****

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Call Off Order Form for Management Consultancy Services**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

12/08/2013

**FRAMEWORK SCHEDULE 4**

**CALL OFF ORDER FORM AND CALL OFF TERMS**

12/08/2013

**PART 1 – CALL OFF ORDER FORM**

**SECTION A**

This Call Off Order Form is issued in accordance with the provisions of the Framework Agreementfor the provision of **RM3745**

The Supplier agrees to supply the Services specified below on and subject to the terms of this Call Off Contract.

For the avoidance of doubt this Call Off Contract consists of the terms set out in this Call Off Order Form and the Call Off Terms.

|  |  |
| --- | --- |
| **Order Number** | CCCC21A74 |
| **From** | Department of Health and Social CareREDACTED("CUSTOMER") |
| To | Redquadrant REDACTED ("SUPPLIER") |

**SECTION B**

**call off contract period**

|  |  |  |
| --- | --- | --- |
|  | **Commencement Date**: | Contract deemed to have started 29th March 2021 |
| **1.2** | **Expiry Date**: | 30th October 2021 |

**Services**

|  |  |  |
| --- | --- | --- |
| **2.1.**  | **Services required**:  | **A quality Manager:** * Establish QMS plan and managing the generation of the manual system.
* Draft of controlled procedures, forms and templates in collaboration with function owners.
* Responsible for issuing approval requests across the organisation for the controlled procedures and releasing the documentation on approval.
* Regulatory control change to determine if there is an impact on product development.
* Lead auditor.

**A quality and Compliance Specialist:** * Provide Risk Management technical expertise through the product life cycle.
* Support Development, remediation and maintenance of Risk Management Files according to ISO 14971 and MDR requirement.
* Train and support risk management activities related to new product introduction (NPI).
* Participate in or manage quality assessments of internal operations and suppliers to analyse compliance and assess risk.
* Participate in complaint investigation, including definition of investigation level, root cause analysis, timeliness and quality of response and trending
* Participate in the review and recall of defective product, as necessary, to minimise patient risk.
* Facilitate development and completion of risk assessments for field issues/complaints in the field.
* Work with cross-functionally to ensure the accurate application, use and updates of risk management files.
* Handling of Change Control Requests, Non-Conformities and CAPAs, ensuring their adequate and timely closure.
* Answer enquiries in the area of quality management, regulations or complaints as the internal competent advisor for all quality-relevant topics.
* Support the process owners in the creation of guidelines and quality documents.
* Assist in preparation, multi-site collaboration and review of changes to Quality Management System procedures.
* Assist in selection and approval of suppliers/sub-contractor  Maintaining, updating and communicating key processes, SOPs, policies  Monitor internal audit non-conformances, perform trend analyses, and present findings.
 |

**contract performance**

|  |  |  |
| --- | --- | --- |
| **4.1.**  | **Standards**: | see Clause 11 (Standards) and the definition of Standards in Call Off Schedule 1 (Definitions). Specify any particular standards that should apply to this Call Off Contract, including those which relate to the Cyber Essentials Scheme. |
| **4.2** | **Service Levels/Service Credits**:Not applied | *Not applicable* |
| **4.3** | **Critical Service Level Failure**:Not applied | *Not applicable* |
| **4.4** | **Performance Monitoring:** Not applied | *Not applicable* |
| **4.5** | **Period for providing Rectification Plan:**   | see Clause 39.2.1(a) (Rectification Plan Process) |

**personnel**

|  |  |  |
| --- | --- | --- |
| **5.1** | **Key Personnel**:  | REDACTED |

**PAYMENT**

|  |  |  |
| --- | --- | --- |
| **6.1** | **Call Off Contract Charges** (including any applicable discount(s), but excluding VAT):  | REDACTED |
| **6.2** | **Payment terms/profile**  | REDACTED |
| **6.3** | **Reimbursable Expenses**:  | see paragraphs 4 and 5 of Call Off Schedule 3  |
| **6.4** | **Customer billing address**  | 39 Victoria StreetWestminsterLondonSW1H 0EU |

**LIABILITY and insurance**

|  |  |  |
| --- | --- | --- |
| **7.1** | **Estimated Year 1 Call Off Contract Charges**: | Consider Clauses 37.2.1 and 37.2.2 in respect of limitation of liability and see the definition of “Estimated Year 1 Call Off Contract Charges” in Call Off Schedule 1 (Definitions).  |
| **7.2** | **Supplier’s limitation of Liability** (Clause 37.2.1 of the Call Off Terms);In Clause 37.2.1 of the Call Off Terms | Consider Clause 37 (Liability) and confirm the Supplier’s financial limits of liability. Consider whether the default limits to the Supplier’s liability in Clause 37.2.1 are appropriate for the Call Off Contract and represent the right apportionment of risk between the Customer and the Supplier. The aim should be to establish liability ceilings reflecting a combination of the best estimate by the Customer of the losses that it (and any other associated bodies) might suffer in the event of a Default by the Supplier, the likelihood of those losses occurring and the value for money considerations in limiting liability.  |
| **7.3** | **Insurance** (Clause 38.3 of the Call Off Terms): | See Clause 38 (Insurance). Include any specific minimum insurance policies and related requirements pursuant to Clause 38.3.  |

**TERMINATION and exit**

|  |  |  |
| --- | --- | --- |
| **8.1** | **Termination on material Default** (Clause 42.2.1(c) of the Call Off Terms)): | Guidance Note: consider Clause 42.2.1(c) (Termination on Material Default).  |
| **8.2** | **Termination without cause notice period** | The period of thirty (30) Working Days in Clause 42.7.1 |
| **8.3** | **Undisputed Sums Limit** | In Clause 43.1.1 of the Call Off Terms |
| **8.4** | **Exit Management:**   | Not Applied  |

**FORMATION OF CALL OFF CONTRACT**

**BY SIGNING AND RETURNING THIS CALL OFF ORDER FORM (which may be done by electronic means) the Supplier agrees to enter a Call Off Contract with the Customer to provide the Services in accordance with the terms Call Off Order Form and the Call Off Terms.**

**The Parties hereby acknowledge and agree that they have read the Call Off Order Form and the Call Off Terms and by signing below agree to be bound by this Call Off Contract.**

**In accordance with paragraph 7 of Framework Schedule 5 (Call Off Procedure), the Parties hereby acknowledge and agree that this Call Off Contract shall be formed when the Customer acknowledges (which may be done by electronic means) the receipt of the signed copy of the Call Off Order Form from the Supplier within two (2) Working Days from such receipt.**

|  |
| --- |
| **For and on behalf of the Supplier:** |
| Name and Title | REDACTED |
| Signature | REDACTED |
| Date |  |
| **For and on behalf of the Customer:** |
| Name and Title | REDACTED |
| Signature | REDACTED |
| Date |  |