

## Portable detection systems for bacterial contamination

Microbiological testing of pharmaceutical and medical device products is critical to ensuring patient safety. While this is particularly the case for sterile products such as parenterals, implants, stents and contact lenses, oral dose pharmaceuticals must also meet strict regulatory microbial standards. Detecting microbial contamination remains a challenge. The initial microbial cell load of the sample is typically low, thereby necessitating the culturing of the microorganisms to enable detection and enumeration by current methodologies. This process is inherently slow, taking several days and delaying the release of products to the market or resulting in equipment down-time. Any analytical solution to this problem must be able to detect microbiological contamination at the levels present during, or shortly after, sampling. To be suitable for a typical quality control laboratory, any test method should have simple sample preparation procedures and should not require complex and expensive equipment.

**MICROPRINT** meets these challenges and offers the potential for development of rapid and highly sensitive cell detection assays using cell imprinted electrochemical sensors.

## Cell Imprinted Electrochemical Sensors

- Integrated microfluidics
- Cell imprinted polymer for selective capture
- Electronic sensors - cellular enzyme profiles

**MICROPRINT** is an analytical microbiology technology based on cell-enzyme profiling sensors. The technology consists of a single-use cell capture and detection cartridge; BIO-CARD and a portable electronic reader which processes cartridges and collects data on specific microorganisms. BIO-CARD device encompasses novel cell-capture membranes integrated with electrode sensors which quantifies electrons derived from assigned cellular enzyme reactions.

## MICROPRINT

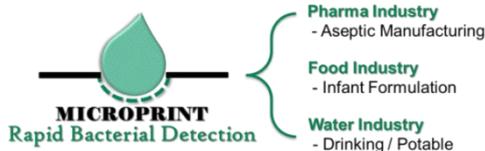
- No user training required
- No sample preparation
- Cost effective (reader €500 and <€1 per analysis)
- Self-contained (no external reagents required)
- Results available within same shift (<8 hrs)
- Sterile and non-obligatory sterile products
- Facilitate rapid go/no-go decisions within manufacturing environment
- Sensitive; 1 cfu/mL
- Multiple, specific organism tests into single card

## Sterile Manufacturing

Manufacturing in cleanroom environments is standard practice in Biotechnology and Pharma quality management. To avoid lengthy production down-time, sources of microbial contamination must be quickly located and remedial action undertaken. Contamination may originate from the raw materials or may be introduced during manufacture. Water, raw materials & ingredients, products of sterile filtration and environmental swab samples are assessed to identify and enumerate indicator microorganisms. Rapid bacterial analysis must be established to detect at the alert level of 1cfu/100mL.

## Opportunities

MICROPRINT allows on-the-spot microbiological analysis, whether at the laboratory bench or at the production line. A portable bench form of the system is being scrutinised for the evaluation of total viable aerobic count (TVAC) in pharmaceutical preparations. It is envisaged that the technology will be extended to other industrial needs including food and water testing. The technology is also being assessed for continuous on-line/in-line monitoring QA applications.



**MICROPRINT BIO-CARD & HANDHELD READER** is under development at MiCRA for the detection of bacteria in water and food samples. In water testing, a water sample is injected through a sampling strip which is then inserted into the BIO-CARD. After a period for on-cartridge culturing, the card is introduced to the handheld reader for processing. Readout follows in minutes identifying the micro-organism and cell count.

- *Staphylococcus*
- *Salmonella*
- *Aspergillus niger*
- *Micrococcus*
- *Escherichia coli*
- *Candida albican*

**Industrial technologies for rapid microbiological testing currently cost up to \$100 per sample, require high capital equipment costs and still lead to identification error rates of 20% or greater.**

## Microbiological Technologies from MiCRA

MiCRA - Biodiagnostics is advancing new electrochemical sensors and electrode devices to meet a diverse range of industry applications. In addition to the range of cell imprinted electrochemical sensors, under development are a suite of microbiological assays, on-the-spot cell diagnostics and in-line electronic sensors for identification and enumeration of bacteria.

### MOXYS - Microbial Oxygen Sensor

'MOXYS' is a thin-layer electrochemical oxygen sensor, built using printed polymer laminates, and designed to monitor real-time microbial oxygen metabolism. The sensor is used to enumerate catalase positive bacteria.

### Coliform Sensors

Electronic sensors detect *E. coli* and *coliforms* by measuring beta-galactosidase and related enzyme activities. The detection system is being used for water testing for the presence of *E. coli*, providing rapid cell count results.

### CATOXE – Staphylococci & Micrococci Dual Sensors

BIO-CARD cartridges are under development using integrated dual sensors for the identification and differentiation of *staphylococci* from *micrococci* in sterile manufacturing samples.

### TVAC UNIVERSAL

'TVAC UNIVERSAL' is a technology to detect respiring microorganisms using CO<sub>2</sub> gas monitoring sensors. The electrode-based instrument evaluates total viable counts and has a range of industrial applications where microorganism contamination is an issue.



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