Sanguine

Supplier Self-Assessment

The purpose of this document is to inform our customer about the quality management system of Sanguine Biosciences. We developed this self-assessment in an effort to answer your questions about our business and capabilities. We trust that our quality measures meet our customer's and industry expectations and exceed general standards.

1 Introduction

Sanguine Biosciences is accelerating personalized medicine by empowering donors with their healthcare data and facilitating participation in biomedical research. Sanguine actively bridges the gap between donors and researchers through direct-to-donor engagement, in-home collection of fully annotated biospecimens, apheresis product offerings, and a suite of biorepository services.

2 General Information | Locations

City, State	Contact	Capabilities
Woburn, MA	Tel: 855-836-4759	Kitting Facility
San Diego, CA	Tel: 855-836-4759	Processing Lab
Los Angeles, CA	Tel: 855-836-4759	Apheresis Site

Business Name:	Sanguine Biosciences, Inc
Street, City, Postcode:	400 West Cummings Park, Suite 3050, Woburn, MA 01801
Years in Business:	Since 2010
Legal Ownership:	Private
Website:	www.sanguinebio.com
Email:	LearnMore@sanguinebio.com
Total # of employees: (subject to change)	115
Telephone Number:	855-836-4759
CEO:	Brian Neman, CEO
Head of Quality:	AnnMarie Fleshman, VP of Quality & Compliance (reports to CEO)
Scope of products and/or services:	Sanguine provides minimally invasive human biospecimen collections and laboratory services for translational research. The collection, handling, shipping, processing, analysis, and storage of biospecimens are all tightly controlled and recorded in accordance with documented procedures across Sanguine's three sites. Our headquarters and kitting office is in Woburn, MA, our apheresis center is in Los Angeles, CA, and our laboratory and biorepository services including processing and cell analysis is in San Diego, CA.
Qualifications / Standards:	FDA registration: SanDiego Lab: 3029699739 LA Apheresis Site: 3028013052 Complies with: ISO9001:2015; 27001:2022; and 27701:2019 regulatory requirements ICH E6 Guideline for Good Clinical Practice 21 CFR Part 11 Electronic Records; Electronic Signatures GDPR; HIPAA and Privacy Protection Good Clinical Laboratory Practice (GCLP) ISO 15189 Medical Laboratories – Requirements for quality and competence

3 Organization, Quality, Environmental, Computer Systems, Sample Management and Lab

Organization and Personnel Information		Yes	Comment
1.	FDA registration	X	SanDiego Lab: 3029699739 LA Apheresis Site: 3028013052
2.	Do you have a code of business conduct?	X	POL100 – Sanguine Code of Conduct
3.	Do you have a written anti-bribery and corruption policy?	X	POL105 - Anti-Bribery and Corruption Policy
4.	Do you have a written policy relating to corporate governance and business ethics?	X	POL100 – Sanguine Code of Conduct
5.	Do you have a policy concerning equality and diversity?	X	POL101 – Employee Handbook
6.	Do you have a disaster recovery plan? (BCDR)	X	GEN103 – Business Continuity, Disaster Recovery and Response, and Pandemic Response Plan

Quality System / Document Control		Yes	Comment
1.	Do you have a Quality Manual with documented procedures to support your QMS?	X	POL102 – Quality Policy and Compliance Manual
2.	Is your quality manual approved by management?	X	All documents within Sanguine's QMS is approved by management
3.	Is the quality manual available to all employees?	X	In Sanguine's Zen eQMS
4.	Do you have business and management processes for the regular review of quality performance identifying areas for improvement?	X	In management review meetings.
5.	Do you have an established, documented, implemented, and maintained Quality Management System?	X	Zen eQMS
6.	Is there a governing SOP that outlines the creation, revision, approval, distribution, document control, and retirement of SOPs?	X	QA102 – Standard Operating Procedure (SOP) Creation, Maintenance, Review, Distribution, and Retirement – SOP on SOPs
7.	Do you have a system in place to ensure that only the latest version of procedures or SOPs are used?	X	QA102 – Standard Operating Procedure (SOP) Creation, Maintenance, Review, Distribution, and Retirement – SOP on SOPs
8.	Do you have a procedure for destroying documents?	X	QA105 – Facility, Study, and Quality Assurance Records Control, Classification, Retention, and Archival

9.	Do you have procedures for internal audits?	X	QA106 – Internal Audits and Facility Inspection Program
10.	Does QA track and trend deviations?	X	QA107 – Deviation Management
11.	Do you have a documented complaint handling procedure?	X	QA108 – Complaint and Adverse Reaction Management
12.	Do you have a formal procedure for implementing corrective and preventive actions?	X	QA109 – CAPA (Corrective Action and Preventive Action) Management
13.	Does the CAPA process provide for the investigation of the root cause of quality issues and the determination of the corrective action needed to eliminate the root cause?	X	QA109 – CAPA (Corrective Action and Preventive Action) Management
14.	Do you have a quality assurance group that is independent from operations?	X	QA100 – Roles and responsibilities of the Quality Assurance Unit
15.	Does QA audit computer system validation documentation?	X	IT102 – Computer Systems Validation and Risk Assessment
16.	Does QA qualify vendors and suppliers?	X	QA111 – Vendor Management / Service Provider Program
17.	Do you have an Approved Suppliers List?	X	QA111 – Vendor Management / Service Provider Program
18.	Do you have a segregated area for incoming products and materials?	X	OPS403 – Kit Creation, Supply Management, and Distribution Logistics
19.	Are there personnel curricula (training matrix) established and documented for each individual?	X	QA112 – Personnel Qualifications, Training, Competence, and Associated Records
20.	Does each employee have a written resume/CV and training records demonstrating they are competent to perform their duties and maintained along with Job Descriptions?	X	QA112 – Personnel Qualifications, Training, Competence, and Associated Records
21.	Does your facility train employees on data integrity?	X	QA112 – Personnel Qualifications, Training, Competence, and Associated Records
22.	Is there a list of consultants and are their qualifications maintained?	X	QA112 – Personnel Qualifications, Training, Competence, and Associated Records
23.	Do your electronic signatures require 2-component authentication (e.g. user name and password)?	X	IT100 – IT Infrastructure, Setup, Security, Monitoring, and Incident Management
24.	Do you maintain documentation to certify that user's electronic signatures are equivalent to their hand-written signature?	X	GEN104 – Employee and Vendor Onboarding and Offboarding

Environmental / Facilities	Yes	Comment
1. Is access to the facility controlled and limited?	X	SITE100 – General Facility Information, Access, and Security
2. Are there environmental controls within laboratory and are the controls monitored?	X	SITE101 - Qualification, Monitoring, and Maintenance of Lab Equipment
3. Is there a system in place to address the maintenance, calibration and validation of equipment?	X	SITE101 - Qualification, Monitoring, and Maintenance of Lab Equipment
4. Do you have electronic temperature monitoring on your cold storage systems, including alarm notification for excursions?	X	SITE101 - Qualification, Monitoring, and Maintenance of Lab Equipment
5. Is a pest control program in place?	X	SITE100 – General Facility Information, Access, and Security
6. Are waste disposal systems in place?	X	SITE100 – General Facility Information, Access, and Security
7. Where required by law and other recognized standards, is PPE provided to your employees and their use of it enforced?	X	SITE102 - Lab and Site Safety
8. Do you have Safety Data Sheets (SDS) at your facility?	X	SITE107 - Chemical Hygiene Plan

Computer Systems	Yes	Comment
1. Do you have a list of all computer systems used?	X	IT100 – IT Infrastructure, Setup, Security, Monitoring, and Incident Management
2. Is computer usage governed by procedure?	X	IT100 – IT Infrastructure, Setup, Security, Monitoring, and Incident Management
3. Are computers and computer systems password protected?	X	IT100 – IT Infrastructure, Setup, Security, Monitoring, and Incident Management
4. Do you have procedures on computer systems validation?	X	IT102 – Computer Systems Validation and Risk Assessment
5. Do you have procedures for disaster recovery and restoring data back-ups?	X	IT101 - Backup, Archive, and Restore of Data
6. Do you use a validated cloud server to back-up data?	X	IT101 - Backup, Archive, and Restore of Data

7.	Do you assign individual user accounts to each employee to access a computer system that generates study data?	X	IT100 – IT Infrastructure, Setup, Security, Monitoring, and Incident Management
8.	Are records of computer system errors maintained and investigated?	X	IT100 IT Infrastructure, Setup, Security, Monitoring and Incident Management
9.	Are computer systems used FDA 21 CFR Part 11 compliant?	X	IT100 – IT Infrastructure, Setup, Security, Monitoring, and Incident Management
Sample Management		**Yes**	**Comment**
1.	Are there established written SOPs for the receipt, handling, storage, retrieval, and management of donor patient samples to prevent mix-ups and maintain their integrity?	X	OPS500 – Biospecimen Handling
2.	Does your laboratory assign a unique sample ID to each clinical sample?	X	OPS509 – CloudLIMS Accessioning
3.	Are donor samples transported in a manner that integrity and viability are not compromised?	X	OPS515 - Biospecimen Shipping - Laboratory
4.	Are donor samples checked upon arrival to confirm their identification and identify any discrepancies?	X	OPS500 – Biospecimen Handling
5.	Are records maintained and retained to confirm the storage conditions of donor samples?	X	OPS509 - CloudLIMS Accessioning
6.	Are there any contingency plans in place to cover the actions to be taken in the event of the malfunction of equipment or facilities that could impact sample storage to ensure integrity of stored samples?	X	SITE101 - Qualification, Monitoring, and Maintenance of Lab Equipment
7.	Are records of disposal of any retained samples maintained and retained by the facility?	X	OPS500 – Biospecimen Handling
8.	Has the collection protocol been approved by an institutional review board?	X	OPS300 - Protocol Creation, IRB Submission, and Approval
9.	Are all participants required to sign informed consent forms prior to collection?	X	OPS202 - Informed Consent Process
10.	Are there established procedures for collection of participant data?	X	OPS201 - Screening Study Participants, Assessing Eligibility
Lab		**Yes**	**Comment**
1.	Does the laboratory certify its processing by any third-parties?	X	ISBER
2.	Is your training program defined in procedure?	X	QA112 – Personnel Qualifications, Training, Competence, and Associated Records SITE109- Injury and Illness Prevention Program SITE106 - Bloodborne Pathogen Exposure Control Plan

3.	What grade(s) of water supply your facility?	X	City and DI Water
4.	Are cleaning procedures established?	X	GEN110 - Lab Housekeeping
5.	Are there written SOP's for calibration of instruments?	X	SITE101 - Qualification, Monitoring, and Maintenance of Lab Equipment
6.	Are there alarms on freezers and refrigerators?	X	SITE101 - Qualification, Monitoring, and Maintenance of Lab Equipment