bioPharma

The international newsletter for bioMérieux pharmaceutical & cosmetics partners

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BIOMÉRIEUX INDUSTRY

Focus on Efficient Microbiology

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EDITORIAL

Nicolas Cartier
Corporate Vice-President
Industrial Microbiology

Welcome to the 8th issue of bioPharma, the newsletter for Quality Assurance professionals in the Pharmaceutical, Biotechnology and Cosmetics industries worldwide.

2013 is a key year for bioMérieux as we celebrate our 50th anniversary delivering microbiology control solutions worldwide and continually innovating to meet our customer's evolving needs.

Looking at the present and towards the future, this issue is focused on efficient microbiology thanks to precise and Rapid Microbiology Methods (RMM) that are designed to improve your laboratory workflow and time-to-result. Accelerating the product release and decreasing the storage costs are of major concerns for our Company's activity. Jeffrey Weber (Pfizer Inc.) is an avid proponent of scanRDI® for sterility testing and has stated regarding RMM: *"This technology represents a shift from replacing current lab methods that provide information about a specific quality attribute towards understanding and predicting the factors that cause the microbiological effect."*
Kim Lim (Ultimate Labs - USA), an advocate of our VITEK® MS (Mass Spectrometry) system has quoted: *"If our clients' results are critical and impact human lives, then the faster we can get results to them, the better."*

In this issue we will also celebrate the 10th anniversary of BioBall® success. Seok Nam Song (Berna Biotech Korea Corp.) has been successfully using BioBall® since 2011 and explains how its precision helps perform growth promotion tests.

I would like to thank you for your sustained contribution and support to this newsletter. As you look through these pages, think of what you would like to see developed in future editions and send it along to us. Your feedback will continue to make bioPharma a valuable resource for you and your peers throughout the world.

Pfizer Inc.

INTERVIEW

Pfizer Inc.

Interviewee
Jeffrey Weber

Title
PAT Project Manager/Chairman Pfizer Rapid Microbiological Methods Steering Team

Company
Pfizer Inc.

Country
USA

bioPharma: Would you please tell our readers about you and your company?
I work for Pfizer Inc., interacting with manufacturing and research and development. I am the chairman for Pfizer Rapid Microbiological Methods steering team, charged with the implementation and replication of appropriate RMM systems across the network.

bioPharma: What types of products are tested in your facility and how did you historically perform microbial detection?
Pfizer manufactures a wide variety of products; including solid dosage, lyophilized, and sterile formulations. The majority of the testing is performed in accordance with the compendial testing requirements. Many of these assays are time consuming and require a large amount of training and expertise to be performed correctly.

ScanRDI®

bioPharma: What are some of the key reasons you decided to implement a new technology?
The driver for selection of any alternative or rapid method should be cost savings, quality – both process knowledge or human error reduction, cycle time, safety, and in some cases a strategic development for future developments. We try to avoid new technologies for the sake of novelty or a solution-looking-for-a-problem approach.

bioPharma: How did your partnership with bioMérieux start?
bioMérieux is a provider of many applications and has been a key partner in developing and implementation of many routine lab supplies (plates, agar, etc.) and has worked with Pfizer to seek customer input for the needs of the future applications.

bioPharma: How was the integration of ScanRDI (training, workflow) in your microbiology lab?
The initial use for the ScanRDI in Pfizer was for investigations and rapid screening (risk reduction) of high value samples. The ScanRDI was a great addition to the suite of tools to provide rapid low level quantification that allowed manufacturing to return back to operations. Through special case investigations, the units easily paid for themselves by reducing risk and allowing the sites to target the scope of investigations.

bioPharma: Today can you point out the benefits in using ScanRDI in routine for your microbial detection?
After a close look at the real costs of sample handling, records review, and supply chain – the ScanRDI has found a role for routine sterility testing at one of the Pfizer facilities. The reduction in labor of these activities has yielded an annual savings of approximately $55,000 and enables the site to make effective business decisions for each lot.

bioPharma: As an expert in rapid methods you have tried and worked with several different methods. What is your vision for the future of rapid microbiology in the pharmaceutical industry?
The movement of RMM systems should closely emulate the example set by process analytical technologies (PAT) that are used to monitor and control processes in a characterized manner. This will be a shift from replacing current lab methods that provide information about a specific quality attribute towards understanding and predicting the factors that cause the microbiological effect. An example may include a method that monitors the absence of microbes in the total volume of the product as it is filled in vials rather than testing a small subset of the lot; this improves quality assurance and decreases product loss for testing.

Berna Biotech Korea Corp (Crucell)

INTERVIEW

Interviewee
Seok Nam Song

Title
Senior microbiologist

Company
Berna Biotech Korea Corp

Country
Korea

bioPharma: Can you tell us your name and position?
My name is Seok Nam Song and I am working as a senior microbiologist in a microbial laboratory in Korea.

bioPharma: How long have you been using BioBall®?
My lab has been using BioBall® products since 2011.

bioPharma: What type of BioBall® have you been using? Standard off-the-shelf product (Singleshot, Multishot, High & 10E8) and/or custom products?
We have been using Multishot for Growth promotion test of several types of media used for microbiological tests in the microbial laboratory.

bioPharma: Have you been satisfied with the performance of BioBall®?
We have been using BioBall® products with a great deal of satisfaction.

bioPharma: How has usage of Custom BioBall® helped you in your daily routine?
As you may know this well, Growth Promotion Test is very important to make sure that test results generated from our laboratory are reliable and reflect true condition of samples. However I think, it is not easy to meet a supplier who can provide reliable products for GPT which have sustainable and high quality. In light of this fact, I think that BioBall® is one of the products that is the closest to these conditions.

bioPharma: What features of BioBall® appeal to you the most?
Needless to say, I think it comes from high quality product and reputation that BioBall® has accumulated so far in this area.

bioPharma: Are you satisfied with the level of service you have received from bioMérieux?
I am satisfied with services that have been provided from my bioMérieux contact person. He is a really warm hearted and well trained person trying to help his customers get the answer they want to hear.

bioPharma: Would you recommend BioBall® usage to other customers?
Of course, if I have a chance, I will recommend BioBall® to others working in this field.

Please note that interview answers above are based on an individual opinion of the interviewee. It does not represent opinions of the company, Berna Biotech Korea Corp.

PDA Conference in Berlin

Around 120 attendees from the pharmaceutical industry

The Parenteral Drug Association conference on Pharmaceutical microbiology was held on February 26-27, 2013, in Berlin.
The theme for this year's conference was "Product Quality Microbiology – Keys for Successful Implementation".

The first day of the conference targeted the contamination control whether environmental or of the product. The first session had a talk on the use of new technologies for head-space analysis of sterile media fills. Followed by case studies on microbial control strategies with a special emphasis on observed gaps and what could be done to mitigate these in the future. FDA was also here to give a talk on regulatory mandates and inspectional observations. Of course the never-ending discussion on objectionable microorganisms happened, with questions from industry about whether to have a list of objectionable microorganisms. FDA answered that a list is a start but cannot be sufficient.

The second and third session of the first day were mainly focused on water monitoring and biofilms. bioMérieux invited the French INRA to give a talk about the science of biofilms. This talk, filled with examples and videos, induced a high enthusiasm from the audience, even though it showed it's not that easy to get rid of those biofilms!

The last day focused on new technologies, rapid microbiological methods and hot topics in microbiology. During that day, Scan RDI® was presented as a bioMérieux product, with a case study from Baxter, Italy, about how they did their validation, and the regulatory pathway that can be somehow difficult sometimes. A discussion followed where regulatory agencies explained how they are willing to help implement those alternative methods, with emphasis on the importance of exchange between manufacturers and regulatory agencies to make things smoother.

Objectionable microorganisms was probably the subject of this debate

The science of biofilms attracted many attendees

BaseClear BV

INTERVIEW

BaseClear BV

Interviewee
Richard de Winter

Position
Director DNA sequencing and Microbiology

Company
BaseClear BV

Country
Netherlands

bioPharma: Would you please tell our readers about you and your company?

BaseClear is an independent and ISO17025 certified company specialized in molecular testing. The company was founded in 1993 and known to be a reliable partner in DNA testing and Microbiology. We offer our partners complete packages for identification, strain typing and genome analysis of micro-organisms. I am head of the DNA sequencing and Microbiology department. In my department 2 product specialists and 8 technicians are working on various Microbial and sequencing assignments.

bioPharma: What types of products are tested in your facility and how did you historically perform microbial identification testing?

We have started more than 10 years ago with our "home-brew" microbial identification service based on PCR and sequencing of the 16S rRNA of bacteria and the ITS genes of fungi. After this we started to implement other (microbial) services, mostly on request of the clients like MLST and strain typing. Also we extended our Identification service by testing more and other genes. This identification services were a success right away and clients came from the food, pharmaceutical and biotech industry. Blasting of the sequencing results (sequencing was and still is our core business) was done in public databases. When we noticed that results became less reliable due to "pollution" of the public databases with wrong sequences, our search for a validated, more controlled system started. We purchased the MicroSEQ® system from Applied Biosystem/Life Technologies (also based on PCR and sequencing but using validated kits) and all of its validated databases. Unfortunately the kits are extremely expensive… We still offer various possibilities for microbial identification and strain typing, validated and non-validated to our clients so they can make a choice, based on their needs. For some of our clients the need for faster and cheaper identification results became more important over the past few years. For the coming years we think that Next-generation sequencing will become more and more important. Right now it is used for testing communities of microbes (metagenomics) but when the sequencing prices drop even further, Next-gen technology can also be used for straintyping of bacteria. We have done the first typing experiments using our current Next-gen platform (Illumina HiSEQ 2500) and results looked okay. Challenge is the interpretation of the data for which we are now developing a routine pipeline…

bioPharma: What are some of the key reasons you decided to implement a new identification technology?

When we heard about the possibility to produce fast and cheaper identification results we were interested right away.

bioPharma: How did your partnership with bioMérieux start?

We have tested a MALDI-TOF system several years ago (before the VITEK® MS came to the market) but we were not convinced of the additional value for BaseClear. Few years later, when bioMérieux introduced the VITEK® MS, we re-evaluated and decided to test the VITEK® MS and the system from a competitor again using a panel of bacterial and fungal strains. Databases had significantly improved then. Both systems performed well but we have decided to start a partnership with bioMérieux. First and most important reason for choosing bioMérieux is the extensive microbial knowledge present within the company. This knowledge is, to our opinion, essential for building up a robust and reliable database. Secondly, the way the partnership between BaseClear and bioMérieux was setup is very attractive for all parties involved (bioMérieux, BaseClear AND clients). Whenever we find microorganisms that cannot be identified using the VITEK® MS, the sample is automatically identified using sequencing. When we have permission from the client, the sample is re-cultured, and new Maldi-profiles are generated using our second VITEK® MS system containing the RUO (research) database. After checking and validation of all results (sequencing and Maldi-TOF) by bioMérieux, the new results are added to the database. Next time the organism is found, it will be recognized in the database and this will result in a reliable identification. This way the database is extended fast and in a validated/controlled manner, according to agreed specifications set by bioMérieux. Clients from bioMérieux identification systems (API®, VITEK-1 or -2, VITEK® MS, etc.) can benefit from the cooperation between BaseClear and bioMérieux because they can send in problematic organisms for identification. This way bioMérieux and BaseClear hope to receive as much problematic organisms as possible, with the aim to extend the databases with new species at a fast rate.

Microbiology technologist working in the lab

bioPharma: How was the integration of VITEK® MS (training workflow…) in your microbiology lab?

We have two MALDI-TOF systems: the IVD version is used for the identification of client samples and the RUO system with the saramis database is used for validation of new species, in cooperation with bioMérieux. We have decided to train all technicians on the IVD (production) machine and only 3 on the RUO machine. Reason for this is that the RUO system is run only ones or twice a week, special protocols are used and handling of the machine request a little more skills from the technicians/product specialist. Training on both systems was done by Valerie Monnin from bioMérieux (R&D) in La Balme. She did a perfect job, was very open and patient. Because of our cooperation with bioMérieux in order to further increase the content of the IVD database with validated spectra, we have monthly meetings with her.

bioPharma: Today can you point out the benefits in using VITEK® MS in routine for your microbial identification?

Most microbial identifications are performed internally using many different biochemical or phenotypic characterization systems. Only the difficult cases, misidentifications and organisms of which the identity has to be confirmed, are sent to BaseClear. This means that we do not receive the usual spread of organisms found in environmental monitoring. Because we only receive the difficult cases none identified by many systems on the market, in addition of VITEK® MS MALDI-TOF technology we provide to our customers without extra costs backed up by our DNA sequencing service so that our clients can always be secured from a valid identification result. Because we generate sequence and MALDI-TOF results from a lot of problematic microorganisms, expectation is that the percentage of successful MALDI-TOF identifications will significantly improve over the coming months.

bioPharma: Did you know bioMérieux before using VITEK® MS and if so, which solution did you use?

Everyone working in microbiology knows bioMérieux but since we are mainly specialized in genetic testing instead of traditional microbiology, our contact with bioMérieux was limited. But we have done big sequencing projects together with the different R&D department in France before we purchased the VITEK® MS so also for our Sequencing department bioMérieux was and still is one of our key clients.

Ultimate Labs

INTERVIEW

Ultimate Labs

Interviewee
Kim Lim

Title
CEO

Company
Ultimate Labs

Country
USA

bioPharma: Describe your company and vision.
Ultimate Labs is a San Diego-based microbiology laboratory that helps save lives by testing for harmful microbes. The vision for the company is to be innovative and cutting edge. We like to challenge the status quo, such as those conventional methods not proven to be the most efficient and effective way to do testing. We continuously improve our technology, instruments, processes, and staff.

bioPharma: What benefits do you feel rapid microbiology methods will have on your laboratory?
Rapid microbiology methods help us provide better service to our clients and make us more efficient internally. If we can run 96 samples at a time instead of 12 samples, then we can save time and increase productivity. If our clients' results are critical and impact human lives, then the faster we can get results to them, the better. But equally important is how rapid microbiology methods impact our personnel. The method has to be one they can easily understand and be trained on. It can't be laborious on their end. It has to result in less errors.

bioPharma: What made you consider mass spectrometry?
We considered mass spectrometry both for the client and for ourselves. For our clients, mass spec provides the most quantitative results, most efficiently, with higher quality. For our staff, mass spec provides ease-of-use for the operator or technician.

bioPharma: How does mass spectrometry improve on quality of results?
The typical approach uses phenotypic analysis, so it's however the organism that reacts to certain biochemical test. It's the same thing with genotypic analysis. Even if you use rapid method, it's still a biochemical test. Mass spec is definitive. It has a protein profile and it's the only protein profile you're going to get.

bioPharma: Why did you choose bioMérieux?
We have a long standing relationship with bioMérieux; we have a VITEK® and purchase plates from them. They have been known in the industry to have the latest and greatest technology. They have a long history dating back to Louis Pasteur of innovating on new diagnostic tests. Like us, they are always looking to improve their processes. Now they are acquiring other companies to offer services to build that vision. We like where they are going. Their customer service is also wonderful. Their technicians, sales people, and reps, work as a team and are all helpful and knowledgeable. They want to help us grow. They say, "If you grow, we grow." They've directed customers our way; they are always willing to spread our name. We feel they are more of a partner than they are a vendor.

bioPharma: What key advantages do you feel the VITEK® MS will bring to your lab?
They key advantages of the VITEK® MS are the time savings, technology, and accuracy. We looked at other mass spec systems. The VITEK has an innovative configuration. Most mass specs take up an entire lab space because they are all horizontal. They have really made the VITEK® MS accommodate small spaces. We also like that we can build our own database. It's customizable and it allows us to do research work as well.

bioPharma: How will this impact your quality management systems?
The validation package for the VITEK® MS doesn't impact our quality management systems, it actually marries right into it. I think the challenge is that most people don't have a quality system put in place. The package bioMérieux put together for the VITEK® MS provides that quality system. In our particular case, because it is such a high quality system, and that's what we prescribe to, it was an easy transition for us.

bioMérieux Symposium in Marcy l'Étoile

The 9th annual "Current Topics and Perspectives in Pharmaceutical Microbiology" symposium

The 9th annual "Current Topics and Perspectives in Pharmaceutical Microbiology" symposium was held as usual at the Marcy l'Étoile site last May under autumnal weather conditions, although this did not cool off the intensity of exchanges! After an opening introduction made by Mr. Jean-Luc BELINGARD (CEO of bioMérieux) - highlighting bioMérieux's position in industrial microbiology and the importance accorded to the pharmaceutical sector by our company - presentations followed, concerning issues with the management of biological risks in pharmaceutical manufacturing.

From the left to the right: Benoît RAMOND (SANOFI), Jean-Denis MALLET (SNC LAVALIN), Christian POINSOT (ICARE), Robert NERI (SANOFI), Sylvie GUYOMARD (ACM Pharma), Olivier CHANCEL (MERIAL), Pierre DEVAUX (EXCELVISION)

This year's program enjoyed presentations touching on both regulatory aspects and their application at an industrial site, as well as lessons learned as reported by users who agreed to share their work experience with the audience.

- Participants spent their morning focusing on operating difficulties with biological indicators, microbiological follow-up for an aseptic filling line, and monitoring according to new USP 1 116 recommendations. This first part finished with a "Participative Session". This was an opportunity to exchange ideas on questions posed during audits which had been widely commented on by international authorities.
- The second part of the day was dedicated to issues with "biofilm" risk management in pharmaceutical water loops, extending the discussion started in 2012 on this subject, and also to the interpretation of the new EU GMP Annex 2 and the pragmatic implementation of a method for testing the integrity of sterile pharmaceutical containers.

Throughout that day, there were no less than 130 persons coming from France, Belgium and Switzerland, who were able to freely exchange ideas with colleagues and experts on current issues.

This was also an opportunity for our clients to meet and exchange ideas with bioMérieux staff (CSI, Marketing, Quality, etc.) who were there to enjoy the experience with them. This major meeting on pharmaceutical activities by the French subsidiary is a key event attended by our industrial clients. It reinforces the connection between our company and our valued partners, maintains our role as an actively involved player, and allows us to participate in the sharing of information.

The comments and feedback gathered throughout the day demonstrate the value of these sessions for our customers and encourage us to continue in this direction. The 10th annual meeting, which will be held in 2014, is already being planned following virtually unanimous requests from participants: gratifying feedback for all!

Rapid Microbiology Testing of Cosmetic and Personal Care Products **with CHEMUNEX® Technology** in partnership with YVES SAINT LAURENT

Cosmetics and Personal care products industries are microbiologically controling their products before their release on the market. They are usually doing enumeration of TVC (Total Viable Count), Yeast and Molds, and presence/absence tests of some specified microorganisms.
With the D-Count® CHEMUNEX technology, based on the flow cytometry, cosmetic manufacturing plants can release their products 2 to 3 days faster on the market than with the traditional methods.

Yves Saint Laurent (YSL) adopted the CHEMUNEX technology several years ago to release their finished products using a 24 hours TVC (Total Viable Count) Presence/Absence test.

In order to improve the quality of raw material, a partnership has been established between YSL and CHEMUNEX to develop a rapid protocol for yeast and molds detection. This protocol has been evaluated using a range of YSL products like a shampoo, lotions, powders, raw materials and creams, with validation steps from EU and US Pharmacopoeia, and from "The validation of compendial methods < 1225 >" or "the PDA Technical Report 33". The validation procedure followed the standards defined for the performance qualification (PQ).

Methods

Samples (shampoo, shower gel, lotion, powder, mascara, skin foundation, hair spray, raw material and Face and body creams) were treated as below:

- 10 g of cosmetic product (artificially contaminated or not) in 90 ml of ChemBoost C (preservatives neutralization and enrichment broth provided by AES CHEMUNEX, also used for TVC application);
- Vortex and incubate 1 hour at room temperature;
- Add 1 ml of the neutralized suspension in 20 ml bottle of enrichment broth (ChemBoost F, specific enrichment broth for yeast and molds);
- Incubate 50 hours at 25+/-2 °C to increase the detectable level of microorganisms;
- Enriched samples are submitted to blending to cut mycelium when present and then filtrated;
- Samples are then automatically labeled and analysed using the CHEMUNEX system (D-Count) with our specific reagents labeling only viable microorganisms.

A complete batch of analysis is performed within 45-60 minutes and provides the first result within 20-25 minutes. A cleaning procedure is performed between each analysis to prevent any carryover and/or cross-contamination.

For the Detection limit determination, artificial contaminations were preliminary realized at different levels with 5 different microorganisms for each product (Table 1).

Table 1

Concentration level			
Strains	Level 1	Level 2	Level 3
Candida albicans	0	5-10	50-100
Aspergillus niger	0	5-10	50-100
Mucor plumbeus	0	5-10	50-100
Penicillium glabrum	0	5-10	50-100
Aureobasidium sp	0	5-10	50-100

In parallel, contamination levels where controlled by plate count: after the 50 h incubation time, 1 ml of enriched samples diluted 1/10 were plated on Sabouraud dextrose agar and incubated 3 to 5 days at 25 °C.

Results and Discussion

CHEMUNEX's flow cytometer has been validated to demonstrate the capability to provide consistent and reliable results for the presence/absence test of yeasts and molds in a wide range of personal care products following the recommendations of EU and US Pharmacopoeia, and PDA 33.

Specificity and Selectivity of the method

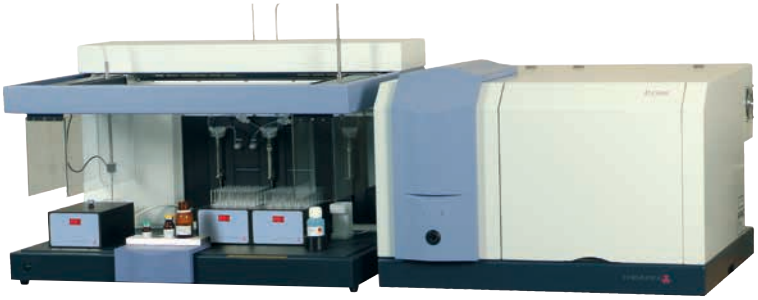
Using this protocol, Yeasts and molds strains are detected (Table 2) by the presence/absence test and there are no cross reactions with non-yeasts & non-molds strains (Table 3) after a 50-hour incubation time.

Table 2

Specificity	
Yeast	Molds
• *Candida albicans*	• *Aspergillus niger* • *Mucor plumbeus* • *Penicillium glabrum* • *Aureobasidium sp*

Table 3

Exclusivity	
• *Pseudomonas aeruginosa* • *Staphylococcus aureus* • *Bacillus subtilis spores*	• *Escherichia coli* • *Acinetobacter liquefaciens* • Industrial strains



D-Count®

Limit of detection (LOD)

LOD is here defined as the lowest number of microorganisms that can be detected with a 50% confidence, but not necessarily quantified, under the stated experimental conditions. The concentration levels used for each strain are included in table 4.

The Spearman-Karber 50% Endpoint is used to calculate the microbial analyte concentration (and confidence limits) in a given matrix that corresponds to a 50% probability of positive result. The table 5 summarizes the LOD 50% of yeasts and molds using the Presence/Absence test protocol in pure culture in 50-hour incubation at 25 °C in ChemBoost F compared to reference method on plate count.

Table 4

Concentration level				
Strains	Level 1	Level 2	Level 3	Level 4
Candida albicans	0	1,4	1,6	17
Aspergillus niger	0	0,3	0,9	19
Penicillium glabrum	0	0,5	1,1	14
Mucor plumbeus	0	0,9	2,4	15

Table 5

Relative detection level (UFC/21 ml in ChemBoost F)		
Strains	Reference method	Alternative method
Candida albicans	0.184 [0.063-0.542]	0.390 [0.109-1.398]
Aspergillus niger	0.410 [0.120-1.398]	0.384 [0.102-1.443]
Penicillium glabrum	0.225 [0.066-0.769]	0.449 [0.132-1.532]
Mucor plumbeus	0.196 [0.057-0.668]	0.292 [0.082-1.046]

Correlation of CHEMUNEX® D-Count results and Plate Count

The methods has been done in parallel during 6 months at YSL microbiology laboratory on a total of 618 tests, including artificially, naturally and non-contaminated samples. It can be seen in Table 6 a good correlation between the CHEMUNEX® D-Count method and the traditional plate counts.

Table 6

Synthesis table of results			
	Negative results Plate count	Positive results Plate count	**TOTAL**
Negative results D-Count	516	0	**516**
Positive results D-Count	10	92	**102**
TOTAL	**526**	**92**	**618**

Conclusion

The ability of the D-Count to provide a 2 days product release for Yeasts and Molds has been demonstrated with a wide range of YSL personal care products. In all cases, the data were a consistent agreement between rapid method result after 50 hour incubation in enrichment broth and the 5 day plate count method. The D-Count is able to detect very low *inocula* of either yeasts or molds in the products tested.
This new Yeast and molds protocol is mainly used for raw material due to the risk of molds contamination compare to finished products. That's why for YSL microbial lab TVC presence/absence test remain the main criteria for finished products release control.
By combining the TVC presence/absence test for Bacteria with the presence/absence test for yeasts & molds, YSL microbial lab is able to provide a complete result for finished product with bacteria criteria within 24 hours and Yeast and molds results for raw material within 2 days that now enables the company to release finished products 3 to 5 days earlier compared to traditional methods.

bioMérieux Industry celebrates the 10th anniversary of BioBall®, a revolutionary solution for Quantitative Microbiological Quality Control

The patented BioBall technology uses a small, water-soluble ball containing a precise number of viable micro-organisms derived from strains sourced from internationally-recognized culture collections. Over the past 10 years, BioBall technology has been used in quality assurance to verify the performance of control methods and allow certification of the quality of culture media faster and with unprecedented accuracy than other methods.

With more than 25 strains currently available, the BioBall menu has experienced constant development over the last decade. Since 2010, customers wishing to perform quality control with their own plant isolates or wild strains have been able to do so thanks to the BioBall Custom Services (Plant Isolate) option. In addition, the BioBall Mixed Kits in packs containing 10 of the most relevant pharmacopoeia strains required for quantitative microbiology brought additional flexibility and convenience to laboratories performing small numbers of samples per day. Today, BioBall is used routinely by the top 20 biopharmaceutical industries worldwide.

Did you know?

The sterility test was introduced for the first time in the British Pharmacopeia in 1932. *(Source "Microbiology and sterility assurance in pharmaceuticals and medical devices " Mr. Saghee, T. Sandle, EC. Tidswell, 2011 Business Horizon).*

An examination of stored water supplies showed that 98% of the contaminants were Gram-negative bacteria. *(Baird RM, et al 2000; Handbook of microbiological quality control: pharmaceuticals and medical devices, CRC Press).*

Visit **www.biomerieux-industry.com** to know more about bioMérieux solutions for environmental monitoring.

SMI Conference in London

bioMérieux sponsored the SMI conference held in the UK

In January 2013, bioMérieux industry sponsored and participated in the SMI conference on Pharmaceutical Microbiology. The program covered a wide range of topics of interest in this field including rapid methods, media fill testing, auditing and endotoxin testing. There was a high calibre of speakers from around the world with many of the top pharmaceutical companies in the industry being represented.

The first day was chaired by Olivier Chancel of Merial Sas, and the second by Scott Smith of Sanofi-Aventis. Dr Chancel, kicked-off the first day with a presentation on Integrity testing. It was interesting for the audience to learn of common challenges facing laboratories in performing this type of evaluation successfully. It was of particular *interest to bioMérieux, with the imminent launch of BioBall Brevundimonas diminuta.*

On the second day, Pranav Somaiya, Lead Researcher at the University College London, and Victoria Girard, R&D Microbiology Manager at bioMérieux, gave a well-received, joint presentation entitled 'Revolutionising Microbial Identification with Mass Spectrometry Technology'. Mr. Somaiya began by showing the parallels in history in the evolution of mass spectrometry and MALDI-TOF technology and in the field of Microbiology. He went on to introduce the technology and its application for microbial identification in the VITEK® MS system.

Dr Girard followed this introduction with details of the developments that have enabled the move from R&D use only, to the introduction of MALDI-TOF technology for the application of rapid, microbial identification in the routine laboratory with VITEK® MS. She then presented the approach used by bioMérieux to create a robust, validated database for this product.

It was concluded that with the ultra-rapid time-to-result, the ability to process samples efficiently and the facility to identify bacteria and fungi, the VITEK® MS and MALDI-TOF technology represented a revolution in microbial identification. Considerable interest was generated in this new development in microbial identification and delegates were able to ask further questions and to see the VITEK® MS system at the bioMérieux stand.

bioPharma

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