

# Engage

## AIT announces name, brand identity for new division



AIT Bioscience will provide quantitative bioanalytical analysis and drug development support services to pharmaceutical and biotech companies as of this fall.

Moving full speed ahead with plans to establish a new pharmaceutical testing division, AIT Laboratories is proud to announce the name of its latest endeavor as AIT Bioscience, LLC. AIT Bioscience will operate as a separate entity to provide quantitative bioanalytical analysis and drug development support services to pharmaceutical and biotechnology companies by using the most sensitive triple quadrupole mass spectrometry and UPLC® instrumentation available in the industry.

"AIT Bioscience will operate under the same quality principles that I founded AIT Laboratories on nineteen years ago and that we still operate under today," said AIT Laboratories President and CEO Michael A. Evans, Ph.D. "We have some of the industry's most veteran scientists leading the new division, including Ronald Shoup, Ph.D., who brings more than thirty years of leadership, entrepreneurship, and scientific expertise to AIT Bioscience."

The decision to create AIT Bioscience was based on AIT's desire to improve upon the traditional CRO model. The

new company will provide clients the capability to monitor sample activity from point of collection to the final report, with production taking place in a completely paperless environment that assures correctness from one step to the next. Instead of addressing issues as they arise, AIT Bioscience will aim to prevent them from the start with automated equipment and processes that reject activity out of sync with lab standards and methodologies.

"Bioanalytical testing is closely aligned with what AIT Laboratories already does in terms of processes and equipment. AIT Bioscience wants to take those resources and apply them to the pharmaceutical industry in ways other CROs only wish they could," Shoup explained. "Our talent and lack of legacy systems allow us to build an organization from the ground up that caters to the client's specific needs. The goal is to work as a partner with drug developers to coordinate activities throughout the testing process and provide access to data in real time as it's produced by our laboratory."

AIT began acting on its anticipated expansion into the Pharma industry last year, when construction plans were drafted for a new lab and Shoup was named executive director of AIT's pharmaceutical division. Objectives for AIT Bioscience in 2009 include creating testing methods and standard operating procedures that are compliant with FDA regulations, preparing for audits by the FDA and potential clients, partnering with drug companies to ensure the testing they receive produces the data

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## AIT honored by Indiana Chamber of Commerce for corporate, cultural initiatives

### "SMALL BUSINESS OF THE YEAR"

This past February, AIT Laboratories was chosen from more than fifty nominees to be the state of Indiana's 2009 "Small Business of the Year" by the Indiana Chamber of Commerce. Other top small businesses from throughout the state as well as legislative advocates for the small business community were also recognized at the annual awards luncheon held in downtown Indianapolis.

"AIT Laboratories really stood out in several ways. Its overall business growth in terms of both revenue and employees was simply tremendous," said Indiana Chamber President Kevin Brinegar. "It was also impressive to see the many and varied ways it takes care of and rewards employees for doing a good job."

AIT provides numerous cultural initiatives to its employees throughout the year, including a wellness program, paid registration fees to community events, profit sharing, flexible work hours, up to \$5,000 tuition reimbursement, free gym memberships, and various staff picnics, barbecues, and outings.

Founded nearly twenty years ago by Michael A. Evans, Ph.D, AIT Laboratories started with five employees and grew to nearly 250 at the time nominations were accepted. Today, AIT's employee count exceeds 300.

Companies recognized as finalists for "Small Business of the Year" were: Elwood Staffing Services, headquartered in Columbus; Hinsey-Brown Funeral Service of New Castle; MonoSol of Merrillville;

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## “Be the Same Leader in Good Times as in Bad”

:: By AIT Founder, President, and CEO Michael Evans, Ph.D.

I was asked to give my perspective on how to lead a company in tough economic times while preparing for the inevitable upswing and recovery of the economy. There are countless volumes written on the subject of leadership. A simple Internet search provides more than 24 million hits on the subject



Michael Evans, Ph.D. started AIT 19 years ago.

ranging from articles on the art and science of leadership, guides for leadership, skills needed for leadership, and ... you get the picture.

In reality, leadership is about providing a vision or a goal and making possible the belief that you will provide the opportunity to achieve that vision. It isn't complicated, but like most simple concepts, leadership does require honesty, authenticity, and a deep, firm, and constant commitment to the vision. Leadership isn't about management, although without the discipline of management, leadership becomes akin to a Don Quixote fighting at windmills. Thus in my mind, leadership begins with providing a vision—a vision that individuals believe in, a vision that is real and attainable, a vision that brings people together and most importantly remains

constant in an ever-changing world.

I am always amazed when people talk about leadership and motivation—as if leadership consists of motivating individuals to achieve a goal or a vision. Providing bribes or threats (bonuses/layoffs) does nothing to achieve a vision. It drives people to achieve the bribe or avoid the threat. When it comes down to it, I don't know how any one person can motivate another. I do know that if I can learn and understand the personal vision that does motivate, a vision that the person wants and most importantly believes he/she can achieve, then that vision can become the motivation. My role as the leader then becomes simple—one of clarifying and communicating (and over-communicating) that vision to everyone who will listen.

What makes a person want to follow a leader? People want to be led by those they respect, by those they believe in (because that leader believes in them), and by those who have a clear sense of direction. A clear sense of direction is achieved by conveying a strong vision of the future.

So how does one lead in tough economic times? I think you should lead the exact same way no matter the state of your business or the economy. Good leaders lead all the time. For example, President Dwight D. Eisenhower was the same leader during the victory parade as he was when making the D-Day decision. Great coaches like Vince Lombardi and Knute Rockne were the same kinds of leaders whether their football teams won a game or lost. The great Indianapolis Colts Coach Tony Dungy continuously told his team to take it one game at a time when they started the season with a 3-4 record just as he did when they won the Super Bowl. All of these leaders were honest and open with their people, led with passion and conviction, and didn't

try to bluff their way through it.

AIT Laboratories experienced a record year in 2008. However, early in the company's inception, I lost my biggest client and was urged by advisors to file for bankruptcy and close the place down. I knew that it wasn't my employees' fault that the company was in this position; I knew that it was my lack of strong leadership. Entrepreneurs are driven by a strong sense of avoiding failure. I had to learn to get through one day at a time and then worry about day two. I knew I didn't have all the answers, but I had the same vision then as I do now.

During tough times, my employees chose to stay with the company and even take a pay cut because they believed in me. That is because I communicated to them all the time about the situation that “we” were in. I opened the financials of the company to employees, I worked with them on how to solve problems, and I accepted new ideas on how to solve those problems. That is exactly how I lead my company today, and we have grown from 25 employees to more than 300.

My employees still see the financials on a monthly basis, I still accept new ideas, and I encourage an atmosphere of teamwork that lets every employee know it is not one person's responsibility to make the company a success but a collective effort by everyone. I can be the best CEO in the country, but the work is done by the employees. I may own AIT Laboratories, but my employees are owners, too.

I always say that the best investment a company can make is in its employees. Without the backing of my team, there would be no AIT. I would have closed up shop 19 years ago like all of those advisors wanted me to. Instead, I established my leadership style and kept it consistent. I became a leader.

a closer look into the industry's widely used substances

# DRUGOGRAPHY

## Basics

Pregabalin is an anticonvulsant drug used to treat neuropathic pain and an adjunct therapy for partial onset seizures in adults. It can also be effective for treating chronic pain in disorders such as fibromyalgia and spinal cord injury and is approved to treat generalized anxiety disorder in Europe. Designed as a more potent alternative to gabapentin, pregabalin binds to calcium channels on nerves and may modify the release of neurotransmitters. Reducing communication between nerves may contribute to pregabalin's effect on pain and seizures. (The exact mechanism of action is unknown.) Pregabalin is marketed by Pfizer, the world's largest research-based biomedical and pharmaceutical company, under the trade name Lyrica.

Considered to have a low potential for abuse and a limited dependence liability if misused, pregabalin is classified as a central nervous system depressant Schedule V drug in the United States. Common side effects include but are not limited to dizziness, drowsiness, blurred vision, lethargy, memory impairment, euphoria, dry mouth, loss or decrease of libido, and weight gain.

## Backstory

Pregabalin was initially developed by medicinal chemist Richard Bruce Silverman at Northwestern University in the United States. It received U.S. Food and Drug Administration (FDA) approval for use in treating epilepsy, diabetic neuropathy pain, and post-herpetic neuralgia in December 2004 and appeared on the U.S. market in fall 2005. In June 2007, pregabalin became the first medication approved by the FDA specifically for the treatment of fibromyalgia. It was the first drug to be approved for this indication and remained the only one until duloxetine (trade name Cymbalta) gained FDA approval one year later.

Pregabalin as Lyrica fell under scrutiny in January 2008 when the FDA issued an alert that it and ten other "antiepileptic" drugs may double the risk of suicidality in patients. In the FDA's analysis of 27,863 patients in drug treatment groups and 16,029 patients in placebo groups, findings from close to 200 placebo-controlled clinical studies showed that 0.43 percent of patients in the drug treatment groups experienced suicidal behavior or thoughts as opposed to 0.22 percent of the patients in placebo groups. That December, Pfizer received letters from the FDA proposing safety labeling changes and the submission of a Risk Evaluation and Mitigation Strategy (REMS) for Lyrica. At the time Engage went to press, Pfizer posted a notice on [www.lyrica.com](http://www.lyrica.com) stating that the company would "work closely with the FDA to update the labeling for our antiepileptic medicines, including Lyrica, in a timely manner."



**AIT**  
**on the**  
**ROAD**

## Events

- |                           |   |
|---------------------------|---|
| <b>June 18-20, 2009</b>   | :: American Academy of Nurse Practitioners (AANP)<br>Nashville, TN                                      |
| <b>June 27-29, 2009</b>   | :: American Society of Interventional Pain Physicians (ASIPP) – 11th Annual Meeting<br>Washington, D.C. |
| <b>July 13-17, 2009</b>   | :: Georgia Association of Physician Assistants (GAPA)<br>Hilton Head Island, SC                         |
| <b>August 2-4, 2009</b>   | :: International Association of Coroners and Medical Examiners (IACME)<br>Las Vegas, NV                 |
| <b>August 14-16, 2009</b> | :: 16th Annual Napa Pain Conference<br>Napa, CA   |
| <b>August 16-18, 2009</b> | :: International Homicide Investigators Association (IHIA)<br>Clearwater Beach, FL                      |



AIT President Michael Evans, Ph.D. accepts the company's "Best Places to Work" award from Indiana Chamber President Kevin Brinegar.

Scorpion Coatings of Cloverdale; and Unified Group Services of Anderson.

“We are proud of the ongoing efforts of all the winning companies and the small business community at-large. These companies impact all of us. They contribute to many working families’ income, to the prosperity of respective communities, and to the entire state’s economic competitiveness,” Brinegar said.

The “Small Business of the Year” award is open to all Hoosier companies with 250 employees or fewer and has been given annually since 1993.

### “BEST PLACES TO WORK IN INDIANA”

For the second consecutive year, AIT Laboratories has been named one of the “Best Places to Work in Indiana” by the Indiana Chamber of Commerce. AIT joins other large and small- to medium-sized companies throughout Indiana on this prestigious list.

“I want to thank our employees for their hard work that makes this honor possible,” said AIT President and CEO Michael A. Evans, Ph.D. “Our employees are our best asset, and AIT is proud to continue to invest in our people, who are responsible for our success and record growth.”

AIT was honored at a dinner at the Indiana Roof Ballroom in downtown Indianapolis on May 5, when the Indiana Chamber announced the company rankings.

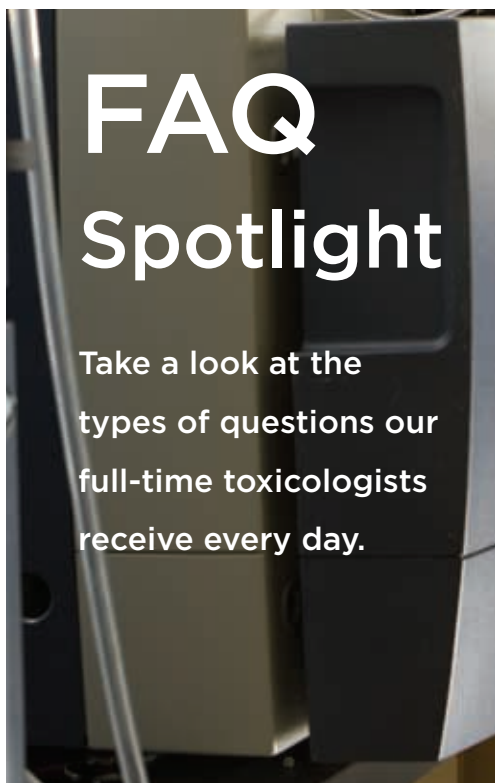
“In 2008, AIT put more than 60 new cultural initiatives into place to benefit employees,” said Chief Operating Officer Eric Orme. “Among those were the Quality of Life Committee, the Circle of Champions award, and a paid maternity leave program.”

Initiatives for 2009 include the formation of an AIT racing circuit to help encourage wellness among AIT employees and the

creation of a wellness coordinator position to oversee a more formal company-wide wellness program.

“Because our mission is to encourage employees with dignity and respect, it is fitting that AIT would be honored as one of Indiana’s best places to work for the second year in a row. Of all the accolades that AIT receives, this is perhaps the most meaningful. With a team of dedicated employees, we can meet any challenge,” said Chief Information Officer Ron Thieme, Ph.D.

At AIT, the culture of the company doesn’t happen by chance. AIT looks at ways to improve the culture as strategically as it looks at how to grow the business. “Without our valued and highly talented employees, AIT would not exist,” said Evans. “Making sure that our employees have a great work/life balance, get the training they need, and are fulfilled in their lives is what AIT is all about.”



### Could the result be a false positive?

A positive test result in the absence of the drug of interest is often called a “false positive.” This phenomenon is typically associated with screening tests based on immunoassay technologies. (Point-of-care devices and laboratory screening tests are good examples of these.) Immunoassay technologies detect the presence of a drug or drug class based primarily on its chemical structure or shape. While the immunoassay test is fairly selective for the drug or drug class of interest, other drugs having a similar chemical structure or shape may cross-react to give a “false-positive” result.

AIT Laboratories recognizes the potential for “false-positive” results when relying on immunoassay screening tests alone and the importance of accurate and reliable results. For these reasons, AIT’s results are based on secondary confirmation testing utilizing state-of-the-art mass spectrometry. Unlike immunoassay based technologies, the mass spectrometry technique provides what is effectively a “chemical fingerprint” pattern unique for each individual drug. This “chemical fingerprint” pattern eliminates the possibility of a “false positive.” Therefore, when AIT Laboratories reports a drug positive, the result is 100-percent accurate.

For more frequently asked questions, check out AIT’s FAQs page online:

[www.AITLABS.com/faqs.aspx](http://www.AITLABS.com/faqs.aspx)



# EXPERT RESEARCH

## The importance of meconium testing to determine maternal drug use during pregnancy

:: An editorial by AIT Toxicologists Josh Gunn, Ph.D. and Scott Kriger, Ph.D.

Due to the significant physical, mental, and developmental problems that can plague infants exposed to drugs in the womb, prenatal substance abuse is an on-going concern in prenatal care that crosses traditional socioeconomic lines. National findings from the 2006 National Survey on Drug Use and Health indicate that the rate of illicit drug use among pregnant women aged 15 to 44 years has remained steady since 2003 [1]. Estimating the prevalence of drug use among pregnant women based on maternal history or broad-scale surveys often proves unreliable, as mothers might be afraid to report drug use due to guilt, embarrassment, fear of reprisal, or loss of custody [2]. And even in the case of maternal admission, information regarding the type and/or extent of drug use is often inaccurate [3]. As a result, identifying drug-exposed newborns is a difficult task.

However, recognizing the damage done to infants through prenatal drug exposure is not. Drug use during gestation is associated with higher risks for poor obstetrical outcomes including placental abruption, premature labor, low birth weight, microcephaly, congenital anomalies, necrotizing enterocolitis, neonatal withdrawal, neurobehavioral effects, subarachnoid and intracerebral hemorrhage, and fetal death [4-12].

Traditional identification of neonatal drug exposure is accomplished using a combination of maternal history, newborn clinical symptoms, and laboratory toxicology testing of the mother and the infant [13]. In the case of the latter, traditional toxicological analyses used to identify prenatal exposure to illicit substances have relied on various maternal and neonatal specimens.

Maternal blood is routinely analyzed for the presence of illicit substances in the mother. However, due to the short window of detection and the invasiveness of sample collection, blood analysis is somewhat limited. For infants, urine is the most widely analyzed biological fluid for the determination of in utero drug exposure, but it's difficult to collect, not to mention invasive, and the specimen must be collected as close to birth as possible, as appreciable levels of drugs and/or metabolites are expected to be present in the first specimen only [14, 15]. Drugs present in the infant's urine represent recent drug use by the mother, but depending on the physiochemical properties of the drug, the urine may test negative if the mother is an infrequent user or abstained from use in the days leading up to delivery [14, 15].

In recent years, meconium has become the specimen of choice for the detection of prenatal exposure to several drugs of

drugs and other xenobiotics present as a result of fetal swallowing.

Meconium's popularity as a tool for the identification of prenatal exposure has continued to increase over the past two decades for several reasons. The relatively simple and non-invasive procedure used to collect meconium samples makes for a more successful collection compared to urine [55], and it extends the window of drug detection to approximately the last twenty weeks of gestation. In addition, meconium is one of the most sensitive matrices for the detection of prenatal drug exposure due to the accumulation of substances over several months of gestation. While the analysis of maternal and newborn blood or urine can be useful for identifying recent drug use (one to four days), mothers who have abstained from use in previous days will likely go undetected using these traditional matrices. But due to the nature of meconium formation, which

Meconium analysis extends the window of drug detection to approximately the last twenty weeks of gestation.

abuse [16, 17]. A dark-green mass of water, epithelial cells, mucopolysaccharides, bile pigments, and other lipids, meconium begins to form between the twelfth and sixteenth week of gestation and accumulates until birth. It materializes as a blackish, tar-like material that passes from the newborn's rectum in the first few days following delivery and can be used to identify the accumulation of

occurs over several months of gestation, isolated drug use during the second and third trimesters will still be detectable through meconium analysis long after drugs have been metabolized and excreted from the blood and urine.

For the full article and references, please visit AIT's "Expert Research" page at: [www.AITLABS.com/expert-research.aspx](http://www.AITLABS.com/expert-research.aspx).

## Meet the people behind AIT Bioscience

The AIT Bioscience team includes industry veterans with numerous years of experience in bioanalytical testing.

- **Ronald Shoup, Ph.D., executive director:** Shoup comes to AIT after most recently serving as chief scientific officer at Bioanalytical Systems, Inc. (BASi) in West Lafayette, Ind., where he served in various capacities. Shoup spent the past fifteen years at BASi building a contract research facility that offered services including drug safety testing, bioanalytical sample analysis, analytical chemistry for GMP-stability studies, and Phase I human clinical trials.
- **Timothy Grever, laboratory director:** Grever comes from Bioanalytical Systems, Inc. (BASi), where he rose through the ranks over ten years of service from a project manager to become director of bioanalytical operations, leading a 54-member bioanalytical team. Grever's diverse experience includes multiple successful FDA GLP audits, conversion of old

laboratory technologies to 96-well automated platforms, and non-routine repair of analytical instruments.

- **Brian Beato, Ph.D., senior scientist, mass spectrometry:** Beato previously served as laboratory and technical manager for Covance Bioanalytical Services in Indianapolis, Ind., where he assisted in the development and expansion of a bioanalytical LC/MS/MS laboratory and led Six Sigma projects focused on improving the efficiency and success of LC/MS/MS methods used in production.
- **Laurel Branstrator, director of quality assurance - GxP:** Branstrator comes from Bioanalytical Systems, Inc. (BASi), where she rose through the ranks during her 16-year tenure to senior director of quality assurance, where she managed a multi-site, diverse unit of auditors, archivists, and support personnel, supervised all internal and external audits by BASi and its clients, and was the principal representative for FDA inspections.

"New division" :: continued from page 1

they require, and building demonstration methods to show the speed at which AIT Bioscience can produce results.

Though it will employ its own production staff and operate as a separate financial entity from AIT Laboratories, AIT Bioscience will utilize many of the company's existing resources in areas like accounting, human resources, communications, and IT.

Miles Design, the Carmel-based design firm that created the new brand identity for AIT Laboratories last year, is responsible for the AIT Biosciences logo.

For more information about AIT Bioscience, contact Ronald Shoup, Ph.D. at [rshoup@aitbioscience.com](mailto:rshoup@aitbioscience.com) or visit [www.AITBioscience.com](http://www.AITBioscience.com).



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