Transitioning from RUO to GMP

At some point during development of products for human diagnostic or therapeutic use, you will have to transition the raw materials from research use only (RUO) to those manufactured under good manufacturing practices (GMP) according to ISO 13485:2016 standards. Products manufactured under GMP conditions have stringent requirements for traceability, change control, and testing. But you may not be sure when you should switch or if you should start with GMP. This white paper explains the difference between RUO and GMP products, discusses when to transition from RUO to GMP, provides tips on what to look for in a GMP manufacturer, and gives you an idea of how it would look if you worked with Teknova to produce GMP products.

RUO compared to GMP

The difference between products marked for RUO and those with GMP documentation is that RUO products are appropriate for basic research, drug discovery, preclinical development, and process optimization. RUO products should not be used for clinical applications, such as therapeutics or diagnostics. Products for clinical end use must be manufactured under GMP conditions and typically require raw materials that are also manufactured under GMP conditions.

When can you use RUO reagents for products intended for human use?

You can use RUO products in the design control research phase. The final design control stage is your opportunity to transition to GMP products for clinical manufacturing. However, you may consider using GMP regents earlier to avoid the interruption of the transition from reagents marked RUO.

Starting with GMP reagents prevents you from having to revalidate your reagents at the time of switching from RUO to GMP. If you were developing an investigational new drug (IND), it would significantly reduce the time required to prepare the submission because your product development would start with raw materials of the appropriate grade.

What to look for in a GMP manufacturer

To facilitate efficient commercialization of your products, a GMP product supplier must meet many requirements, including:

- Rapid process transition and fast timelines
- Lot-to-lot consistency
- Accelerated scale-up
- Easy implementation of post-optimization changes after design lock
- Affordability

In addition, the supplier should have the appropriate technical expertise and provide easy access to the facility for auditing. Features to look for include:

End-to-end support. Ensure that the manufacturer consistently uses high-quality products that will support your progress to market as you grow and transition from product development to clinical and commercial production.

Scientific product expertise. Check for extensive experience and expertise in manufacturing biological products to ensure that you will have a reliable partner that can provide the appropriate guidance and recommend the necessary testing to meet your needs.

Open-door audit policy. A reputable manufacturer must be registered with the US Food and Drug Administration (FDA), have a quality management system (QMS) that is certified ISO 13485:2016 compliant, and accommodate on-site process or product spot audits.

Logistical support. This is particularly important if you are a small company or startup. Consider a manufacturer that can hold or store the finished product. Storage decreases the pressure on your logistical team and reduces inventory management costs.

High-quality and cost-effective raw materials. Look for a manufacturer that tests and validates raw materials and equipment in compliance with state and federal law.

GMP products at Teknova

Teknova manufactures an extensive array of products for the life sciences and healthcare industries, including pre-poured plated media, reagents for cell culture, and buffers and solutions. Our product offerings are categorized under two classes: RUO-labeled products for laboratory use and GMP-labeled products (www.teknova.com/gmp-manufacturing) for clinical and cosmetic manufacturing. Most manufacturers offer both product classes, usually producing GMP reagents in a dedicated facility within the larger premises or in a separate GMP facility.

At Teknova, our entire manufacturing facility is certified ISO 13485:2016 compliant. Our manufacturing buildings feature an environmental monitoring program that measures the quality of our manufacturing conditions to detect potential sources of contamination, which ensures final product safety. ISO 13485:2016 specifies the requirements for a quality management system (QMS) for providing medical devices and services that consistently meet customer and regulatory requirements. Therefore, all Teknova products, RUO- and GMP-labeled, are manufactured to the standards required for medical devices for human use. For GMP-labeled products, we offer an advanced, customer-dictated process for reagent sourcing to avoid unnecessary changes to any current processes and procedures.

We perform extensive quality checks on every product:

Raw material analysis ensures product quality from the outset and includes microbiology, chemistry, and toxicology tests.

Bioburden testing measures microbial contamination levels in a product to ensure its safety for downstream applications.

Secondary reviewer verification means we have a second person review all documents and records to verify their accuracy.

We also include additional customer-defined quality control checks, enhanced traceability, and change notification:

With **enhanced traceability**, each product is documented through the entire production process, allowing us to track down and determine the source of any issues that may arise, even years later.

We issue a **change notification** when any component of a product or the manufacturing process changes; we evaluate and document the change and notify regulatory authorities.

Finally, we implement good documentation practices (GDP) for all products, a set of standards that provide a reliable method of documentation.

How Teknova can support your unique journey to producing clinical products

We partner with large and small pharmaceutical companies as well as academic institutions nationally, providing cost-saving solutions for molecular diagnostics, drug discovery and production, disease research, and microbiology.

Teknova strives to develop a deep understanding of the unique constraints and needs of your organization:

Academic institutions: An academic team shifting from research to clinical products will likely have little to no background in manufacturing and will probably be working with a regionally distributed research team.

Small biotechnology companies: Small biotech companies have exceptionally high stakes due to funding and the market need for speed.

Larger biotechnology and pharmaceutical companies: Larger organizations have specific challenges related to cost savings and typically choose between producing materials in-house or buying materials from vendors.

While GMP requirements for these organizations are similar, each organization will have a different journey to having their GMP product needs met. Teknova strives to understand your institution's broad goals and unique constraints, and we adapt to your processes from basic research through product development to commercialization.

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