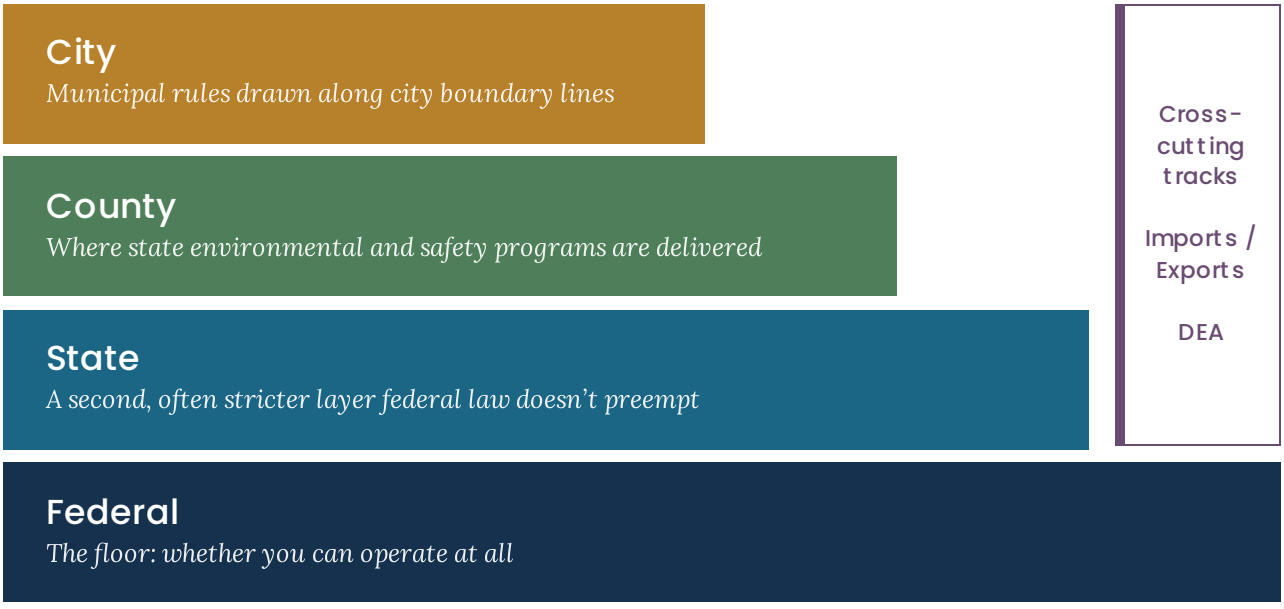
Regulatory | Compliance Hierarchy

A case study for biotech in San Diego, California, USA



The compliance stack, from the federal floor upward

Contents

Each section carries its layer's color along the page edge, so you always know which level of government you're reading about.

Layer 1: Federal

Federal (USA)

Quick Reference Guide of US Code | Regulations

US Code	CFR
Title 15 – Commerce & Trade	Title 15 – Commerce & Foreign Trade
Title 17 – Copyrights	Title 16 – Commercial Practices
Title 21 – Food & Drugs	Title 19 – Customs Duties
Title 26 – Internal Revenue Code	Title 29 – Labor
Title 29 – Labor	Title 37 – Patents, Trademarks, & Copyrights
Title 35 – Patents	Title 21 – Food & Drugs
	Title 40 – Protection of Environment
	Title 42 – Public Health
	Title 45 – Public Welfare

Layer 2: State

State (California)

The California Legislature

The California Legislature is bicameral — an 80-member State Assembly and a 40-member State Senate — and pharma-related bills typically run through each house's Health Committee (and often Business & Professions as well) before a floor vote and the Governor's signature. It's the body that writes the Sherman Law and everything downstream of it, so it's worth knowing as the actual source of the statutes CDPH and the state Board of Pharmacy enforce.

A few landmark bills show the range of what it's done specifically to pharma:

SB 1765
2004

The marketing/gift-ban law covered in the next section (now Health & Safety Code §§119400–119402), requiring manufacturers to adopt a comprehensive compliance program and cap gifts to prescribers.

SB 17 2017	California's drug price transparency law, requiring manufacturers to notify purchasers and justify price increases above set thresholds; it drew a manufacturer-backed constitutional challenge (on dormant Commerce Clause grounds) that ultimately failed.
AB 824 2019	Targets "pay-for-delay" patent settlements, where a brand manufacturer pays a generic competitor to keep a cheaper version off the market; California made these presumptively anticompetitive under state law, going further than federal antitrust doctrine at the time.
SB 852 2020	Created CalRx, the state's own generic and biosimilar drug manufacturing initiative; it's what led California to partner with Civica Rx to produce lower-cost biosimilar insulin under the state's own label.
AB 1277 recent	The more recent amendment to the Sherman Law itself, updating the state's core drug/device statute.

The throughline

The Legislature has been especially active in the pricing/market-access and marketing-conduct space rather than in device/drug approval itself (that stays federal) — which is consistent with everything else here about California layering state-specific rules on top of, not instead of, the federal framework.

Sources

- Legislative Process — California State Assembly
- SB-1765 Pharmaceuticals: marketing practices (CA Legislative Information)
- SB 17 — California Legislative Information
- AB-824 Business: preserving access to affordable drugs (CA Legislative Information)
- SB 852 — California Legislative Information
- California Selects Civica Rx as Its Insulin Manufacturing Partner (CalRx)

Layer 2: State

State of California

Sherman Food & Drug Act and the state-only requirements layered on top of federal law

Statute (leginfo) leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=104.&title=&part=4.&chapter=4.&article=2.
Sherman Law (CDPH) cdph.ca.gov/Programs/CEH/DFDCS/PAGES/SHERMANLAW.ASPX

The Sherman Food, Drug, and Cosmetic Law

This is California's own version of the federal FD&C Act, codified in the California Health & Safety Code. It largely mirrors federal drug, device, and cosmetic law by reference, but it's a separate state statute that California's own Department of Public Health can enforce independently of the FDA — including state misdemeanor and civil penalty provisions. It's the reason California even has its own device/drug regulatory apparatus rather than just deferring to FDA. One federal wrinkle worth knowing: 21 CFR 808.55 specifically addresses California, because the Sherman Law predates the federal Medical Device Amendments and California was grandfathered in as one of the few states allowed to impose device requirements that go beyond FDA's without being preempted.

CDPH state manufacturing license (Food and Drug Branch)

This is the one most likely to catch a growing biotech off guard: any drug or device manufacturer physically operating in California needs a separate state manufacturing license from CDPH's Food and Drug Branch (FDB), in addition to (not instead of) FDA registration. Per CDPH's own FAQ, this covers device manufacturers, IVD/analyte-specific reagent manufacturers, and biologics manufacturers, and the trigger point is earlier than people expect — licensing kicks in once you move past internal R&D into any activity involving human use, including feasibility studies and IDE/IND-phase clinical trials, whether run domestically or abroad. Applications should go in at least 90 days before you're ready for inspection.

Proposition 65

California's chemical-warning law requires a "clear and reasonable" warning on any product sold in California that exposes users to a chemical on California's list of carcinogens or reproductive toxicants above certain thresholds — and FDA regulation of a drug or device does not exempt it from Prop 65. This has become an active compliance area specifically for medical devices (sterilized-with-ethylene-oxide devices and devices containing phthalates or lead are common triggers), and several device manufacturers now carry standing Prop 65 statements for exactly this reason.

The California marketing/gift-ban compliance law (Health & Safety Code §§119400–119402)

This is separate from the federal Sunshine Act and requires California-selling drug and device manufacturers to adopt a formal Comprehensive Compliance Program modeled on the HHS Office of Inspector General's guidance, adopt policies consistent with the PhRMA Code on interactions with healthcare professionals, set an actual annual dollar cap on gifts/promotional items given to prescribers (excluding samples, CME support, and fair-market-value service payments), and publicly declare compliance every year with the program posted online and reachable by a toll-free number.

Cal/OSHA

California runs its own OSHA-approved state plan (not just federal OSHA), and it's often more prescriptive — for example, its Injury and Illness Prevention Program requirement and its lab-specific Chemical Hygiene Plan rules under Title 8 CCR are more detailed than federal equivalents. Any lab or manufacturing floor in California needs a Cal/OSHA-compliant program, not just a federal one.

DTSC hazardous waste rules

California's Department of Toxic Substances Control regulates hazardous waste more strictly than the federal RCRA baseline — lower generator thresholds and additional waste categories can apply to biotech/pharma lab and manufacturing waste streams that wouldn't trigger federal hazardous-waste status.

California Board of Pharmacy

If a company does any sterile or nonsterile compounding (not just manufacturing) — for example, formulation work, clinical-trial drug product prep, or specialty compounding — that activity falls under the state Board of Pharmacy's separate sterile/nonsterile compounding licensure regime, distinct from CDPH's drug manufacturing license.

The practical takeaway

California is one of the few states that layers meaningful additional regulation on top of federal 21 CFR rather than just deferring to it, and the two most commonly missed pieces by companies scaling up are the **CDPH state manufacturing license** (people assume FDA registration is sufficient — it isn't if you physically operate here) and **Prop 65** (people assume FDA-regulated status makes them exempt — it doesn't).

A caveat worth stating plainly

This is general regulatory information, not legal advice, and several of these thresholds (Prop 65 exposure levels, DTSC generator status, Cal/OSHA program specifics) depend heavily on your exact product and process, so specifics should get reviewed with counsel or a compliance specialist before you rely on them.

Sources

- Food and Drug Branch Procedure for Obtaining a New Medical Device License (CDPH)
- Medical Device Safety and Drug Manufacturing Safety FAQ (CDPH)
- Medical Device and Drug Safety Programs Licensing Requirements (CDPH)
- Sherman Food, Drug, and Cosmetic Law overview (Justia)
- California Marketing Compliance Law Mandates Comprehensive Compliance Programs (Holland & Knight)
- Key Insights and Best Practices for Prop 65 Compliance of Medical Devices (Intertek)
- California's Proposition 65 (Fisher & Paykel Healthcare)
- Biotech Lab Waste Compliance: RCRA, OSHA, and California Regulations for Life Sciences
- Cal. Code Regs. Tit. 8 — Chemical Hygiene in Laboratories (Cornell LII)
- California Business and Professions Code §4127.2 — Sterile Drug Products (Justia)
- California Sterile Compounding Application Packet (Board of Pharmacy)

Layer 2: State

California Regulatory Agencies

CDPH vs. California Legislative Information

California Law and CDPH are not cross-linked to each other — they're two separate state websites for two separate branches of government, so there's no click-path between them. The connection is legal/organizational, and it mirrors the same three-layer structure mapped out for the federal side (statute → agency → agency's own regulations).

1: Statute
Sherman Food, Drug, and Cosmetic Law
HSC Division 104, Part 5
leginfo.legislature.ca.gov

→

2: Agency
CDPH Food and Drug Branch (FDB)
Licensing, inspection, enforcement
cdph.ca.gov

→

3: Regulations
California Code of Regulations, Title 17
Office of Administrative Law
oal.ca.gov

Layer 1 — The Legislature's code database

First is the California Legislature's own code database (leginfo.legislature.ca.gov), where **"Health and Safety Code - HSC"** is just one of California's 29 codes. Buried inside that code, in Division 104, Part 5 (roughly sections 109875–111915), is the **Sherman Food, Drug, and Cosmetic Law** — the actual statute text the Legislature wrote and passed.

Layer 2 — CDPH's Food and Drug Branch

The second is CDPH's own website, specifically its **Food and Drug Branch** (FDB) page. **CDPH** is the executive-branch department that the Sherman Law itself designates as the agency responsible for administering, licensing, and enforcing it — the same relationship FDA has to the federal FD&C Act. The Legislature writes the law; CDPH is who actually runs the licensing program, issues the device/drug manufacturing licenses, and does inspections and enforcement under it.

Layer 3 — California Code of Regulations, Title 17

There's a third layer too, which is where CDPH's own regulations live: California Code of Regulations, Title 17 — the state-level equivalent of the CFR. That's where you'd find CDPH's specific implementing rules (application requirements, fee schedules, inspection procedures) rather than just the broad statutory authority. Title 17 is administered through California's Office of Administrative Law, a separate site again from both of the others.

Tracing a requirement back to its legal source

The practical path, if you wanted to trace a specific FDB requirement back to its legal source, is: FDB's webpage tells you what to do → the requirement's legal authority is usually cited as either a Sherman Law section (searchable on leginfo under HSC Division 104, Part 5) or a Title 17 CCR section (searchable via the CA OAL's regulations site) → nothing currently stitches all three together in one place the way Cornell Law's site does for the federal U.S. Code and CFR. That gap is actually a reasonable argument for a "how these connect" explainer on a Legal Sources page, with California-specific sources folded in later.

Sources

- California Health and Safety Code, Division 104, Part 5 — Sherman Food, Drug, and Cosmetic Laws
- 2024 California Code, HSC, Division 104, Part 5 (Justia)
- California Code of Regulations, Title 17, Division 1 (CDPH)

Layer 2: State

California Regulatory Notice Register

Office of Administrative Law (OAL)

The **California Regulatory Notice Register** is the direct equivalent of the Federal Register. It's published every Friday by the **Office of Administrative Law (OAL)**, and it's where state agencies (CDPH included) announce proposed regulatory actions — adopting, amending, or repealing rules — before they take effect. One real difference from the federal version: the Federal Register actually prints the full text of new regulations; California's Notice Register mostly prints notices *about* proposed actions rather than the regulations themselves, so you often have to go to the individual agency for the actual proposed text until it's finalized.

Once a regulation clears that process, it gets codified into the **California Code of Regulations (CCR)** — that's the direct equivalent of the federal CFR. So the parallel is clean, run by OAL the same way the National Archives' Office of the Federal Register runs the federal side:

California (OAL)		Federal (Office of the Federal Register)
Notice Register	↔	Federal Register
CCR	↔	CFR

On alerts

OAL doesn't have a slick self-service "get email updates" button like federalregister.gov does. To get on their proposed-rulemaking notification list, you have to email oalproposedrulemakings@oal.ca.gov and manually ask to be added — a manual request process, similar to Japan's PMDA rather than FDA's instant self-serve signup.

Sources

- California Regulatory Notice Register (Wikipedia)
- OAL Frequently Asked Questions
- OAL Rulemaking Calendar

Layer 4: Local: City

City of San Diego, California

Rules triggered specifically by being inside city limits

A handful of things are triggered specifically by being within the City of San Diego's boundaries, separate from anything county-wide or federal. Worth flagging since San Diego's biotech cluster (Torrey Pines, Sorrento Valley, UTC) sits almost entirely inside city limits, not the unincorporated county.

Business Tax Certificate

Every business operating within city limits must register with the City Treasurer, regardless of size or industry — a $38 base fee (covering the business tax plus a state-mandated SB-1186 accessibility fee), plus roughly $1.47 per employee annually for minimum wage enforcement. This is purely a city requirement; a facility in unincorporated San Diego County wouldn't need it at all.

Fire-Rescue permits

The hazmat/installation permits (tanks, LPG, CNG, medical gases, cryogens) go through San Diego Fire-Rescue specifically for addresses inside the city. A facility in the unincorporated county uses the separate San Diego County Fire Authority instead — different department, different fee schedule, different inspectors.

Industrial Wastewater Discharge Permit

Also city-specific — it's run by City of San Diego Public Utilities under the city's own Industrial Wastewater Control Program. A facility outside city limits discharges through a different sanitation district entirely, with its own fee structure.

Building Energy Benchmarking Ordinance (BEBO)

A genuinely city-only climate ordinance: commercial or mixed-use buildings over 50,000 square feet must track and publicly report annual energy use through EPA's ENERGY STAR Portfolio Manager. The interesting wrinkle for biotech specifically — scientific and industrial buildings are exempt, so a wet lab or GMP manufacturing building likely doesn't trigger it, but a large corporate headquarters or office building over that size would.

Coastal Overlay Zone / Coastal Development Permit

This is the one that's easy to miss. Torrey Pines — one of the two or three densest biotech clusters in the city — sits within the city's designated coastal community planning area. New construction or a significant expansion there can trigger a Coastal Development Permit review under the city's Local Coastal Program, layered on top of ordinary zoning approval. Sorrento Valley and UTC are generally further inland and less likely to be affected, so this is really a site-specific check rather than a blanket rule — but it's worth confirming for any Torrey Pines address specifically before assuming standard zoning review is all that's needed.

City stormwater / Best Management Practices review

The City's Development Services Department runs its own Storm Water Guidelines and Municipal Code stormwater provisions (San Diego Municipal Code Ch. 4, Art. 3, Div. 1) for construction and industrial sites, tied to the regional Municipal Stormwater Permit but enforced at the city level for anything within its boundaries.

The general pattern

Hazmat/medical waste/air permitting (the county programs) apply county-wide regardless of city vs. unincorporated area, but taxation, fire jurisdiction, wastewater discharge, building energy rules, and coastal-zone land use are all drawn along city boundary lines specifically — so the first practical question for any San Diego facility is simply whether the address is inside city limits or not.

Sources

- Apply for a Business Tax Certificate — City of San Diego
- Permits & Fees — San Diego Fire-Rescue Hazmat
- Industrial User Discharges — City of San Diego
- Building Energy Benchmarking Ordinance (BEBO) Fact Sheet
- Torrey Pines Community Plan — City of San Diego
- Stormwater Guidelines — City of San Diego

Layer 3: Local: County

San Diego County

Department of Environmental Health and Quality (DEHQ)

A fair amount of regulatory compliance worth knowing is "county-level" in the sense of who administers it, even though the underlying law is state law. California designates counties as the local enforcement agency for several statewide environmental and safety programs, and San Diego County runs all of these through its **Department of Environmental Health and Quality** (DEHQ).

Hazardous materials — CUPA

San Diego County is the local **Certified Unified Program Agency** (CUPA), which consolidates six state programs under one roof: the Hazardous Materials Business Plan (HMBP), hazardous waste generator/treatment rules, underground storage tanks, aboveground petroleum storage, and **CalARP** (California Accidental Release Prevention, for facilities holding large quantities of certain acutely hazardous chemicals). Almost any biotech or pharma lab in the county trips at least the HMBP threshold — it's triggered by fairly modest quantities of common lab chemicals, compressed gases, or flammables — so this is usually the first county-level permit a new lab needs, filed and inspected through DEHQ's Hazardous Materials Division.

Air emissions — San Diego County Air Pollution Control District (APCD)

Any equipment that emits regulated air pollutants needs a Permit to Operate from the county APCD — this covers things like emergency generators, boilers, certain fume hood exhaust configurations, and especially ethylene oxide sterilization equipment, which draws particular scrutiny given EtO's status as a carcinogen. APCD permitting is separate from, and in addition to, CUPA hazmat permitting.

Medical / biohazardous waste

Under **California's Medical Waste Management Act**, DEHQ runs the local registration program: facilities generating under 200 lbs/month of sharps, biohazardous, or non-RCRA pharmaceutical waste can register under the county's biennial Small Quantity Generator program, while larger generators, anyone treating waste on-site, or anyone generating RCRA-hazardous pharmaceutical or chemo waste needs a full Unified Program Facility Permit instead.

Industrial wastewater

If any process water, cleaning water, or lab waste goes down the drain, it needs an Industrial User Discharge Permit — from the City of San Diego's Industrial Wastewater Control Program if the facility is within city limits, or through the relevant county sanitation district otherwise. Labs handling biological or chemical waste streams are routinely classified as "significant industrial users" and inspected accordingly.

Fire code / hazmat storage

The local fire authority (San Diego Fire-Rescue within city limits, or the county fire authority elsewhere) enforces the California Fire Code's hazardous-materials storage and handling provisions on top of DEHQ's programs — separate inspection, separate permit, often triggered by the same chemical inventory that triggered the HMBP.

Zoning and building occupancy

Lab and manufacturing space has its own occupancy classification (typically Group H or B with special provisions) under the local building and planning department, which matters when leasing or building out space — not every commercial building is zoned or built for lab use.

Often assumed to be county, but isn't

Radioactive materials and radiation-emitting devices go through the state's CDPH Radiologic Health Branch, not the county, though DEHQ sometimes coordinates locally.

The practical pattern

The same across most of these: California passes the substantive law, the state agency (Cal/EPA, CDPH) sets the standard, and San Diego County's DEHQ is the boots-on-the-ground permitting and inspection authority for hazmat, medical waste, and related programs specifically because the state designated it as the CUPA for this county.

Download QStead's Excel Trackers for San Diego County Biotech Permits 2026

Sources

- Certified Unified Program Agency (CUPA) — San Diego County
- Hazardous Materials Business Plan (HMBP) — San Diego County
- Unified Program Facility Permits — San Diego County
- Medical Waste Program — San Diego County
- Small Quantity Medical Waste Registration Program
- Permits — San Diego County Air Pollution Control District
- Industrial User Discharges — City of San Diego

Beyond California

Other US States

A review of some specific regulations to be aware of elsewhere in the US

Massachusetts — the strictest marketing/gift law in the country

Chapter 111N goes further than California's version: it flatly bans cash payments to prescribers (with narrow exceptions for bona fide services), restricts meals tied to recreational events, requires a designated compliance officer plus employee training and internal audits, and mandates public annual disclosure of every gift over $50 to a practitioner or facility — enforced by the Massachusetts Department of Public Health with penalties up to $5,000 per violation.

Vermont — the cautionary legal precedent behind all of these laws

Vermont's original marketing-restriction law (limiting pharmacies from selling prescriber data to detailers) was struck down in part by the U.S. Supreme Court in *Sorrell v. IMS Health* (2011) on First Amendment grounds — worth knowing because it's the reason every state's marketing/gift law since has been carefully drafted to survive that same challenge.

Prescription Drug Affordability Boards (PDABs) — a newer and more consequential category

Maryland, Colorado, Washington, and Minnesota now have PDABs with actual upper-payment-limit (UPL) authority — meaning the state can cap what payers reimburse for a specific expensive drug. None has a UPL actually in effect yet (Colorado's first one was finalized in October 2025 but doesn't take effect until January 2027), but this is a genuinely new lever states are building, and it's reimbursement risk, not manufacturing compliance, so it matters more for pricing/market-access strategy than for a plant's operations.

Drug price transparency/reporting laws — roughly 23 states now have one

These require manufacturers to report or justify price increases above a state-specific threshold. The thresholds and lookback windows are genuinely different state to state, so a national pricing calendar needs a state-by-state check, not one federal rule.

State	Reporting trigger
New Jersey	10% WAC increase in 12 months
New York	16%
Texas	15% annually (or 40% over three years)
Louisiana	50% for drugs with a $100+ list price

Florida — unusually strict wholesale/manufacturer distributor permitting

After a wave of counterfeit-drug scandals in the early 2000s, Florida's Department of Business and Professional Regulation built one of the most rigorous state prescription-drug wholesale distributor permitting regimes in the country — more background-check and bonding scrutiny than most states require, worth knowing if distribution (not just manufacturing) touches Florida.

New Jersey — an environmental trigger tied to closing or selling a facility

The Industrial Site Recovery Act (ISRA) requires an environmental assessment — and often remediation — before a facility on NJDEP's list of regulated industries (which includes most pharma/biotech manufacturing) can be sold, closed, or transferred. It's easy to miss because it's not triggered by operating the facility, only by ending or transferring operations there.

The pattern across all of these

Environmental/hazmat and facility licensing tend to look similar state to state, but marketing/gift-ban laws, drug-pricing transparency laws, and the newer PDAB/UPL boards are where states genuinely diverge and change year to year — that's the category worth re-checking per state rather than assuming it matches what you already know from California.

Sources

- Background information about the Pharmaceutical Code of Conduct (Mass.gov)
- Massachusetts Law Imposes Limitations on Medical Device and Pharmaceutical Company Interactions (Crowell & Moring)
- Prescription Drug Affordability Boards Face Implementation Hurdles (MultiState, 2026)
- State Drug Transparency Laws — 2025 Update (Goodwin)
- Prescription Drug Pricing Transparency Law Comparison Chart (NASHP)
- Application for Prescription Drug Wholesale Distributor Permit — Florida Admin Code (Cornell LII)
- Industrial Site Recovery Act (ISRA) — NJDEP

Cross-cutting track

Imports / Exports

Its own regulatory track, separate from FDA marketing authorization and the state/county pieces

Import/export is genuinely its own regulatory track, separate from the FDA marketing-authorization and state/county pieces covered here, and it splits cleanly into what governs bringing things into the US versus sending things out.

Import side

Every drug, biologic, or device entering the US crosses a joint FDA/CBP checkpoint. FDA cross-checks the shipment (through the same electronic filing CBP uses, the Automated Commercial Environment) against the foreign manufacturer's FDA establishment registration and product listing before release is allowed — an unregistered foreign facility or an unlisted product can get the whole shipment refused or detained at the border, independent of whether the product itself is fine. Related to that: FDA maintains "Import Alerts" — a standing list of specific manufacturers, products, or even entire countries with a history of violations — and anything matching one gets automatically detained without physical examination until the importer proves compliance, which can add weeks.

A few narrower import permits come up specifically for biotech:

If you're importing…	Permit / agency	Authority
Infectious biological agents, pathogen samples, or reference strains for R&D	**CDC Import Permit**	42 CFR 71.54 — separate from FDA entirely
Animal-derived material, or anything that could carry an animal/plant pathogen	**USDA APHIS**	APHIS permitting can also apply
A controlled-substance API or reference standard	**DEA import permit**	21 CFR Part 1312, filed per the registrant's DEA registration

Export side

FDA export requirements for medical devices run through four distinct certificate types, and picking the wrong one is a common mistake:

Certificate	Use it for
Certificate to Foreign Government (CFG)	Devices already legally marketed in the US
Certificate of Exportability 801(e)(1)	A device not approved for US sale but built to the foreign buyer's specs and destination-country law
Certificate of Exportability 802	Unapproved Class II/III, investigational, or even banned devices — but only when shipped to a "Tier 1" list of countries (Australia, Canada, EU, Japan, and similar)
Non-Clinical Research Use (NCR) certificate	Research-only materials never intended for human use

For unapproved drugs, FDCA Section 802 doesn't require FDA's prior permission at all — just a notification filed through CDER's eCATS system — but only if the destination country has already granted marketing authorization in one of a specific list of reference countries (Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, or the EU/EEA). Controlled-substance exports need their own DEA export/re-export permit under 21 CFR 1312, again tied to the registrant.

New and easy to miss: ECCN 3A069

In January 2025, Commerce's Bureau of Industry and Security created a new export control category (ECCN 3A069) specifically for lab equipment used in biotech — high-parameter flow cytometers (26+ detector channels) and mass spectrometers built for top-down proteomic analysis. A license is now required to export this equipment to essentially anywhere outside the closest US allies, and there's a presumption of denial for China, Russia, and several other countries.

Two general practices underneath all of this

These sit underneath everything rather than being one specific permit: every export transaction should be screened against Treasury's **OFAC sanctions list** and Commerce's **Denied Persons/Entity List** before shipping anything (reagents and instruments included, not just finished product), and any work involving biological select agents or toxins triggers the separate **Federal Select Agent Program**, which governs transfer and export independent of ordinary customs rules.

Sources

- FDA Import Process
- Importing Medical Devices and Radiation-Emitting Electronic Products into the US (FDA)
- Types of Export Certificates (FDA)
- Export Requirements for Unapproved Drugs (FDA)
- 21 CFR Part 1312 — Importation and Exportation of Controlled Substances (eCFR)
- CDC Import Permit Program — 42 CFR 71.54 (eCFR)

- US Enhances Export Controls on High-Parameter Flow Cytometers and Mass Spectrometry Equipment

Cross-cutting track

DEA

Controlled-substance registration under 21 CFR Part 1301

DEA registration is the base license under 21 CFR Part 1301 — separate from (and required before) the import/export permits in Part 1312. Any entity that manufactures, distributes, dispenses, imports, exports, or does research with a Schedule I–V controlled substance needs its own DEA registration, and it's tied to a specific business activity at a specific physical address, not the company as a whole.

The categories that matter for a biotech/pharma company

Manufacturer, Distributor, Researcher, Analytical Laboratory, Importer, and Exporter are each separate registration categories. A company doing more than one of these at the same site — say, manufacturing and in-house research — generally needs a registration for each activity, though DEA does allow certain "coincident activities" to be covered together under specific conditions.

Fees and renewal cycle

These are annual for the categories above (not the 3-year cycle DEA gives individual practitioners/pharmacies):

Registration category	Annual fee
Manufacturer	$3,699 / year
Distributor (and reverse distributor)	$1,850 / year
Researcher	$296 / year, covering either Schedule I or Schedule II–V research

DEA sends renewal reminders at 60, 45, 30, 15, and 5 days out, and there's a one-calendar-month grace window to reinstate after expiration — but federal law prohibits handling any controlled substance during a lapse, even briefly, and missing that one-month window means starting over with a brand-new application rather than a renewal.

Timeline

A new application typically takes 4–6 weeks, but that stretches out meaningfully for a manufacturer, importer, or exporter registration, since DEA generally conducts a pre-registration investigation and physical site inspection for those categories before approval — plan for longer than the headline number if this is a new manufacturing site.

Security requirements — the part that catches people off guard

21 CFR 1301.71 requires "effective controls to guard against theft and diversion," evaluated against 15 factors — building construction, vaults/safes with proper locks, alarm systems with supervised transmission and backup power, employee screening and visitor procedures, and local police response availability. It's a performance standard, not a checklist — DEA allows "substantial compliance" and will evaluate an alternative security design as functionally equivalent if you propose one to the local DEA Special Agent in Charge before implementing it.

Schedule I research is its own track

Beyond the standard Form 225 application, a Schedule I registration requires submitting the actual research protocol, and DEA reviews it substance-by-substance — this is the category that most often intersects with an IND at FDA or NIH funding requirements, so the three usually need to be coordinated together rather than pursued independently.

California adds a layer on top — but a narrower one than a full duplicate license

The state DOJ runs its own Controlled Chemical Substance Program (CCSP), which regulates precursor and List I/II chemicals — its thresholds and requirements can differ from the federal ones, so a company using certain regulated solvents or reagents in synthesis may need a CCSP permit in addition to (not instead of) the federal DEA registration, even though the underlying controlled-substance registration itself is federal.

Sources

- Diversion Control Division — Registration (DEA)
- 21 CFR Part 1301 — Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances (eCFR)
- 21 CFR §1301.71 — Security requirements generally (Cornell LII)
- DEA Registration Requirements: Forms, Fees, and Renewal (LegalClarity)
- Researcher's Manual — DEA Diversion Control Division
- Controlled Chemical Substance Program (California DOJ)

For awareness

Other Regulatory | Compliance

To be aware of, but not referenced by QStead as of 2026

Area	Reference
Business Code | Tax Code	—
Human Resources	—
Employers Rights	www.eeoc.gov/employers www.dol.gov/agencies/whd/workers www.usa.gov/labor-laws

Bringing it together

Final Summary

Federal

Federal is the floor everyone starts from: FDA governs whether a drug/device can be sold at all (21 CFR, the FD&C Act, sitting under the U.S. Code and built by notice-and-comment rulemaking through the Federal Register). Layered on top of that are the agencies that only kick in for specific activities — DEA if you touch any controlled substance (its own registration under 21 CFR Part 1301, plus separate import/export permits under Part 1312), CDC if you import infectious biological agents, and Commerce's BIS if you export certain dual-use lab equipment (the new flow cytometer/mass spec controls are a good example of how this layer keeps evolving). Federal is also where global market access lives — FDA plus the "top five" markets (EU, Japan, China, and so on) each have their own version of this same federal layer.

State

State is where California adds its own parallel structure rather than just deferring to Washington. The Sherman Law is California's own mini-FDCA, CDPH's Food and Drug Branch is California's own licensing agency (a real state manufacturing license on top of FDA registration, not instead of it), and then there's a cluster of state-only rules that don't exist federally at all: Prop 65 warnings, the marketing/gift-ban compliance law, Cal/OSHA's own lab safety rules, and DTSC's stricter hazardous-waste thresholds. The Legislature is the body actually writing all of this, and it's been most active in pricing and marketing conduct rather than approval standards.

County

County is mostly where California's state environmental and safety programs actually get administered and inspected, not a separate law-making body. San Diego County is the local Certified Unified Program Agency, so hazmat, medical waste, and related permitting happen there even though the underlying authority is state law — plus its own air district and its own fire authority for unincorporated areas.

City

City is where a handful of genuinely separate municipal rules live: San Diego's Business Tax Certificate, its own Fire-Rescue permitting (distinct from the county fire authority), its Industrial Wastewater Control Program, its Building Energy Benchmarking Ordinance, and coastal-zone land-use review for sites like Torrey Pines. These apply only inside city limits — a facility in the unincorporated county skips them entirely and deals with the county's separate equivalents instead.

The way to actually think about this stack

Federal law sets whether you can operate at all; state law adds a second, often stricter layer that federal law doesn't preempt (California is unusually aggressive here); county government is mostly the delivery mechanism for state environmental/safety programs rather than its own source of law; and city government is where a genuinely separate, narrower set of municipal rules — taxation, local fire code, local wastewater, and land use — kicks in based purely on which side of a boundary line the address sits on.

Practically, that means the right first question for any new location isn't "what does the FDA say" (you'd know that already) — it's these three, since they determine which of these five layers actually apply:

1. What state is this in?
2. Is it inside or outside a city?
3. Does this activity touch anything federal agencies beyond FDA care about?