

ZeptoMetrix begins biodefense program

Given ZeptoMetrix's unique ability to safely handle deadly microorganisms, it was only a matter of time before the company began work in the biodefense area. Today ZeptoMetrix has programs that include testing methods to kill Avian Influenza, developing improved diagnostic tests for tularemia and bubonic plague, and creating cures for anthrax and botulism. Much of this work is based on collaborations with academic and government laboratories and with other biotechnology companies.

Any microorganism that can be used as a biological weapon is termed a "Select Agent". Although many select agents are a threat because they are deadly to humans, those that infect animals are important too because they can devastate a country's agriculture.

The United States government has strict rules and regulations governing work with select agents. This includes having the appropriate biocontainment facilities to protect the public and the environment, having biosafety equipment and procedures in place to protect those working with the agents, and



Tricia Hoover working inside a Biological Safety Level-3 laboratory at ZeptoMetrix's Buffalo facility.

also having high security to prevent those agents from falling into the wrong hands.

Select Agent Permit granted

In order to work with these agents, ZeptoMetrix had to obtain a "Select Agent Permit". Under the Public Health Security and Bioterrorism Preparedness Response Act of 2002, which was signed into law by the President, the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (HHS) through the Centers for Disease Control and Prevention (CDC) regulate select agents jointly. The law is designed to help the government prevent or respond to bioterrorism or other public health emergencies.

The Buffalo facility of ZeptoMetrix underwent an extensive biosafety inspection. Also, the company's directors and all employees who have access to select agents were put through an FBI security risk assessment that included fingerprinting and background checks.

The Buffalo facility houses two large Biological Safety Level-3 (BSL-3) laboratories. BSL-3 labs are the second

highest containment level recognized. Special safety practices and equipment are required to protect laboratory workers and the environment.

BSL-3 labs are sealed from the environment and special safety practices are in place, which include life-support systems worn by laboratory workers.

Some Select Agents regulated by the CDC

Anthrax
Botulism
Plague
Avian influenza (H5N1)
Ebola
Smallpox
Lassa fever
Marburg hemorrhagic fever
Monkeypox
Tularemia

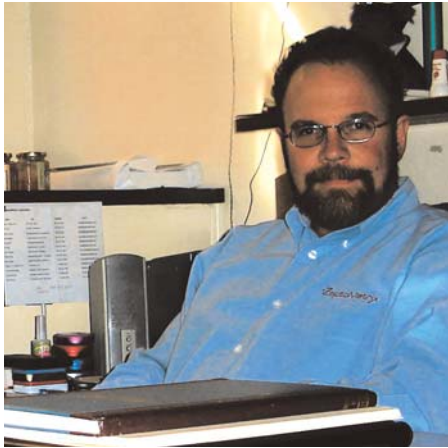
In future issues of the ZeptoGram we will have articles that go into more detail about some of the exciting work we are doing in the biodefense area.

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Letter from the President



We're happy to present you with the first issue of our corporate newsletter, the ZeptoGram. Our purpose in publishing the ZeptoGram is to give you a look at exciting events in the company and to acquaint you with the great group of people working at ZeptoMetrix. We plan on publishing one issue each quarter.

ZeptoMetrix has achieved things beyond any of our dreams. Our revenues, profits, and successes are testament to that. Over the last 5 years we've seen 35% growth of revenues

per annum and have been solidly profitable.

I thought this first "Letter" would be an opportunity to discuss the core values and the core purpose of ZeptoMetrix. First and foremost ZeptoMetrix is a partner to each and every customer. You see the motto "Partner to our Customer" on our business cards, our web site and our literature. This is a core value that we view central to our business. We focus on partnering with our customers and doing everything we can to ensure their success because their success means continued growth and opportunity for us. As our customers succeed, we succeed and as customer needs change, so does the company.

These partnerships frequently mean we become an extension of a customer's research, development or manufacturing efforts. Because of this core value we now have collaborative efforts with many leading scientists, diagnostic, and pharmaceutical companies. Our success is intimately linked to their success. Our partnerships also mean we have an

extensive list of new products we want to develop.

ZeptoMetrix's core purpose is relatively simple. Our research products business is an opportunity-generating machine in focused areas of the life science industry. When ZeptoMetrix is presented with new opportunities we are positioned to rapidly capitalize on them.

As we move forward, our plans will change, our strategies will change, and our markets will change. But our core focus of being a partner to our customer will remain constant.

James C.D. Hengst, PhD
President and CEO

ZeptoMetrix achieves ISO 9001:2000 and ISO 13485:2003 certification

In July of 2004, ZeptoMetrix initiated a plan to put a certified Quality System in place. ISO certification helps tremendously when dealing with pharmaceutical and diagnostic companies who often require their vendors to have ISO certification.

A grant obtained from the New York State Department of Labor helped cover much of the cost of ISO implementation. ZeptoMetrix's ISO implementation team consisted of **David Reinlander (Manager of Regulatory Affairs)**, **Michelle Ferreri-Jacobia, PhD (Director of Virology)** and **Ronald Urmson (Controller)**. The ZMC ISO Implementation team brought the company up to compliance for both ISO 9001:2000 and ISO



ISO implementation team members (left to right): Michelle Ferreri-Jacobia, PhD, David Reinlander, and Ron Urmson.

13485:2003. Within seven months a first round of internal audits was complete. In April 2005, Intertek was chosen as the certifying body and auditing company. Intertek is a worldwide organiza-

tion that has acted as the certifying agency for hundreds of companies including, Fujifilm, Gibraltar and Mayflower. They are affiliated with ANAB; ANSI-ASQ National Accreditation Board and the Standards Council of Canada. The registration audit was performed in May and certification was granted June 1, 2005.

According to company president **Jim Hengst, PhD**, "Achieving certification just 11 months after starting the initiative is a remarkable accomplishment."



Centers for Disease Control and ZeptoMetrix collaborate *Unique seroconversion panels launched*

A seroconversion panel is a collection of blood samples, drawn from a person who becomes infected with a virus such as HIV. These samples are obtained every few days from the time before the person becomes infected until several weeks after the infection has occurred. These samples typically come from paid donors with high risk profiles, who may donate blood several times each week. The blood is further processed and used to manufacture pharmaceutical products.

Ideally, a diagnostic test should identify an infection as soon as possible so the person can begin therapy. It is also important to detect infected people so they are not used as blood donors. Since some of the samples are collected at or around the time the person becomes infected, a seroconversion panel is a very important tool in developing new diagnostic tests.

During the past two years the Centers for Disease Control and Prevention (CDC) in Atlanta has undertaken a program to define a better way to diagnose HIV infection with new tests now available. In this program, CDC scientists are evaluating every HIV diagnostic test on the market including the new "rapid tests" that are now being used more frequently.



Seroconversion panels in frozen storage at the Franklin, MA site.

For this program, ZeptoMetrix has been providing the CDC with a large number of different seroconversion panels at no charge. In exchange for this, the CDC will provide the data to ZeptoMetrix.

The result of this collaboration is that ZeptoMetrix will be able to provide customers with highly characterized seroconversion panels that have comprehensive data from all of the diagnostic tests currently available. The plasma in these panels is unprocessed and has data from more than forty diagnostic tests. These panels have been published in multiple journals and have been used by most current

blood screening assay FDA submissions.

New seroconversion panels are very hard to find today because infected donors are identified by Nucleic Acid Tests which can identify the presence of virus in the donor's plasma within a few days after they become infected. The individuals are then prevented from making future donations. The rarity of these panels makes them even more valuable to diagnostic manufacturers who require them to receive FDA approval on their products.

ZeptoMetrix also has 14 new HIV seroconversion panels that will be commercialized. These are panels that ZeptoMetrix has had in its extensive specimen archive at its Franklin, MA facility, but for which no data was available until now.

According to **Greg Chiklis, PhD**, Vice President of R&D, ZeptoMetrix is the only company to launch new seroconversion panels in over five years. No other company has such extensive, well-characterized panels. ZeptoMetrix also plans to launch a number of seroconversion panels in the next year from people infected with Hepatitis B virus and Hepatitis C virus.

New in Design & Development

Products Coming Soon

Goat IgG ELISA: Detects and quantifies goat IgG
Rabbit IgG ELISA: Detects and quantifies rabbit IgG
Bovine IgG ELISA: Detects and quantifies bovine IgG

These species specific ELISA's are useful for antibody production monitoring in serum and other biological samples. These assays can be completed in 2 hours and are sensitive to 7.8 ng/ml.

Horseradish-Peroxidase Conjugate Stabilizer: Stabilizes HRP conjugates for long term storage at use dilutions.



*ZeptoGram is published quarterly
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*We strive to be a partner to each customer
and we welcome your comments and sug-
gestions. We wish you much success in
your research.*

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Bulletin Board

Welcome New Employees

Franklin, MA

*Phillip Nicholson
Materials Management Assistant*

Buffalo, NY

*Laura Wolfe Laboratory Technician
Justin Zoladz Laboratory Technician*

Happy Birthday

<i>Ron Urmson</i>	<i>4/8</i>
<i>Patrick Conner</i>	<i>4/29</i>
<i>Chris Collins</i>	<i>5/20</i>
<i>Anton Manuelpillai</i>	<i>6/17</i>
<i>Jane Smigiera</i>	<i>6/21</i>
<i>Michelle Ferreri-Jacobia</i>	<i>6/25</i>

Visit us at:

The 22nd Annual Clinical Virology Symposium
Hilton Clearwater Beach Resort
Clearwater, FL
April 30th-May 3rd, 2006

AACC Clinical Laboratory Expo
McCormick Place Convention Center
Chicago, IL
July 25th-27th, 2006

What is a ZeptoGram?

Zepto is a prefix adopted in 1991 by the SI system of units denoting a factor of 10^{-21} or a sextillionth. It comes from the Latin "septem" meaning seven, for the seventh power of a thousandth. That's 0.000000000000000000001 gram!

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