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# The Best BioWest Yet

COMES TO DENVER AUGUST 23-24, 2006



Sizing up the state of Colorado bioscience at BioWest 2005.



Ira Flatow, host of NPR's Science Friday, will deliver a keynote at BioWest 2006.



Cowboy poet Baxter Black will entertain the crowd at the annual CBSA awards dinner August 24.

Featuring an impressive list of speakers, the popular venture showcase and a packed exhibit hall, BioWest 2006 promises to bring the *best of the* (Rocky Mountain) West from the medical device and biotech communities to the Colorado Convention Center this summer on August 23-24.

Attendees can enjoy two jam-packed days of activities and networking. Highlights include:

## KEYNOTE PRESENTATIONS

- Eric Sondermann, political consultant – "Colorado's 2006 Elections – Preview and Analysis"
- Patrick Kelly, BIO state relations – "What to Expect in the 2006 National Elections"
- Ralph Ives, executive vice president, global strategy and analysis, AdvaMed – "America's Medical Device Industry and Global Challenges"
- Ira Flatow, host of National Public Radio's *Talk of the Nation: Science Friday*® – "The Trials and Tribulations of Presenting Science to the Public"

- Chris Nolet, Ernst & Young, Palo Alto – Highlights from "Beyond Borders: The Global Biotechnology Report"
- Mike Orlando, Denver Federal Reserve – "Where Innovation Starts"

## COMPANY SHOWCASES

- In the *Venture Showcase*, seven emerging companies present themselves to a panel of national venture capitalists. Only one winner will be named. Who do you think will go home with the award?
- The *Investor Forum* brings together five of Colorado's more mature bioscience companies presenting their late-stage clinical trial results and anticipated market strategy to investment analysts and the community. Keep an eye out for these companies to take off in the next year or two.

## CBSA ANNUAL AWARDS DINNER

We promise that the evening of August 24th won't be your typical dull awards presentation as we're entertained by humorist Baxter Black, America's Cowboy Poet and favorite large animal veterinarian. Be there to cheer on your friends and associates who are vying for a CBSA award and to learn which emerging company will walk away with the prestigious Faegre & Benson Venture Showcase Award.

For conference registration and booth reservations, go to [www.BioWestConference.com](http://www.BioWestConference.com).



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## Subcommittee Encouraging Access to University Core Labs



**Report from  
Tim Estep,  
Co-Chairman  
CSU/CBSA Technology  
Transfer and Sponsored  
Research Subcommittee**

**THE OBJECTIVE  
IS TO IDENTIFY  
WHICH  
FACILITIES ARE  
INTERESTED IN  
WORKING  
WITH THE  
INDUSTRY AND  
HAVE THE  
PROCESSES  
AND CAPACITY  
IN PLACE TO  
DO SO  
EFFICIENTLY.**

The CSU/CBSA Tech Transfer and Sponsored Research Subcommittee initiated two projects to encourage industry access and facilitate collaboration with university core facilities.

The first is a vetting process to review core facilities with expertise in the development of bio-science products.

The objective is to identify which facilities are interested in working with the industry and have the processes and capacity in place to do so efficiently.

Core facilities that meet these criteria will be listed in a database on the Technology Transfer and Sponsored Research section of the CBSA Web site. The information will include a synopsis of their capabilities, con-

tacts, and a link to the facility's Web site.

Currently, four core facilities from CSU have undergone review by the subcommittee. We anticipate reviewing additional CSU facilities as well as facilities from other Colorado research institutions once an expanded vetting process is established.

A second, related project is the development of template contract agreements to expedite the contract negotiation process. Standard contract agreements are reviewed and modified to incorporate best practice terms. Once approved by the committee and the appropriate institutional representatives, template documents will be posted on the CBSA and institution's Web sites.

We recognize that no one document can adequately address all situations, but we believe that the initial use of templates derived from the joint review and modification process should facilitate negotiation by presenting a balanced best practice point of departure. Moreover, CSU's use of unaltered template documents will only require minimal signature review, allowing a highly expedited approval process. One template has already been developed by this process. A CSU materials transfer agreement is now available on both the CBSA and CSU Web sites.

To view the list of core labs and materials transfer agreement, go to [www.CoBioScience.com](http://www.CoBioScience.com) and click on Tech Transfer. ☛

# TheraTogs

POSITIONED FOR SUCCESS, WITH HELP FROM THE COLORADO FUND I

**FOR BEVERLY CUSICK, THERATOGS IS THE CULMINATION OF THIRTY YEARS OF WORK AND RESEARCH. WITH HELP FROM COLORADO INVESTORS, HER DREAM TO CHANGE THE WAY PATIENTS WITH MOVEMENT OR POSTURAL DYSFUNCTION ARE MANAGED IS TAKING A BIG FIRST STEP.**

The TheraTogs system is an orthotic undergarment and strapping system that gives clients with neuromotor and orthopedic impairments a new modality for improving postural alignment and stability. Stated more simply, Cusick describes it as a way for physical therapists to replicate the manual assists, directions and modalities that they use in treatment sessions – and send them home with a patient.

Cusick has been a pediatric physical therapist and instructor for over 30 years and is the president of TheraTogs Inc., based in Telluride. She is internationally known for developing methods to help children with neuromotor dysfunction live healthier and happier lives.

Like many other medical innovators, the motivation for Cusick's product came from the profound frustration she felt in her own prac-



tice. "I was having trouble getting the movement training work I was doing to 'stick' with the patient between sessions," said Cusick.

After years of searching for a solution, she finally discovered the combination of the right materials. TheraTogs became a reality. "There were a few garment-like products on the market, but nothing worked correctly or it wasn't made out of the correct material," said Cusick. "There were good ideas with unsatisfactory execution."

To get the desired results, therapists typically use tapes, rubberized bands and a variety of braces and casts. According to Cusick, TheraTogs offers better results and is durable, comfortable and customizable. The garment and strapping systems are made of patented composite fabrics consisting of nylon and Spandex, with a rubber-free and latex-free foam backing.

"The material is unique," said Cusick. "It allowed us to design live-in systems for kids and adults that function as movement or balance-training aids." Armed with

the right materials and product, in the fall of 2004 TheraTogs set out to tell its story to as many investors as possible.

"We were very lucky in our search for investors, said Lee Taylor, Cusick's husband and CEO of TheraTogs. "We met the right people."

After a series of presentations, the company was invited to the Colorado Capital Conference. That pitch led TheraTogs to Mark Lupa, a principal in High Country Venture, the manager of the Colorado Fund I. After reviewing its business plan, the Colorado Fund I agreed to invest in the company.

"What caught my eye was a video of a child before and after putting on the TheraTogs," said Lupa. "I was able to see how it improved walking ability. It was really striking." Thanks to the investment from the Colorado Fund I, TheraTogs was able to complete the necessary research to market the product. The company has completed a revised business plan and is planning to close the first round of funding this summer.

It has been a long road, but Cusick and Taylor believe that TheraTogs will revolutionize the way therapists work with their patients.

According to Taylor, there are currently 26 million people suffering from neuromotor dysfunction with 1.6 million new cases reported each year. TheraTogs also plans to tap the orthopedic market which it believes affects 55 million individuals nationwide. "The market for our products is huge," said Taylor. "We fully expect to hit \$15 million in revenues by the end of the decade."

## About The Colorado Fund I

The Colorado Fund I is a venture capital fund that invests in seed and early stage businesses in Colorado. It was established in 2005, in part by an investment from the Venture Capital Authority (VCA).

The Colorado Fund I is managed by High Country Venture, LLC of Boulder, and is currently invested in four bioscience companies: SmartCare Family Medical Centers, Surginetics, Inc., Taligen Therapeutics and TheraTogs.

Because the Venture Capital Authority is a limited partner, High Country Venture adheres to the VCA's requirements when investing. The fund's approach is unique because it works with companies to establish a direction at a formative stage.

"We tend to look at companies very early. Many don't even have business plans," said Mark Lupa, a principal in High Country Venture. "We spend a lot of time with these companies to get them headed in the right direction. Then we can start building value."

According to Lupa, while High Country Venture plans to diversify the fund by investing in companies from other sectors, it is looking for an additional bioscience company to invest in.

For more information about the Colorado Fund I visit [www.coloradofund1.com](http://www.coloradofund1.com).



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Authority**

**Forest City**

**Gambro**

**Hogan & Hartson**

**Holland & Hart**

**Longmont Area  
Economic Council**

**Pfizer**

**Snell & Wilmer**

**University of Colorado**

## Designing an Effective Design Control Program

BY CLAY ANSELMO

Each time I write my next CBSA *Focus* column, I begin by looking for a relevant, interesting topic. While the words *interesting* and *regulatory* may seem mutually exclusive to some of you, there is usually one topic that people continually ask me about.

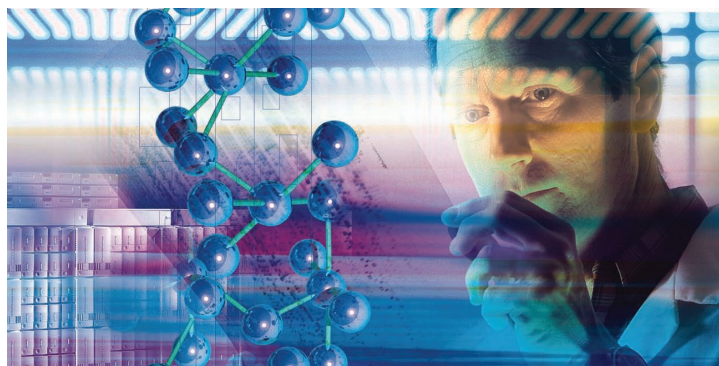
Lately, I have been overwhelmed with questions relating to design controls. While the application of design controls to new medical devices has been a requirement for nearly 10 years, the confusion surrounding this topic has increased dramatically in recent years as pressure mounts to bring new products to market faster and with reduced costs.

### RIGHT SIZING

When it comes to design controls, one size definitely does not fit all. Designing a system that scales with your company and your projects is essential. When I review design control programs there are typically two distinct flavors.

The first is a one-procedure system copied mostly from FDA guidance that simply restates the regulation without instructions, forms or templates for implementation. The second involves the opposite end of the spectrum, where the system generally contains twenty or more procedures with extremely specific requirements that don't scale with the complexity of a given project.

One type simply meets a regulatory requirement with little consideration for the difficulties involved in execution. The second is the result of applying the manufacturing quality system



formula to the much more variable design process. Neither is an optimal solution.

### COMMON CHARACTERISTICS

Several factors about design and development make it unique:

- The physical product is undefined at the start of the process.
- Design is a creative process.
- Each product can vary greatly in complexity and risk.
- New product development is typically executed on an infrequent basis.

These factors make designing a successful system challenging. But there are certain characteristics that are commonly present in successful systems:

- A reasonable number of procedures, typically one for each key element (i.e. – design planning, design input, design out, verification and validation, etc.) with one top level SOP showing the interrelationship of elements.
- Procedures that contain many examples and utilize flexible templates for each document type.
- Deliverables including documents and reviews that

are scaled to the scope of the design project (i.e. – new product, safety related change to existing product, non-safety related change to existing product, additional indication for use, etc.).

- Best practice examples for each deliverable type are available to development teams to avoid reinventing the wheel on each project.

While some people consider design controls simply something they must do because of the regulatory requirements, a well executed, scalable system has definitive benefits. Not only will it simplify your design transfer process by providing well characterized specifications that have proven capability, but it can improve field performance, reduce regulatory risk and even speed time to market.

Before your next development project, consider an evaluation of your design control program. Making an initial investment in system design now can yield extensive rewards down the road.

*Clay Anselmo is president and COO of Reglera Corporation, providing regulatory consulting and resources to biomedical companies: [www.reglera.com](http://www.reglera.com).*

# Oil Seed's Beauty Proves to Be Skin Deep



**Laurie Jones**  
President, Sterling Biotech

**"AT TRADE SHOWS,  
I WOULD PROVE  
THE OILS WERE  
NON-TOXIC BY  
TASTING THEM AND  
PUTTING THEM ON  
MY SKIN.  
I NOTICED THE  
OILS MADE MY  
SKIN SOFT."**

The saying goes, 'one thing leads to another.' But when Laurie Jones, president of Sterling Biotech, began developing alternative motor oil three years ago, she had no idea that it would lead into the personal care market.

Based in Sterling, the business was founded in June 2003 to make motor oil from oils extracted from seeds. The company was licensing the technology and had plans in place to manufacture the oil. But problems got in the way, making the prospect of bringing the product to market difficult.

Determined to keep the company moving forward, Jones brainstormed other uses for the technology until she uncovered a realization that would take the company in an entirely new direction.

"At trade shows, I would prove the oils were non-toxic by tasting them and putting them on my skin," said Jones. "I noticed that the oils made my skin soft."

Jones investigated the possibility of using the same oil seeds to create a line of organic personal care products. She approached a chemical engineer with the idea. Ironically, he had been working with Sterling Biotech on the motor oil product but had a background in the personal care industry.

"He looked at the chemical properties of the oils and said 'this looks doable,'" said Jones. By 2005, Sterling Biotech had completely left the motor oil industry and was developing all-natural personal care and skin care products.

Today Sterling Biotech develops products under its WÜR<sup>TM</sup> skin care line, including several varieties of lip balm, massage oil, foot cream and hand balm. While the initial target market was the active individual concerned about his or her health, Jones is also targeting smaller niche markets. She believes there is a large demand for natural products for individuals with health concerns who develop complications from common skincare products. One of these markets is skincare for diabetics.


Because of poor circulation, a diabetic's skin becomes very dry, which can lead to skin damage and put them at a higher risk for infection. Ordinary problems, such as cracking, can lead to more serious complications. According to Jones, many over-the-counter products contain chemicals and alcohol that also have an adverse affect. Sterling Biotech is currently working with a physician on a series of trials to gain hard data to quantify the benefits of the product.

The market for organic and natural food is booming, and Jones believes the demand for all-natural personal care products is not far behind. "People are becoming more aware of what they put in their bodies," said Jones. "People are starting to look at personal products the way they look at food."

Jones points out that the natural personal care market reached \$4.5 billion in 2005. "What we would like to do is establish strong marketing and sales partnerships with companies that are already in this industry," said Jones.

Because the market for natural skin care products is larger in Europe, Sterling Biotech is already manufacturing products for a company that will market them overseas. But regardless of how much the company grows, Jones maintains that she will continue to operate in Northeast Colorado. The vice chair of the state's economic development commission and Colorado's Venture Capital Authority believes that Sterling offers the ideal location for her company. "We enjoy the lower cost of doing business here and we have easy access to rail lines, private airports and a variety of carriers," she said.

As another old saying goes, "If it ain't broke, don't fix it."

For more information visit [www.wurxskincare.com](http://www.wurxskincare.com) or [www.sterlingbiotech.com](http://www.sterlingbiotech.com). 

# People in the News

From the State Bioscience Initiatives 2006, prepared by the Battelle Technology Partnership Practice and SSTI

- Colorado's bioscience establishments are growing faster than the national average. From 2001-2004, Colorado grew by 5.9% compared to a national rate of 4.8%.
- Colorado's bioscience average annual wage is higher than the national average. In 2004, Colorado's bioscience average annual wage was \$40,217 compared to \$39,003 nationally.

Bioscience occupations in the Colorado workforce in 2004 included:

- Agriculture, food and nutrition scientists and technicians - 200
- Biomedical and biochemical scientists and engineers - 330
- Biological scientists and technicians - 3,250
- Medical and clinical laboratory technicians - 4,640



Kevin Smith enjoying time out of the office.



Gear head Frank Amoroso in his Lotus Elise.

**GEAR HEAD  
SICKNESS,  
A CHRONIC  
CONDITION WITH  
NO KNOWN CURE,  
IS SPREADING  
RAPIDLY AMONG  
CBSA MEMBERS.**

**Frank Amoroso**, vice president of Silicon Valley Bank, has "gear head sickness," a chronic condition with no known cure. Frank does the auto reviews for the *Boulder County Business Report*, *Colorado Company* magazine and WB2 News. He tells us that other gear heads are very envious about his Lotus Elise when he drives it at National Auto Sport Association events.

The insidious disease is spreading rapidly among CBSA members. **Kevin Smith**, president of Gam-

bro, just returned from racing his Spec Racer Ford in the Sports Car Club of America national event. And GlobelImmune's president and CEO **Tim Rodell** races Formula cars through the Skip Barber Racing School and drives Porsche 911's in the local Porsche track club.

Do your Colorado bioscience colleagues have any interesting hobbies that we should know about? Let us know.

Vitro Diagnostics Inc. appointed **James R. Musick** president and chief executive officer.

Boulder's Pharmion Corp. named **Andrew R. Allen** to the newly created role of chief medical officer. Most recently, Dr. Allen served as vice president of BioPharma Development and the head of the Oncology Therapeutic Unit for Emeryville, CA based Chiron.

**James V. Caruso** was appointed chief commercial officer at Allos Therapeutics.

**Jill Sikora Farnham** was named executive director of the Fitzsimons Redevelopment Authority (FRA). Farnham will oversee the Authority's operations as it moves forward with a proposed long-term partnership with Forest City Enterprises, and will also oversee

on-going transactions with the Veterans Administration for a new hospital at Fitzsimons and with the Pauls Corporation for the residential/mixed-use complex.

Welcome to **Olena Burda-Lassen**, the CBSA's newest employee. Olena is an administrative assistant in charge of the CBSA database, membership dues, event coordination and as many other duties as we can give her. Olena brings years of international expertise to the CBSA. Please make her feel welcome.



Baxa's **Marian Robinson** (left) received the AMA Marketer of the Year Award.

**Marian Robinson**, vice president of marketing for Baxa Corporation, won the American Marketing Association Marketer of the Year award exemplifying outstanding marketing leadership and accomplishment. Accepting the award, Robinson credited her team for making it possible to do great work. The American Marketing Association's Colorado Chapter is a professional marketing association in Denver dedicated to advancing the field of marketing in Colorado. The group's annual PEAK Awards recognize extraordinary work in marketing campaigns. **C**



# CBSA NewsMakers

The **University of Colorado** is set to unveil a new master plan for its 95-acre research park in Boulder, including a \$113 million biotechnology center. CU plans to transform the park on Colorado Avenue, between 30th Street and Foothills Parkway, into a research campus that will better serve students, faculty and researchers.

**CU Boulder** received a four-year \$1.9 million bioscience education grant from the Howard Hughes Medical Institute to fund programs benefiting undergraduates and K-12 teachers and their students.

**Lifeline Therapeutics Inc.** of Denver announced a partnership with MyMedLab Inc. to provide consumers with medical testing of the effects of Lifeline's Protandim on oxidative stress.

**AcuNetx** of Superior filed for patent protection for its HawkEye HGN Trainer, manufactured by the company's VisoNetx division. The HawkEye device, which captures eye movements, is used as a training tool to teach police officers how to administer a standardized field sobriety test.

**Massively Parallel Technologies, Inc.** a provider of on-demand high-performance computing announced that its Powered by HOWARD high-performance BLAST is the first commercial on-demand software service to make a *priori* estimates of sequence search times. Massively's Powered by HOWARD high-performance BLAST service is available on the BioTech Virtual Power Center (VPC).

Massively also announced a new partnership with Fulcrum Strategic Partners, Inc., a leading U.S. biometric consulting company. Ken Nosker, FSP founder and president, recognized the tremendous opportunity to bring to bear the speed, power and processor efficiency of Massively's patented HOWARD software technology to address short-comings of conventional biometric solutions.

**Amgen Inc.** will open a new office in a free trade zone in Dubai, moving the company's operations in the Middle East to the new location. The office will also be a hub for the sales of its various arthritis and cancer-relief drugs to area customers.

**Spectranetics Corp.** of Colorado Springs announced it intends to offer an aggregate of about \$43 million of its common stock. Spectranetics also intends to grant the underwriters a 30-day option to purchase about \$6.5 million of additional common stock to cover over-allotments.

**Sage Public Relations Group** won a Bronze Peak award from the American Marketing Association for the 2005 *Bioscience Colorado* magazine.

**Isonics Corp.** has raised \$16 million in financing through convertible debenture and warrant financing. Isonics has divisions for homeland security and defense, semiconductors and life sciences.

**Governor Bill Owens** signed an historic \$26.5 million economic development bill on June 5, 2006. The bill designates \$2 million to the advancement of new bioscience discoveries at Colorado research institutions.

**Baxa Corporation** received a Gold PEAK award from the American Marketing Association for its Real Pharmacy direct mail campaign. The award recognized the successful campaign to generate customer testimonials on Baxa products through a fun photo contest about a day in the life of a real pharmacy.

**Allos Therapeutics** presented findings from a preclinical study showing that EFAPROXYN™ was found to reduce tumor hypoxia and HIF-1-alpha expression in human breast cancer xenografts.


**Globelimmune** announced the initiation of a randomized, placebo-controlled, multi-center Phase 2 clinical trial of GI-4000, Globelimmune's therapeutic vaccine for the treatment of patients with early-stage pancreas cancer.

**Encision Inc.**, a Boulder medical device company with patented surgical technology used in minimally-invasive surgery, was the recipient of the Colorado Software and Internet Association Apex Award for Technology Product of the Year.

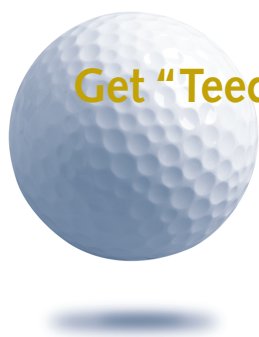
**Denver Biomedical Inc.** has been sold to Cardinal Health Inc. Denver Biomedical, located in Golden, designs and manufactures specialized medical products for hospital and home use, primarily for terminally ill cancer patients. The company has 50 employees.

**Bal Seal Engineering**, a California-based medical device maker, announced that it will open a manufacturing facility in Colorado Springs. The company plans to eventually hire more than 100 employees and build its own 50,000-square-foot plant near the Colorado Springs Airport in 2008.

The **Fitzsimons Redevelopment Authority** and the **University of Colorado Hospital** signed lease for a state-of-the-art clinical training center at Bioscience East, a newly renovated 25,000 square foot building in the bioscience park at Fitzsimons.

Please remember to include the **Colorado BioScience Association** on your press release distribution list. Recognizing your achievements is another member benefit that the CBSA is proud to provide. 

## COMING EVENTS




**Get "Teed Off"...** at the BioScience Bogie on September 18. CBSA's annual golf tournament will be held again this year at the beautiful Omni Interlocken Resort Golf Club. Opportunities for sponsorship are still available. Keep an eye out for announcements and more details on player registration. 

Join us for the Colorado BioScience Association and Colorado Software and Internet Association Wine Tasting on the evening of August 3.


This year our event will be held in the newly opened and beautifully renovated historic Carriage House and Grounds

## Wine

### THE WORLD'S FIRST BIOTECH PRODUCT?

in the Governor's Residence at the Boettcher Mansion, 400 East Eighth Avenue. Parking, paid and otherwise, is available just to the west of the Governor's Mansion. 

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