocol.

Where a supplier has indicated they do not individually wrap multiples in no more than 10 products, please select the Not Applicable option.

**COMPLIANCE Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**F3** The outer wrap will be labelled with the contents including quantities, batch number, expiry, and storage conditions.

Please provide images for each product range offered as an attachment following the naming protocol.

**MANDATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**F4** Under sections 3 and 6 of the Health and Safety at Work Act 1974 there is a duty to protect people not in a company's employment who may be affected by handling loads they have supplied.

Therefore, it is good practice for manufacturers and suppliers to mark weights (and, if relevant, information about the heaviest side) on loads if this can be done easily.

Please see: <http://www.hse.gov.uk/msd/labellingloads.htm>

The Supplier (Offeror) must comply with all relevant packaging and labelling regulations and outer packaging must be sealed.

**COMPLIANCE Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

|  |
| --- |
| **All specification points listed above in “F: Outer Packaging”** |
| **I confirm I have read and understood and will comply with all the above specification points and where applicable have completed Document 8 Parenteral Nutrition (PN) Tender Response (PART B)** **If NO, please provide further details here………………………………………** |

**G: Delivery**

**G1** Suppliers (Offerors) are required to offer ordering and delivery arrangements which ensure continuity of supply and ensuring cover for all public holidays and match the core opening hours of Participating Authorities at such times. This should be read in conjunction with specification point E1.

Normal working hours are classified as Monday to Friday, 09.00hrs to 17:00hrs.

The Supplier (Offerors) normal working hours (hours of service provision) must match or exceed Monday to Friday 09:00hrs - 17.00hrs excluding bank holidays.

Suppliers (Offerors) are required to provide at least one month's notice of planned closures around bank holidays and these closures should not last for more than two normal working days.

Suppliers (Offerors) must advise in advance of any increase in product lead times as a result of these closures (the increase in lead time should not be greater than two days). Closure includes any of the following activities: -

* Receipt and processing of orders
* manufacturing of product
* delivery of prepared orders.

Suppliers (Offerors) will be required to specify their operating lead time for normal deliveries in days. Details to be provided in Document 6 Commercial Schedule, Terms of Business

Participating Authorities require a consistent delivery lead time, and this consistency may be measured using the Key Performance Indicators detailed in Document 6b Contract Management Information.

Suppliers (Offerors) are required to provide an emergency service if, in exceptional circumstances, an urgent delivery within normal hours within less than the agreed lead time or outside normal working hours is deemed essential by a Participating Authority. Suppliers (Offerors) are required to provide emergency service contact details in Document 6b

**COMPLIANCE Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**G2** Suppliers (Offerors) and Participating Authorities are required to work together to meet variations in demand, recognising that significant changes in service levels require time on both sides to be implemented.

**For Information only (Not Evaluated & Not Scored)**

**G3** Evidence of temperature-controlled shipping for all deliveries must be made available to Participating Authorities on request.

**For Information only (Not Evaluated & Not Scored)**

**G4** Products within the expiry date which have been damaged as a consequence of the Suppliers (Offerors) delivery or poor packaging will be replaced or refunded in an agreed timeframe at no cost to the Participating Authority.

**COMPLIANCE Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

|  |
| --- |
| **All specification points listed above in “G: Delivery”** |
| **I confirm I have read and understood and will comply with all the above specification points and where applicable have completed Document 8 Parenteral Nutrition (PN) Tender Response (PART B)** **If NO, please provide further details here………………………………………** |

**H: Product Shortages**

**H1** In the event of a manufacturing or supply problem beyond the control of the Supplier (Offeror), the Supplier (Offeror) will notify the Participating Authority as soon as reasonably practical and both parties will work in partnership to minimise additional costs to the Participating Authority whilst maintaining patient safety. Where this is a national problem The Authority (YHPPC) should be notified.

**COMPLIANCE Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

|  |
| --- |
| **All specification points listed above in “H: Product Shortages”** |
| **I confirm I have read and understood and will comply with all the above specification points.****If NO, please provide further details here………………………………………** |

**I: Communications**

**I1** Key individuals will be designated the point of contact for this service within each Participating Authority and they will confirm when they join the agreement. Details will be provided using the Order Form.

**For Information only (Not Evaluated & Not Scored)**

**I2** Suppliers (Offerors) are required to provide named individuals and contact details for the categories indicated below. It will be the responsibility of the Suppliers to keep this information up to date and inform all parties.

The Supplier (Offerors) will submit information in Document 6 Commercial Schedule, Terms of Business.

**Categories**: -

* Contact details of person completing the tender
* Company Details
* Ordering Details
* Emergency Out of Hours
* Technical Queries
* Contract Queries
* Finance / Invoice Queries
* Delivery Terms
* Evaluation Contact Availability
* Data Provider
* Framework Agreement Sign off contract(s)

**COMPLIANCE Point (Evaluated & Scored) please provide response in Document 6 Commercial Schedule, Terms of Business.**

|  |
| --- |
| **All specification points listed above in “I: Communications”** |
| **I confirm I have read and understood and will comply with all the above specification points** **If NO, please provide further details here………………………………………** |

**J: Ordering & Invoicing**

**J1** Suppliers (Offerors) shall indicate if they are able to perform electronic transmission of ordering and invoicing information through the Pharmacy Messaging Service (PMS) in Document 6 Commercial Schedule, Terms of Business. If currently unable to do so Suppliers (Offerors) shall work towards meeting this specification point**.**

**COMPLIANCE Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**J2** Orders will be placed separately by the individual Participating Authority and payment for goods will be made direct by them.

On receipt of an order, Suppliers (Offerors) will notify the Participating Authority as soon as is reasonably possible if the agreed lead times or the complete order delivery may be compromised.

Suppliers (Offerors) should only submit one invoice per delivery.

Part deliveries are acceptable in exceptional circumstances only. Where part deliveries are anticipated, they should be notified to Participating Authorities in advance.

**COMPLIANCE Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**J3** Suppliers (Offerors) are required to indicate during the life of the framework how they plan to manage price variations of active ingredients in line with market conditions to ensure that the Participating Authorities continue to receive value for money (e.g., when generic products become available following a patent expiry of a branded medicine).

**COMPLIANCE Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**J4** If a ready to administer product licensed in the UK becomes available to replace any of the listed products during the life of the agreement, the Participating Authorities reserve the right to purchase that product in the place of the unlicensed product within this agreement. It may however be necessary to re-tender this medicine.

**For Information only (Not Evaluated & Not Scored)**

|  |
| --- |
| **All specification points listed above in “J: Ordering & Invoicing”** |
| **I confirm I have read and understood and will comply with all the above specification points** **If NO, please provide further details here………………………………………** |

**K: Contract Management**

**K1** Contract monitoring meetings will be held with each of the successful Suppliers (Offerors) by the Participating Authorities and / or The Authority, twice yearly or at more frequent intervals if required.

**For Information only (Not Evaluated & Not Scored)**

**K2** Suppliers (Offerors) will ensure that Management Information (MI), Complaints and KPI data is supplied to the Authority and where applicable the Participating Authority monthly, within 10 working days from the end of the previous month.

Participating Authorities will also keep their own record so that issues, complaints, and concerns can be logged, compared, and raised with relevant suppliers.

Example of the template to be used for data collection is included in Document 6b - Contract Management Information.

A final version of the template will be provided following the contract award. Suppliers (Offerors) must ensure that all lines are completed correctly.

Suppliers (Offerors) will comply with all requests for ad hoc data to be provided in respect of the products supplied and service charges under this agreement. This information is to be provided within 10 working days for ad hoc requests.

 **COMPLIANCE Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

|  |
| --- |
| **All specification points listed above in “ K: Contract Management”** |
| **I confirm I have read and understood and will comply with all the above specification points** **If NO, please provide further details here………………………………………** |

**L: Planned or Unplanned Aseptic Unit Shut Down**

**L1** In the event of a planned or unplanned shutdown involving a Pharmacy Aseptic Unit based in one and/or more of the Participating Authority(s) region, the Supplier (Offeror) will agree to provide support in the form of the aseptically prepared, batch manufactured Parenteral Nutrition in ready-to-administer presentations. Please see Description of Service (this document section 2) for further information and Document 8 Tender Response Part B Appendix B for the sample quality technical agreement.

**For Information only (Not Evaluated & Not Scored)**

|  |
| --- |
| **All specification points listed above in “M: Planned or Unplanned Aseptic Shut Downs”** |
| **I confirm I have read and understood and will comply with the above specification point.****If NO, please provide further details here………………………………………** |

**4. Specification (Social Value Model)**

**M: Environmental & Social Value**

**M1** Under the Public Services (Social Value Act), the Supplier will consider where added value and benefit, in relation to economic, social and environmental aspects (Social Values) can be achieved as part of this procurement exercise

* High level info/context: <https://www.gov.uk/government/publications/social-value-act-information-and-resources/social-value-act-information-and-resources>
* Procurement Policy Notice: <https://www.gov.uk/government/publications/procurement-policy-note-0620-taking-account-of-social-value-in-the-award-of-central-government-contracts>
* Direct link to the quick reference table: <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940828/Social-Value-Model-Quick-Reference-Table-Edn-1.1-3-Dec-20.pdf>

**For Information only (Not Evaluated & Not Scored)**

**M2** Social Value -

The Theme is **Fighting Climate Change**

 The Policy Outcome is **Effective stewardship of the environment**

Supplier (Offeror) is asked to describe how they have embedded effective measures to deliver additional environmental benefits in the performance of the framework including working towards net zero greenhouse gas emissions.

Detail how, through the delivery of the framework agreement, you will reduce the amount of **single use plastic used as part of the manufacturing process of products** that will be provided.

Using a maximum of 1,000 words describe the commitment your organisation will make to ensure that opportunities under the framework deliver the outcome and Award Criteria. Please include:

● your ‘Method Statement’, stating how you will achieve this and how your commitment meets the Award Criteria, and

● a timed project plan and process, including how you will implement your commitment and by when. Also, how you will monitor, measure and report on your commitments/the impact of your proposals. You should include but not be limited to:

○ timed action plan

○ use of metrics

○ tools/processes used to gather data

○ reporting

○ feedback and improvement

○ transparency

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**M3** Social Value -

The Theme is **Tackling Economic Inequality (Workforce)**

The Policy Outcome is **Create new businesses, new jobs, and new skills**

The Supplier (Offeror) is asked to describe how they plan to create new jobs and new skills in your workforce which benefits in the performance of the framework including:

* Create employment and training opportunities, particularly for people in industries with known skills shortages or in high growth sectors.
* Support educational attainment relevant to the contract, including training schemes that address skills gaps and result in recognised qualifications.

Detail how, through the delivery of the framework, how you will ensure that there is a skills policy that focuses on increasing the average level of skills of the workforce and reduce inequalities in the way skills are distributed among the population, keeping the supply of skills aligned and responsive to market needs

Using a maximum of 1,000 words describe the commitment your organisation will make to ensure that opportunities under the framework deliver the outcome and Award Criteria. Please include:

● your ‘Method Statement’, stating how you will achieve this and how your commitment meets the Award Criteria, and

● a timed project plan and process, including how you will implement your commitment and by when. Also, how you will monitor, measure and report on your commitments/the impact of your proposals. You should include but not be limited to:

○ timed action plan

○ use of metrics

○ tools/processes used to gather data

○ reporting

○ feedback and improvement

○ transparency

**ADJUDICATED Point (Evaluated) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

|  |
| --- |
| **All specification points listed above in “L: Environmental & Social Value”** |
| **I confirm I have read and understood and will comply with all the above specification points and where applicable have completed Document 8 Parenteral Nutrition (PN) Tender Response (PART B)** **If NO, please provide further details here………………………………………** |

**Appendix 1**

|  |
| --- |
| **Abbreviations**  |
| BCP | Business Continuity Plan / Contingency Plan |
| BP | British Pharmacopoeia |
| CC | Change Control |
| GAMP | Good Automated Manufacturing Practice |
| cGDP | Current Good Distribution Practice guidelines issued by MHRA |
| cGMP | Current Good Manufacturing Practice guidelines issued by MHRA |
| GPhc | General Pharmaceutical Council |
| NHSE CMU | NHS England Commercial Medicines Unit |
| DHSC | Department of Health and Social Care |
| EEA | European Economic Area  |
| EMA | European Medicines Agency |
| ICH | The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use  |
| ISO | International Organization for Standardization  |
| KPI | Key Performance Indicators |
| MA | Marketing Authorisation |
| MHRA  | Medicines and Healthcare Products Regulatory Agency |
| MRA | Mutual Recognition Agreement  |
| MS | Manufacture Specials (Human) |
| NHS | National Health Service |
| PA | Participating Authority |
| PLGB | Great Britain Product License  |
| PMSG | Pharmaceutical Market Support Group |
| PN | Parenteral Nutrition |
| QM | Quality Manual |
| SLA | Service Level Agreement |
| SMF | Site Master File |
| SSQ | Standard Selection Questionnaire |
| TA | Technical Agreement |
| TSE | Transmissible Spongiform Encephalopathies |
| WDA(H) | Wholesale Distribution Authorisation (Human) |
| YCD | Yellow Cover Document  |
| YHPPC | Yorkshire and Humber NHS Pharmaceutical Purchasing Consortium |

**Appendix 2**

| **Definitions** |
| --- |
| Authority | For the purpose of this Framework the Authority is the Yorkshire & Humber NHS Pharmaceutical Purchasing Consortium (YHPPC). |
| Business Continuity Plan / Contingency Plan | Contingency arrangements for managing an unexpected interruption to one or more of their facilities or logistics partner. ISO 22301 is the business standard for a robust Business Continuity Plan. |
| British Pharmacopoeia | The national pharmacopoeia of the United Kingdom. It is an annually published collection of quality standards for medicinal substances in the UK, which is used by individuals and organisations involved in pharmaceutical research, development, manufacture, and testing. |
| Call-off Contract | Means any contract entered into under this Framework Agreement by any Participating Authority with a Framework Supplier as further defined in the Call-off Terms and Conditions for the Supply of Goods & Services.  |
| Change Control | A systematic approach to proposing evaluating, approving, implementing, and reviewing changes. (MHRA Orange Guide - ICH Q10 International conference on harmonisation of technical requirements of registration of pharmaceuticals for human use). |
| Consortia / Consortium | The Yorkshire & Humberside NHS Pharmaceuticals Purchasing Consortium supports the contracting and procurement of medicines and medicines services, including full quality assurance support for all the fourteen acute Trusts in Yorkshire & the Humber. The consortium provides member Trusts (Participating Authorities (PA)) and commissioners with strategic purchasing support, procurement expertise and commercial skills. |
| Current Good Manufacturing Practice (cGMP) | The minimum standard that a medicines manufacturer must meet in their production processes. Products must be of consistent high quality be appropriate to their intended use. |
| Eligible Participating Organisations | Includes and for the benefit of publicly funded (both wholly and partially funded) entities in the United Kingdom, including Northern Ireland, Scotland, Wales and England. This will include but is not limited to: Acute; (including their third party providers); Ambulance; Mental Health; Clinical Commissioning Groups; Health and Care Trusts; Area Teams; Local Authorities and Special Health Authorities; HSC in Northern Ireland; NHS Scotland and NHS Wales, including any successor or emerging organisations, which will include but is not limited to the emerging landscape of combined health and social care commissioners and providers. (Ref Doc 7 - YHPPC Members & Eligible Participating Authorities). |
| Framework Agreement | The Framework Agreement for Parenteral Nutrition, the overarching agreement that Suppliers are awarded to from which Call-Off Contracts with Participating Authorities can be made.  |
| Good Automated Manufacturing Practice (GAMP) | This is both a technical subcommittee of the International Society for Pharmaceutical Engineering (ISPE) and a set of guidelines for manufacturers and users of automated systems in the pharmaceutical industry. |
| Key Performance Indicators (KPI's) | Key Performance Indicators are quantifiable measurements, agreed to beforehand, that reflect the critical success factors of an organisation.  |
| Manufacture Specials (Human) | To make, assemble or import human medicines, a company will need a manufacturers' licence, issued by the Medicines and Healthcare Products Regulatory Agency (MHRA). To qualify for a manufacturer licence the company will must show the MHRA that they comply with EU good manufacturing practice (GMP) and pass regular GMP inspections of their site. |
| Marketing Authorisation  | Medicines which meet the standards of safety, quality and efficacy are granted a marketing authorisation (previously a product licence), which is normally necessary before they can be prescribed or sold. This authorisation covers all the main activities associated with the marketing of a medicinal product. |
| Out of hours  | Any time not specified as normal working hours (Monday to Friday 9am to 5pm) for the relevant activity. |
| Offeror | The supplier submitting the tender offer. |
| Order Form | The receipt by the Participating Authority of an Order Form countersigned by the Supplier shall form a binding call-off agreement between the Supplier and the Participating Authority for the Provision of the Products specified in the relevant Order. |
| Procedure | For the purposes of this specification 'procedure' is used to describe, but is not limited to, any of the following determined on how your company manages documents; • Work Instruction• Standard Operating Procedures• Procedures• Policies• Guidance Notes/Documents |
| Participating Authority  | The Trust / Authority entitled to place Orders under this Framework Agreement as set out in the Key Provisions (Doc 7 - YHPPC Members & Eligible Participating Authorities). |
| Product Range | A group of products of a similar nature. |
| QAAPS | Quality Assurance of Aseptic Preparation Service Standards |
| Sub-Contractor | A company that undertakes work on behalf of the Supplier. This could include subcontract manufacturing or distribution services. |
| Supplier | The "Offeror" submitting the tender offer and the Aseptic Compounding Manufacturer awarded to supply unlicensed medicines to the Participating Authority (PA). |
| Supplier Quality Assessment | Assessment of the supplier against the award methodology and evaluation criteria by QA Specialists (Yorkshire & Humber NHS Pharmaceutical Purchasing Consortium).  |
| Unlicensed Medicine | A medicine that does not have a UK Marketing Authorisation (PLGB) OR a licensed medicine that is being used for an un-licensed indication OR a manufactured special (MS) or extemp or borderline substances OR re-packaged licensed products.  |
| Wholesale Dealers Licence | Any company or individual wishing to wholesale deal medicinal products (defined as selling, supplying or procuring to anyone other than the end-user) within the EU must hold a WDA(H) – Wholesale Distribution Authorisation (Human). |
| Yellow Cover Document | Guidance documents prepared and issued by the NHS Pharmaceutical Quality Assurance Committee.  |