Cryologics, Inc.
Specializing in Microbial Cryopreservation

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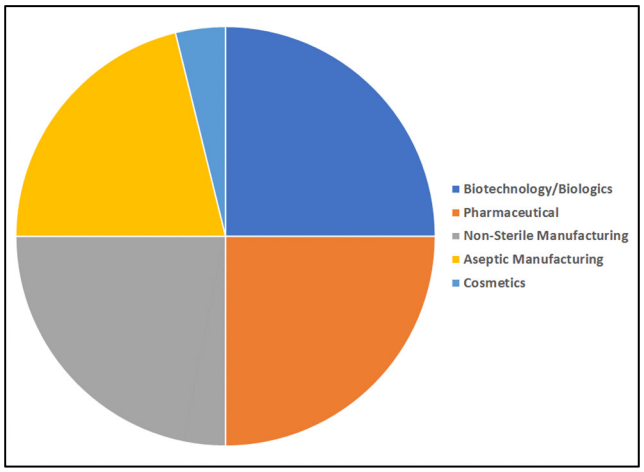
In-House Microbial Isolates: A Regulatory Perspective Webinar Survey Results Report

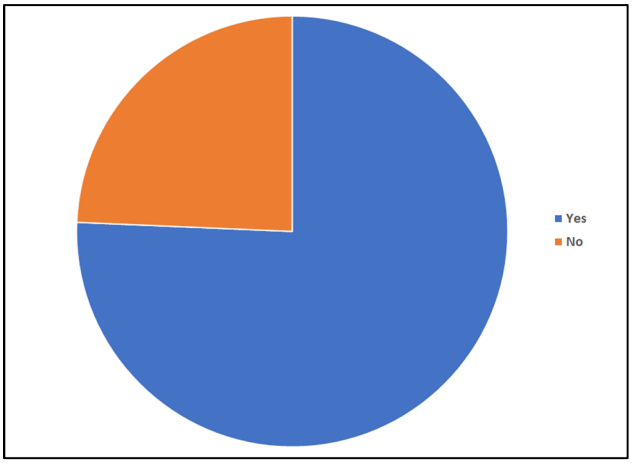
This report summarizes the results of the survey, and includes some insights into them.

1. Please indicate which answer best describes your industry.



The majority of respondents reported that they work for a biotechnology/biologics firm or a pharmaceutical firm (or both). It is encouraging that some folks from the cosmetics industry also attended! Roughly equal numbers of respondents reported that they work either for an aseptic manufacturer or a non-sterile manufacturer. The field of non-sterile manufacturing has quickly become a regulatory focus, including the use of in-house isolates in testing.

2. Do you incorporate your in-house microbial isolates in compendial tests?



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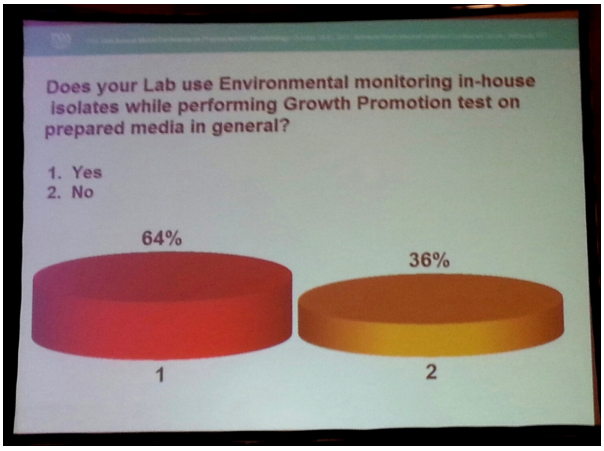
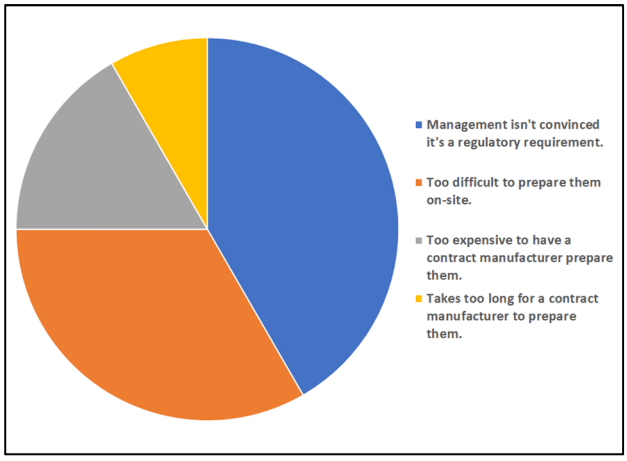
Approximately two-thirds of respondents answered that they currently use in-house isolates in their testing (and therefore are avoiding regulatory enforcement!). Interestingly, one-third currently do not (the reasons are cited in responses to the next question). If you recall from the presentation, this is consistent with the straw poll results of the question asked during the 2015 Global Conference on Microbiology:



3. If no, what is the primary reason for not using in-house isolates in your testing?



Nearly the same number of respondents indicated that either management isn't convinced it's a regulatory requirement, or that it's too difficult to prepare in-house isolates for use in testing. As was stressed so frequently throughout the presentation, the regulatory enforcement history shows that this is an Agency-wide requirement. If your management isn't convinced, then they are imperiling your firm to risk regulatory enforcement (our survey shows that there's a one-in-three chance of this happening, see Question #6). We recommend that you provide them with the presentation handout, this survey report, and a link to our bibliography page (http://cryologics.com/resources/bibliography/).

Regarding preparation of your in-house isolates for use in testing, we agree that it is very difficult. We can help! For very little cost and in very little time (other concerns noted by some respondents), you can have your isolates in a ready-to-use format.

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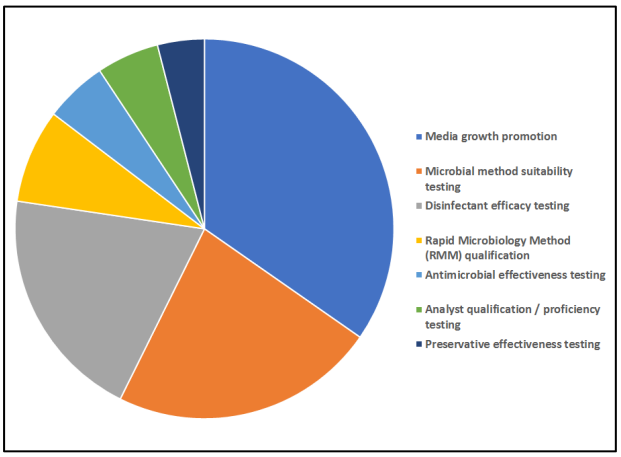
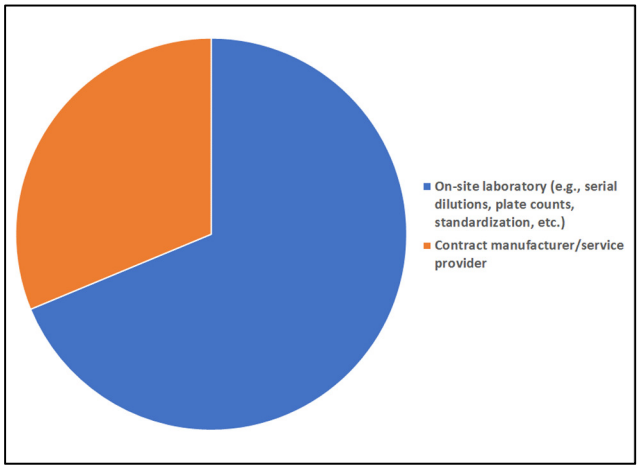
4. If yes, for which types of compendial tests do you use in-house isolates?



Media growth promotion, method suitability and disinfectant efficacy testing round out the top three tests for which respondents use their in-house isolates. Growth promotion and disinfectant efficacy testing have a long history of regulatory enforcement, as described during the presentation. It is also encouraging to see that several folks are thinking progressively with regard to implementing RMMs, and including their in-house isolates in their qualifications.

5. If yes, how do you prepare your suspensions of in-house microbial isolates?



Two-thirds of respondents reported that they prepare their in-house isolates for use in testing. As described in Question #3 above, we recognize that this is an onerous task. It consumes valuable time and resources, which could be better utilized for other laboratory tasks. For example, in a six-month period, one person spending half of his/her time to prepare the suspensions (our estimate, based upon experience) amounts to ~500 hrs. Applying the standard "salary + benefits" hourly rate of $100, that comes out to ~$50,000. And that's not including materials (or the fact that your lab analyst is unavailable for half the time). For a third of that, you could have three organisms preserved and always ready to use, and your analyst's time is freed up. Even underestimating the time

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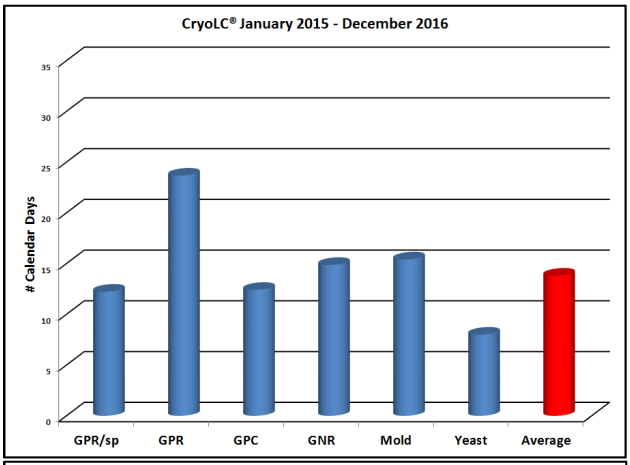
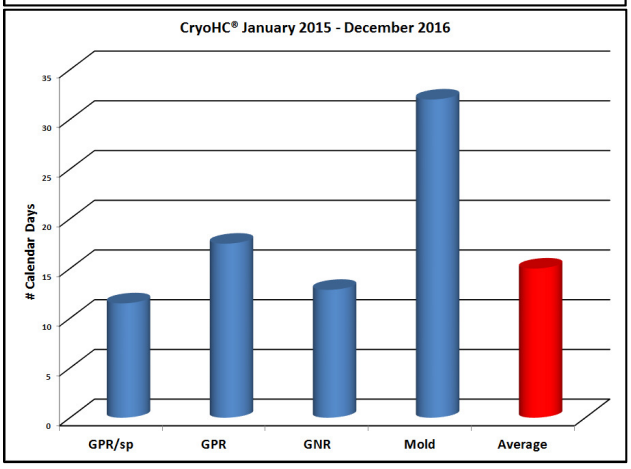
an analyst needs to prep the organisms, in the end it's still a tremendous cost savings. These are savings that you would attain and for which you would be recognized!

One-third answered that they use a contract manufacturer to prep their organisms. Respondents' answers to Question #3 above are revealing. Several reported that it is too expensive and takes too long for a contract manufacturer to prep in-house isolates. The one-third who answered that they use a contract manufacturer (and who don't use Cryologics) undoubtedly experience these frustrations. As described during the presentation, Cryologics' prices and turnaround times are the lowest in the industry. Our pricing is fully published on our website, not a claim that our competitors can make. And if you recall from the presentation, our average turnaround time is just *two weeks*, not *months* like our competitors:





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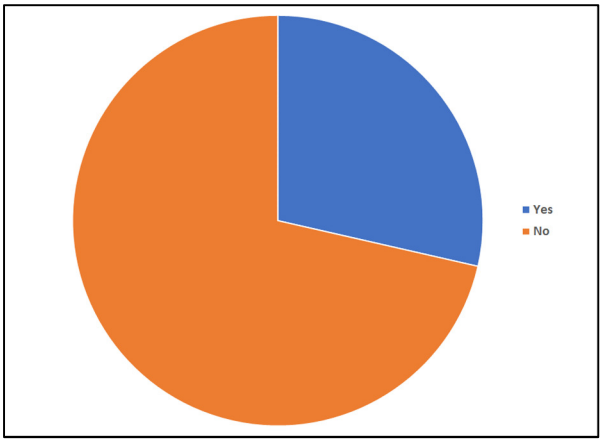
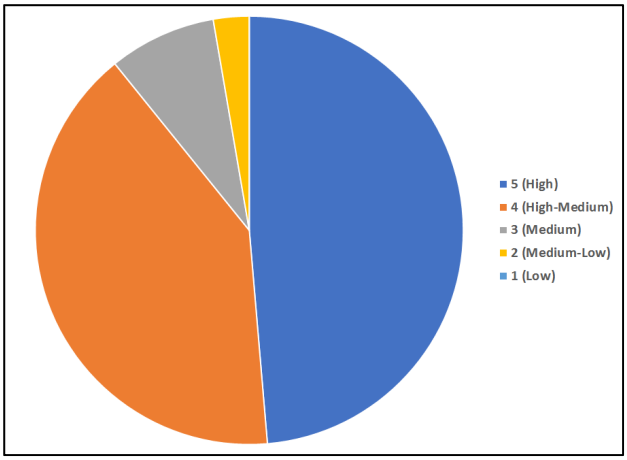
6. Have you experienced regulatory enforcement or feedback requiring you to use in-house microbial isolates in testing?



As described in Question #2, one-third of respondents answered that they do not incorporate their in-house isolates in compendial testing. Interestingly, and coincidentally, one-third of respondents answered here that they have experienced regulatory enforcement for not doing so. Given the low cost and turnaround time that Cryologics' offers, it is an easy fix to put into place and avoid a one-in-three chance of becoming the object of regulatory enforcement!

7. Please rate the value of the information presented in this webinar.



We are very pleased that the majority of respondents found high value in the information presented during the webinar!

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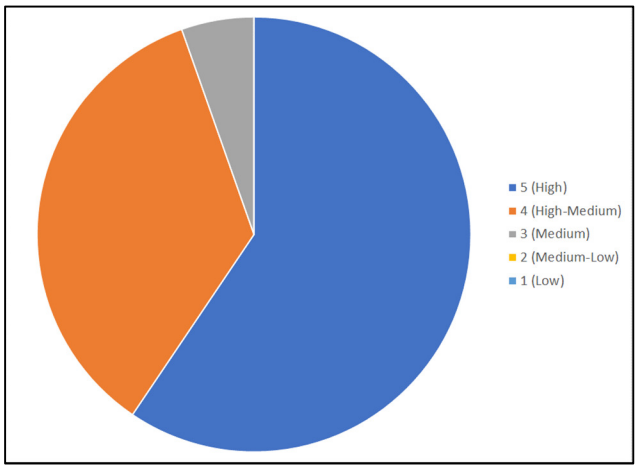
8. Please rate the overall quality of the presentation.



Again, the majority of respondents rated the quality of the presentation highly. Thank you!

Please don't hesitate to contact me personally if Cryologics can be of assistance. As fellow Microbiologists, we are absolutely confident that our services will represent savings in terms of time, materials and efficiencies.

We look forward to providing free webinars in the future!

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