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| --- | --- |
| CTC Reference number: | (Internal use only) |
| Date: |  |
| Company Name: |  |
| Address: |  |
| Telephone Number: |  |
| Fax Number: |  |
| Email Address: |  |
| Number of employees: |  |
| Nature of Business: |  |
| Person Responsible for Quality Assurance: | **Name:** |
| Job Title: |
| To Whom is He/She Responsible: | **Name:** |
| Job title: |

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| 1.0 | QUALITY ASSURANCE | | | |
|  | Question | Yes/No | Comments | Score |
| 1.1 | What are the main activities at your facility/site? |  |  |  |
| 1.2 | Does the organisation operate at other sites? |  |  |  |
| 1.3 | Do you have an organisation chart? |  |  |  |
| 1.3.1 | Can a copy be provided? |  |  |  |
| 1.4 | Do you have your own QA department? |  |  |  |
| 1.4.1 | If no, how is this function supported? |  |  |  |
| 1.5 | Does the site have a formal Quality System? |  |  |  |
| 1.5.1 | If yes, list any formal main standards complied with(e.g. ISO, GLP) |  |  |  |
| 1.6 | How many staff dedicated to Quality Assurance are employed at this facility? (If external QA consultancy or part-time QA support is used, please provide details, including the number of days per year) |  |  |  |
| 1.7 | Provide a brief overview of the QMS documents available at the site. (For example: Quality Manual, Policies, Procedures, Work Instructions, controlled forms) |  |  |  |
| 1.7.1 | Do you have an up to date quality manual? |  |  |  |
| 1.8 | Is there a staff training programme? |  |  |  |
| 1.9 | Are records of training available? |  |  |  |
| 1.9.1 | If yes describe format (paper/electronic) and outline of content |  |  |  |
| 1.10 | Are all personnel adequately qualified and trained? |  |  |  |
| 1.11 | Are all staff appraised on a regular basis? |  |  |  |
| 1.12 | Do you have a corrective action, preventative action procedure? |  |  |  |
| 1.13 | Do you have a customer complaints procedure? |  |  |  |
| 1.14 | Is there a formal process for reporting and investigating deviations and non-conformances? |  |  |  |
| 1.15 | Does your organisation conduct internal audits? |  |  |  |
| 1.16 | Do you perform vendor audits and/or distribute quality questionnaires to your suppliers? |  |  |  |
| 1.17 | Do you have an approved supplier list? |  |  |  |
| 1.18 | Do you have procedures to ensure that shipped supplies have not been tampered with in storage and during transit? |  |  |  |
| 1.19 | Please provide a list of computerised systems used by your site |  |  |  |
| 1.20 | Is there a policy and procedure in place for validation of computerised systems? (Please outline) |  |  |  |
| 1.22 | Are there any new systems currently undergoing validation or revalidation? |  |  |  |
| 1.22 | Has the facility been subject of merger or acquisition within the last 3 year period? (If yes, please describe) |  |  |  |
| 1.23 | Is it planned that the facility will be involved in merger, closure of all or part of the site, or significant expansion within the next six month period? |  |  |  |

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| 2.0 | DOCUMENTATION | | | |
|  | Question | Yes/No | Comments | Score |
| 2.1 | Do you have SOPs relating to all important aspects of operation? (E.g. Validation, change control, deviation management, study approval) |  |  |  |
| 2.2 | Do you have a list of all current SOPs and other controlled documents (e.g. forms)? |  |  |  |
| 2.2.1 | Can a copy be provided? |  |  |  |
| 2.3 | Do you provide controlled documents in paper form, online or both? |  |  |  |
| 2.4 | Are controlled documents (SOPs, forms, etc.) periodically reviewed, revised when necessary and approved by authorised personnel? |  |  |  |
| 2.5 | How often do you review controlled documents? |  |  |  |
| 2.6 | Do you ensure that invalid or obsolete documents are promptly removed from all points of use to assure against inadvertent use? |  |  |  |
| 2.6.1 | If yes, how do you ensure this? |  |  |  |
| 2.7 | Where activities are performed offsite, are these covered by company SOPs or protocols? |  |  |  |
| 2.7.1 | If yes, how is it ensured that current documents are used? |  |  |  |
| 2.8 | Do you have a procedure that documents the: |  |  |  |
| 2.8.1 | * Responsibilities of QA Department |  |  |  |
| 2.8.2 | * Assessment Of Suppliers & sub-Contractors (i.e. Quality Questionnaire / Vendor Audit) |  |  |  |
| 2.8.3 | * Calibration Of Inspection Equipment Traceable To National Standards |  |  |  |
| 2.8.4 | * Validation of Equipment |  |  |  |

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| This questionnaire was completed as a self-audit by: |  |
| Company Role: |  |
| Signature: |  |
| Date |  |

Please return the completed questionnaire either by post or a PDF copy via email to:

|  |
| --- |
| Insert name of contact Cell Therapy Catapult Limited  12th Floor Tower Wing,  Guys Hospital,  Great Maze Pond,  London SE1 9RT |

Email: Insert email address @ct.catapult.org.uk