**General Information**

|  |  |
| --- | --- |
| Company name |  |
| Company address |  |
| Contact person / Position |  |
| Contact details *(phone, email)* |  |

|  |  |
| --- | --- |
| Product name |  |
| Classification | [ ]  IVD [ ]  Excipient [ ]  API [ ]  Other: Click here to enter text. |
| Intended use of product *(Please describe)* |  | [ ]  non-sterile[ ]  sterile |
| Project phase | [ ]  R&D [ ]  preclinical [ ]  clinical phase I [ ]  clinical phase II[ ]  Other: Click here to enter text. |
| Applicable regulations | [ ]  ISO 9001 [ ]  ISO 13485 [ ]  EXCiPACT[ ]  EU GMP Guideline Part II and Annexes[ ]  Others:Click here to enter text. |
| Supplier qualification requirements |  |
| Contractual requirements | [ ]  Non-Disclosure Agreement (NDA)[ ]  Supply Agreement (SA)[ ]  Quality Assurance Agreement (QAA) |

**Product Specifications**

|  |  |
| --- | --- |
| Type of oligonucleotide | [ ]  CpG ODN [ ]  ASO [ ]  siRNA [ ]  sgRNA [ ]  Aptamer[ ]  Other: Click here to enter text. |
| Backbone | [ ]  Phosphodiester [ ]  Phosphothioate |
| Sequence and position of modifications (5´-> 3´) | 1st strand |
| 2nd strand [ ]  N/A  |
| Modifications / Molecular weight (MW) | [ ]  5´ end: |  | MW: |  |
| [ ]  3´ end: |  | MW: |  |
| [ ]  internal: |  | MW: |  |
| [ ]  internal: |  | MW: |  |
| [ ]  internal: |  | MW: |  |
| Molecular weight (MW) Product (Da) |  |
| Chemical structure Product | *Please insert if needed* |
| Quantity delivered [unit] |  |
| Purification |  |
| Delivery form | [ ]  lyophilzed[ ]  in solution/concentration adjustedSolvent: Click here to enter text. Final concentration [unit]: Click here to enter text. |
| Number of aliquots |  |
| Primary packaging |  | [ ]  no special requirements |
| Secondary packaging |  | [ ]  no special requirements |
| Additional comments |  |

**Quality control and Release criteria**

|  |  |
| --- | --- |
| Identity [unit] | [ ]  LC-MS: Click here to enter text. |
| Analytical purity [unit] | [ ]  RP-HPLC: Click here to enter text. [ ]  IEX-HPLC: Click here to enter text.[ ]  Other: Click here to enter text. | [ ]  No requirements |
| Impurities |  |
| Bact. Endotoxin [unit] / Reference |  | [ ]  No requirements |
| Bioburden [unit] / Reference | [ ]  TAMC: Click here to enter text.[ ]  TYMC: Click here to enter text. | [ ]  No requirements |
| Residual solvents [unit] |  | [ ]  No requirements |
| Heavy metals [unit] |  | [ ]  No requirements |
| Na+ content [unit] |  | [ ]  No requirements |
| Others |  |

**Additional Requirements**

|  |  |
| --- | --- |
| Manufacturing and Control | *Please provide CMC part of Investigational Medicinal Product Dossier (IMPD) or appropriate other regulatory documents (e.g. toxicity)*[ ]  Documents attached:1.2.3.4. |
| Environment | [ ]  ISO 7 cleanroom area[ ]  ISO 8 cleanroom area[ ] Other: Click here to enter text. | [ ]  No special requirements |
| Documentation | [ ]  Manufacturing Protocol / Batch Record[ ]  Certificate of Analysis (CoA)[ ]  Certificate of Manufacturing Compliance (CoMC)[ ]  TSE/BSE Statement[ ]  Others: Click here to enter text. |
| Transport | [ ]  Temperature controlled [unit]: Click here to enter text.[ ]  Ambient | [ ]  No special requirements |
| Stability studies |  | [ ]  No requirements |
| Others |  | [ ]  No requirements |

|  |  |
| --- | --- |
| **Intended project start [mm/yyyy]** |  |
| **Budget [currency]** |  |
| **Requester name** |  |
| **Position** |  |
| **Date** | **Signature** |

**Please send back to sales@metabion.com**