Quality and Certification Reference Guide:

Understanding Certifications in Life Sciences Manufacturing:
What They Mean, Who Needs Each One, and How to Verify Them

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Introduction

Certification claims are easy to make but hard to verify. The certification landscape is complex, and the terminology is frequently misunderstood or misused. A reagent supplier might describe itself as "FDA certified," for example — but that credential doesn't exist, because the U.S. Food and Drug Administration (the FDA) certifies neither reagent manufacturers nor their products. These distinctions matter: a wrong assumption about which companies a standard applies to, or what a certification actually covers, can surface late — during an audit or a program transition — when it is expensive to resolve.

This guide explains the certifications and regulatory standards that apply in life sciences manufacturing, which companies each one applies to, and how to verify a claim before you rely on it. It also shows where Teknova fits within that framework, so you can see how it applies to a reagent supplier.



teknova:

Key Takeaways

- Certification requirements depend on what you manufacture. A company making a therapy and a company making the reagents used to produce it are held to different standards. Because reagents are consumed during manufacturing and not intended to remain in the finished product, the requirements that govern drug and device makers do not apply to the suppliers of those reagents.
- For a reagent supplier, ISO 13485 is the credential that counts. FDA frameworks such as current Good Manufacturing Practice (cGMP) under 21 CFR 210/211, Quality Management System Regulation (QMSR), and in vitro diagnostic (IVD) clearance govern finished drugs and devices, not the reagents used to make them.
- Starting with an ISO 13485-certified reagent supplier ensures your ability to scale. Early-stage work using research-grade reagents doesn't require it, but selecting an ISO 13485-certified manufacturer during the R&D phase avoids the need to change reagent suppliers later — and repeat qualification — when a program advances toward clinical trials.
- Certification language is often used incorrectly. "FDA certified" and "cGMP certified" are not real credentials; "FDA approved" applies to a finished drug or device product, never to a reagent or its manufacturer. "cGMP" refers to a set of federal regulations applicable to drug makers. It is not a certification. How precisely a supplier describes its credentials is itself a quality signal.
- A reagent supplier supports qualification, but does not perform it. The reagent manufacturer provides the quality documentation — Certificates of Analysis (COAs), batch records, evidence of certification and its scope, change notifications, and similar records — to the specifications set by the organization using the reagent. That organization qualifies the reagent for its specific application under its own quality system and owns any regulatory submission the reagent supports.



TEKNOVA TIP

You may not need every part of this guide. Here's where to start:

Evaluating or qualifying a GMP or RUO+ reagent supplier? Start with Parts 2–3, then work through the checklist in Part 7.

Trying to sort out FDA vs. ISO terminology? Part 1A and Part 4 cover this directly.

Need to verify a specific certification claim? Part 8 walks through how, with free public tools.

New to this space, or running an early-stage research program? Start with the grade table in Part 3, then read Part 1A for context.

Part 1A: The Certification Landscape

Reagent manufacturers and therapy manufacturers operate in the same ecosystem but face different regulatory obligations. Understanding which rules apply to which companies, and why, is essential for making sound supplier decisions.

Note: As you are reviewing the overview below, keep in mind that a therapy manufacturer and its reagent supplier must comply with fundamentally different requirements. Part 2 will explore this in more detail.

ISO 9001: The General Quality Baseline

ISO 9001 is a general-purpose quality management system (QMS) standard applicable across virtually every industry. It establishes a framework for consistent processes, risk-based thinking, and continual improvement.[1]

Who typically holds it: General manufacturers, reagent suppliers who only manufacture research-grade products, and service organizations. Because ISO 9001 certification is so widely held — from consumer goods to industrial manufacturing — its presence on a supplier's credentials doesn't mean a supplier is capable of meeting the complex requirements of life sciences manufacturing.

What it means: A documented, audited QMS is in place — but not the specific controls that making products for use in the manufacture of medical devices or therapies require, such as process validation, traceability, and risk management.

Where it fits: For a reagent supplier, compliance with ISO 9001 can be adequate for products used in early-stage research, but not for products that customers will use in the manufacture of therapies or diagnostics. Whether it's enough for your purposes depends on your program's stage and the regulatory requirements that could govern a future application to the FDA or other body.

ISO 13485:2016: The Standard for Reagent Manufacturers

ISO 13485:2016 is a standalone QMS standard specifically designed for medical device manufacturers, including makers of IVD tools. The "2016" refers to the most recent published revision of the standard — the version currently in force. Although it shares a similar structure with ISO 9001, ISO 13485 is not built on top of it and does not require ISO 9001 as a prerequisite.

Reagent manufacturers are not themselves required to hold ISO 13485 certification, because reagents are "ancillary materials," not medical devices. Ancillary materials are used during the manufacture of therapies and diagnostics but are not intended to remain in the finished product. As such, they fall outside the FDA's regulations governing medical devices and drugs. However, reagent manufacturers supplying

customers making therapies and diagnostics, or who are engaged in other GMP production activities, voluntarily obtain ISO 13485 certification because it indicates compliance with stringent requirements around risk management, process validation, documentation, and traceability — the quality infrastructure drug and medical device makers depend on to meet their own regulatory obligations.[2]

ISO 13485 certification requires:

- Rigorous raw material testing and traceability
- In-process and finished goods quality control
- Validated manufacturing processes and qualified equipment
- Defined aseptic and contamination controls
- Formal document control and change management
- Comprehensive deviation, Corrective and Preventive Action (CAPA), and non-conformance systems
- Ongoing internal and external audit readiness

Who typically holds it: Medical device manufacturers, IVD manufacturers, and contract manufacturers of finished devices (required); reagent manufacturers supporting organizations engaged in the manufacture of drugs, diagnostics, and other GMP manufacturing programs (voluntary, best-practice adoption).

What it signals: The organization's relevant facilities operate under a QMS certified to the medical device QMS standard.

Note: ISO 13485 certification applies to a facility's QMS within a defined scope, not to every product the manufacturer offers. When evaluating a supplier, confirm that they will manufacture your products and carry out the other activities relevant to your program in facilities covered by the certification.

WHAT THIS MEANS AT TEKNOVA

TEKNOVA'S ISO 13485:2016 CERTIFICATION

Teknova's QMS is certified to ISO 13485:2016, covering manufacturing operations at our Hollister, California, facilities. All the products we manufacture — across Research Use Only (RUO), RUO+, and GMP grades — are produced within this single certified quality management system.

FDA 21 CFR 210/211: cGMP for Drug Manufacturers

Parts 210 and 211 of the U.S. Code of Federal Regulations (CFR) set out the FDA's cGMP regulations for the manufacture of drug substances and drug products. These regulations govern facilities that produce finished drugs or drug components that will remain in a final therapeutic product administered to patients.[3]

Who this applies to: Drug manufacturers, biologics manufacturers, and contract manufacturers producing drug substances or products that are part of a final therapy.

Who this does NOT apply to: Manufacturers of ancillary materials, including buffers, media, and other reagents that are consumed during the process of manufacturing a drug or drug substance and that are not present in the final therapeutic product. As such, they are not required to comply with 21 CFR 210/211. Rather, as explained above, manufacturers of ancillary materials may make their products within facilities operating quality management systems certified to the ISO 13485:2016 standard, which suppliers adopt voluntarily as the recognized quality system standard for this category of products.

A COMMON MISCONCEPTION

THE FDA DOES NOT CERTIFY OR APPROVE REAGENT MANUFACTURERS

You may see some reagent suppliers claiming to be "FDA certified" or "FDA approved" — language that implies 21 CFR 210/211 compliance or formal FDA endorsement. This language is incorrect, because the FDA does not certify or approve reagent manufacturers, and there is no such thing as an "FDA-certified" facility. The same applies to cGMP: cGMP refers to a set of FDA regulations, not a certification — there is no cGMP certificate or certification.

For organizations the FDA does regulate — manufacturers of drugs, biologics, and finished medical devices or IVDs — the FDA maintains establishment registration databases and inspects registered facilities. However, it's important to note that registration is not approval, and a registered facility is not necessarily an inspected one.

FDA 21 CFR Part 820 / QMSR: Quality Management System Regulation for Medical Devices

21 CFR Part 820 was formerly known as the Quality System Regulation (QSR), the FDA's quality system rule for medical devices. Effective February 2, 2026, it was amended and retitled the Quality Management System Regulation (QMSR), incorporating ISO 13485:2016 by reference and adding FDA-specific requirements such as labeling, Unique Device Identification (UDI), and records retention provisions. This means that medical device manufacturers regulated under Part 820 are now legally required to operate a quality management system that meets ISO 13485:2016, plus the FDA-specific additions the QMSR retains.[4]

Who this applies to: Manufacturers of finished medical devices, including IVDs intended for commercial sale in the U.S.

Who this does NOT typically apply to: Reagent manufacturers, for the same reason described above — their ancillary materials are not finished devices.

EXAMPLE

TEKNOVA AND QMSR / 21 CFR PART 820

Because the FDA's QMSR now incorporates ISO 13485:2016 by reference, Teknova's certification — held since 2017 — aligns with the requirements of QMSR / 21 CFR Part 820, within the scope applicable to a reagent manufacturer. For organizations operating under QMSR, this means Teknova's quality infrastructure is built around the same standard they're now required to meet, covering document control, change management, deviation handling, CAPAs, batch records and traceability, supplier qualification, and risk management. Provisions of ISO 13485 that don't apply to a reagent manufacturer are formally excluded from the scope of Teknova's certification: design and development (clause 7.3), UDI (clause 7.5.8), and reporting to regulatory authorities / Medical Device Reporting (MDR) (clause 8.2.3).

The result for QMSR-regulated organizations: the supplier-side activities your QMS depends on are governed by the same standard at Teknova as in your own operations, removing a meaningful variable from supplier qualification.

Part 1B: What Teknova Actually Sells — Ancillary Materials

The category that our products occupy is important context for everything else in this guide. All our GMP products — buffers, media, reagents, agar plates, and water — are intended for use as ancillary materials (also called ancillary reagents) in the downstream manufacture of therapies or diagnostic products. Our RUO and RUO+ products are for use in research only.

What Are Ancillary Materials?

GMP ancillary materials (AMs) are reagents, buffers, media, and other materials used in the manufacture or testing of a therapy or diagnostic but that are not intended to be present in the final product. The most developed framework for this category is USP <1043> Ancillary Materials for Cell, Gene, and Tissue-Engineered Products, which establishes a risk-based qualification approach for reagents used in cell and gene therapy (CGT) manufacturing. USP (the United States Pharmacopeia) is an independent, non-profit scientific organization that publishes public, "compendial" standards applicable to the quality, purity, strength, and consistency of medicines. While USP <1043> applies specifically to CGT products, the underlying concept — that ancillary reagents are those consumed during the manufacture of a drug and not present in the finished product — applies more broadly across regulated workflows, including to the manufacture of biologics and finished IVD kits, and diagnostic assay development.[5]

Examples of ancillary materials include:

- Cell culture media and culture supplements
- Buffers used in upstream and downstream processing
- Reagents used in cell isolation, purification, expansion, and washing
- Cryopreservation media
- Process additives, stabilizers, and excipients consumed during manufacturing

CONTINUED

Note: A reagent's regulatory category is determined by its intended use — what the manufacturer labels and promotes the product for — not by what the product physically contains. As a result, the same reagent can fall into entirely different regulatory categories depending only on how it's labeled. For example:

How it is labeled	Regulatory category	What that triggers
DNA Suspension Buffer, 10 mM Tris-HCl, 0.1 mM EDTA, pH 8.0	Ancillary reagent	Not subject to FDA premarket review. Qualified by the user under USP <1043>. Maker typically holds ISO 9001 or ISO 13485.
DNA Suspension Buffer, 10 mM Tris-HCl, 0.1 mM EDTA, pH 8.0, for use in autologous CAR-T cell processing	Ancillary material for a regulated biologic	Qualified by the therapeutic manufacturer under USP <1043> and their own QMS. Reagent maker typically holds ISO 13485.
DNA Suspension Buffer, 10 mM Tris-HCl, 0.1 mM EDTA, pH 8.0, for use in BRCA1/2 mutation screening	IVD component	Subject to FDA IVD regulations (21 CFR Part 809 and QMSR / 21 CFR Part 820). Maker must register with the FDA and operate a QMSR-compliant QMS.

The product itself hasn't changed, only the intended use identified on the label. Regulatory classification depends on how a reagent is labeled and promoted, not on what's in the bottle.

What Ancillary Materials Mean in Practice

Ancillary materials are defined by their function, not by an FDA regulatory category. They are not finished medical devices, not drug substances, not biologics, not IVDs. Manufacturers of ancillary materials are not subject to FDA establishment registration, and the materials themselves do not require premarket clearance or premarket approval. There is no such thing as an "FDA-certified" ancillary material.

Instead, the manufacturer of a drug, biologic, or medical device that uses an ancillary material bears responsibility for complying with the regulations applicable to its product.

- Qualification of ancillary materials is the responsibility of the company using them, following the framework appropriate to their program, e.g., USP <1043> for CGT manufacturing or equivalent approaches in their own quality system for other regulated workflows
- Qualification follows a risk-based approach considering the material's role, source, contact with the finished product, and downstream removal

- Suppliers of ancillary materials do not qualify materials for a specific application. They manufacture each material to the specifications defined by the organization using the materials and provide the quality documentation — COAs, batch records, change control notifications, evidence of their ISO 13485 certification and its scope, etc. — that the user draws on for their own qualification, often tailored to the program's particular needs.

Where Teknova Products Fit Within the Ancillary Reagent Category

Teknova manufactures ancillary materials, including ready-to-ship catalog products and products made to custom specifications. Our customers use our products throughout the development, testing, and manufacture of their products, including — in the case of our GMP-grade products — in the clinical trials and commercialization stages of therapies and diagnostics. Teknova sells its products by what they are — in their composition, specifications, and technical function — not by what they are used for. That means we don't label or promote our products for use in any specific clinical assay, diagnostic application, or finished therapy. Teknova's quality management system is ISO 13485:2016 certified, and we operate within the scope of that certification as a reagent manufacturer.

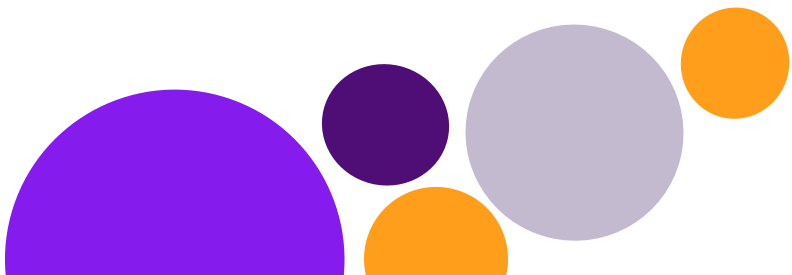
Teknova does not manufacture finished medical devices, drugs, or biologics and is not registered with the FDA. Teknova's facilities are not subject to FDA establishment registration or inspection, and our products do not require device listing or premarket review.



WHY THIS MATTERS FOR YOU

GET THE SUPPORTING DOCUMENTATION YOU NEED

When you purchase products from Teknova, you are purchasing ancillary materials — reagents intended for use during your research, product development, or manufacturing process, depending on the grade, not as components of the final product you deliver. We provide the supporting documentation — COAs, batch records, ISO 13485:2016 certificate, and change control notifications — that serve as inputs into your qualification process.



Part 2: Who Needs What? The Manufacturer vs. Reagent Supplier Distinction

This is one of the most important distinctions in the industry, and one of the most frequently confused. The regulatory obligations applicable to a company producing a therapy are fundamentally different from those applicable to a company manufacturing the reagents used in making that therapy.

If You're Manufacturing a Therapy

Drug developers and their CMO/CDMO partners producing therapies for use in clinical trials or for commercial sale must comply with the FDA's cGMP regulations (21 CFR 210/211 for drugs; 21 CFR Part 820 / QMSR for devices). These requirements govern the entire manufacturing process, documentation, testing, release, and chain of custody for materials that become part of the final therapeutic product.

Key obligations include:

- Full process validation and equipment qualification
- Approved Biologics License Application (BLA) or New Drug Application (NDA) for commercial products
- FDA inspection and oversight
- Detailed change control that may require regulatory notification or amendment
- Supplier qualification programs for all materials used in manufacturing

As a manufacturer of a therapy, you are responsible for qualifying your reagent suppliers, which is why ISO 13485 certification of those suppliers matters so much to your own compliance posture.

REQUIRED VS. EXPECTED CERTIFICATIONS

UNDERSTANDING THE DIFFERENCE

No regulation requires a reagent supplier to hold ISO 13485 certification. Yet for suppliers serving clinical, diagnostic, or commercial programs, it functions as a requirement in practice. The distinction is between what a regulation mandates and what a supplier qualification program makes necessary.

A manufacturer of a therapy running an FDA-regulated CGT program must qualify its suppliers as part of its own compliance obligations under 21 CFR 210/211 or QMSR. In practice, that means requiring ISO 13485-certified suppliers as a condition of qualifying them, because an uncertified supplier is harder to defend in an audit. An IVD kit manufacturer with QMSR obligations faces the same logic.

The result: ISO 13485 functions as the de facto standard for any reagent manufacturer supplying customers engaged in the manufacture of therapies or diagnostics for clinical trials or commercial sale. No regulation requires it, but every customer whose own compliance depends on supplier qualification will ask for it.

If You're Qualifying a Reagent Supplier

Part 1B established that a reagent supplier's products function as ancillary materials, which are not finished medical devices, drug substances, or biologics, and so are not governed by the FDA's cGMP drug regulations (21 CFR 210/211) or the QMSR / 21 CFR Part 820. The relevant standard is instead ISO 13485.

That holds across program stages. When supporting the manufacture of a therapy or diagnostic for clinical trials or commercial sale, it means GMP reagent manufacturing anchored in ISO 13485. For early-stage research programs, an ISO 13485-certified manufacturer would produce RUO-grade reagents using the same underlying quality infrastructure, positioning programs to seamlessly and efficiently scale into GMP without switching suppliers later.

Ideally, you want a single reagent supplier that can support a program from early research through commercial production, so you qualify once and scale without switching. A capable supplier offers grades spanning that range, including a bridge grade between research and "full" GMP (like Teknova's unique RUO+ manufacturing grade).

Across every grade, look for:

- ISO 13485-certified QMS covering formulation, testing, documentation, and release
- Raw material qualification programs scaled to grade, including identity testing where compendial monographs (official standards published in pharmacopeias such as USP) are available
- Validated manufacturing processes, qualified equipment, and qualified cleanroom environments
- Formal change control with advance notification
- Comprehensive COAs, batch records, and deviation documentation tailored to grade
- In-house QC testing against defined release specifications appropriate to grade and intended use
- Manufacturing capacity that scales from research-scale through commercial-volume lots

Regulatory or Certification Requirements	Therapy Manufacturer	Reagent Manufacturer
Governing framework	FDA 21 CFR 210/211 (drugs) or 21 CFR Part 820 / QMSR (devices)	ISO 13485 (aligned with QMSR-incorporated ISO 13485:2016 as of February 2, 2026)
FDA approval required?	Yes, for commercial products	Not applicable. Reagents are ancillary materials, not finished drugs or devices
FDA registered and inspected?	Yes, mandatory	Not applicable. Reagent manufacturers are not required to be FDA-registered or inspected
Supplier qualification	Must qualify all suppliers	Required under ISO 13485 and internal policy; scope tailored to program specifications
Ancillary materials	Must qualify ancillary material suppliers	Supplies documentation to support qualification

Part 3: Reagent Grades From R&D to Commercialization

Reagent grade selection isn't just a procurement decision; it's a strategic one. Reagents are classified by grade, from research use through GMP, and the grade you start with shapes how smoothly you can transition later to meeting the requirements applicable in the clinical trials and commercial production stages. These grades describe how manufacturers classify ancillary materials by quality level, and they are distinct from the cGMP and QMSR standards that govern the final drug or device product itself.

Note: The table below references IND (Investigational New Drug) applications — the FDA filing that permits clinical trials to begin.

Grade	What It Is	Facility Certification	Audit Requirement	Best For
RUO	Research Use Only. Cost-effective reagents for discovery and development. As ancillary materials, less exacting documentation and quality controls are required at this stage.	ISO 9001 minimum; ISO 13485 preferred	Not typically required at RUO stage	Early-stage research, method development
RUO+ (or other bridge grade)	A bridge grade made in GMP facilities without the full GMP documentation burden. Manufacturers offer this under various names (e.g., RUO+ is Teknova's designation).	ISO 13485 (required)	Supplier audit supported; recommended as programs approach the clinical trials stage	Preclinical through IND-enabling; building toward GMP without full GMP cost
GMP	Required for reagents used in manufacturing therapies in the clinical trials and commercial production stages. Full documentation, change control, and audit readiness requirements apply.	ISO 13485 (required)	Supplier audit required or expected as part of vendor qualification	Commonly adopted starting at IND, required starting in later-phase clinical trials through commercial production
cGMP (drug)	Current GMP under FDA 21 CFR 210/211. Applies to drug/biologic components in the final product.	FDA 21 CFR 210/211	FDA inspection	Drug/biologic substance or product component
QMSR (device)	Quality Management System Regulation for finished medical devices, incorporating ISO 13485:2016 by reference as of February 2, 2026.	FDA 21 CFR Part 820	FDA inspection	Finished medical device / IVD manufacturers

TEKNOVA TIP

WHY STARTING WITH ISO 13485 MATTERS

If you begin a program using reagents made in an ISO 9001-only facility, the transition to manufacturing your product for clinical trials will require finding a new supplier with ISO 13485 certification and going through additional validation and qualification work. Starting with a reagent manufacturer already certified to ISO 13485 eliminates that transition cost entirely. Even if you begin with RUO-grade products, the quality infrastructure is already in place.



Part 4: Certifications That Don't Apply — Common Misconceptions

Our customers often ask about certifications that don't apply to our products, usually because those frameworks govern different categories of products altogether. This section explains which ones don't apply, and why.

IVD Classification: What It Is and Who It Applies To

In vitro diagnostics (IVDs) are reagents, instruments, or systems specifically intended and labeled for use in the diagnosis of disease or other conditions by examining specimens taken from the human body. The FDA classifies IVDs into Class I (low risk), Class II (moderate risk, typically requiring 510(k) clearance), and Class III (high risk, requiring premarket approval, or PMA).[6] IVD manufacturers must comply with FDA device regulations including establishment registration, labeling under 21 CFR Part 809, and the QMSR.[7]

Why this doesn't apply to Teknova's products: Teknova manufactures ancillary reagents — buffers, media, and other materials used as inputs in the downstream manufacturing and product development workflows. This is true whether our reagent is built into a finished product (such as a component in an IVD kit) or used directly in a diagnostic workflow (such as a collection or buffer reagent in a screening test): in both cases, the organization bringing that product to market is the registered manufacturer who owns its regulatory status. We provide the documentation and quality information needed to support their qualification.

If you're asking whether a Teknova product is "FDA cleared" or "IVD approved," the accurate answer is that ancillary reagents do not require and do not undergo IVD clearance or approval.

DMF (Drug Master File): What It Is and When It Applies

A Drug Master File (DMF) is a confidential submission to the FDA that provides detailed information about facilities, processes, or materials used in the manufacture of human drug and biologic products. DMFs allow manufacturers to share proprietary information with the FDA without disclosing it directly to applicants. There are several DMF types: Type II (drug substances and intermediates), Type III (packaging materials), Type IV (excipients, colorants, flavors), and Type V (FDA-accepted reference information).[8]

When a DMF is required: DMFs are relevant when a manufacturer produces active pharmaceutical ingredients (APIs), excipients incorporated into drug products, or packaging materials for drugs, and wishes to protect that proprietary information while supporting a partner's drug application (NDA, ANDA (the generic-drug pathway), IND, or BLA).

Can Teknova support my DMF filing? Yes. If you file a DMF for a product we manufacture for you, you will own that filing, but we can support you by supplying the manufacturing and quality information you need, such as specifications, testing and release data, and process documentation. Teknova does not hold any DMFs, because we do not make finished drug products that require them. The quality documentation behind the ancillary materials we manufacture comes from our ISO 13485 system.

GPR (General Purpose Reagent): What It Is and How It Applies

General Purpose Reagents (GPRs) are a formal FDA classification under 21 CFR 864.4010. GPRs are chemicals or biologicals — buffers, stains, dyes, indicators, and similar reagents — that a manufacturer has registered with the FDA, listed under the GPR classification, and labeled per 21 CFR Part 809 for general clinical or diagnostic laboratory use. Common examples include a manufacturer registering and selling a Tris buffer to clinical chemistry labs as a GPR, or a histology stain sold to pathology labs as a GPR.[9]

GPRs are formally classified as Class I medical devices, but most are exempt from premarket review (510(k) or PMA). The defining requirement of GPR status is FDA establishment registration, device listing, and GPR-compliant labeling. A manufacturer cannot self-declare its products as GPRs. The classification is conferred by registering the manufacturing establishment, listing the products, and complying with 21 CFR Part 809 labeling, which qualifies the product for general clinical or diagnostic laboratory use.

The key distinction: GPR is a regulatory category defined by what the manufacturer has registered, listed, and labeled for. The same chemical can be a GPR (when its manufacturer has taken on that registration and labeling responsibility) or not a GPR (when its manufacturer hasn't). A buffer sold by a registered GPR manufacturer to a hospital clinical lab is a GPR. The same buffer sold by a non-registered manufacturer for use in research, biomanufacturing, or as a component used in an IVD kit is not, even if the chemistry is identical.

Why this matters for Teknova: Teknova manufactures reagents for a wide range of customers, including drug manufacturers, biologic manufacturers, IVD kit manufacturers, and tools and diagnostics companies. Teknova has not registered with the FDA, has not listed products under the GPR classification, and does not market its reagents for general clinical laboratory use under 21 CFR Part 809. Teknova's products are ancillary reagents, not GPRs.

ASR (Analyte-Specific Reagent): A Related Category to Know

Analyte-Specific Reagents (ASRs) are antibodies, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents that are intended for use in a diagnostic application to identify specific analytes. ASRs are reagents with diagnostic specificity that are used by labs to develop their own tests (laboratory-developed tests, or LDTs), and they are regulated under 21 CFR 864.4020. ASR manufacturers are subject to FDA establishment registration and device listing.[10]

Why this matters: Teknova's products are ancillary reagents, not ASRs. They have no specific analyte target and are not promoted for diagnostic specificity. Teknova does not manufacture ASRs.

510(k) Clearance: What It Is and Why Ancillary Reagents Don't Require It

A 510(k) is a premarket notification submitted to the FDA to demonstrate that a new medical device is substantially equivalent to a legally marketed predicate device. It is required for most Class II medical devices before they can be marketed in the U.S.[11]

Why ancillary reagents don't require it: Ancillary reagents are not Class II medical devices requiring 510(k) clearance. They are not finished medical devices at all, so the framework simply does not apply to any Teknova product. The appropriate quality documentation for ancillary reagents is the manufacturer's QMS certification, COAs, and batch records.

CLIA Certification: What It Is and Why It Doesn't Apply Here

CLIA (the Clinical Laboratory Improvement Amendments) is a federal program administered by the Centers for Medicare & Medicaid Services (CMS) that regulates clinical laboratories performing testing on human specimens for diagnostic purposes. CLIA certification is a requirement for the laboratory, not for the manufacturers of the reagents those laboratories use.[12]

CLIA classifies laboratory tests into complexity categories (waived, moderate complexity, and high complexity) based on risk and technical difficulty. These classifications govern the requirements a laboratory must meet to perform a given test: personnel qualifications, quality controls, and performance specifications. They apply to the test and the lab performing it, not to upstream reagent suppliers.

Why CLIA doesn't apply to Teknova: Teknova does not perform diagnostic testing on human specimens. It manufactures ancillary reagents that laboratories use in their own workflows; no reagent manufacturer holds or needs CLIA certification.

If your laboratory is CLIA-certified and you are using Teknova products in a CLIA-regulated test, the relevant question for your quality and regulatory team is whether those products meet the performance specifications your test requires, not whether Teknova holds CLIA certification.

DHF (Design History File): What It Is and When It Applies

A Design History File (DHF) is an FDA requirement under the QMSR / 21 CFR Part 820 for manufacturers of finished medical devices. It documents the complete design history of a device — design inputs, outputs, verification and validation records, and design reviews — to demonstrate that the device was designed per an approved plan. Under the QMSR, the DHF concept is now aligned with the Medical Device File (MDF) terminology in ISO 13485.[13]

When a DHF/MDF is required: When you are the manufacturer of a branded medical device or IVD that you are bringing to market under your own label. If you design and sell a diagnostic assay kit, your organization is responsible for maintaining a DHF/MDF for that product.

Why Teknova has no DHF obligation for its products: Teknova manufactures ancillary reagents, not branded finished medical devices. Teknova does not perform design control functions for finished devices. Teknova's COAs, batch records, and quality documentation serve as supplier documentation within your quality system. Your DHF/MDF, if required, documents your own design.

A note on "cGMP" vs. "GMP" — and "FDA-compatible" language: These terms are often used interchangeably in supplier communications, but they have distinct meanings in a regulatory context:

Term	What It Means	Is It a Certification?	Who It Applies To
GMP	Good Manufacturing Practice. A general principle of quality-controlled manufacturing applied across multiple industries — pharmaceutical, food, cosmetics, medical device — and anchored in different standards depending on the product category. For ancillary reagent manufacturers supplying drug and diagnostic product manufacturers and other GMP manufacturing programs, GMP practices are commonly aligned with ISO 13485.	No. GMP is a manufacturing principle. No certificate is issued for GMP itself. Manufacturers may demonstrate alignment with GMP principles through quality system certifications such as ISO 13485, which is a certification, issued by accredited certification bodies.	Reagent manufacturers supplying drug and other GMP manufacturing programs
cGMP	Current Good Manufacturing Practice. FDA-regulated standards under 21 CFR 210/211. The "c" means "Current," referring to the requirement that manufacturers use up-to-date technologies and practices. Applies to drug and biologic manufacturers.	No. cGMP is a regulatory compliance obligation under FDA regulations. No certificate is issued for cGMP. Compliance is demonstrated through FDA inspection, not certification.	Drug manufacturers, biologic manufacturers

Teknova uses "GMP" to describe our manufacturing standards, products (GMP-grade), services (GMP manufacturing), and facilities (GMP-compliant), because the QMS we use to manufacture our products in our facilities is ISO 13485:2016 certified. This is accurate language for a reagent manufacturer of ancillary materials. Claims of "cGMP certified" from a reagent manufacturer warrant scrutiny.

You may also see suppliers describe their products as "FDA-compatible" or "FDA-compliant." These are marketing claims, not official FDA designations. They carry no formal meaning and no verification pathway. Ask what specific standard or regulation any "FDA" claim refers to and verify that standard directly.

Part 5: Quick Reference Summary

Standard / Certification	Applies To	How to Verify
ISO 9001	General manufacturers	Issued by accredited certification body. Request the certificate; verify the certifying body is accredited.
ISO 13485:2016	Medical device and IVD manufacturers (required); reagent manufacturers (voluntary best-practice adoption)	Issued by accredited certification body (e.g., Intertek, BSI, TÜV SÜD). Request the certificate and scope; verify the certifying body via its accreditation registry (ANAB directory, UKAS directory).
FDA 21 CFR 210/211 (cGMP)	Drug and biologic manufacturers	Self-compliance verified through FDA inspection history. Search the FDA Warning Letters database and the FDA Inspection Classification Database.
FDA QMSR / 21 CFR Part 820 (as of February 2, 2026)	Finished medical device manufacturers (incorporates ISO 13485:2016 by reference)	Self-compliance verified through FDA inspection. Search the FDA Establishment Registration and Device Listing database.
FDA Registration (drug)	Drug establishments	FDA assigns registration number. Search the Drug Establishments Current Registration Site (DECRS).
FDA Registration (device)	Device establishments	FDA assigns registration number. Search the FDA Establishment Registration & Device Listing database.
IVD Classification (510(k) / PMA)	Finished IVD device manufacturers	FDA premarket clearance or approval. Search the 510(k) Premarket Notification database and the Premarket Approval (PMA) database.
Ancillary Materials / Ancillary Reagents	Reagents and materials used during a manufacturing or product development workflow but not present in the final product they deliver	Functional category, not a certification. The organization using the reagent qualifies it under their applicable program quality framework (USP <1043> for CGT manufacturing; equivalent qualification approaches under their own QMS for biologic, IVD kit, and other regulated workflows). Supplier provides quality documentation as inputs.
ASR (Analyte-Specific Reagent)	Reagents with diagnostic analyte specificity used in LDTs	FDA classification under 21 CFR 864.4020. ASR manufacturers are subject to FDA establishment registration and device listing; verify via the FDA Establishment Registration and Device Listing database. Check labeling for analyte-specific claims.
GPR (General Purpose Reagent)	Chemicals or biologicals manufactured for general clinical/diagnostic laboratory use	FDA classification under 21 CFR 864.4010. Requires FDA establishment registration, device listing, and labeling per 21 CFR Part 809. Search the FDA Establishment Registration & Device Listing database for the specific manufacturer and product listing.
DMF (Drug Master File)	Manufacturers of drug substances, APIs, excipients, packaging for drugs	Confidential FDA submission; FDA does not approve or disapprove DMFs. See the FDA list of Drug Master Files. Relevant to drug component manufacturers only.
CLIA Certification	Clinical laboratories testing human specimens	CMS-administered program. Applies to the laboratory and the test, not to upstream reagent manufacturers.
DHF / MDF	Branded finished medical device or IVD manufacturers	Internal record held by the finished device manufacturer; not externally verifiable. Required under QMSR / 21 CFR Part 820 and ISO 13485.
"FDA Certified" or "FDA Approved"	Not applicable (not a real credential)	The FDA does not issue these designations. Ask the supplier for underlying documentation; search the FDA databases directly to verify what they actually hold.
"FDA-Compatible" or "FDA-Compliant"	Informal supplier marketing language	No issuing body and no formal verification pathway. Ask what specific standard or regulation the claim refers to and verify that standard directly.

Part 6: Teknova's Certification Position

Teknova manufactures ancillary reagents under a GMP-compliant quality management system certified to ISO 13485, supporting life sciences research, the manufacture of drugs and diagnostics at the clinical trials and commercial production stages, and other GMP manufacturing applications.

What Teknova Holds

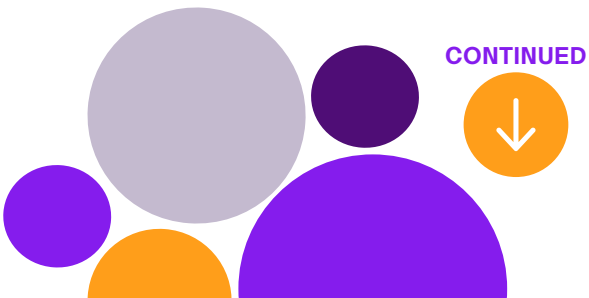
- ISO 13485:2016 certification issued by Intertek, an accredited certification body. Teknova's QMS is certified to ISO 13485:2016 within a defined scope. Several clauses are documented as not applicable to Teknova's operations: design and development (clause 7.3), because Teknova manufactures to established specifications rather than designing devices; and Unique Device Identification (clause 7.5.8) and regulatory reporting / MDR (clause 8.2.3), which apply only to finished-device manufacturers. Because the QMSR / 21 CFR Part 820 now incorporates ISO 13485:2016 by reference (effective February 2, 2026), Teknova's certified QMS meets that standard within the scope applicable to a reagent manufacturer. Download the certificate.

- Alignment with the applicable portions of QMSR / 21 CFR Part 820. Through ISO 13485:2016 certification, Teknova operates to the parts of the QMSR that incorporate ISO 13485:2016 by reference and that apply to a reagent manufacturer. (See "Teknova and QMSR / 21 CFR Part 820" for the in-scope and out-of-scope details.)

- GMP-compliant manufacturing practices, including more than 10,000 square feet of ISO 7 and ISO 8 cleanrooms,[14] over 30,000 square feet of animal-origin-free, endotoxin-controlled facilities, and a fully integrated electronic QMS (MasterControl).

- Aseptic processing under validated controls, including gowning validation, environmental monitoring, and documented sanitization, to maintain low-bioburden, endotoxin-controlled manufacturing conditions.

- 30 years of reagent manufacturing experience. Teknova was founded in 1996 by a Genentech scientist, with a quality leadership team carrying pharmaceutical and medical device backgrounds.



CONTINUED

What Teknova Does Not Claim

- FDA registration, FDA "certified," or FDA "approved." Teknova is not registered with the FDA. Ancillary reagent manufacturers are not subject to FDA establishment registration or inspection and their products do not require device listing or premarket review.
- cGMP compliance under 21 CFR 210/211. Teknova's GMP standard is anchored in ISO 13485, the appropriate quality system framework for ancillary reagent manufacturers. cGMP under 21 CFR 210/211 is the regulatory framework applicable to drug and biologic manufacturers.
- Compliance with QMSR / 21 CFR Part 820 as a whole. Teknova is not a finished medical device manufacturer and is not subject to QMSR. Through our ISO 13485:2016 certification, Teknova operates to the portions of QMSR that incorporate ISO 13485:2016 by reference and that apply to a reagent manufacturer. (See "Teknova and QMSR / 21 CFR Part 820" for additional context.)
- IVD clearance or 510(k) clearance. Teknova manufactures ancillary reagents, not finished medical devices; premarket review requirements do not apply to our products.
- CLIA certification. Teknova does not perform diagnostic testing on human specimens and has no CLIA-related obligations.
- DMF filing. Teknova does not file DMF submissions for the ancillary materials we manufacture, but we do support customers who file their own. When a company hires Teknova to manufacture a product on their behalf, that company owns any DMF for it, not Teknova.
- Design control activities. Teknova does not perform design control functions associated with finished medical device manufacturers.



PRECISION IS A QUALITY SIGNAL

THE LANGUAGE MATTERS

When evaluating supplier credentials, the precision of the language a manufacturer uses is itself a quality signal. Vague claims or incorrect terminology, like "FDA certified," "cGMP certified," or "FDA-compatible," may be signs of imprecise communication or of credentials that wouldn't hold up under scrutiny. Either way, the underlying documentation is what should determine your confidence. Accurate self-description — ISO 13485 certified, GMP compliant, backed by specific proof points — demonstrates the same rigor in communication that a manufacturer applies to the work itself.

Part 7: Reagent Partner Evaluation Checklist

Use this checklist when evaluating a manufacturer of GMP or RUO+ reagents as a potential supplier. For RUO-only programs in early R&D, not all items will apply, but starting with an RUO supplier that already meets these criteria may spare you a costly, time-consuming supplier change when the program advances toward clinical trials.

QUALITY SYSTEM

- ☐ I**SO 13485 certification (current, in-scope).** Request the certificate and verify that the scope covers the relevant manufacturing activities and facilities. Confirm the certifying body is accredited via ANAB or UKAS.
- ☐ **Integrated electronic QMS (eQMS).** Look for document control, training records, batch records, deviation management, CAPA, and complaint tracking in a single system. MasterControl, Veeva, or equivalent.
- ☐ **Change control policy with advance notification.** Any change to formulation, raw materials, or process that could affect your product should trigger advance notice. Confirm this is documented in a quality agreement.
- ☐ **Non-conformance and CAPA system.** How does the manufacturer identify, investigate, and resolve quality events? Ask to see the process, not just the policy.

RAW MATERIALS

- ☐ **Incoming raw material qualification program.** Ask how the manufacturer qualifies incoming raw materials. Testing and qualification scope is typically determined by the manufacturer's internal procedures and varies by material — including the availability of compendial monographs and the criticality of the material to the finished product. If you have specific testing expectations or critical-material requirements that go beyond a manufacturer's standard incoming qualification, you should discuss those requirements during supplier qualification.
- ☐ **Raw material traceability to finished product.** Can the manufacturer trace a specific raw material lot to every finished product lot that contained it? This is essential for investigations and recall readiness.
- ☐ **Critical supplier qualification.** Ask how the manufacturer identifies and qualifies its critical raw material suppliers. Most reagent manufacturers focus qualification effort on critical materials — for example, raw materials with the highest potential to affect finished-product quality (active ingredients, sterility-critical materials) — rather than every raw material on the bill of materials. Discuss your program's expectations during supplier qualification: if the manufacturer's definition or scope doesn't match what your program needs, raise it during qualification — most manufacturers can extend their scope for specific programs.

FACILITY AND MANUFACTURING

- [ ] **Cleanroom certification.** Confirm the range of classifications in use, what operations happen in each, and how the maintenance program is designed and documented to meet aseptic control requirements — covering gowning validation, sanitization, HVAC qualification, equipment qualification, and ongoing particulate and microbial monitoring.
- [ ] **Bracketed or platform validation across facilities, processes, and container formats.** A robust bracketed validation approach should cover all three — facilities, manufacturing processes, and container formats — allowing custom orders to be manufactured without requiring a full new validation cycle for each product. Ask how the manufacturer handles novel formulations or non-standard formats and confirm the scope of their validation program.

DOCUMENTATION

- [ ] **Customizable Certificate of Analysis (COA).** COA content and format should be configurable to match your internal requirements.
- [ ] **Batch records accessible and audit-ready.** Ask whether records are electronic and how quickly they can be produced in response to an audit or investigation.
- [ ] **Side samples available.** For customers making therapies in clinical trials, samples from each lot may be available for independent QC testing at your facility or a third-party lab — typically as a customer-led activity. Discuss expectations during supplier qualification.
- [ ] **Stability data available or obtainable.** For custom GMP formulations, stability is typically established through customer-led or jointly designed studies. Ask whether the manufacturer offers stability testing as a service, or whether you'll need to arrange for it independently. Confirm what is included in standard documentation versus what is available as an add-on.

CONTINUED



AUDIT AND QUALIFICATION — RUO+/GMP PROGRAMS

- ☐ **Open-door audit policy.** Confirm that the reagent manufacturer will accommodate on-site or virtual audits. This is a standard expectation for RUO+ and GMP supplier qualification.
- ☐ **Audit documentation package available.** Ask what documentation the manufacturer makes available during the audit. A solid facility overview, QMS summary, certifications, and supporting records should be accessible in the audit room. General pre-audit materials such as quality manuals, certifications, and high-level QMS summaries may be available on request, but detailed audit documentation (batch records, deviation logs, CAPAs) is typically reviewed during the agreed audit timeframe — not circulated in advance.
- ☐ **Virtual audit capability.** For geographically distant suppliers, ask whether remote audits are supported, including virtual facility tours, and what documentation is available electronically.
- ☐ **Quality agreement available.** For GMP programs, a formal quality agreement defining both parties' responsibilities, change notification requirements, and documentation obligations is standard practice. Quality agreements are generally reserved for GMP programs; at earlier stages, a bridge grade (such as RUO+) can provide many of the same quality assurances without a formal quality agreement in place.

SUPPLY CONTINUITY

- ☐ **Redundant facility infrastructure.** Ask whether the manufacturer has redundant cleanroom suites and production equipment so manufacturing can continue if a single area or piece of critical equipment is unavailable. For customers producing therapies or diagnostics at the clinical trials stage or for commercial sale, this is a meaningful continuity question.
- ☐ **Customer-owned material storage.** Some manufacturers can purchase and hold critical raw materials on your behalf, stored under your control for your exclusive use. This can be valuable for long-lead-time or single-source materials.
- ☐ **Supply redundancy for critical raw materials.** How does the manufacturer ensure continuity if a raw material becomes unavailable? Ask about qualified alternate sources for critical materials.
- ☐ **Lead time and expedited production options.** What is the standard lead time for custom orders? Is expedited production available for urgent needs?

Part 8: Verify Before You Rely — How to Check Certification Claims



CHECK THOSE SPECS

CERTIFICATION CLAIMS AREN'T ALWAYS WHAT THEY SEEM

Credentials that suppliers claim may be misleading or simply inaccurate. Some claimed credentials, like "FDA certified," don't even exist. Other credentials, like ISO 13485 certification, are real, but are sometimes claimed without the documentation to back them up.

Before relying on a certification claim, verify it independently. The rest of this section explains how, using free, publicly available tools.

Verifying ISO 13485 Certification

ISO 13485 certifications are issued by accredited certification bodies (registrars), not by the International Organization for Standardization (ISO) itself. To verify:

- Ask the supplier for their current ISO 13485 certificate. A valid certificate will show the issuing certification body, the scope of certification, the certificate number, and the expiration date.
- Confirm the certification body is accredited. Bodies like ANAB (ANSI National Accreditation Board) and UKAS (United Kingdom Accreditation Service) maintain public registries of accredited certification bodies.[15]
- Confirm the certificate is current and in scope. ISO 13485 certifications operate on a 3-year cycle: a recertification audit at the start of the cycle, followed by surveillance audits in years 2 and 3.[16] Confirm the scope of the certification covers the manufacturing activities and facilities relevant to your program.

Red flag: a vague scope statement, an expired date, or a certification body you cannot verify as accredited. Follow up before relying on the certificate.



VERIFYING TEKNOVA'S CERTIFICATION

SEE FOR YOURSELF

Teknova's ISO 13485:2016 certificate is issued by Intertek. The current certificate is publicly available for download, no request required.

Verifying FDA Registration

FDA registration applies to certain types of manufacturers and their facilities — primarily drug, biologic, and finished medical device / IVD establishments. Ancillary reagent manufacturers (including Teknova) are not subject to FDA establishment registration, so an FDA database search will not return a Teknova entry. This section is provided as general industry guidance for verifying claims from suppliers who do operate in FDA-registered categories.

The FDA does not issue certification certificates. What it maintains are searchable public databases of registered establishments.

For Medical Device Establishments (including IVD manufacturers):
Database: FDA Establishment Registration and Device Listing
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

For Drug Establishment Registration:
Database: Drug Establishments Current Registration Site (DECRS)
www.accessdata.fda.gov/scripts/cder/drls/default.cfm

Annual renewal between October 1 and December 31 is required; non-renewing establishments are removed from the database.[17]



AN IMPORTANT DISTINCTION

REGISTRATION ≠ APPROVAL ≠ CERTIFICATION

FDA registration means a facility has registered with the agency, not that it has been inspected, approved, or certified. The FDA does not issue “certificates” for drug, device, or reagent establishments. Any document presented as an “FDA Registration Certificate” is a third-party document, not an FDA-issued credential. Verify through the official FDA databases above.

What to Ask a Supplier

When evaluating a reagent manufacturer's certification claims, here are the direct questions to ask:

"Can you share your current ISO 13485 certificate, and what's the scope of certification?"

Look for: a certificate from a named, accredited certification body; a clear scope statement covering the products and manufacturing activities you intend to source; and a current expiration date.

"Who is your certification body, and how can I verify they're accredited?"

Look for: a named body verifiable via ANAB, UKAS, or another national accreditation body's public registry.

"When was your last surveillance audit? Can you confirm whether any non-conformances were identified, and that they've been resolved?"

Look for: a recent audit (within the 3-year cycle); a high-level, transparent answer about findings (full audit reports are confidential between supplier and certification body, but suppliers should be willing to confirm general findings and resolution status). Redacted excerpts or summary statements may be provided as evidence.

"Will you notify us of changes to formulation, raw materials, processes, or facilities that could affect our products?"

Look for: a formal change control process with notification for GMP products, ideally documented in a quality agreement.

"Do you accommodate on-site and virtual audits?"

Look for: yes, with reasonable scheduling. Hesitation here is a meaningful signal.

"What documentation do you provide to support our qualification of your products?"

Look for: Certificates of Analysis, supplier qualification questionnaires, batch record templates, formulation sheets, and product specifications. A supplier may also offer a general quality questionnaire or overview covering its QMS at a high level. COAs are provided per-lot, change notifications per-event. Completed batch records are reviewed during audits rather than provided in advance; a formulation sheet, batch record template, and agreed specifications can typically be shared earlier. Documentation can often be tailored to specific program requirements — ask about custom packages if your program has particular needs.

Sources

[1] International Organization for Standardization. ISO 9001:2015 — Quality management systems: Requirements. iso.org/standard/62085.html

[2] International Organization for Standardization. ISO 13485:2016 — Medical devices: Quality management systems: Requirements for regulatory purposes. iso.org/standard/59752.html

[3] U.S. Code of Federal Regulations. 21 CFR 210/211: Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs. ecfr.gov

[4] U.S. Food and Drug Administration. Quality Management System Regulation (QMSR), effective February 2, 2026. Final Rule amending 21 CFR Part 820 to incorporate ISO 13485:2016 by reference. fda.gov/medical-devices/quality-management-system-regulation-qmsr

[5] United States Pharmacopeia. USP <1043> Ancillary Materials for Cell, Gene, and Tissue-Engineered Products. usp.org

[6] U.S. Code of Federal Regulations. 21 CFR Part 814: Premarket approval of medical devices. ecfr.gov

[7] U.S. Food and Drug Administration. Overview of IVD Regulation. In vitro diagnostic products classification (Class I, II, III); 21 CFR 809.3. fda.gov/medical-devices/ivd-regulatory-assistance/overview-ivd-regulation

[8] U.S. Food and Drug Administration. Drug Master Files (DMFs): Guideline and Types. fda.gov/drugs/drug-master-files-dmfs

[9] U.S. Code of Federal Regulations. 21 CFR 864.4010: General purpose reagents. ecfr.gov

[10] U.S. Code of Federal Regulations. 21 CFR 864.4020: Analyte specific reagents. ecfr.gov

[11] U.S. Code of Federal Regulations. 21 CFR Part 807 Subpart E: Premarket notification procedures. ecfr.gov

[12] Centers for Medicare & Medicaid Services (CMS). Clinical Laboratory Improvement Amendments (CLIA). cms.gov/medicare/quality/clinical-laboratory-improvement-amendments

[13] U.S. Food and Drug Administration. QMSR Final Rule FAQ. Under QMSR, the Design History File (DHF) concept aligns with the Medical Device File (MDF) terminology in ISO 13485. fda.gov/medical-devices/quality-management-system-regulation-qmsr

[14] International Organization for Standardization. ISO 14644-1:2015 — Cleanrooms and associated controlled environments: Classification of air cleanliness by particle concentration. iso.org/standard/53394.html

[15] ANSI National Accreditation Board. Directory of accredited organizations. anab.org. United Kingdom Accreditation Service. Search accredited organisations. ukas.com

[16] International Organization for Standardization. ISO/IEC 17021-1:2015 — Conformity assessment: Requirements for bodies providing audit and certification of management systems, Part 1. iso.org/standard/61651.html

[17] U.S. Code of Federal Regulations. 21 CFR 207.29: When and how must I update my registration. ecfr.gov

Note: This guide is intended as an educational reference and focused on U.S. regulatory frameworks; organizations operating under other regional requirements should consult the equivalent standards for those jurisdictions. It reflects the regulatory landscape as of early 2026. Regulatory requirements evolve — consult your quality and regulatory affairs team for program-specific guidance. For questions about Teknova's certifications or to request documentation, contact **info@teknova.com**.

Do reagent suppliers need to be FDA registered?

No. Reagents used in manufacturing are ancillary materials, not finished drugs or devices, so their manufacturers are not subject to FDA establishment registration, device listing, or premarket review. FDA registration and inspection are required of drug, biologic, and finished device/IVD makers.

Is ISO 13485 required for reagent manufacturers?

No regulation requires it. Obtaining ISO 13485 certification is voluntary for reagent suppliers, but it is the de facto standard for any supplier serving customers making drugs or diagnostic products because it supports supplier qualification.

What is an ancillary material?

A reagent, buffer, medium, or other component used during a manufacturing or testing process but not intended to remain in the finished product. The category is defined by how a material is used, not by its chemistry.

Is “FDA certified” a real credential?

No. The FDA does not certify reagent manufacturers or their products. “FDA approved” applies only to specific finished products, such as drugs and certain devices — never to a reagent or its manufacturer.

What’s the difference between GMP and cGMP?

GMP is a general manufacturing-quality principle; for reagent suppliers, it is typically anchored in ISO 13485. cGMP refers specifically to the FDA’s regulations under 21 CFR 210/211 for drug and biologic manufacturers. Neither is a certification — no certificate is issued for either.

Does a reagent supplier’s ISO 13485 certification make my product compliant?

No. A supplier’s certification supports your supplier qualification, but qualifying a reagent for your specific application — and any regulatory submission it supports — remains your responsibility, under your own quality system.

Have a question? We’re here to help

Get in touch with our team to get started at **info@teknova.com** or **1.800.209.4488**.

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