analytichem
your science enabled

redipor
an analytichem brand

Evaluating and Validating New Suppliers of Prepared Microbiology Media

This guide provides a practical, GMP-aligned framework for assessing and validating potential new suppliers of prepared microbiology media. It's designed as a companion to **our blog**, Evaluating and Validating Potential New Suppliers of Prepared Microbiology Media, by Steven Brimble, AnalytiChem UK's Director of Quality and Technology.

Treating evaluation and validation as separate but connected processes helps laboratories manage risk, focus resources effectively, and build confidence in both supplier capability and product performance in a time-efficient and cost-effective manner. This Guide translates the principles covered in detail by the blog into clear, concise, step-by-step guides and checklists.

Evaluation—Establishing Supplier Suitability

Evaluation determines whether a supplier is capable of meeting your quality, regulatory, and operational requirements before embarking upon the more resource-intensive validation stage. The aim is to confirm suitability, not to prove product performance.

Evaluation Step 1: Confirm Regulatory and Quality Alignment

Begin by establishing that the supplier operates within an appropriate quality framework for your environment. Confirm that the supplier:

- Works in alignment with GMP expectations relevant to prepared microbiology media
- Demonstrates compliance with applicable pharmacopeial requirements
- Can provide clear documentation supporting formulation and performance claims

Request and review a Certificate of Analysis (CoA) for representative products. This should include:

- Test organisms and culture collection references
- Test methodologies and acceptance criteria
- Evidence of compliance with relevant standards

This documentation provides early assurance that the supplier understands regulatory expectations and applies appropriate quality controls.

Evaluation Step 2: Assess Product Configuration and Operational Fit

Practical suitability is as important as compliance. Confirm that the supplier can provide products in formats compatible with your workflows, such as:

- Required container types and closures
- Media volumes and presentations
- Packaging suitable for your handling and storage conditions

Consider whether the supplier can adapt to future needs, including changes in:

- Packaging or formats
- Order volumes
- Contamination control strategies

Flexibility at this stage reduces the risk of disruption later.

Evaluation Step 3: Review Supplier Capability Through Audit (where practical)

Document review alone is rarely sufficient. Where feasible, an on-site audit provides valuable insight into how the supplier operates in practice.

Key areas to assess include:

- Raw material sourcing and control
- Contamination control measures
- Storage and handling practices
- Cleanroom classification and environmental monitoring
- Quality control testing, including evidence of homogeneity and stability

Reviewing how batches are tested—for example, sampling at the start, middle, and end of production runs—helps demonstrate manufacturing consistency.

Evaluation Step 4: Evaluate Communication and Risk Management

Effective communication is critical when issues arise. Review how the supplier:

- Manages complaints and deviations
- Investigates failures or non-conformances
- Communicates during urgent or unexpected situations

As part of a broader risk-mitigation strategy, consider whether maintaining a secondary supplier is appropriate. Smaller or more agile suppliers can be valuable for continuity if a primary supplier experiences disruption.

Only once a supplier has successfully passed evaluation should validation be considered.

Validation—Confirming Performance and Consistency

Validation provides the documented evidence required to confirm that the supplier's prepared microbiology media perform consistently and reliably in routine use. It builds directly on a successful evaluation stage.

Validation Step 1: Perform Comparative Performance Testing

Validation typically involves comparative testing between media from the new supplier and existing, approved products. Confirm that:

- Microbiological performance meets pharmacopeial expectations
- Recovery rates align with defined acceptance criteria
- Results demonstrate equivalent or acceptable performance

In some cases, testing may extend beyond minimum regulatory requirements by including additional organisms to provide broader assurance.

Validation Step 2: Define and Apply a Validation Protocol

Before testing begins, establish a clear validation protocol that defines:

- Scope and objectives
- Test methods
- Acceptance criteria
- Number of batches to be assessed

A well-documented protocol provides a consistent framework for evaluating results and supports audit readiness.

Validation Step 3: Assess Batch Consistency

Testing multiple batches is essential to demonstrate lot-to-lot consistency. While three batches are commonly used as a minimum, the appropriate number should be determined based on:

- Product characteristics
- Intended use
- Internal risk assessment

Consistent results across batches help confirm process control and manufacturing robustness.

Validation Step 4: Review Stability and Shelf-Life Data

Validation should also consider long-term stability.

Request and review shelf-life data to confirm that media performance is maintained throughout the stated storage period. Routine stability testing provides confidence that products remain fit for purpose under defined conditions.

Validation Step 5: Implement Change Control and Ongoing Monitoring

Transitioning to a new supplier requires robust change control. Validation documentation should typically include:

- Approved validation protocols
- Test results and supporting data
- Risk assessments
- Performance Qualification (PQ) reports confirming acceptance criteria have been met

Following implementation, ongoing performance monitoring supports continued compliance and confidence.

Using This Guide

Evaluation and validation serve different but equally important purposes. Evaluation establishes supplier suitability; validation confirms product performance.

Following this structured, risk-based approach and using the checklists below helps laboratories introduce new suppliers of prepared microbiology media with confidence, supporting compliance, operational continuity, and reliable microbiological testing.

analytichem
your science enabled

Supplier Evaluation and Validation Checklists

Evaluation Checklist

- [ ] Operates within appropriate GMP-aligned quality framework
- [ ] Relevant pharmacopeial compliance confirmed
- [ ] CoA reviewed and acceptable
- [ ] Product formats compatible with operational requirements
- [ ] Demonstrates adaptability to future needs
- [ ] Audit completed or sufficient evidence reviewed
- [ ] Raw material sourcing and contamination control assessed
- [ ] Quality control testing and batch homogeneity demonstrated
- [ ] Complaint handling and communication processes reviewed

Validation Checklist

- [ ] Validation protocol defined and approved
- [ ] Comparative performance testing completed
- [ ] Acceptance criteria met for all required organisms
- [ ] Multiple batches assessed and consistent
- [ ] Shelf-life and stability data reviewed
- [ ] Change control documentation completed
- [ ] PQ report approved
- [ ] Ongoing monitoring plan in place

America & Asia
salesna@analytichem.com

EMEA
info@analytichem.com

www.analytichem.com