Medical Device Safety and Drug Manufacturing Safety FAQ

Do only medical device manufacturers require licensing in California?

No. A medical device or drug manufacturing license obtained from the California Department of Public Health (CDPH), Food and Drug Branch (FDB), is required for all firms manufacturing medical devices or drugs in the State of California. In vitro diagnostic (IVD) and analyte specific reagent (ASR) manufacturers are considered medical device manufacturers. Biologics manufacturers are considered drug manufacturers if the finished products are intended for therapeutic use. Medical devices and drugs that are manufactured for use in human clinical trials are required to be manufactured in a licensed facility in the State of California. The definitions for “medical device”, “drug” and “manufacture” can be found in the California Health and Safety Code under Sections 109920, 109925 and 109970, respectively.

What is the process for medical device and drug manufacturers to submit a license application?

There are two separate license applications for the drug and medical device manufacturing programs. The process for applying for a medical device or drug manufacturing license is described in the respective instructions for filling out each application. The medical device and drug license applications and instructions can be found on the CDPH website.

If a drug manufacturer is involved in the production and handling of prescription material (both active ingredients and/or finished pharmaceuticals), the principal individuals must also disclose any past criminal history and submit to background checks as a condition of licensure. Disclosure Statements (Form CDPH53) must be submitted along with the license application, by the five highest ranking corporate officers, as well as the facility operator of the firm.

The license application (and other required documents) must be submitted with the appropriate fees prior to assignment for inspection. Once the application has cleared our accounting office, and a proper review of accompanying documentation has been completed, the company’s is assigned to a Food and Drug Inspector. The Inspector contacts the applicant and sets up an inspection appointment. If the firm is found to be in compliance with the California Health and Safety Code requirements, licensure is recommended. The firm must obtain the license prior to distributing the manufactured medical devices or drugs.

At what stage in a company’s medical device or drug development should they submit a medical device or drug manufacturing license application?

The application should be submitted at least 90 days prior to the firm's anticipated readiness for inspection. This period will allow the application and fee to be processed through accounting and reach the licensing desk for assignment.

In the R & D phase?

No. When the firm is making medical devices or drugs for internal testing and bench testing, e.g., non-clinical research, and there is no intent or possibility that the products will be used on humans, the firm is not required to be licensed. However, the firm is strongly encouraged, during this time, to begin developing their quality systems and documentation control so that they have the foundation in place to transition from development to the next phase.

In the feasibility clinical phase (e.g., conducting initial clinical research outside the U.S.)?

Yes, the company is required to submit a license application to obtain approval to manufacture medical devices or drugs for human use, regardless of if product will be used in California, the U.S. or exported. California Health and Safety Code (HSC) Sections 109920 defines device and specifically states "Intended for use in…humans or any other animal." HSC Section 109925 uses similar terminology to define drugs.

When clinical phase is in the U.S. (US IDE/IND phase)?

Yes. See answer above.

What triggers requirement for a medical device or drug manufacturer to be licensed?

Licensure requirements are required at the point that the medical device or drug use is intended for the diagnosis, cure, mitigation, treatment or prevention of disease in human beings or any other animal, or any article that is intended to affect the structure or any function of the body of human beings or any other animal. As described above in item 3, when a manufacturer is manufacturing medical devices or drugs for use in or on humans (whether clinical or commercial), a California manufacturing license is required.

(Note: If a medical device or drug manufactured in California is intended for animal use for the diagnosis, cure, mitigation, treatment of prevention of disease, that drug or device is also required to be manufactured in a licensed drug or medical device facility.)

The websites for on the FDB Medical Device Safety and Drug Safety programs, contain further details on the Sherman Law, and license applications.