

Visual Inspection Qualification for Cell and Gene Therapy

FDA Source Review and Readiness Questions

Source-based practice report

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GMP Training Architecture for Biotech & Pharma

Selected FDA records and guidance are analyzed individually. This report does not estimate the prevalence of training gaps or claim measured remediation outcomes.

EXECUTIVE SUMMARY

What the identified sources support

FDA staff discussed visual inspection of CAR T-cell drug product in a March 2024 CBER webinar. The speaker described inspection of each drug product lot against black and white backgrounds before release and distinguished visual inspection for particulates and defects from product appearance testing. This is a CGT-specific discussion, not a finding that a defined group of CGT facilities failed qualification. [S1]

FDA's December 2021 *draft* guidance on visible particulates in injectable products discusses trained inspectors, qualified inspection equipment, representative defect libraries, controlled test sets, and documented qualification protocols. The draft is nonbinding and excludes subvisible particulates. It is not a 2023 CGT guidance. [S2]

Two identified FDA records illustrate qualification-control problems in other drug-manufacturing settings. A January 2025 Form 483 for Zhejiang Huahai reports deficiencies in test kits, defect identification records, and answer-key control. A July 2025 warning letter to Daewoo discusses missing inspector-training procedures and challenge-kit design. Neither is a CGT-sector study or a basis for a facility-rate estimate. [S3, S4]

HOW TO READ THE EVIDENCE

A Form 483 records an investigator's observations at the end of an inspection and is not FDA's final agency determination. A warning letter communicates FDA's stated concerns and requested response. GxP Frame's readiness questions on page 4 are professional interpretation, not quotations from FDA or a guarantee of compliance. [S5]

Scope of this revision

The prior version's four-facility cohort, percentages, attributed Form 483 quotations, anonymous remediation outcomes, and "15+ facilities" claim lacked traceable records. They have been removed. The underlying dataset was not recovered, so this revision does not present an empirical trend or comparative risk estimate.

SOURCE FINDINGS

FDA records, with their limits

CGT-SPECIFIC FDA DISCUSSION | S1**CAR T-cell drug product**

In the March 2024 CBER webinar, an FDA speaker described visual inspection of CAR T-cell drug product before release, using black and white backgrounds, and differentiated inspection for visible particulates or defects from appearance testing. The transcript does not set a universal CGT inspector-qualification sample size or an acceptable defect-detection percentage. Transcript p. 16.

DRAFT RECOMMENDATIONS | S2**Visible-particulate inspection of injectables**

The December 2021 draft addresses visible particulates. Its training section discusses formalized qualification, defect libraries reflecting product and process, quality-unit control of test sets, documented acceptance criteria, and requalification. It excludes subvisible particulates and remains marked “Draft — Not for Implementation.” Draft pp. 1, 12–13.

INSPECTION OBSERVATION, NON-CGT EXAMPLE | S3**Zhejiang Huahai Pharmaceutical, January 2025**

Observation 3 of the Form 483 describes incomplete liquid-vial qualification kits and a defect library, records that did not identify which specific defect inspectors recognized, and an absent answer key after vial renumbering. These are investigator observations about this drug manufacturer, not final FDA conclusions or evidence of CGT prevalence. Form 483 pp. 6–7 of 11; FEI 3003999190.

FDA WARNING LETTER, NON-CGT EXAMPLE | S4**Daewoo Pharmaceutical, July 2025**

FDA stated that inspector training lacked a procedure and that the challenge kit required identification of a bottle rather than the defect. The letter also requested details on defect-library qualification and an inspection program with training and qualification. The record concerns that firm's drug products, not a CGT facility cohort. Section 3, “Visual Inspection.”

GXP FRAME INTERPRETATION

Readiness questions for a specific product

The following questions translate the identified source themes into an internal review. They are recommendations for scoping and quality review. Product presentation, approved specifications, process history, and applicable requirements should determine the final program.

1. Inspection purpose

Which visible defects and particulates must inspection detect for this product and container? Is appearance testing separately defined? [S1, S2]

2. Qualified conditions

Are lighting, backgrounds, handling, duration, equipment, and actual inspection conditions defined and qualified where applicable? [S1, S2]

3. Defect library

Do representative and controlled examples cover relevant defect types? Are identity, classification, suitability, and changes to test-set contents traceable? [S2, S3, S4]

4. Inspector qualification

Does the protocol test recognition of the defect, record results against approved criteria, address failures, and define retraining or requalification? [S2, S3, S4]

5. Quality oversight

Does the quality unit approve test sets and protocols, control answer keys, and review performance and defect trends? [S2, S3]

6. Method boundary

Is subvisible particulate control handled through the appropriate separate methods? Naked-eye visual inspection should not be represented as a subvisible-particle test. [S2]

NEXT STEP

For a scoped review, GxP Frame can help map product-specific inspection tasks to training, qualification evidence, documentation, and quality-unit decisions. Scope, timing, and acceptance should be agreed for the facility and product. [Explore consulting support.](#)

SOURCE REGISTER AND METHOD

Traceable records

[S1] FDA CBER webinar transcript, 7 March 2024. *Considerations for the Development of CAR T Cell Products*, p. 16 (PDF p. 17). [fda.gov/media/178014/download](https://www.fda.gov/media/178014/download)

[S2] FDA draft guidance, December 2021. *Inspection of Injectable Products for Visible Particulates*, pp. 1 and 12–13 (PDF pp. 4 and 15–16). FDA's current guidance page labels it draft and nonbinding. [FDA guidance page](#) | [Draft PDF](#)

[S3] FDA Form 483, issued 24 January 2025. Zhejiang Huahai Pharmaceutical Co., Ltd., Observation 3, pp. 6–7 of 11; FEI 3003999190. [fda.gov/media/186642/download](https://www.fda.gov/media/186642/download)

[S4] FDA warning letter, 2 July 2025. Daewoo Pharmaceutical Co., Ltd., Section 3, “Visual Inspection,” WL 706371. [FDA warning letter](#)

[S5] FDA Form 483 FAQ. Explains the purpose and status of inspection observations. [FDA FAQ](#)

Method and limits

This is a selected-source, qualitative review. Each record was read for the specific point attributed to it. The two facility records were chosen because they document inspector-qualification control issues; neither is a CGT facility example. No sampling frame was constructed, no denominator was established, and no statistical or remediation-outcome claim is made. The draft guidance is identified as draft wherever used. The original February 2026 version is retained separately for review.

A Form 483 or warning letter should be read in its full context, including subsequent responses and FDA correspondence where available. This report does not determine a firm's legal compliance status or provide a facility-specific regulatory conclusion.