

- a. All labour costs have been provided. These have been provided on the basis of employee type, time and *per diem* rate on a coverage of costs only basis. These are summarised in the attached spreadsheet.
- b. There is a service cost for the use of the dryer. This is summarised in Appendix (TBD). This includes start-up, operation and post run cleansing between operations, gas supply and vacuum oil. The human and other resource for this activity is an overhead and not itemised/charged elsewhere.
- c. An overhead charge is made for laboratory activities. This covers all sundry consumables used in the laboratory. It is costed on a *per diem* rate and the value is associated with the specific laboratory utilised.
- d. This proposal includes the generation of all internal documentation to the ISO 13485 QMS standard currently being implemented (for future certification) within FGL.
- e. In-stock items will be used wherever possible to expedite the programme.
- f. The contract is considered to be research and development and therefore it contains a finite element of risk. However, no *significant* technical risk is foreseen and FGL will undertake the work in a best faith effort approach to deliver the programme to the defined number of proposed phases and costs.
- g. Each phase has been planned to provide enough coverage to allow the delivery of the required technical capability. Should the technical requirement not be achieved within the allocated cost, resource and timeframe, there may be the need for an additional execution of that phase. The costs of a second or later round of development will be the same as the first as detailed.
- h. Activities associated with commercial launch of the product (other than quality documentation) are not included in this proposal. These activities included the preparation of primary and secondary packaging and labelling. A range of options may be possible that require user specifications to be generated. FGL will undertake this work at an agreed cost.
- i. Background intellectual property shall remain the property of both parties. FGL grants no rights of use for its background technology. FGL will not disclose any proprietary process as part of this agreement.
- j. Any foreground intellectual property arising from the work undertaken during this contract shall be noted in writing to the customer. The principle of ownership of foreground IP generated under this contract is joint ownership. FGL would assign rights to the customer free of charge for any foreground intellectual property (generated as part of the contract) which is required to commercialise the product.
- k. Certain rights to FGL background intellectual property are transferred with the sale of goods to allow those goods to be used for their intended application.
- l. All costs are in £GBP. Transactions may be made in EUROS or \$USD. The value deposited shall be the contracted value. All transactions costs are paid by the customer. The PO shall be accompanied by a local tax code (VAT). The work may qualify for VAT exemption.
- m. 20% of the value of the contract (or phase of contract) is required upfront for work to begin. The balance is required no later than 30 days (strictly). All rights and ownership to the work (intellectual property and/or goods) remain the property of FGL until the account is settled.
- n. Work for the programme, or a requested phase can begin on issue of a PO and 20% of the item value (as m.)
- o. Materials supplied by the customer shall be stored and retained by FGL during the period work. They may be destroyed after completion of the project (or on their expiry date if earlier). If the customer requires the return of these items this should be requested during the study.
- p. Where the customer chooses to supply materials such as biologics (e.g. primers, probes, enzymes and template) as part of the programme then:
 - i. the materials may not have *certificates of analysis* or *raw material specifications* unless these are provided by the customer.
 - ii. the quantities required for the programme shall be provided to the customer (by FGL) after initiation of the described study (in the quotation). If the amounts supplied by the customer are insufficient then FGL shall have the rights to either decline the contractual obligations, or offer procurement (at a specified value 5% handing charge) of the items providing the specification is made available to FGL. The customer should endeavour to provide a single batch of sufficient quantity of each material to complete the proposed study (as described in the quotation).

- iii. where the customer offers multiple small batches of these materials the total quantity received shall be calculated by subtracting the amount required for any goods-in quality control or equivalence studies within the programme. FGL reserves the right to charge for any goods-in quality control or equivalence studies if multiple small batches of these materials are supplied.
- iv. where the customer offers multiple small batches of these materials shipped at different times then FGL reserves the right to alter R&D timescales and scheduling accordingly.
- v. they shall be delineated within the shipment container such that they may be handled upon opening appropriately to avoid environmental contamination with any template. The customer shall endeavour to place template into screw cap vials wherever possible prior to shipment to reduce the risks (upon opening) of environmental contamination.
- vi. FGL reserves the right to charge for any goods received which are deficient in their labelling and packaging (FGL may choose to charge for time to rectify). The customer should endeavour to clearly label each vial with product name, code, concentration (in standard international units where possible), storage conditions, expiry date and LOT number as a minimum requirement.