

## Evaluating the Benefits of Outsourcing Microbial Identifications to a Contract Laboratory

### *Introduction*

It has become routine practice for many pharmaceutical, medical device, nutraceutical and personal care companies to use external resources to facilitate their manufacturing processes. The reasons they seek external support is influenced by a number of factors, including: lack of sufficient internal resources, cost reduction, and process quality improvement by gaining technical expertise without accruing capital investment costs. Many organizations view outsourcing as a way to improve efficiency as witnessed by the growth trend in outsourcing operational activities and testing. For organizations that have modest internal manufacturing (e.g. early stage biotech companies), outsourcing is a highly desirable solution. Companies that have higher levels of internal manufacturing capacity may strategically choose to outsource their microbial identification work because the outsourcing laboratory offers phylogenetic expertise, improved quality of results and cost savings. By judiciously selecting which projects to internalize and which to outsource, the use of available capacity and capabilities can be optimized across a portfolio of product lines or manufacturing sites enabling the company to concentrate on its own market core capabilities.

### *The Evaluation Process*

It is not uncommon to find companies outsourcing their microbial identification testing to contract laboratories to improve their business practices as part of “Lean Quality” initiatives. In QC Microbiology, significant time and resources are devoted to performing a multitude of tasks: preparing media, monitoring production areas for airborne organisms, testing water, surface and personal gowning contaminants, performing assays for bioburden, sterility and growth promotion to support product quality, risk assessment analysis, preparing documentation, execution of validations to support facility changes, tracking and trending isolates and the list goes on and on. Microbial identification is one functional area within the job spectrum that can be outsourced to a specialized contract laboratory service to acquire greater operational efficiency and quality. By outsourcing the identification step, staff time can be diverted and reorganized to perform these other tasks. Experts in testing, taxonomy and data interpretation can then perform the critical responsibility of microbial identification, yielding greater savings and improved accuracy. When considering the outsourcing option, managers must be prepared to purposely deliberate between scientific opportunity to improve a process, demonstrate the quality benefits and provide the monetary benefit to garner internal support for program changes. Outsourcing to a contract laboratory service can provide both a cost savings and value to your brands.

Many companies reach the decision to outsource microbial identifications because they can improve the effectiveness and efficiency of their department’s overall performance at a lower cost. To help justify a decision to outsource, an accurate analysis is required to determine the cost and benefits. Presented below are six critical elements needed to evaluate a contract laboratory service for microbial identifications.

#### **1. The focus of microbial identification and characterization: Environmental monitoring isolates or clinical diagnostic microbiology.**

A contract laboratory must understand your business model and work with you as a strategic partner not just as a service provider. The laboratory must provide in-depth technical expertise and test methods designed to effectively and consistently give the most accurate species level identifications.

#### **Keywords**

Microbial Identification, Microbial Characterization, Environmental Monitoring, Contract Laboratory Services, Outsourcing Microbial Identifications, 16S rDNA Sequencing, MALDI-TOF, Phenotypic Identification

This information is required for tracking and trending your events, managing your risk, and implementing appropriate corrective actions into your processes, which ultimately result in product safety. The library database used for your microbial identifications will have the greatest impact on the accuracy, reproducibility and cost. Database libraries that are deficient will lead to errors in species level identification or inconclusive results that will directly lead to higher costs due to additional testing for identification. For superior service, the contract laboratory should perform frequent library updates encompassing taxonomic changes and adding novel organisms that have been encountered for continued reliability and relevance. Library species coverage should be reflective of not only the most frequently occurring organisms in a manufacturing environment but also the less frequently encountered environmental species. Libraries must go well beyond the IVD or clinical pathogens for the greatest ability to achieve a correct species level identification for your program.

## **2. The available technologies to meet or exceed your performance expectations.**

There are many technology platforms to consider for microbial identifications: phenotypic systems that rely on biochemical reactions, mass spectrometry (MALDI-TOF) systems that analyze ribosomal protein spectra and DNA sequence based systems. The goal is finding the right platform for microbiological identification that is accurate, robust and reliable for the purpose of monitoring the state of environmental control and reasonably priced given its performance. Objectivity is required to analyze and interpret product claims against your own historical performance indices to determine the right outsourcing solution. For example, are you seeking comparable performance or is this an opportunity to improve your performance without having to invest in a capital expenditure and costs to undertake validation studies? Some criteria to consider in a technology evaluation are: the library coverage, expected number of identifications, acceptable error rate, the number of samples requiring retest, growth requirements, sample preparation methods, test limitations, the time to first results and cost to acquire, validate and operate.

## **3. Testing and documentation under strict adherence to cGMP guidelines.**

Our industry is heavily regulated and compliance to regulatory statutes is a strict requirement. On-site vendor qualification by your Audit Team to assure that the service provider has implemented and enforces a comprehensive Quality Management System is necessary. Regulators hold different industry segments accountable to specific guidelines and standards. Depending on your industry segment, the auditors must ensure that the service provider complies and conforms to the regulations and the expectations of your internal operating standards. An audit of the laboratory should include the validation process used to determine new entries or taxonomy corrections to the library database.

## **4. Capacity and flexibility to meet your demands.**

Business needs are dynamic. When you are contracting a service, you need to know the impact your business demands have on your supplier. Interview your prospective provider to determine the impact that your potential sample volume will have on their operation and ability to deliver results in the expected timeframe you need to carry on your operation. Any reliable contractor will know their volume capacity limits and operational constraints to deliver timely results. Volume capacity, testing and sample preparation methods can drive turnaround times. Business is not only about making the sale. It is about delivery of the promise made to you. You should be seeking a provider that is flexible in order to meet your business and operational objectives. For routine identifications, long turnaround times (TAT) may be acceptable (1-2 weeks). However, when an adverse event occurs, an excursion or a sterility failure, timing for a result is critical and working with a flexible partner that can deliver results quickly (same day from an isolated colony) for an investigation is essential for your operation. The intangible benefits of flexible TAT's can minimize the economic impact to the manufacturing operation by accelerating recovery time from contamination events while not overspending on routine environmental isolates. The platform used for identifications can dictate the best case and TAT before a result is available. Classical phenotypic methods that depend on biochemical reactions catalyzed by the organism can be variable, and dependent on growth parameters. Most of these systems require off-line testing such as Gram stain, oxidase, coagulase tests, etc., before determining the appropriate test card. These factors can contribute to a longer TAT. Contrary to the typical phenotypic methods, MALDI-TOF and DNA sequencing do not require upfront tests and can yield results within a fraction of day.

## **5. Sample preparation and shipment convenience.**

When enlisting the services of a contract laboratory ease of use is an important consideration. Sample preparation and requisition forms should not hinder one's ability to send microbial samples for identification. Sample preparation methods are driven by the methodology. For example, phenotypic methods require a live culture plate or slant, shipped overnight. Alternatively, a viable colony is not required for genotypic methods. For this reason, alternative shipping methods can be utilized such as FTA Elute Micro Cards, DNA extraction preparations or Ethanol preparations of your isolates. These alternative shipping methods save shipping costs, and allow for original sample plate retention. MALDI-TOF technology, which normally does require fresh culture for identification, does have alternative sample prep methods in lieu of shipping fresh plates. Ethanol preparations can be used provided the culture was extracted less than 48 hours after growth appeared, the culture was not previously stored at refrigerator temperatures and the sample did not begin to sporulate. These alternative shipping methods allow customers with multiple sites to

ship samples from anywhere in the world and have ID results of uniform quality. These alternative shipping methods must include qualified validation studies. The use of electronic, or web secure, communication for request forms for sample identification testing and test results can also result in time and monetary savings.

## 6. Sample identification price comparison.

Support from internal management to outsource requires a financial analysis to demonstrate that you can achieve comparable or improved performance at a cost savings over in-house testing. This demonstration must include more than comparing your annual reagent and consumable costs divided by the annual number of identifications. To determine your true cost per sample identity requires an analysis that includes investigation of both fixed and variable costs attributed to obtaining identifications as well as the inclusion of expected key performance indicators. The model shown is an example of a complete cost calculator for purchasing a sequencer to determine the true cost per sample identification. Assumptions have been made for providing a model but each lab needs to adjust as per their specific situation.

### Assumptions made in this model are:

1. Average monthly volume of 50 samples
2. Cost of a new sequencing platform
3. Amortization rate of 48 months
4. Compliance expenses for performing IQ, OQ, PQ and validation studies
5. Training expenses
6. Overhead for facilities and space
7. Fully loaded labor rate/benefits of \$100/hr
8. First pass identification rate of 60% based on monthly volume. Retesting samples are required due to equipment failures, laboratory errors and low confidence results. Samples with missing library entries are not retested
9. Identifications are obtained upon an additional retesting rate of 27%
10. Assumes 13% of samples requiring an ID are outsourced

Fixed and variable expenses heavily influence your true costs above annual reagent and consumable costs. In comparison, outsourcing to a known contract laboratory for a comparable genotypic identification and turnaround times at the same monthly volume given in the model above, can range from \$75- \$100 per sample. This example shows that a company potentially can achieve savings by outsourcing.

### Conclusion

To understand the benefits of outsourcing, a complete and thorough analysis of performance, quality, service and pricing allows an informative internal decision on your return on investment. A fair comparison of vendor prices truly requires understanding all the elements contributing to the true cost per sample identification. A complete investigation of your options to outsource microbial identification to the right Contract Laboratory for your business needs, can lead to more accurate results, cost reductions and diverting staff time to other key tasks to gain overall improved efficiency for your department.

| <b>Step 1. Fixed Costs &amp; Investments</b>             |                                |                         |                           |                        |
|--|--------------------------------|-------------------------|---------------------------|------------------------|
|  | <u>One Time</u>                | <u>Per Year</u>         | <u>Per Month</u>          | <u>Per Sample</u>      |
| Equipment  | \$ 125,000                     |                         | \$ 2604.17                | \$ 52.08               |
| Software & Libraries                                     | 30,000                         |                         | 625.00                    | 12.50                  |
| Service Contracts  |                                | \$ 15,500               | 1291.67                   | 25.83                  |
| IQ, OQ   | 6,000                          |                         | 125.00                    | 2.50                   |
| PQ Documentation & Analysis                              | 10,000                         |                         | 208.33                    | 4.17                   |
| Facilities   | 5,000                          |                         | 104.17                    | 2.08                   |
| Validation   | 20,000                         |                         | 416.67                    | 8.33                   |
| Training (1 FTE for 1 month)                             | 10,000                         |                         | 208.33                    | 4.17                   |
| <b>Total:</b>  | <b>\$ 206,000</b>              | <b>\$ 15,500</b>        | <b>\$ 5,583.33</b>        |                        |
| <b>Amortized Expenses / Sample:</b>                      |                                |                         |                           | <b>\$ 111.67</b>       |
| <b>Step 2. Lab Expenses</b>                              |                                |                         |                           |                        |
|  | <u>Time/ Sample/ FTE (min)</u> | <u>Max Samples/ FTE</u> | <u>FTE Loaded Rate/Hr</u> | <u>Cost Per Sample</u> |
| Labor + Benefits   | 15                             | 500                     | \$ 100.00                 | \$ 25.00               |
| Reagents & Consumables                                   |                                |                         |                           | \$ 24.00               |
| <b>Labor, Overhead &amp; Materials per Sample:</b>       |                                |                         |                           | <b>\$ 49.00</b>        |
| <b>Labor, Overhead, Materials, Equipment per Sample:</b> |                                |                         |                           | <b>\$ 160.67</b>       |
| <b>Total Net Cost for 1st Pass:</b>                      |                                |                         |                           | <b>\$ 8,033.33</b>     |
| <b>Step 3. Performance Parameters</b>                    |                                |                         |                           |                        |
| 1st Pass Result Rate - 60%                               | Average cost / Reportable ID:  |                         | \$ 267.78                 |                        |
| Retest Rate (% of Monthly Total) - 27%                   | Cost for Retest:               |                         | \$ 686.00                 |                        |
| <b>Total Net Cost after 2nd Pass:</b>                    |                                |                         |                           | <b>\$ 8,719.33</b>     |
| Reportable IDs:  |                                |                         |                           | 44                     |
| <b>Average cost / Reportable ID:</b>                     |                                |                         |                           | <b>\$ 200.44</b>       |
| <b>Step 4. Final Sample Resolution</b>                   |                                |                         |                           |                        |
| Samples with no IDs Outsourced for Resolution:           |                                |                         |                           | 6                      |
|  |                                |                         |                           | \$ 50.00               |
| <b>Additional Costs Missing IDs:</b>                     |                                |                         |                           | <b>\$ 300.00</b>       |
| <b>Monthly Grand Total:</b>                              |                                |                         |                           | <b>\$ 9019.33</b>      |
| <b>Average cost / ID Testing:</b>                        |                                |                         |                           | <b>\$ 180.39</b>       |



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**Accugenix has the experience and technology necessary to rapidly and accurately handle all your identification needs, improve your processes and reduce your costs while helping you to protect your brands.**

It has become routine practice for many companies to use external resources to facilitate their manufacturing processes. The main drivers to outsource are lack of sufficient internal resources, cost reduction, and quality improvement by gaining technical expertise without accruing capital investment costs. Why do over 500 companies choose Accugenix as their preferred outsourcing solution for their microbial identifications?

- Our validated, relevant bacterial and fungal libraries are considered the industry's gold standard.
- Our proprietary identification services have an industry leading 98% reportable rate, and an impressive 99% on-time delivery rate.
- cGMP compliant laboratories, validated databases and robust methods ensure consistent and reproducible results required for EM programs.
- Dedicated technical support and phylogenetic experts are available to answer all of your questions.
- Our core competencies are microbial identification and strain typing, allowing your company to concentrate on its core capabilities.
- We guarantee a lower cost and higher accuracy per reportable result than in-house testing or comparable contract laboratory service providers using commercial systems.



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