

Biotechnology BOM Reagent & Consumable Audit Checklist 2026

Reagent Specification & Grade Verification

Verification of chemical purity levels, biological grade (e.g., molecular biology grade), and technical specifications against standardized protocols.

Reagent Chemical Name

Purity Grade

- ☐ Analytical Grade
- ☐ ACS Grade
- ☐ Molecular Biology Grade
- ☐ USP/EP Grade
- ☐ Technical Grade

Concentration/Molarity (mol/L)

Required Standard Certifications

- ☐ ISO Certified
- ☐ GMP Compliant
- ☐ REACH Compliant
- ☐ FDA Regulated

Technical Specification Sheet

 Upload File

Verifier Authentication

Batch & Lot Number Traceability

Audit of unique lot numbers, batch IDs, and manufacturer manufacturing dates to ensure full upstream traceability within the BOM.

Primary Batch/Lot Number

Write something...

Manufacturing Date

Enter date...

Traceability Status

- ☐ Fully Traceable
- ☐ Partial Traceability (Missing Link)
- ☐ Untraceable

Batch Traceability Documentation

 Upload File

Auditor Verification Signature

Expiration & Shelf-Life Monitoring

Review of expiration dates, stability data, and remaining usable life for all perishable reagents and temperature-sensitive consumables.

Reagent Expiration Date

Enter date...

Remaining Shelf Life (Days)

Enter a number...

Storage Temperature Status

- ☐ Stable
- ☐ At Risk
- ☐ Expired

Stability Test Report Attachment

 Upload File

Observed Degradation Notes

Write something...

Auditor Verification Signature

Storage & Cold Chain Compliance

Validation of storage requirements (e.g., -80°C, -20°C, 4°C) and verification of continuous temperature monitoring logs during transit and storage.

Required Storage Temperature Range

- ☐ Ambient (15°C to 25°C)
- ☐ Refrigerated (2°C to 8°C)
- ☐ Frozen (-20°C)
- ☐ Ultra-Low Frozen (-80°C)
- ☐ Liquid Nitrogen (Cryogenic)

Current Recorded Temperature

Enter a number...

Last Temperature Log Review Date

Enter date...

Cold Chain Monitoring Equipment Used

- ☐ Digital Data Logger
- ☐ Continuous Thermometer
- ☐ IoT Temperature Sensor
- ☐ Manual Temperature Strip

Temperature Log Evidence/Export

 Upload File

Storage Deviation Notes

Write something...

Auditor Verification Signature

Certificate of Analysis (CoA) Documentation

Confirmation that all corresponding Certificates of Analysis and Safety Data Sheets (SDS) are present, up-to-date, and digitally archived.

CoA Digital Archive

 Upload File

CoA Verification Status

- ☐ Verified & Matching
- ☐ Discrepancy Found
- ☐ Missing Documentation

Date of Document Review

Enter date...

CoA Reference Number

Write something...

Auditor Verification Signature

Supplier Quality & Compliance Audit

Assessment of vendor compliance with GMP (Good Manufacturing Practice), ISO standards, and regulatory biotechnology certifications.

Supplier Certification Status

- ☐ ISO 9001 Certified
- ☐ GMP Compliant
- ☐ GLP Compliant
- ☐ Uncertified

Last Supplier Audit Date

Enter date...

Supplier Quality Certificate Upload

 Upload File

Compliance Documentation Verified

- ☐ Certificate of Analysis (CoA)
- ☐ Safety Data Sheet (SDS)
- ☐ ISO Accreditation Proof
- ☐ Material Origin Declaration

Audit Findings & Discrepancy Notes

Write something...

Quality Assurance Auditor Signature

Quantity & Inventory Reconciliation

Physical count verification against the BOM digital records to identify discrepancies in unit quantities or packaging sizes.

BOM Listed Quantity

Enter a number...

Physical Count Quantity

Enter a number...

Reconciliation Status

- ☐ Match
- ☐ Discrepancy Found
- ☐ Shortage
- ☐ Surplus

Discrepancy Details

Write something...

Inventory Log Evidence

 Upload File

Auditor Verification

Contamination & Integrity Inspection

Visual and technical inspection of packaging integrity, seal status, and presence of any signs of microbial or chemical contamination.

Seal Integrity Status

- ☐ Intact
- ☐ Compromised
- ☐ Tampered

Observed Contamination Types

- ☐ Visible Particulates
- ☐ Microbial/Mold Growth
- ☐ Leaking/Spillage
- ☐ Discoloration
- ☐ None Detected

Detailed Inspection Findings

Write something...

Contamination Evidence Photos

 Upload File

Inspector Authentication

Regulatory & Safety Labeling Compliance

Verification of GHS (Globally Harmonized System) labeling, hazard warnings, and instructional clarity on all consumable packaging.

GHS Labeling Status

☐ Fully Compliant

☐ Non-Compliant

☐ Pending Update

Required Safety Symbols Present

☐ Flammable

☐ Toxic

☐ Corrosive

☐ Oxidizing

☐ Environmental Hazard

Missing Labeling Details

Write something...

Safety Data Sheet (SDS) Verification Document

 Upload File

Compliance Officer Approval

Post-Audit Discrepancy & CAPA Logging

Documentation of any identified non-conformities and the initiation of Corrective and Preventive Actions (CAPA) for the 2026 audit cycle.

Discrepancy Detection Date

Enter date...

Discrepancy Severity Level

- ☐ Critical (Immediate Stop)
- ☐ Major (Action Required)
- ☐ Minor (Observation Only)

Detailed Description of Non-Conformity

Write something...

Assigned CAPA Owner

Write something...

Target Resolution Deadline

Enter date...

Evidence of Discrepancy (Photos/Reports)

 Upload File

Auditor Verification Signature

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✔ Finish

✎ Generate Sample Report