



# GBL NEWSLETTER

APRIL 25, 2008

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VOLUME 1, NUMBER 2

## New Address

**SAMPLE DELIVERY**  
**16 Montesano Rd.**  
**Fairfield, NJ 07004**

**Mail**  
**Accounts Receivable**  
**[No change]**  
**Gibraltar Laboratories**  
**Inc.**  
**122 Fairfield Rd.**  
**07004**

## What's New

We are really enjoying our new state-of-the art-microbiology facility. We moved in around April 1, 2008. If, for regulatory purposes, you need a Change Control letter please contact us.

Our new facility also permits the expansion of our Chemistry Department which remains at 122 Fairfield Road.

All of our telephone and email addresses remain the same except that now, to reach the microbiology and receiving departments, the first digit of the extension starts with a 6 rather than a 5. An exception is, Ms. Hussain was ext. 531 and she is now ext. **623**.

Cleanability Studies are becoming a major industry focus. Preparation of Artificial Soil Medium. Devices are challenged with an artificial soil containing *Geobacillus stearothermophilus* and then cleaned in an automated instrument washer/sanitizer or manually. Each is visibly inspected and whether 99.9% organism removal was achieved as per AAMI TIR 30, is determined.

Example Sterilization Conditions [other times and temperatures are possible]

Cycle: Gravity and Pre-Vacuum Steam Temperature  
270°F/132°C

Time: 5 minutes [Half-cycle] and 2 minutes [Half-cycle]

The picture below shows one of our study directors hard at work in our new large USP/FDA CGMP Microbiology laboratory. The facility also contains a large ISO 6, Class 1000 Sterility Suite with an integrated large walk-in incubator and large BSL-3 laboratory for research on the efficacy of micro-biocides to combat dangerous organisms.

## OUR LOCATIONS

### Microbiology

16 Montesano Road  
Fairfield, N J, 07004

### Chemistry

122 Fairfield Road  
Fairfield, NJ 07004



MRSA



Antibiotic assay

### Publications

Our paper, ANTIMICROBIAL SILVER IN ORTHOPEDIC AND WOUND CARE PRODUCTS will be appearing soon in ORTHOPEDIC DESIGN AND TECHNOLOGY. Rodman Publishing, Ramsey, NJ.

### Course Offering

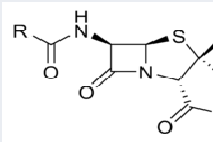
On March 24, 2008 we held an interesting seminar entitled "Analytical Chemistry: Methods, Instrument Maintenance & Case Studies" March 24, 2008, 8:30 AM.

### Feature article: Antibiotic Therapy at Crossroads

Drug companies no longer see billion dollar opportunities in antibiotic therapy. In fact, since the 1990s big pharma has shied away from antibiotic research and development. At the same time the threat from microorganisms has increased in main due to widespread resistance.

#### History of Antibiotic Development

Year Introduced	Class of Drug
1935	Sulfonamides
1941	Penicillin's
1944	Aminoalvcosides



Penicillin

Bacteria have been on earth billions of years—much longer than man.

Bacteria reproduce themselves very, very quickly—in some cases every 20 minutes

1944	Aminoglycosides
1945	Cephalosporin's
1949	Chloramphenical
1950	Tetracycline
1952	Macrolides
1956	Glycopeptides
1957	Rifamycins
1959	Nitroimidazoles
1962	Quinolones
1968	Trimethoprim
2000	Oxazolidinones
2003	Lipopeptides

Source: C&EN Volume 86, number 15, April 14, 2008, page 16.

***GBL can test your product against MRSA using MIC and Zone of Inhibition Assays***

Resistance is explained by the fact that microorganisms possess fine crafted evolutionarily selected tools that effectively counter billion dollar research and development efforts in a relatively short period of time skewing the risk reward equation faced by drug companies against drug development.

The advantage lies with the organisms because they have been on earth for billions of years—much longer than man has. In addition, bacteria can reproduce very quickly; in some cases every 20 minutes. Thus, a single organism will cone itself into a million organisms in about only 7 hours.

To be efficacious the drug first must be able to penetrate the cell and not be cleared out. Most bacteria have very efficient pump processes that among other things recognize the antibiotic and remove it to the environment. In addition, it must not be toxic to the patient.

Today, smaller companies are stepping up to meet the challenge and choosing a new strategy. Rather than developing a broad spectrum agent, active against many bacteria at the same time, they are looking to knock at specific organisms. This has the benefit of decreasing the occurrence of multiple drug resistant organisms.

*C. difficile* is being targeted by two new small pharmaceutical companies. However, the biggest threat that patients face comes from gram negative organisms such as members of the Enterobacteriaceae family like, *Serratia* and *E. coli*. More on the methods to utilize to test therapies designed against gram negatives will be discussed in a later issue.