California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Outsourcing Facility Self-Assessment

Business and Professions Code section 4102 requires the designated quality control personnel (DQCP) to complete a self-assessment of the outsourcing facility's compliance with federal and state laws identified on the form.[1] **The assessment shall be performed by July 1 of every odd-numbered year. The DQCP must also complete a self-assessment within 30 days of any of the following:** (1) A new outsourcing facility license is issued; (2) there is a change in the DQCP; (3) there is a change in the location of the outsourcing facility to a new address. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Please mark the appropriate box (Yes, No, or N/A) for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If the specific legal requirement referenced in the question clearly and objectively does not apply to your facility, then mark the box "N/A". If more space is needed, you may add additional sheets. The self-assessment must be completed in its entirety. It may be completed online and printed, initialed, and signed (use original signatures or digital signatures that comply with California Code of Regulations, title 16, section 1700). The completed form shall be kept on file in the outsourcing facility and made available to the Board upon request. A new self-assessment form must be filled out each time the self-assessment process is required to be completed; do not use or copy from a previous self-assessment form. Each self-assessment must be kept on file in the outsourcing facility for three years after it is performed.

An outsourcing facility licensed by the Board dispensing patient-specific compounded preparations pursuant to a prescription for an individual patient shall not be required to be licensed as a pharmacy, but shall otherwise comply with the same requirements of a pharmacy pursuant to BPC 4129(e).

[1] Note: This self-assessment is not an all-inclusive compilation of all laws and regulations that may be applicable to an outsourcing facility. The facility is responsible for complying with all applicable laws and regulations, regardless of whether they are referenced on this self-assessment.

Outsourcing Facility Name:				
Address:			**Telephone:**	
FDA FEI#:			**Initial Registration Date:**	
			Re-registration Date:	
CA License #:			**Expiration Date:**	
Residence State License # (If located outside of CA)	**License #**		**Expiration Date:**	**Type of license:**
Residence State License # (If located outside of CA)	**License #**		**Expiration Date:**	**Type of license:**
Residence State License # (If located outside of CA)	**License #**		**Expiration Date:**	**Type of license:**
DEA Registration #			**Expiration Date:**	
Date of DEA Inventory:				
Date of Last FDA Inspection:				
Hours:	Weekdays	Saturday	Sunday	24 Hours

	Type of Compounding* Check all that apply.
	Nonsterile
	Sterile
	Office Use
	Patient Specific Prescription
	Product Types Check all that apply.
	Injectable
	Intrathecal / Intraocular injection
	Inhalation
	Ophthalmic
	Implantable
	Oral
	Subcutaneous
	Topical
	List Others

*Outsourcing Facilities are not legally required to identify the products they provide to the Board; however, this can be helpful to both the Board and the licensee in assessing compliance.

Outsourcing Facility Staff:

(Provide license number, if applicable)

Name: Designated Quality Control Personnel (e.g.: Head of Quality)		**Residence State:**		**License#:**		**Expiration Date:**	
Name: Supervising Pharmacist		**Residence State:**		**License#:**		**Expiration Date:**	
Name: Most in Charge of the Firm		**Residence State:**		**License#:**		**Expiration Date:**	
Name: Most in Charge of Manufacturing Unit		**Residence State:**		**License#:**		**Expiration Date:**	

References:

Abbreviation	Full Reference
BPC	California Business and Professions Code
CCR	Title 16 California Code of Regulations
CFR	Code of Federal Regulations
CGMP	Current Good Manufacturing Practice
CURES	Controlled Substance Utilization Review and Evaluation System
DQCP	Designated Quality Control Personnel
FDA	Federal Food and Drug Administration
FEI	Facility Establishment Identifier
HSC	California Health and Safety Code
USC	United State Code
USP	United States Pharmacopeia

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Section 1: Designated Quality Control Personnel Responsibilities

	Reference	Topic	Yes	No	N/A	Corrective Action Plan
1.1	BPC 4034 BPC 4129	The facility is an "Outsourcing Facility" as defined in BPC 4034 and is concurrently licensed in California and registered with the FDA.				
1.2	BPC 4129.1 BPC 4129.2	All sterile and nonsterile products are compounded in compliance with federal current good manufacturing practices applicable to outsourcing facilities.				
1.3	BPC 4129.1(e) BPC 4129.2(e)	The outsourcing facility has provided the Board with all notices and documents required to be provided pursuant to BPC 4129.1(e) or 4129.2(e), as applicable, within the required timeframes.				
1.4	BPC 4129.9	The facility contacts the recipient pharmacy, prescriber, or patient of the recalled drug and the Board as soon as possible within 24 hours of issuing a recall notice if the recalled drug was dispensed, or is intended for use, in California, and use of or exposure to the recalled drug may cause serious adverse health consequences or death.				
1.5	CCR 1709	The facility reports any changes in the license as required by law (e.g., change of ownership).				
1.6	21 USC 353b(a)(2) 21 CFR 207.3	If the facility compounds using bulk drug substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations), the bulk drug substances are each accompanied by a valid certificate of analysis.				
1.7	21 USC 353b	The facility does not compound: • Drugs that have been withdrawn or removed				

	Reference	Topic	Yes	No	N/A	Corrective Action Plan
		from the market because such drugs or components of such drugs have been found to be unsafe or not effective; • A drug that is essentially a copy of one or more approved drugs; • Drugs that have been determined to be demonstrably difficult to compound.				
1.8	21 USC 353b(a)(10)	The facility labels its compounded drugs in accordance with the requirements set forth in 21 USC 353b(a)(10).				
1.9	BPC 4129(e)	If the facility dispenses patient-specific compounded preparations pursuant to a prescription for an individual patient, the facility complies with the same requirements of a pharmacy.				

Section 2: Organization and Personnel (21 CFR Part 211 Subpart B)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
2.1	21 CFR 211 Subpart B	The facility is in compliance with 21 CFR sections 211.22 through 211.34 in their entirety.				
2.2	21 CFR 211.25(a)	Training in current good manufacturing practice is conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.				
2.3	21 CFR 211.25(c)	There are an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product.				

Section 3: Buildings and Facilities (21 CFR Part 211 Subpart C)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
3.1	21 CFR 211 Subpart C	The facility is in compliance with 21 CFR sections 211.42 through 211.58 in their entirety.				
3.2	21 CFR 211.42(c)(10)(iv)	There are separate or defined areas or such other control systems for the facility's operations as are necessary to prevent contamination or mixups during the course of the procedures itemized in 21 CFR 211.42(c), including, with respect to aseptic processing, a system for monitoring environmental conditions.				
3.3	21 CFR 211.46(d)	The facility's air-handling systems for the manufacture, processing, and packing of penicillin are completely separate from those for other drug products for human use.				
3.4	21 CFR 211.56	Any building used in the manufacture, processing, packing, or holding of a drug product is maintained in a clean and sanitary condition, and any such building shall be free of infestation by rodents, birds, insects, and other vermin (other than laboratory animals).				

Section 4: Equipment (21 CFR Part 211 Subpart D)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
4.1	21 CFR 211 Subpart D	The facility is in compliance with 21 CFR sections 211.63 through 211.72 in their entirety.				
4.2	21 CFR 211.63	Equipment used in the manufacture, processing, packing, or holding of drug products is of appropriate design, size, and suitably located to				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
		facilitate operations for its intended use and for its cleaning and maintenance.				
4.3	21 CFR 211.67(a)	Equipment and utensils are cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.				
4.4	21 CFR 211.68(b)	Appropriate controls are exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.				

Section 5: Control of Components and Drug Product Containers and Closures (21 CFR Part 211 Subpart E)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.1	21 CFR 211 Subpart E	The facility is in compliance with 21 CFR sections 211.80 through 211.94 in their entirety.				
5.2	21 CFR 211.80(b)	Components and drug product containers and closures are at all times handled and stored in a manner to prevent contamination.				
5.3	21 CFR 211.82(b)	Components, drug product containers, and closures are stored under quarantine until they have been tested or examined, whichever is appropriate, and released. Storage within the area conforms to the requirements of 21 CFR 211.80.				
5.4	21 CFR 211.84(d)	Samples are examined and tested with at least one test conducted to verify the identity of each component of the drug product; each component is tested for conformity with all				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
		appropriate written specifications for purity, strength, and quality, or, in lieu of such testing, a report of analysis from the supplier of the component is obtained; containers and closures are tested for conformity with all appropriate written specifications, or, in lieu of such testing, a certificate of testing from the supplier is obtained; components are microscopically examined when appropriate; each lot of a component, drug product container or closure that is liable to contamination with filth, insect infestation, or other extraneous adulterant is examined against established specifications for such contamination; and each lot of a component, drug product container, or closure with potential for microbiological contamination that is objectionable in view of its intended use is subjected to microbiological tests before use.				

Section 6: Production and Process Controls (21 CFR Part 211 Subpart F)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
6.1	21 CFR 211 Subpart F	The facility is in compliance with 21 CFR sections 211.100 through 211.115 in their entirety.				
6.2	21 CFR 211.100(b)	The facility follows written production and process control procedures in the execution of the various production and process control functions and any deviation from the written procedures is recorded and justified.				
6.3	21 CFR 211.110	To assure batch uniformity and integrity of drug products, written procedures are established and followed that describe the in-process controls, and tests, or examinations to be conducted on				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
		appropriate samples of in-process materials of each batch.				
6.4	21 CFR 211.113	Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, are established and followed, and such procedures include validation of all aseptic and sterilization processes.				

Section 7: Packaging and Labeling Control (21 CFR Part 211 Subpart G)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
7.1	21 CFR 211 Subpart G	The facility is in compliance with 21 CFR sections 211.122 through 211.137 in their entirely.				
7.2	21 CFR 211.125 21 CFR 211.130	The facility has written procedures (i) describing in sufficient detail the control procedures employed for the issuance of labeling, and (ii) designed to assure that correct labels, labeling, and packaging are used for drug products, and such procedures are followed.				

Section 8: Holding and Distribution (21 CFR Part 211 Subpart H)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
8.1	21 CFR 211 Subpart H	The facility is in compliance with 21 CFR sections 211.142 through 211.150 in their entirety.				
8.2	21 CFR 211.142	Written procedures describing the warehousing of drug products are established and followed, and such procedures include storage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
8.3	21 CFR 211.150	Written procedures describing the distribution of drug products are established and following, and such procedures include a system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary.				

Section 9: Laboratory Controls (21 CFR Part 211 Subpart I)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
9.1	21 CFR 211 Subpart I	The facility is in compliance with 21 CFR sections 211.160 through 211.176 in their entirety.				
9.2	21 CFR 211.160(b)	The facility's laboratory controls include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality and purity.				
9.3	21 CFR 211.165	For each batch of drug product, there is appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release.				
9.4	21 CFR 211.167(c)	For each batch of controlled-release dosage form, there is appropriate laboratory testing to determine conformance to the specifications for the rate of release of each active ingredient, and the testing procedures are in writing and are followed.				

Section 10: Records and Reports (21 CFR Part 211 Subpart J)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
10.1	21 CFR 211 Subpart J	The facility is in compliance with 21 CFR sections 211.180 through 211.198 in their entirety.				
10.2	21 CFR 211.180(f)	The facility has established procedures to assure that the responsible officials of the facility, if they are not personally involved in or immediately aware of such actions, are notified in writing of any investigations conducted under 21 CFR §§211.198, 211.204, or 211.208, any recalls, reports of inspectional observations issued by the FDA, or any regulatory actions relating to good manufacturing practices brought by the FDA.				
10.3	21 CFR 211.188(b)(7)	The facility prepares batch production and control records for each batch of drug product produced, and these records include a statement of the actual yield and a statement of the percentage of the theoretical yield at appropriate phases of processing.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
10.4	21 CFR 211.192	All drug product production and control records, including those for packaging and labeling, are reviewed and approved by the facility's quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications is thoroughly investigated, whether or not the batch has already been distributed. The investigation extends to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation is made and includes the conclusions and followup.				
10.5	21 CFR 211.198	Written procedures describing the handling of all written and oral complaints regarding a drug product are established and followed, and such procedures include provisions for review by the quality control unit of any complaint involving the possible failure of a drug product to meet any of its specifications, and, for such drug products, a determination as to the need for an investigation in accordance with 21 CFR § 211.192.				

Section 11: Returned and Salvaged Drug Product (21 CFR Part 211 Subpart K)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
11.1	21 CFR 211 Subpart K	The facility is in compliance with 21 CFR sections 211.204 through 211.208 in their entirety.				
11.2	21 CFR 211.204	Returned drug products are identified as such and held, and if the conditions under which returned drug products have been held, stored, or shipped before or during their return, or if the condition of the drug product, its container, carton, or labeling, as a result of storage or shipping, casts doubt on the safety, identity, strength, quality or purity of the drug product, the returned drug product is destroyed unless examination, testing, or other investigations prove the drug product meets appropriate standards of safety, identity, strength, quality, or purity.				

Additional References

Licensees are encouraged to review the additional references provided below for more information about the listed topics. Licensees are advised that the below is a list of selective references that licensees may find helpful, but not an exhaustive list of all pharmacy laws and regulations that may apply to any given topic or in any specific case.

Reference	Topic
CCR 1708.1	Temporary Closures
FDA-Human Drug Compounding	FDA Website: Human Drug Compounding
FAQs on Patient Specific Dispensing by an Outsourcer	Patient Specific Dispensing by an Outsourcer

CERTIFICATION OF DESIGNATED QUALITY CONTROL PERSONNEL

I, (please print) _____,hereby certify that I have completed the self-assessment of this outsourcing facility, of which I am the Designated Quality Control Personnel, to the best of my professional ability. Any deficiency identified herein will be corrected by _____(date). I understand that all responses are subject to verification by the Board of Pharmacy. I acknowledge the self-assessment will be readily available for review during any inspection by the Board. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature* _____ Date: _____
(Designated Quality Control Personnel)

ACKNOWLEDGEMENT BY THE OWNER OR AUTHORIZED OFFICER OF THE OUTSOURCING FACILITY:

I, (please print) _____, hereby certify that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in action by the California State Board of Pharmacy.

Signature* _____ Date: _____
Owner or Authorized Officer of the Outsourcing Facility

*Consistent with 16 CCR Section 1700, the Board will accept digital signatures.