

FREQUENTLY ASKED QUESTIONS: FACT Consulting Audit & Assessment Solution

1. What is the difference between FACT Accreditation and the FACT Consulting Audit & Assessment Solution?

The mission of the Foundation for the Accreditation of Cellular Therapy (FACT) is to improve the quality of cellular therapy through peer-developed standards, education, and accreditation for the benefit of patients. Founded in 1996, it is a dynamic, global non-profit organization that is responsive to the evolving field and the needs of patients.

FACT accreditation is voluntary, based on compliance with the current FACT Standards. Inspectors are volunteers who are experts in cellular therapy. The FACT standards development and accreditation processes reflect a unique perspective that focuses on the relationships among the clinical collection of cells for administration or further manufacturing, the clinical administration of cellular products, and the technical laboratory processing practices. This comprehensive scope is a critical factor to manufacture and administer safe and efficacious cellular therapy products. FACT Standards are unique in depth and breadth, being applicable to:

- all phases of cell collection, processing, storage, transportation and shipping, and clinical administration activities performed at the accredited organizations' sites or by their service providers.
- all phases of clinical application including standard of care therapies and products, licensed (or with other regulatory approval) products, and products administered under regulatory-approved clinical trials.

FACT Consulting Services, LLC ("FACT Consulting") is a FACT subsidiary through which consulting assistance related to accreditation is available but is independent of the accreditation process. A firewall exists between the two entities to maintain the credibility and objectivity of FACT accreditation. FACT Consulting offers solutions through custom engagements, audits and assessments, and new cellular therapy program advisory solutions.

FACT Consulting's Audit & Assessment Solutions have a narrower scope than accreditation and are conducted at the request of a client seeking to evaluate the specific processes at a health care site. Evaluations are conducted by paid auditors employed by FACT Consulting against regulations and product-specific requirements, not the FACT Standards. Both FACT-accredited and non-FACT accredited sites can be assessed.

2. What types of assessments can be performed?

FACT Consulting's Audit & Assessment Solutions include, but are not limited to:

- A **Site Qualification Assessment** verifies that cellular therapy operations can be performed correctly and safely, in compliance with relevant regulations. It includes an evaluation of a site's compliance with regulations and its ability to perform processes that meet the client's needs, including, but not limited to, adequate space; equipment; staff with appropriate training, education, experience, and supervision; and other resources.
- A **Quality Systems Assessment** comprehensively verifies the effectiveness of a program's quality system. It includes an evaluation of a site's existing quality management program to determine its conformance to company policies, contract commitments, and regulatory requirements.
- A **Surveillance Audit** is an ongoing evaluation of a site's processes, records, or quality management system to ensure continued compliance with regulations, policies and procedures, and agreements.
- An **Ad Hoc Audit** is an evaluation of a site conducted out of the regular course for a special or unexpected reason.
- A **For Cause Audit** is an evaluation of a site when information indicates a potential noncompliance or problem (e.g., product quality complaints, adverse events, data compiled from an application, hearsay).

3. What are the characteristics of the clients you intend to serve, and how many do you anticipate utilizing your solution?

FACT Consulting's Audit & Assessment Solutions can accommodate any eligible client, including cellular therapy product manufacturers, clinical trial sponsors, registries, or license holders. Clients can be of various sizes and stages of research and/or commercialization.

FACT Consulting can serve as a client's only assessment provider or supplement a client's existing team. Although many companies already have internal auditing teams, several factors are driving demand for additional resources to alleviate growing pressures on both industry and sites. FACT Consulting is positioned to address this challenge.

We aim to serve many clients and believe demand for FACT Consulting will continue to increase. FACT Consulting intends to curate and market a Report & Assessment Library ("Library"). Clients will be able to purchase existing reports and/or audits of sites (with sensitive information removed), creating efficiencies and time savings that our industry desperately needs. We encourage companies to complete the no-cost, no-obligation [Needs Assessment Form](#) and allow FACT Consulting to present to you a custom assessment program for your consideration.

4. In the case of product- or protocol-specific audits, what is your process for serving different clients?

For Site Qualification and Quality System Assessments, clients' product- or protocol-specific requirements can be added to the standard assessment checklists, which are designed to include all relevant regulations. We perform a full, end-to-end site assessment, and the deliverable is designed to be available for purchase (with sensitive information removed) in the FACT Report & Assessment Library ("Library") by industry customers beyond the initial client. If an assessment report for a particular site is already available in the Library, we will work with the client to determine if any additional requirements can be evaluated via a virtual assessment to provide time and resource efficiencies.

FACT Consulting, over time and with a growing client base, will identify trends in the field. We have discovered that many practices or requirements considered by some companies to be unique to their product or protocol are more widespread across the industry than realized.

5. How long does the assessment process take from start to finish?

The first step is to learn the client's needs, including the scope of assessments, number and location of sites, checklist elements, and timeframe. This work typically takes about a month, depending on the availability of clients' key decision makers.

After the scope has been established, the time to assess a site is between four and eight weeks. This includes requests for and review of documents, the on-site or virtual visit, response to observations, and audit closure. The more that FACT Consulting is able to work with the site prior to the on-site visit, the less time is needed on-site.

6. How long is the assessment report valid?

FACT Consulting Audit & Assessment reports are valid for three years, unless regulatory requirements or client needs dictate a shorter period. For example, some international regulatory agencies require an evaluation every two years. FACT Consulting will meet this requirement.

7. Would our site be able to upload our audit results to the Report Library ourselves?

Only reports of FACT Consulting assessments will be included in the Library. FACT Consulting has developed safeguards to protect both clients and assessed programs. This includes removal of proprietary and confidential information, eligibility requirements for accessing a report, and description of the scope of the assessment. Individual audit results are managed by the sites.

8. What manufacturers have already qualified the FACT Consulting Audit & Assessment Solution?

Two manufacturers have qualified our Audit & Assessment Solution. Additional manufacturers have previously qualified FACT's quality management system as suitable for their use. These qualifications were performed under non-disclosure agreements, so the identities of the manufacturers cannot be shared.

FACT Consulting understands the importance of qualifying service providers. We are prepared and experienced to support such efforts.

9. How much do these services cost and who pays the fees?

Our intention is to provide a cost-effective service to the cell and gene therapy industry that is also a long-term, sustainable solution to increase the efficiencies of site assessments. The cost of an assessment is dependent upon many factors, including geographic location, type and scope of the assessment, number of product- or protocol-specific requests, and duration of the assessment. We will include the fee within the proposed assessment proposal provided to the potential client.

Pricing for a full Site Qualification Assessment, including the audit report and response plan, starts at \$8,500. Reports within the FACT Report Library can be accessed for \$6,500.

Fees are paid by the client requesting the assessment or the report. In most cases, the client will be a cellular therapy product manufacturer, clinical trial sponsor, registry, or license holder. A clinical site is also welcome to proactively request an assessment so that it may have a report in the Report Library and be proactively prepared to assume a new clinical trial or administer a new product. In this case, the clinical site would pay the fee.

10. May cellular therapy programs encourage manufacturers to utilize FACT Consulting's Audit & Assessment Solution?

Absolutely! We foresee cellular therapy programs being important collaborators for spreading awareness of our solution for the benefit of both clinical sites and industry. This solution will allow sites to refocus their energy towards patient care and access and away from perpetual audits. If manufacturers have any questions regarding our solution, please feel welcome to refer them to us. We would be happy to help.

11. What resources are available to learn more about the FACT Consulting Audit & Assessment Solution and provide to key decision makers?

FACT Consulting has resources to create awareness of our new solution, educate interested parties on the process, and assist industry and program personnel in promoting this solution to key decision makers.

A brief, informational video provides highlights of our audit and assessment solution in under four minutes. This video is available online at <https://www.factglobal.org/menu-of-services/audit-and-assessment-services/>.

FACT Consulting has introduced our solution and provided updates via the *Just the FACTs* newsletter and will continue to do so. Past articles are available at <https://news.factglobal.org/tag/audits/>. To subscribe to future newsletters, go to <http://www.factweb.org/forms/cas/login>.

Finally, anyone is welcome to contact us for more information at consulting@factglobal.org and complete the no-cost, no-obligation [Needs Assessment Form](#).