

Guidelines for Initial Application and Routine Inspection of California Biologics facilities – Cord Blood

1. All processes must be in operation, validated, and SOP's must be current, medical-director approved, and in use. CDPH requirements are as on the *website* and include the Ca. Business and Professions Code, the Health and Safety Code, and Title 17 as listed. Current versions of the AABB Blood Bank and Transfusion Standards and the Standards for Cellular Therapy Products and Services, where applicable.
2. The Biologics application (LAB 114) and fee must be submitted; additional CB collection sites fees may be obtained from <http://www.cdph.ca.gov/programs/lfs>. Here are some general considerations:
 - Personnel report (LAB 118) for licensed and unlicensed personnel
 - Job descriptions for all positions related to CB processes
 - Business permit, if applicable
 - Fictitious name permit, if applicable
 - Partnership agreement, if applicable
 - Corporation documents, including Articles of Incorporation, management agreements, and a list of shareholders owning over 5%, if applicable
 - CV of Medical Director (MD)
 - Copies of all Standard Operating Procedures (SOP's) must be complete, including documented MD approval of each, and in place and available for review
 - Copy of patient/donor/client Informed Consent
 - A sample collection kit, if applicable
 - If laboratory testing is performed, test procedures and manufacturer's inserts
 - Evidence of Proficiency Testing (PT) enrollment and test reports as applicable
 - Quality control records, including remedial and corrective action
 - Instrument/equipment list, including manufacturer, model, and serial number
 - Instrument maintenance records, including repair reports
 - Safety Manuals and Emergency Plan
 - Supplier/Vendor qualification as applicable
 - Quality Assessment Plan and evidence of review and action documentation
 - Personnel files, to include training, competency, current licensure and CPR as required – (Sample of processor, for example)
3. Process Validation:
 - If collecting, evidence of successful completion and shipment to processing facility, meeting all requirements
 - If processing, evidence of successful processing and cryopreservation
 - If storing, evidence of processing worksheets, and sample storage inventory location, freezer records, storage stability program, etc.
 - If distributing, example of successful shipment and instructions for thaw, etc.
4. Evidence of Ca. Clinical laboratory license or registration application (Out-of-State license, if applicable), including vendor qualification
5. Evidence of CLIA application, if applicable
6. Once these are complete, call for an inspection appointment – usually requires ~ 3 weeks lead time
7. Ca. clinical lab license or registration, if applicable, will be issued 1-2 days after inspection, if no significant deficiencies are found.
8. CLIA certificate will be issued, if applicable, once the fee is determined, and is paid
9. Biologics license will be issued when the inspection and subsequent report have been completed and there are no significant deficiencies.

* <http://www.dhs.ca.gov/programs/lfs>