Gemini Bioproducts LLC
920 Stillwater Road, Suite 130
West Sacramento, CA 95605
United States of America
Phone: 1 (800) 543-6464
Fax: 1 (916) 273-5222
www.geminibio.com

Supplier Survey Response

Supplier:	Gemini Bioproducts LLC
Manufacturing Site Address:	920 Stillwater Road, Suite 130
(Company Headquarters)	West Sacramento, CA 95605
	United States of America
Additional Manufacturing Site Address:	3230 Reed Avenue
	West Sacramento, CA 95605
	United States of America
Quality Assurance Contact Information:	gembioquality@geminibio.com
Products Manufactured:	Cell culture media, sera, and other reagents.
Current Capabilities:	Up to 10,000L batches.

Last Updated: 05DEC2025

	Name	Title
Approved by:	Sarah Fogenburg Signed by: Sarah Fogenburg Signer Name: Sarah Fogenburg Signing Reason: I approve this document Signing Time: 05 December 2025 | 15:34 PST 904DEAAAAE0A40B0A59478F34E1F59B8	Senior Director, Quality 05 December 2025 | 15:34 PST

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General Supplier Information	Yes	No	Comments
Is the company registered with the FDA or other regulatory agencies?	X		FDA #3006236690
Are Device Master Records (DMRs) maintained?	X		
Is the company ISO certified?	X		ISO 13485:2016 #20173 by NQA
Are any toxic or potent substances manufactured, packaged, or stored at this site?		X	
Is the company a subsidiary of a corporation?		X	
Business Continuity Plan	X		
Emergency Response Plan	X		
Years in operation?	In Operation Since 1985		
Facility Age	The company headquarters, 920 Stillwater Road #130 began operations in 2021. 3230 Reed Avenue began operations in 2023.		
Total Area of Site	~62,000 square feet		
Production Area	~8,000 square feet of classified space (ISO 5, ISO 7, and ISO 8)		
Total Number of Employees	83		
Number of Employees in Quality	16		
Number of Employees in Manufacturing	17		
Number of Shifts	2		
Business Hours	7 AM-4 PM Monday-Friday		
Organizational Chart (Quality and Manufacturing)	See Appendix I		
ISO 13485 Certification	See Attached		
Quality Manual (Table of Contents)	See Appendix II		
Production Area Layout	See Appendix III		
List of Standard Operating Procedures (SOPs)	See Appendix IV		

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Quality Management System	Yes	No	Comments
Is there a Quality Manual?	X		
Are products manufactured under current Good Manufacturing Practices (cGMP)?	X		
Is there a Quality Policy?	X		
Is there an independent Quality Unit?	X		
Does the Quality Unit approve or reject components and finished products?	X		
Does the Quality Unit review procedures, specifications, process changes, and batch records?	X		
Is there a management review procedure?	X		
Is there a recall procedure?	X		
Has there been a recall in the last 5 years?		X	
Is there a process to control changes? If so, how?	X		Change Management in accordance with SOP
Are customers notified of all significant changes?	X		Yes, in accordance with customer quality agreements and change notification agreements
Are there written SOPs available for all areas of production?	X		
Is there a document retention policy? If so, how long?	X		Documents are retained for at least 7 years
Are SOPs periodically reviewed for effectiveness?	X		
Is a history of SOP revisions maintained?	X		
Can copies of procedures be provided?	X		Procedures are available for review during audits
Is a validation program in place?	X		
Is an internal audit program in place?	X		
Is a training program in place?	X		
Are there written job descriptions for all personnel?	X		

Facility	Yes	No	Comments
Is there a pest control program?	X		
Is the facility access controlled?	X		
Is there independent air circulation between office area and manufacturing?	X		
Is there a fire system including smoke detectors, alarm, and sprinklers?	X		
Is the facility designed to facilitate separation of material and personnel flow?	X		
Is there a backup electrical system?	X		

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Material Control	Yes	No	Comments
Are there procedures for the selection and approval of suppliers?	X		
Is there an approved supplier list?	X		
Is supplier performance monitored and periodically reassessed?	X		
Does the supplier quality program require external audits?	X		Yes, in accordance with supplier criticality
Is there a lot numbering system for traceability of starting materials?	X		
Are there written procedures for the receipt, identification, quarantine, storage, handling, sampling, testing, and approval, and rejection of materials?	X		
Is material traceable throughout the manufacturing process?	X		

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Process Control	Yes	No	Comments
Are process excursions, deviations, and changes in materials and methods documented?	X		
Are there written instructions for in-process sampling and testing?	X		
Are records of preventative maintenance and repairs to production equipment maintained?	X		
Are processes validated?	X		Yes, in accordance with Validation Master Plan
Is there a gowning procedure?	X		
Is there an environmental monitoring program in place, including air, surface, and particulate monitoring?	X		
Are there controls in place for cleaning of equipment? If so, what are they?	X		Validated Clean In Place (CIP), single-use tank liners, validated autoclave, and area clearance
Is cleaning performed between manufacturing batches?	X		
Is visual cleanliness confirmed by a second person before production begins?	X		
Is there a documented area clearance?	X		
Is new or revised labeling reviewed and approved by Quality Assurance and Quality Control prior to use?	X		
Are there procedures in place controlling the issuance of labeling so that the correct labeling and quantities are verified prior to use?	X		
Is filtration used as the main sterilization control?	X		
Are computers used in process control or in other functions?		X	
Is final product inspection performed?	X		

Logistics	Yes	No	Comments
Is there a distribution procedure?	X		
Are warehouses appropriately controlled to protect materials?	X		
Are released, rejected, and quarantined materials segregated?	X		

Quality Assurance and Quality Control	Yes	No	Comments
Are complete written laboratory records prepared, reviewed, and maintained?	X		
Are out of specification (OOS) results investigated, documented, and reported?	X		

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Quality Assurance and Quality Control	Yes	No	Comments
Is there a system for handling Corrective and Preventive Actions?	X		
Is there a system for handling nonconformances?	X		
Is there a system for handling complaints?	X		
Is Quality responsible for the approval and release of raw materials, in-process materials, and finished product?	X		
Is a Certificate of Analysis (CoA) provided to the customer?	X		
Are new and modified laboratory instruments and equipment qualified before use?	X		
Are there written test methods and specifications for raw materials, in-process materials, and finished products?	X		
Is there a procedure for rework or reprocessing of material? If so, who approves this?	X		Quality Assurance and Manufacturing/Logistics approve rework
Is lot separation maintained during manufacturing, packaging, and storage?	X		
Do all product containers have affixed identification labels?	X		
Is there an SOP that defines final product sampling?	X		
Is any product testing done at a contract testing facility?	X		Contract testing facilities are qualified in accordance with the supplier approval procedure
Does the CoA clearly indicate the product name and lot number?	X		
Does the CoA report all tests, specifications, and results for the lot?	X		
Are samples of finished goods retained?	X		
Is there a written stability procedure?	X		

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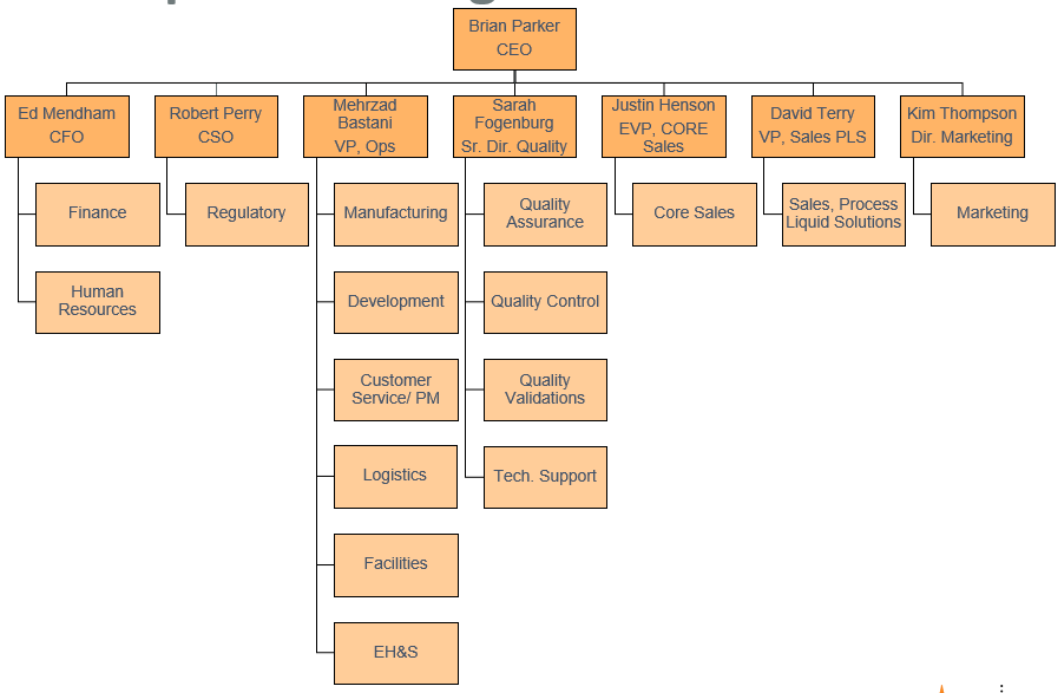
Appendix I

Department Organization Structure



GeminiBio
Empowering cell culture and process liquid workflows

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Appendix II

Table of Contents

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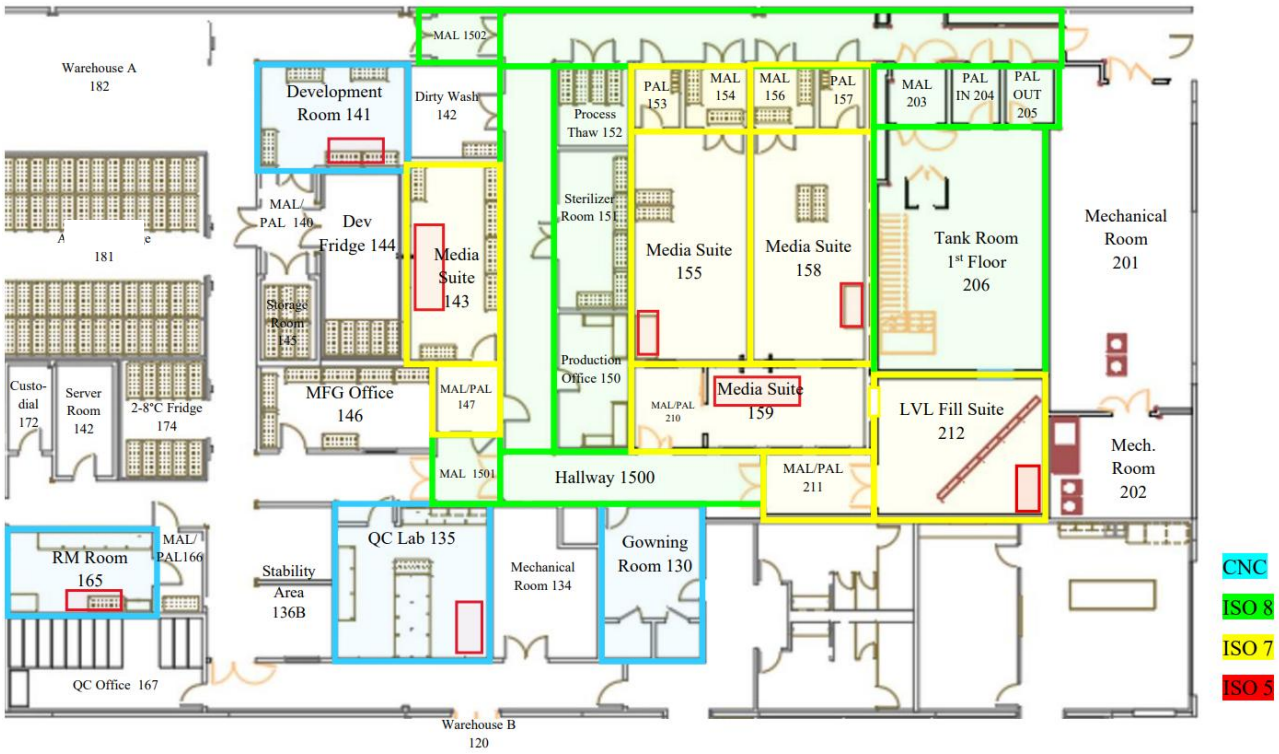
Appendix III

Room Classification – 920 Stillwater 1st Floor



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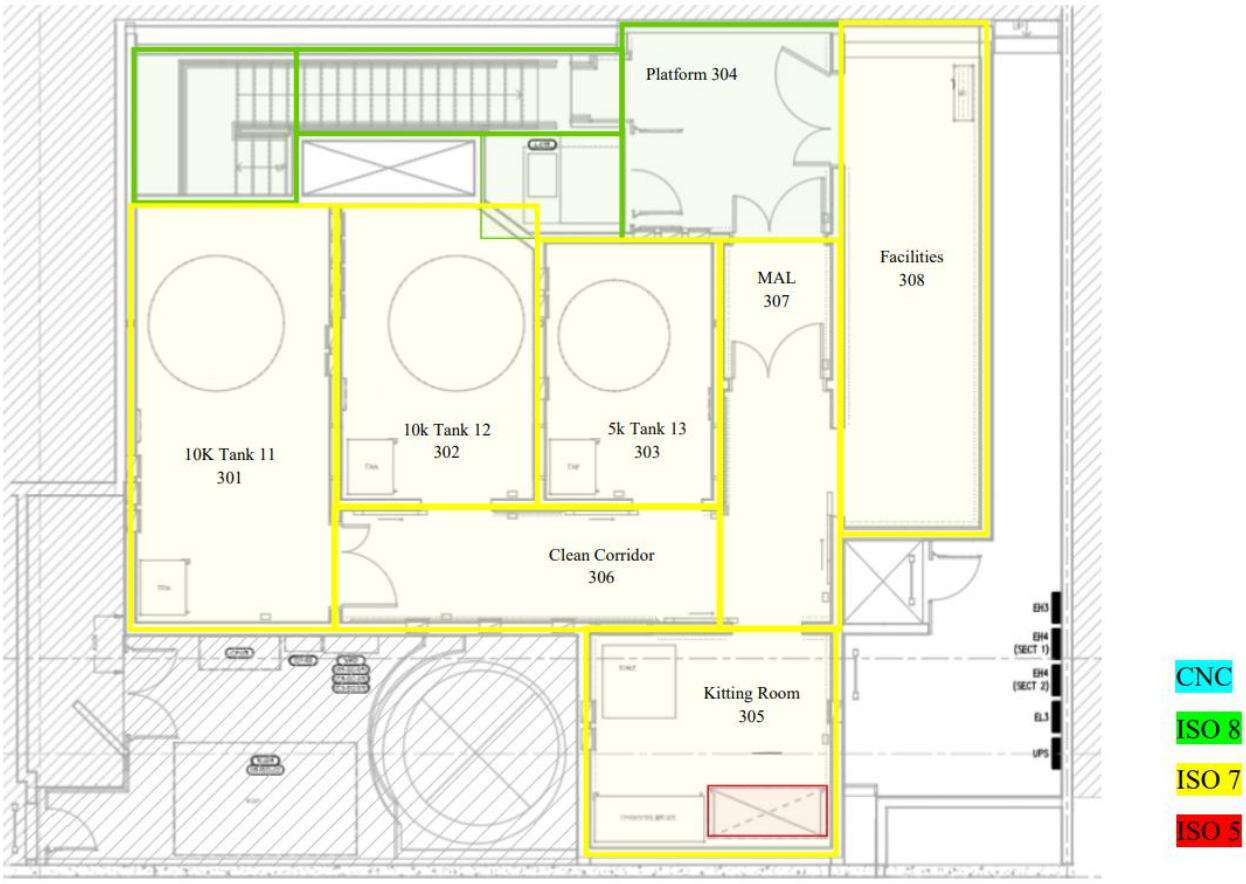
Appendix III

Room Classification – 920 Stillwater 2nd Floor



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Appendix III

Room Classification – 3230 Reed Ave

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Appendix IV

Document Number	Document Title
13	How to Invoice a Sales Order in Sage
1836	Custom Sales Request (CPAP) Process
1837	Contract Manufacturing Organization (CMO) SOP
1838	Reorder SOP
1839	Customer Data Collection (CDC) SOP
1840	Sales Request (SR) SOP
1841	Product Execution Sheet (PES) SOP
1842	Request for Quote (RFQ) SOP
16	Creating Reserves in Sage
17	New CID Creation
19	NPS Customer Feedback Collection Process
14	Placing a Sales Order in Sage
2442	Processing Purchase Orders out of the VWR Supplier Portal
18	Serum Reserve Rules
15	Setting up Sold Storages in Sage
28	Development/Tech Transfer of New Formulations
30	Process Automation System (PAS) Recipe Development
2006	AlisQI Model Management
2242	AlisQI User Management Procedure
32	ComplianceWire Training Management
2241	Managing Analyis Sets in AlisQI
33	Off-Site Physical Document Storage Program
2010	Uploading and Retiring Controlled Documents in AlisQI
31	Use and Maintenance of the Masterlist
44	COVID-19 Prevention Program
42	Sharps Policy and Procedure
45	Facility Walkthrough
47	Emergency Backup Generators
50	Hazardous and Biological Waste Management
51	Personal Protective Equipment
52	Hazard Communication Program
53	Guidelines for Hazardous Materials Storage
57	Chemical Hygiene Plan
58	General Safety Rules
59	Fall Protection Program
1883	Workplace Violence Prevention Plan

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Document Number	Document Title
34	Emergency Action Plan
35	Injury and Illness Prevention Plan
49	Integrative Pest Management Plan
43	Respiratory Protection Program
176	Emergency Shower and Eye Wash Test Procedure
189	Endosafe nexgen-PTS Use and Maintenance
185	Eppendorf Micropipette Usage
150	Operation of the Peristaltic Pumps
156	Operation of the Walk-In Refrigerator
161	Operation of the Walk-In Freezers
162	Operation of Atosa Freezers
163	Operation of the Atosa Refrigerator
164	Operation of the Labconco Biological Safety Cabinet
204	Operation of the Mesa ViewPoint Monitoring System
206	Operation of the Isonas Controlled Access System
232	Standard Operating Procedure for Compressed Dry Air (CDA) System
246	Operation of Drive-In Refrigerator
247	Operation of Drive-In Freezer
252	Operation and Maintenance of Hot Lips Tube Sealer
256	Operation of Drum Lift
258	Standard Operating Procedure of the Sartorius Biosealer TC
225	Equipment Risk and Requalification Frequency Assessment
227	Monitoring and Review of Mesa ViewPoint Data and Alarms
177	N.I.S.T. Weight Traceability Procedure
174	Operation and Cleaning Procedures for the Precision Balances
148	Operation and Cleaning Procedures for the Water Baths
251	Operation and Maintenance of Biowelder® Total Containment
248	Operation and Maintenance of Powered Industrial Trucks (PICs)
229	Operation and Maintenance of the Caron Environmental Chamber and Recirculating System
208	Operation and Routine Maintenance of the BMT Sterivap 559 Sterilizer
249	Operation and Use of the Lasair III Aerosol Particle Counter
153	Operation and Use of the Sartocheck 4 plus Filter Integrity Tester
253	Operation of LVL Metolift
157	Operation of the Incubators
173	Operation of the OHAUS ES Series Bench Scale
239	Operation of the Process Refrigerated Glycol System
186	Operation of the Process Water System

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Document Number	Document Title
175	Operation Procedures for the Analytical Balances
221	Orion Star A Series Conductivity Meter Use and Maintenance
168	Orion Star A Series pH Meter Use and Maintenance
198	Osmette XL Model #5007 Use and Maintenance
2083	Out of Tolerance (OOT) Procedure
158	Preventive Maintenance and Calibration Program
243	Sartocheck 5 Filter Integrity Tester
257	Standard Operating Procedure for Label Machine ID#1707
250	Standard Operating Procedure for Sonitrol Access Controlled System
236	Standard Operating Procedure for the Clean-in-Place (CIP) Skid
2057	Standard Operating Procedure for the MGA Technologies Aseptic Tube Sealer
242	Standard Operating Procedure for the Plant Steam System (Boilers)
235	Standard Operating Procedure for the Pure Steam System
240	Standard Operating Procedure of the Heat Transfer Supply and Return (HTSR) System Temperature Control Unit (TCU)
238	Standard Operating Procedure of the Industrial Wastewater (IWW) System
213	Standard Operation and Cleaning of 1000L Tank
233	Standard Operation Procedure for the 10,000L Solution Tank
234	Standard Operation Procedure for the 5,000L Solution Tank
254	Standard Operation Procedure for the Sterilize-in-Place System (SIP)
241	Standard Operation Procedure for the Water Purification System
181	Temperature Monitoring for Controlled Temperature Units
2090	Use and Maintenance of the Cary 3500 UV-Vis Spectrophotometer
183	Use and Maintenance of the Chemical Fume Hood
193	Use and Maintenance of the M9 Laboratory TOC Analyzer
255	Use and Maintenance of Torque Wrench
215	Use and Storage of LIGHTNIN Mixer
2237	AlisQI 5 Whys
2238	AlisQI Action List
2380	AlisQI Deviations (Planned)
2239	AlisQI Deviations (Unplanned)
2007	AlisQI Document Modification Procedure
2240	AlisQI Extension Requests
2008	AlisQI New and Retire Document Requests
2495	AlisQI Material Review Board
2494	AlisQI Rework
2493	AlisQI Nonconforming Material Report
2009	AlisQI Periodic Document Review Tasks

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Document Number	Document Title
290	Aseptic Technique and Cleanroom Operations
281	Change Control
259	Cleanroom Construction Maintenance and Monitoring Policy
317	Closing of a Work Order for Make to Stock Items
2445	Completing Production Entries for Relabels in Sage
302	Component Number Assignment
326	Computer Systems Controls
261	Controlled Document Development, Approval, and Periodic Review
285	Corrective and Preventive Actions
307	Creating a Work Order in Sage
304	Creating and Marking of BIN Locations
315	Creating New Warehouse Bins in Sage
2376	Creating Production Entries in Sage
301	Dedicated Shoe Cleaning Procedure
260	Document Management Process Overview
296	Facility Flows
292	Fundamentals of Good Documentation Practices
288	Gowning Qualification
297	Product Stability Testing
306	Work Order Template BOM Creation in Sage
309	Electronic Signatures
316	Work Order Time Entry and Parts Usage
319	Creating New Components or Finished Goods Items in Sage
1832	Incoming Material
322	Finding Lot Numbers in Sage
323	How to Attach a Scanned Document to Sage
324	How to Check Sage Component Lot Number for Duplicates
325	Add Contact to CID
327	How to Link an External Testing PO to a WO
328	Site Validation Master Plan
291	Gowning Requirements for Controlled Areas
293	Investigation and Reporting Out of Specification (OOS) Results
273	Issuance of Production Records for Product Manufacturing
2375	Non-Sterile Processing in Cleanrooms
305	Process Flow Between Sage/Scanco
300	QC Sampling Plan
321	Sales Order Shipping in Sage
1955	Sample Chain of Custody

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Document Number	Document Title
299	Significant Figures and Rounding
303	Site Master File
275	Supplier Management
308	Transfer, Segregation, Release of Inventory Items Using Sage
318	Warehouse to Warehouse Inventory Transfer in Sage
320	Work Alone Policy and Procedure
330	Offboarding Procedure
331	Performance Management and Corrective Discipline Procedure
333	Recruitment and Hiring Procedure
338	General Packaging
339	Cleaning Procedure of Warehouse Freezers and Refrigerators
342	Distribution
344	Sold Storage Setup
349	Packaging and Transportation Guide for VWR Shipments
350	How to Label Free Vendor Items
351	Packaging of LAL Reagent Water, Catalog 201-105-125mL
347	Product Transfer Between GeminiBio Locations
341	Shipping with FedEx, UPS, and DHL Applications
2457	Steris Packaging for Gamma Irradiation
337	Sticker Placement, Taping, and Storage of Shipping Boxes
346	Warehouse and Inventory Management
368	Area Clearance
2176	Boxing Procedure for Bottled and Bagged Product
2119	Clean Out of Place (COP) Standard Operating Procedure
363	Cleaning Process for Lab-ware and Utensils
374	Filling of Bioprocess Liquids
378	Filling of Large Volume Bioprocess Liquids
376	Filter Selection Guideline
361	Heat Inactivation Process
355	Manufacturing Area Cleaning and Disinfection
377	Repackaging Procedure
369	Relabeling Procedure
373	Standard Operating Procedure for Filtration of Bioprocess Liquids
2425	Standard Operating Procedures for Weigh and Dispense at GeminiBio Manufacturing Facilities
371	Tubing Set Assembly
620	Marketing Approval
625	How to Create a Purchase Order in SAGE

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Document Number	Document Title
622	Procurement Process
624	Purchasing Customer Supplied Material
623	Purchasing Process
1334	Aseptic Process Simulations
1317	Authorized Signatures
1279	Business Continuity and Disaster Recovery Plan
1281	Certificate of Analysis Generation
1307	Certificate of Origin Generation
1314	Complaint System
2143	ComplianceWire User Management
2175	Computerized Systems Validation
1276	Controlled Material and Finished Product Specifications
2114	Data Integrity
1285	Deviation Reporting and Investigation
1304	Device History Record Compilation
1267	Employee Training Program and Requirements
1312	Gamma Irradiation Initiation, Processing, and Review
1273	Internal Audit
1332	Lot Disposition Procedure for GeminiBio Manufactured Products
1333	Lot Disposition Procedure for OEM Products
1321	Lot Number Assignment
1292	Material Segregation and Status Labeling
1295	Nonconforming Material Reporting Procedure
1262	Protocol Deviation. Discrepancy Report
1259	Quality System Manual
1280	Development Planning Procedure
1298	EU Eligibility Separation Protocol
1310	Rework
1316	Product Recall
1319	USDA Tamper Proofing Process
1322	Quality Risk Management
1326	External Document Use and Revision Check
1327	Control of Customer Property
1328	Memo Process
1264	Qualification and Routine Maintenance of Controlled Temperature Units
1271	Quality Metrics and Management Review

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Document Number	Document Title
1290	Root Cause Investigation Procedure
1260	Validation Protocols and Reports
1802	Collection and Testing of Water Monitoring Samples
1282	Control of Labels Procedure
1813	Determination and Measurement of Solution Density
1775	Environmental Monitoring Program
1809	In-Line Analysis using the M500 Sievers TOC and Conductivity Analyzer
1804	Final Inspection of Finished Product
1807	Appearance Testing
1811	Final Product Label Template Generation and Use
1816	QC Inventory Management
1817	Printing Receipt Labels and Material Disposition
1800	Retain Procedure for Finished Product
1797	Sterility Testing
1795	Thrombin Challenge for Human Serum