



Cherwell's Step-by-Step Guide to Evaluating and Validating a New Supplier of Prepared Media

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Switching prepared media supplier is a major decision requiring detailed evaluation and validation processes to ensure successful transition. This guide covers the steps needed to evaluate potential suppliers and validate their products, providing confidence in the quality, compliance, and reliability of a new supplier.

1. Ensure Compliance with Quality and Regulatory Standards

Begin by assessing whether potential suppliers meet the necessary quality and regulatory standards. For GMP-regulated sectors, the media must align with pharmacopeia guidelines, ensuring it meets strict standards for sterility, microbial recovery, and consistency.

For industries like food and water testing, focus on the supplier's quality credentials such as quality system certifications ISO 9001, and recovery rates, as well as their production practices. It's essential to request a Certificate of Analysis (CoA) to confirm the supplier's quality standards and product consistency.

Why this is important: Adhering to regulatory standards ensures that the media will perform as expected in your operations. Using a supplier that complies with recognised standards helps mitigate the risk of contamination or quality failure, which could disrupt your production and compromise product safety. Verification of quality and compliance is an essential foundation for a successful supplier relationship.

2. Assess Product Configuration Compatibility

Evaluate the supplier's product configurations to confirm compatibility with your specific operational needs. Prepared media can be supplied in various packaging options, cap types, formats and fill volumes. Ensuring that these options align with your storage, handling, and usage requirements is essential. For example, specific cap types or fill volumes might be necessary to maintain sterility or optimise storage. Clearly outlining the specification for the media, such as sterility, pH range, growth promotion and storage conditions, are also important factors.

Why this is important: Compatibility with your workflows prevents costly adjustments and allows the new media to integrate seamlessly into your existing operations. Selecting a supplier that can meet your configuration needs not only minimises disruption, but also enables efficient, consistent use of the products. A supplier that's unable to accommodate your required configurations may hinder productivity and increase costs.

3. Conduct On-Site Audits and Facility Inspections

Request a site audit to gain direct insight into the supplier's facility and practices. An on-site visit allows you to observe cleanliness standards, raw material handling, environmental control measures, and cleanroom procedures first-hand. This is particularly important for industries requiring strict hygiene standards, as it provides assurance that the supplier is capable of producing high-quality products consistently. If a supplier is reluctant to provide access, this could be a red flag.

Why this is important: An in-person inspection provides a level of assurance beyond paperwork, email or phone contact, allowing you to judge for yourself that the supplier follows best practices and maintains stringent quality controls. This step ensures that the supplier's practices align with their documented claims, and that they uphold the quality standards essential for the success of your business.

4. Review Communication and Issue Management Practices

Effective communication is vital to any supplier relationship, so it's essential to evaluate the supplier's responsiveness and issue management processes. Observe how promptly they respond to queries and handle issues, whether technical or logistical. A responsive supplier with reliable issue management can prevent potential delays and reduce the impact of unexpected challenges, especially in time-sensitive industries.

Why this is important: Good communication fosters a reliable partnership, where both parties can quickly resolve issues and prevent disruptions in the supply chain. A slow or unresponsive supplier could lead to delays, operational bottlenecks, and even damage your own reputation if you can't deliver on schedule. Ensuring that your supplier is communicative and solutions-oriented helps establish a smooth, cooperative relationship from the start.

5. Evaluate Long-Term Relationship Potential

Consider the supplier's ability to meet your evolving needs over time. A long-term supplier should be capable of scaling up production, adapting to new product configurations, and shifting with changing market demands. Enquire about their capacity to grow, and investment in future capabilities. Their response will help you gauge whether the supplier can support your company's growth and continue delivering quality media, thereby avoiding the need to change suppliers again within a relatively short space of time.

Why this is important: A supplier who can grow with you reduces the need for repeated validation processes and costly transitions in future. This ability to form a lasting partnership brings stability to your supply chain, and helps ensure that as your business expands, your supplier can keep pace with your evolving needs. Choosing a supplier that can support long-term goals saves both time and resources.

6. Validate the Product's Purpose and Effectiveness

After shortlisting suppliers, test their products to confirm that they're fit for purpose in your operational environment. This involves performing tests to verify that the new media delivers expected results under real-world conditions, whether for microbial recovery, sterility, or other critical metrics. This step helps determine that the media aligns with your specific requirements, and functions correctly within your production processes.

Why this is important: Validation testing provides confidence that the new supplier's media will perform consistently, ensuring compliance and quality. This preliminary testing is crucial before making a

significant investment in a new supplier, as it mitigates the risk of costly disruptions and compliance issues after switching.

7. Conduct Thorough Testing and Certification

Once initial testing is complete, carry out more rigorous testing to verify consistency and quality across batches. Compare the new supplier's media to your current product and conduct tests specific to organisms listed in pharmacopeia guidelines, as well as any additional organisms relevant to your monitoring needs. This stage confirms that the new product meets all quality and compliance requirements.

Why this is important: growth promotion testing ensures that the new supplier's media can match or exceed the performance of your existing products, helping you avoid unexpected quality variances that could impact production. Establishing quality benchmarks through certification is essential for GMP environments, where regulatory compliance is critical.

8. Manage Product Variations with Quantitative Controls

If the new media product offers different configurations or packaging options, validate these variations to make sure they still meet your quality expectations. Use quantitative testing methods to assess recovery rates, sterility, and other performance indicators. This stage confirms that any new configurations are as effective as previous products.

Why this is important: Each product variation needs to meet the same quality standards as the main product. This testing prevents inconsistencies in quality and ensures that all media configurations perform as required. This is particularly important if different configurations are necessary for specific applications within your operation.

9. Test Multiple Batches for Consistency

Perform batch testing by sampling multiple batches (three or more) to verify consistency in quality and performance across different production runs. This testing should include all relevant organisms and quality metrics, such as recovery rates, to confirm that the supplier can maintain product uniformity.

Why this is important: Batch testing confirms that the supplier's production process is stable and capable of delivering consistent quality over time. It's a critical step in ensuring that your supplier can reliably meet your standards, safeguarding your operations against fluctuations in quality that could affect your results.

10. Verify Long-Term Stability of the Media

Review shelf-life data from the supplier and, if possible, conduct your own stability tests to confirm that the product maintains its quality over the expected shelf life. This involves assessing both short-term performance and long-term stability.

Why this is important: Verifying stability is essential to prevent quality degradation over time, which could lead to compliance issues or operational disruptions. Ensuring that the product remains effective throughout its shelf life provides security and reduces waste due to expired media.

11. Implement Change Control and Documentation Protocols

Once validation is complete, manage the transition through a structured change control process. This includes creating detailed documentation to record the transition process, ensuring all stakeholders are informed, and updating regulatory bodies as needed, particularly for GMP compliance.

Why this is important: Change control and thorough documentation ensure a smooth, compliant transition to the new supplier. Properly documented transitions provide a reliable reference for audits and regulatory reviews, demonstrating that due diligence was followed at each stage. This final step solidifies the transition, keeping all parties accountable and providing a clear record of the process. Thorough documentation also enables evaluation and revalidation of any changes the supplier may make in future, that could impact media performance and compliance.

LOOK FOR A RELIABLE, ADAPTABLE PARTNERSHIP FOR QUALITY AND CONFIDENCE

By following these comprehensive steps, you can make an informed decision when selecting and validating a new supplier of prepared media. This guide not only ensures compliance and quality, but will also help you establish a stable, long-term partnership with a supplier capable of supporting your operational needs, and adapting as your business grows.

For information about Cherwell's Redipor® range of prepared media products, available as both off-the-shelf products and customised to your specific requirements, [contact our team](#).

Checklist

- Compliance** – Confirm adherence to industry standards (GMP, pharmacopeia, ISO standards)
- Product Fit** – Verify configurations meet operational needs
- Site Audit** – Visit facility to assess quality practices
- Communication** – Check responsiveness and issue handling
- Growth Potential** – Ensure capacity for future needs
- Effectiveness Testing** – Test performance in your environment
- Certification** – Confirm quality matches current media
- Configuration Testing** – Validate product variations
- Batch Consistency** – Test multiple batches for uniformity
- Stability** – Review and, if needed, test shelf life
- Change Control** – Document transition and update stakeholders



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