horizon™
INSPIRED CELL SOLUTIONS

QUALITY FACT SHEET

Scope of Quality System

Scope	We are a fully integrated life science company that provides enabling products, services and research tools to clients engaged at every stage of the healthcare continuum.
Sites	Headquarters: Cambridge, UK, US Site: Lafayette, CO
Current ISO Registrations	HQ: BSI: ISO 9001:2015 and ISO 13485:2016 US: Intertek: ISO9001:2015
Dates of Registration	See certificates: https://www.horizondiscovery.com/about-us/horizon-quality-management-system
Regulatory Status	All Products are available for Research Use Only, not intended for diagnostic or therapeutic purposes

Quality Practices

Management Responsibility	Quality Policy established and authorized by CEO. Planned Quarterly Management Review ensures its continuing suitability, adequacy, effectiveness and alignment with strategic direction.
Training Program	New starters are provided with an induction followed by job specific training through an electronic Document Management System (eDMS). Personnel are evaluated for competency and actions are taken proportionately to job role. Assigned training records are maintained automatically within eDMS.
Internal Audits	An internal audit program is scheduled annually. This includes auditors from a global cross-functional team to ensure the QMS conforms and is continuously improving. Audit reports are generated and recorded along with any corrections or corrective actions.
Purchasing Control	An Approved Supplier List is maintained from initial approval and is periodically re-evaluated. This is a risk-based approach upon classification or performance of the supplier or supplied material. Documented information for supplier capability and performance is maintained.
Manufacturing Control	Production is controlled from order to remittance to ensure conformance to product requirements. Traceability is maintained by documented information and/or controlled systems. Validation is completed when resulting outputs cannot be verified to prevent detection at customer site.
Quality Control	Process validation and verification is used, as appropriate, based on risk of the process. Products are either released for sale by a trained associate or by monitoring and measuring equipment (M&M).
M&M Equipment and Environment Control	Equipment and environmental management is controlled through scheduled calibration, inspection or documented information. Environment specifications are determined for each operational area.
Nonconformity and CAPA	Quality events are evaluated by risk for correction, investigation, root cause, corrective actions and effectiveness. All corrective action will be proportionate to the effects encountered. Concessions or Deviations may be used depending on risk and justification. Improvements include preventive actions.
Documented Information	All quality and production documents are controlled by eDMS and approved prior to use. Documented information is placed in a life-cycle and only the current revision is available, which prevents unintended use. All new, edit and archive requests are controlled though a change request process. Documented information is kept by a retention schedule to conform to requirements of QMS.
Customer Feedback	Customer feedback is regularly evaluated for areas of improvement and Net Promoter Score is monitored.
Risk Management	Risk management is undertaken for each of our products produced under ISO 13485. Risk-based thinking is incorporated into key processes as Management Review, Complaints, CAPA and Change Control.

Contact Us	quality@horizondiscovery.com