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BIO/PHARMA - MEDICAL DEVICES - COSMETICS - BIOCIDES

Pharma Services News

N° 01 - February 2012

# Eurofins expands global technology portfolio and geographic reach with Lancaster Laboratories

*Lisa Bamford, Eurofins Lancaster Laboratories, USA*

With the acquisition of top US testing firm, Lancaster Laboratories, the Eurofins Group takes a leadership position in North America in two strategic markets: Pharm/Biopharm products testing and Environmental testing. Founded in 1961, Eurofins Lancaster Laboratories brings a significant North American presence with an unmatched breadth of bio/pharmaceutical, environmental and scientific staffing capabilities as well as a sterling track record for regulatory compliance, cost effectiveness and achievement of timelines for customers.

Eurofins Lancaster Labs' FDA, EMA and PMDA cGMP-compliant Bio/Pharma divisions enable 800 global life sciences customers - including 19 of the top 20 bio/pharmaceutical companies - to advance development candidates and release marketed products through a complete set of services for drug substances, drug products, manufacturing and starting materials testing.

With 1,200 employees and state-of-the-art facilities in the USA and Ireland, Eurofins Lancaster Laboratories has built a strong customer following by listening to project needs and delivering solutions through five flexible service models, which all provide a seamless service experience throughout the outsourcing process:

- Fee For Service: Most commonly used in the industry, this model allows Eurofins Lancaster Labs' staff to provide a broad range of pharmaceutical and biopharmaceutical products testing on a project-by-project basis, utilising customized price quotes for each project delivered.

- Managed Hours: This approach allows in-house staff to provide a broad range of pharmaceutical and biopharmaceutical products testing on a project-by-project basis with a simplified quote and payment process based on the number of hours used. This meets the needs of clients who have a high volume of repeat (standardised) testing needs.

- Full Time Equivalent: This provides clients with dedicated full-time employees, working within Eurofins Lancaster Laboratories' facilities and using its infrastructure, equipment and consumables.

- Asset/Operation Ownership: Eurofins Lancaster Laboratories assumes full operational responsibility on the client site. This model can also include acquisition of the client's facility and/or equipment. While this model may only apply to a small percentage of companies in the industry, some firms are seeking ways to fully outsource non-core activities and divest of the associated assets.

- Professional Scientific Staffing: This award-winning model places Lancaster Laboratories' full-time scientists and technical support personnel at the client's facility to provide a non-permanent, long term and cost-effective way to meet staffing needs while maintaining the same services, expertise and cGMP compliance available at the Lancaster Laboratories' facilities.

Among the most innovative and quality oriented international players in the industry, Eurofins Pharma Services with Lancaster Laboratories is ideally positioned to support customers' increasingly stringent quality and safety standards and the demands of regulatory authorities around the world.

For more information on Eurofins Lancaster Laboratories' capabilities, visit *www.eurofins.com/lancasterlabs*.

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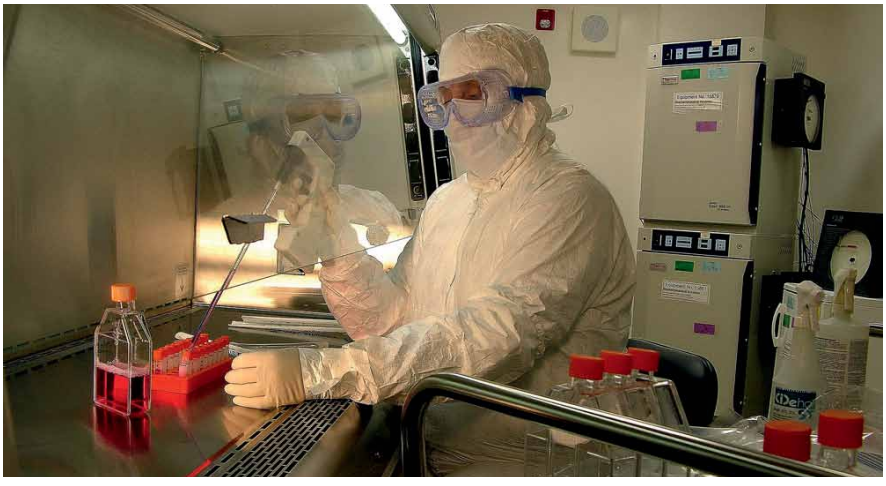

# Eurofins launches new dedicated Global Central Laboratory in India

*Sandra Hageman, Eurofins Global Central Laboratory, The Netherlands*

Today, India has grown to become the global hub of outsourcing of clinical trials. The largest benefits India is offering to the pharmaceutical companies are India's huge population of more than one billion, a great hospital infrastructure, very skilled English-speaking medical staff and most importantly, major cost reductions for conducting clinical trials. McKinsey & Co estimated that around $1-1.5 billion would be spent in 2010 just on drug trials in the country.

In September, Eurofins Global Central Laboratory achieved an important strategic milestone with the opening of a new laboratory site in Bangalore, India. Joining the existing Eurofins Food and Eurofins Genomics laboratory operations in technology hub Bangalore, Eurofins Global Central Laboratory has a clear focus on the Asia-Pacific region by deploying three wholly-owned central laboratories in Singapore, China and India. These laboratories go together with the central laboratories in the United States and Europe to create a true global footprint.

The Bangalore facility operates like an extension of the other Eurofins central labs as all laboratory equipment, methods, operating procedures, LIMS and quality standards are identical.

The Bangalore facility's location gives it easy access to the transportation infrastructure in India, enabling close control over transportation and maintenance of specimen integrity. The Sponsors can expect equal results in India, with the benefit of having a reduced cost because the clinical trial samples are no longer transported to either Europe or United States.

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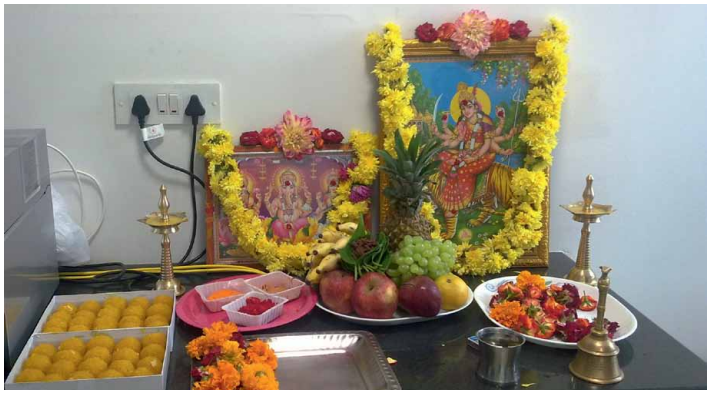

# Disinfectants used in pharmaceutical facility for sterile production

## Risk analysis, efficacy requirements and validation procedures

*Michele Cavalleri, Eurofins Biolab, Italy*

Eurofins proposes four phases to validate the use of disinfectants applied in clean rooms and microbiologically classified environments as well as to verify the efficacy of cleaning and disinfection procedures. Each phase can be independently performed according to regulatory requirements.

**Phase1**: Characterisation of the endogenous microbial contamination:

Identifies endogenous microbial strains that are considered to be most critical and representative of the environment where disinfectants are to be used, which helps to determine the microorganisms that will be subjected to efficacy testing.

**Phase 2**: Experimental evaluation of the disinfectant efficacy under practical conditions of use:

Quantifies the efficacy of the disinfectants vs. the strains chosen in Phase 1 using quantitative carrier test (reference method: EN13697:2001) and surfaces that are representative of the ones to be treated (e.g. glass, stainless steel, PVC, PMMA, etc).

**Phase 3**: Validation of the disinfection process:

Validates the complete disinfection process through a field trial at the manufacturer's site. In this phase, the aspects related to the application mode, real bioburden and structural features of the site will be taken into consideration to establish a validation plan, including evaluation of the sampling points, sampling frequency, duration of the validation, specific SOPs for cleaning and disinfection, validity criteria, etc.

**Phase 4**: Microbial monitoring:

Detects deviations from the required conditions, for example, incorrect use or rotation of the disinfectants, the appearance of more resistant strains or a modification of the characteristic bioburden.

Surface microbiological monitoring is performed to detect the presence of *Bacillus Pumilus* contamination inside a clean room. The site cleaning and disinfection SOPs do not include a highly effective sporicidal disinfectant.

A chlorine releasing agent, such as a ready-to-use disinfectant based on $ClO_2$, is chosen after evaluating its suitability for the relevant surfaces. The efficacy of the disinfectant is assessed via EN13697 carrier test method under simulated practical conditions in order to define the effective contact time against *Bacillus Pumilus* spores.

Once the effective condition has been found, a validation plan is proposed in order to monitor in situ the efficacy of the updated disinfection process, i.e. elimination of *Bacillus Pumilus* spores contamination.

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# Impact of the new European Guideline for the bioanalytical method validation

*Dr. Patrick Duchêne, Eurofins ADME Bioanalyses, France*

For over a decade, the main regulatory reference for the bioanalytical method validation has been the US Food and Drug Administration's (FDA) Guidance on that topic.

Last July, the European Medicines Agency (EMA) proposed its own guideline, effective 1st February 2012.

With regards to the US FDA Guidance and subsequent white papers, the EU Guidance adds new requirements mainly for matrix effect, selectivity and stability.

In addition to the normal matrix, the EU Guidance recommends to investigate the matrix effect on other samples e.g. haemolysed and hyperlipidaemic plasma and also in samples from specific populations. The impact of the co-medications, metabolites (including back-conversion) and excipients on the selectivity also has to be studied.

Stability should be ensured for every step in the analytical method e.g. same anticoagulant, in the presence of metabolites and co-medication. Recommendations differ according to the reference concentration to be used for the calculation of long-term stability, i.e. the nominal concentration (EMA) or the mean of back calculated values on the first day of long term stability testing (FDA).

In conclusion, both guidances are compatible. Even if the FDA does not require these complementary tests, the US and other medical agencies agree on the importance of these criteria to increase and assure the robustness of the bioanalytical method. Concerning long-term stability, both criteria should be satisfied to avoid any discussion. Bioanalytical (BA) procedures within BA Eurofins labs have been reviewed to comply with these new requirements.

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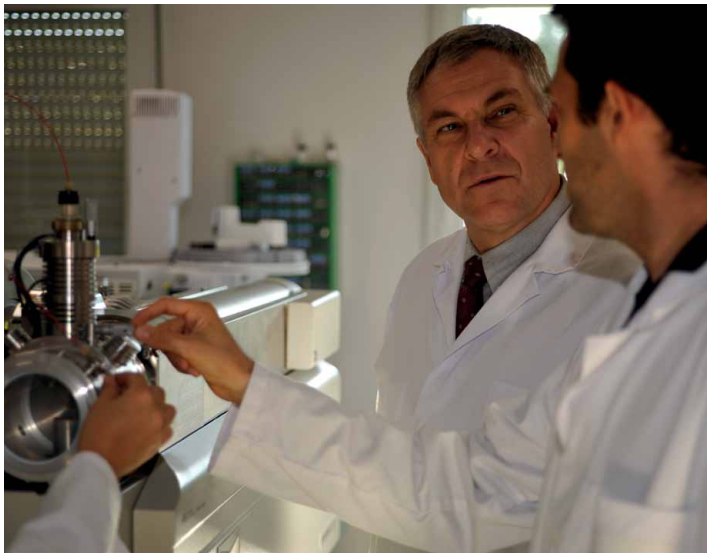
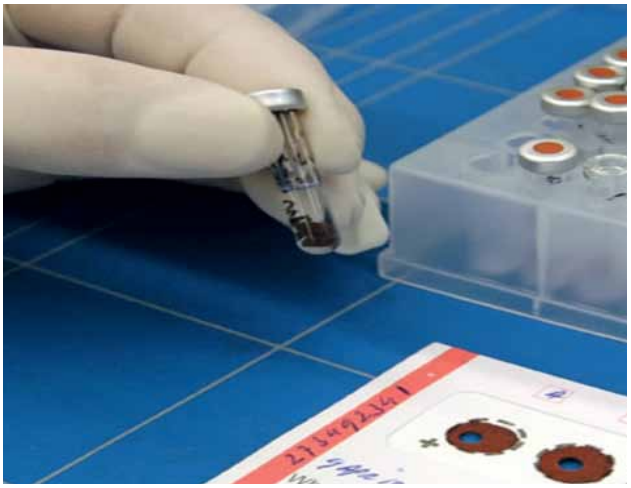


# Dried blood spots reduce cost of drug development

*Dr. Rudi Segers, Eurofins Global Central Laboratory, The Netherlands*

Dried blood spots (DBS) refers to a blood sampling technique where small volumes of blood are spotted on an appropriate filter paper, dried and taken to the laboratory for analysis. The technique is well established in clinical labs for applications, such as neonatal screening for inborn diseases, but has recently experienced a surge of interest in the context of drug development, i.e. toxicokinetic (TK) and pharmacokinetic (PK) studies, biomarker assays and therapeutic drug monitoring.



DBS as a low volume blood sampling technique was introduced in 1963 in the context of neonatal screening of phenylketonurea. Much more recent is the use of DBS in drug development spurred by the ethical advantages of requiring lower blood volumes and fewer animals in the case of preclinical studies. Cost savings are also achieved by the simple shipment of DBS cards compared to the cumbersome dry ice sample shipment.

A rapidly increasing number of bioanalytical methods have been published, underlining the fact that many companies are now considering DBS in at least some part of the development cycle of their drugs. At the same time, not all questions have been answered, and some contentious issues remain, e.g. how best to introduce the internal standard and the impact of hematocrit on the assay result. It can also be expected that the workflow in the lab will be much improved over the years to come as various technological advances are under way at the level of sampling from the DBS cards as well as automation.

At this point, no company is sufficiently advanced to have obtained market authorisation for their compound from the FDA based on DBS. Regulatory authorities have reacted enthusiastically, but cautiously.

DBS offers a new opportunity for drug developers. Eurofins is already helping some of them with PK and pediatric applications, both in our clinic as in our bioanalytical labs. It can be expected that the technology will see increasing use in pediatric studies and therapeutic drug monitoring. Further ramifications to large molecule applications (biomarkers PK and immunogenicity of biologicals) are also on the horizon.

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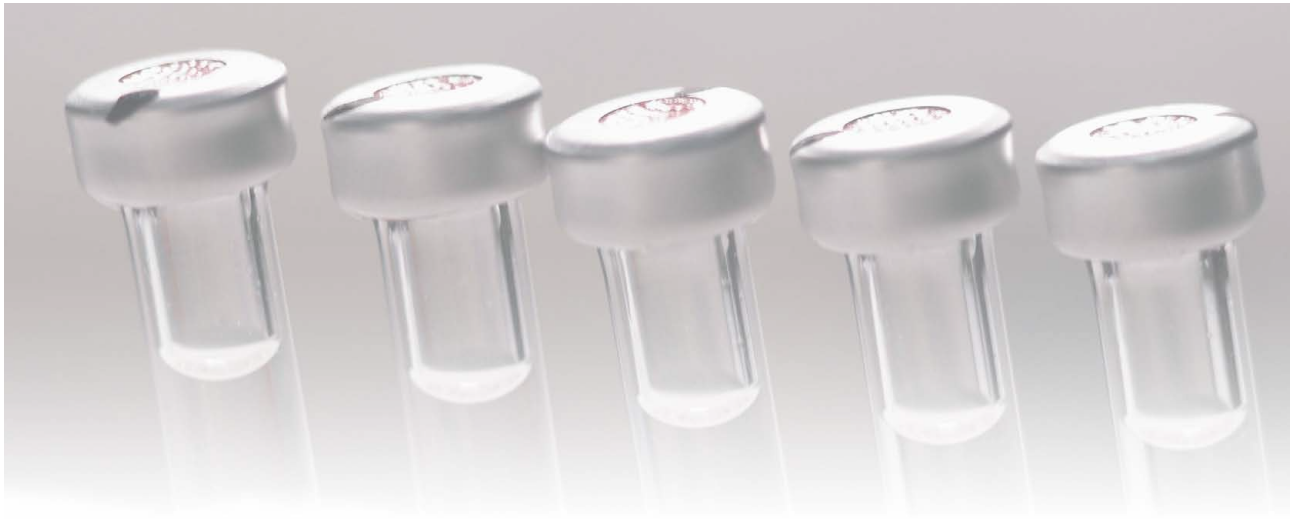
Pharma Services

## COMING EVENTS

| EVENT | DATE & PLACE | MORE INFO | CONTACT |
|---|---|---|---|
| **7th Annual Biomarkers Congress** | 21.-22.02.2012, Manchester, UK | *Booth N°4* | *clinicaltrials@eurofins.com* |
| **Immunogenicity for Biologics** | 21.-22.02.2012, London, UK | *Attend only* | *clinicaltrials@eurofins.com* |
| **Partnerships in Clinical Trials** | 04.-07.03.2012, Orlando, USA | *Booth N°715* | *clinicaltrials@eurofins.com* |
| **ECCMID*** | 31.03.-03.04.2012, London, UK | *Attend only* | *clinicaltrials@eurofins.com* |
| **EXPOMED 2012** | 12.-15.04.2012, Istanbul, Turkey | *Booth N°406/B* | *GMP_EU@eurofins.com* |
| **PDA** Annual Meeting** | 16.-17.04.2012, Phoenix, USA | *Booth N°603* | *GMP_US@eurofins.com* |
| **InterPhex** | 01.-03.05.2012, New York, USA | *Booth N°1022* | *GMP_US@eurofins.com* |
| **AAPS Biotechnology** | 21.-23.05.2012, San Diego, USA | *Booth N°305* | *GMP_US@eurofins.com* |
| **Biosimilars** | 22.-23.05.2012, Prague, Czech Republic | *Attend only* | *clinicaltrials@eurofins.com* |
| **Partnering with Central Labs** | 23.-24.05.2012, Brussels, Belgium | *Booth N°7* | *clinicaltrials@eurofins.com* |
| **52° Simposio AFI** | 30.05.-01.06.2012, Rimini, Italy | *Booth N°35/37* | *GMP_EU@eurofins.com* |
| **EBF*** Focus Meeting** | 12.-13.06.2012, Brussels, Belgium | *Attend only* | *clinicaltrials@eurofins.com* |
| **PCMG**** conference** | 13.-15.06.2012, Albufeira, Portugal | *Attend only* | *clinicaltrials@eurofins.com* |

** European Society of Clinical Microbiology and Infectious Diseases*
*** Parenteral Drug Association*
**** European Bioanalysis Forum*
***** Pharmaceutical Contract Management Group*





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