



NATIONWIDE QUALITY &amp; COMPLIANCE SERVICE PROVIDER

# Sequence Spotlight

## June 2015

ISSUE HIGHLIGHTS

## Sequence announces new nationwide Automation Engineering Division

In February of this year, Sequence, Inc., a leader in quality and compliance consulting for regulated industries, announced the creation of an automation engineering arm to support clients nationwide.

Newly hired automation engineers and an existing Manufacturing Support team have joined forces to form an Engineering and Technical Services division within Sequence. Integration of these teams enables Sequence to provide end-to-end solutions to clients deploying new automation systems and to those enhancing existing systems.

From functional requirements specifications to detailed design, validation and implementation, the Engineering and Technical Services group provides all deliverables needed to ensure successful process control and sound regulatory compliance.

"It is with great pleasure that I announce the newest progression in the growth of Sequence," said Mike Putnam, President and CEO of Sequence, Inc. "This vision was

developed by our management team over three (3) years ago, and to see it solidified in 2015 with the official licensing of Sequence Engineering PLLC is very exciting. The ability to provide engineering services coupled with quality and compliance solutions is key to the future of our organization. Not only will it benefit our existing drug and device clients, but it also serves as a gateway into other regulated industries like energy and transportation."

The Engineering and Technical Services division is off to a successful start in 2015 with multiple greenfield facility start-ups, global Serialization compliance initiatives and implementation of Process Intelligence programs for new and existing clients.

With offices across the country and a global compliance center based near Research Triangle Park, NC, Sequence is poised to support quality, compliance and engineering services for projects ranging from large facility start-ups to individual system optimization initiatives.



### Editor's Note: New Initiative

Beginning with this publication, Sequence is excited to announce the distribution of Sequence Spotlight newsletters for clients and colleagues to keep them informed on the latest Sequence and industry news.



### Another Year, Another Honor

Sequence was awarded the Raleigh Chamber of Commerce Pinnacle Business Award for Steady Growth and Profitability for the 3<sup>rd</sup> consecutive year.

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### Running for a Cause

On May 3, 2015, Sequence sponsored and participated in the 23<sup>rd</sup> Annual Run for Sight 5k Run | 2- Mile Walk | Kids Fun Run in downtown St. Louis, MO.

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## Sequence earns Raleigh Chamber of Commerce Pinnacle Business Award for Steady Growth and Profitability

On May 19, 2015, Sequence Inc. President & CEO Mike Putnam and other top business leaders from around the Triangle (Raleigh-Durham-Chapel Hill) attended BizCon 2015, hosted by the Greater Raleigh (NC) Chamber of Commerce.

At the event, Sequence was awarded the Raleigh Chamber of Commerce Pinnacle Business Award for Steady Growth and Profitability. This marks Sequence's third consecutive year receiving this honor, which graduates Sequence Inc. to a new level of distinction known as the "Steady Growth and Profitability Master Award".

The award signifies that Sequence Inc. has maintained steady growth over the last 3+ years and puts Sequence on a short list with other local businesses who have managed to successfully earn this honor.



BizCon 2015 was an all-day conference featuring a keynote on "The Business of Innovation" by Terry Jones, founder of Kayak.com and Travelocity.com.

The day included:

- Networking with experienced business owners and managers
- An exhibit area displaying products and services from local businesses
- Breakout Sessions to improve business and professional performance—including, hiring best practices, business development and more
- An awards celebration to recognize the accomplishments of successful businesses

## Recent FDA Press Releases

### FDA approves Rapamune to treat LAM

The FDA recently approved Rapamune (sirolimus), to treat lymphangioleiomyomatosis (LAM), a rare, progressive lung disease that primarily affects women of childbearing age. This is the first drug approved to treat the disease.

LAM is characterized by an abnormal growth of smooth muscle cells that invade lung tissues, including the airways, and blood/lymph vessels that cause destruction of the lung, resulting in airflow obstruction, and limiting the delivery of oxygen to the body.

LAM is a very rare disease. According to the U.S. National Library of Medicine, only between two and five women per million women worldwide are known to have the disease.

For the full story, refer to <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm448523.htm>



### FDA releases draft guidance on animal drug compounding from bulk drug substance

As part of its overall efforts to address compounded drugs, the FDA recently released a draft "Guidance for Industry (GFI) #230, Compounding Animal Drugs from Bulk Drug Substances."

Current law does not permit compounding of animal drugs from bulk drug substances, but the FDA recognizes that there are limited circumstances when an animal drug compounded from bulk drug substances may be an appropriate treatment option.

For more the full story, refer to <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm447159.htm>

### FDA proposes rule to collect antimicrobial sales and distribution data by animal species

The FDA proposed a rule recently that would require animal drug sponsors of all antimicrobials sold or distributed for use in food-producing animals to obtain estimates of sales by major food-producing species (cattle, swine, chickens and turkeys).

The additional data would improve understanding of how antimicrobials are sold or distributed for use in major food-producing animals and help the FDA further target its efforts to ensure judicious use of medically important antimicrobials.

For the full story, refer to <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm447244.htm>

# Upcoming Sequence Events



On Jun 15-18, 2015, Sequence will be exhibiting at the 2015 BIO International Convention at the Pennsylvania Convention Center in Philadelphia, PA. BIO covers the wide spectrum of life science innovations and application areas. Drug discovery, biomanufacturing, genomics, biofuels, nanotechnology and cell therapy are just a few of the industries represented at the BIO International Convention.

The world's largest biotechnology gathering, the BIO Exhibition allows exhibitors to reach high-level executives and influential decision makers who come to BIO to discover new players in the industry, form partnerships and evaluate emerging technologies. The 2015 BIO Exhibition will feature more than 1,700 exhibitors and approximately 160,000 square feet. The exhibition also includes 60+ state, regional and country pavilions who in turn host many companies from their regions.

Conveniently organized by product focus zone, the BIO Exhibition will host thousands of organizations including the leading biotech companies, top 25 pharma companies, top 20 CROs and CMOs, more than 300 academic institutions including the major research labs and government agencies and the leading consultants and service companies.

For more information, refer to <http://convention.bio.org/>.

On October 7, 2015, Sequence will be exhibiting at the 24<sup>th</sup> Annual ISPE Product Show at Gillette Stadium in Foxborough, MA.

Education Sessions will include the following:

- Facility Optimization & Process Improvement
  - John Romero
- Oral Solid Dosage Forms – ISPE Baseline Guide
  - Jack Chu
- Future Trends
  - Panel Discussion
- Biotech 201: Intro to Single Use Technologies
  - Speaker to be Announced



The event will also include the following:

- Keynote from John Bournas, ISPE President and CEO
- Career Fair
- Vendor Showcase
- Cheerleaders for Charity - Get a picture and an autograph to help the "Cheerleaders for Charity" raise money for the New England Patriots Charitable Foundation. All proceeds raised will be matched dollar for dollar by the ISPE Boston Chapter.
- After Show Party - Come say thank you, take a picture and get an autographed photo with the 2014 Superbowl hero, #21, player Malcolm Butler.

For more information, refer to <http://www.ispeboston.org/ProductShow/>.



## Recent Industry News

### FDA grants Breakthrough Therapy designation for Genzyme's Olipudase alfa

Genzyme (a Sanofi company) announced recently that the FDA has granted Breakthrough Therapy designation to Olipudase Alfa. This enzyme replacement therapy is being investigated for the treatment of patients with nonneurological manifestations of acid sphingomyelinase deficiency (ASMD), also known as Niemann-Pick disease type B, as opposed to type A which is characterized by neurological involvement.

ASMD is a serious and life-threatening disorder caused by insufficient activity of the enzyme acid sphingomyelinase (ASM), which results in toxic accumulation of sphingomyelin. There are currently no approved treatment options for patients with Niemann-Pick disease type B.

Breakthrough Therapy designation is intended to expedite the development and review of investigational new drugs that target serious or life-threatening conditions. The criteria for granting Breakthrough Therapy designation are preliminary clinical evidence of substantial improvement on a clinically significant endpoint over available therapies.

For the full story, refer to <http://www.businesswire.com/news/home/20150603006716/en/FDA-Grants-Breakthrough-Therapy-Designation-Genzyme%E2%80%99s-Olipudase#.VXXW689VhBc>

### Amazon, Google race to get DNA into the cloud

Amazon.com is in a race against Google to store data on human DNA, seeking both bragging rights in helping scientists make new medical discoveries and market share in a business that may be worth \$1 billion a year by 2018.

Academic institutions and healthcare companies are picking sides between their cloud computing offerings - Google Genomics or Amazon Web Services - spurring the two to one-up



each other as they win high-profile genomics business, according to interviews with researchers, industry consultants and analysts.

That growth is being propelled by, among other forces, the push for personalized medicine, which aims to base treatments on a patient's DNA profile. Making that a reality will require enormous quantities of data to reveal how particular genetic profiles respond to different treatments.

Now an estimated \$100 million to \$300 million business globally, the cloud genomics market is expected to grow to \$1 billion by 2018, said research analyst Daniel Ives of investment bank FBR Capital. By that time, the entire cloud market should have \$50 billion to \$75 billion in annual revenue, up from about \$30 billion now.

For the full story, refer to <http://www.cnbc.com/id/102735413>

### AstraZeneca takes part in joint venture to build a \$125 million plant in Algeria

AstraZeneca CEO Pascal Soriot has made emerging markets part of his 5-point campaign to rebuild the drugmaker's financial health. And now he is taking that piece of his campaign to North Africa, where AstraZeneca is part of a joint venture to build a \$125 million plant.

The drugmaker has formed AstraZeneca al-Djazair, with two companies in Algeria, Salhi and Hasnaoui, to build the facility. As prescribed by Algerian law, the local

companies will have majority ownership while AstraZeneca will have a 49% interest, invest the \$125 million to build the facility, will be in charge of the technological transfer, and manage the project and the facility once it is built.

Emerging markets are already important to the U.K. drugmaker, accounting for more than 22% of its sales last year and growing by 12% to \$5.8 billion. North Africa has been drawing more attention from Western drugmakers scouring the world for markets where they can reap faster growth than in the larger, but slower growing markets in the west.

AstraZeneca has been in the country since 2007 and has about 180 employees there.

For the full story, refer to <http://www.fiercepharma.com/story/astrazeneca-takes-its-emerging-markets-push-algeria-125m-expansion/2015-06-05>

### Crunching The Numbers

Based on aggregated data from *The New York Times*, the 5 highest paid pharmaceutical CEOs in 2014 were the following:

- Lamberto Andreotti, \$26.1 million  
Bristol-Myers Squibb
- Kenneth Frazier, \$21.4 million  
Merck
- Alex Gorksy, \$20.4 million  
Johnson & Johnson
- Ian Read, \$18 million  
Pfizer
- Richard Gonzalez, \$17 million  
AbbVie

For the full story, refer to <http://www.fool.com/investing/general/2015/06/06/the-highest-paid-ceos-in-pharma.aspx>



# Recent Sequence Events

## Sequence exhibits at 2015 ISPE-CaSA Technology Conference



### Carolina-South Atlantic Chapter

On March 10, 2015, Sequence exhibited at the 22nd Annual ISPE-CaSA Technology Conference at the Raleigh Convention Center in Raleigh, NC.

Nearly 200 of the industry's top equipment and service providers attended, and several different tracks of educational sessions on the most current industry issues and case studies were provided, including facilities, process optimization, automation, quality and tech transfer.



## Sequence exhibits at the 2015 Pittcon Conference & Expo



On March 8-12, 2015, Sequence exhibited at the 2015 Pittcon Conference & Expo at the Ernest N. Morial Convention Center in New Orleans, LA.

Pittcon is global exposition that provides the opportunity to get a hands-on look at the latest laboratory instrumentation, participate in live demos and product seminars, talk with technical experts, network with +18,000 attendees from around the world, and find solutions to all your laboratory challenges.





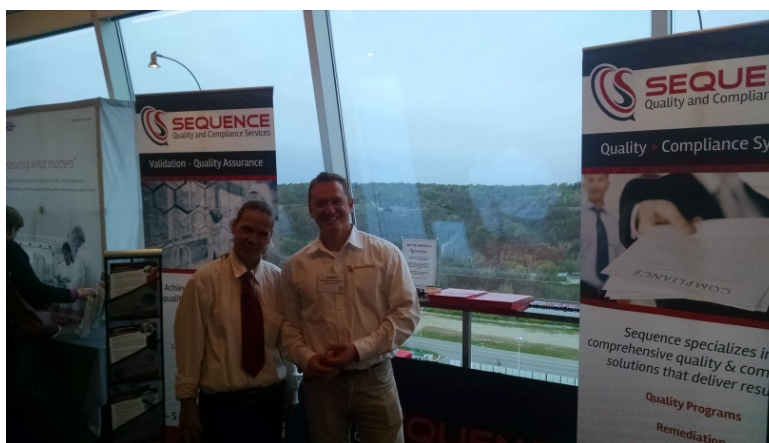
## Sequence exhibits at PDA Missouri Valley Chapter Spring 2015 Conference



On April 13, 2015, Sequence exhibited at the PDA Missouri Valley Chapter Spring 2015 Conference at Arrowhead Stadium in Kansas City, MO.

The event included a tour of Arrowhead Stadium, a cocktail social, and dinner. Speakers included:

- FDA Remarks – Gerald Bromley, Kansas City District Office
- Vendor Qualification and Management – Manuel Garza, Parexel
- Quality Agreements – Bob Williford, Hospira
- FDA Inspection Trends – Industry Panel



## Sequence exhibits at ISPE Midwest Chapter TechEd Day



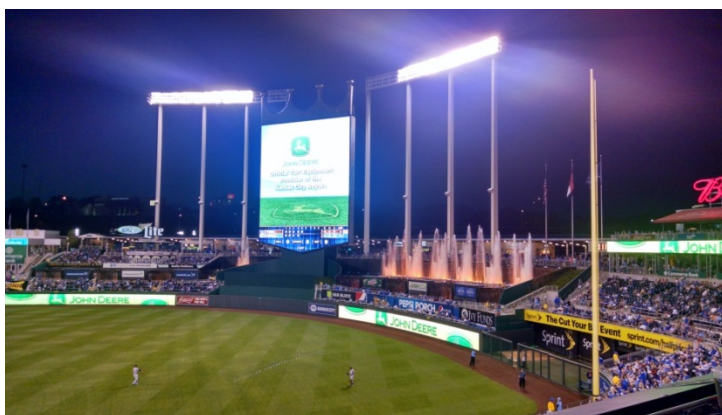
Connecting a World of  
Pharmaceutical Knowledge

**Midwest  
Chapter**

On April 30, 2015, Sequence exhibited at the ISPE Midwest Chapter TechEd Day at Arrowhead Stadium in Kansas City, MO.

The event included quality and facility breakout presentations and discussion and a vendor showcase.

The event concluded with a BBQ tailgate party and seats to the Kansas City Royals vs Detroit Tigers!





## Sequence sponsors 23<sup>rd</sup> Annual Run for Sight



On May 3, 2015, Sequence sponsored and participated in the 23<sup>rd</sup> Annual Run for Sight in downtown St Louis, MO. Dan Santarsiero, Director of Business Development for Sequence, was awarded a medal after finishing 1<sup>st</sup> overall in his age group (35-39) and 12<sup>th</sup> overall among men with a time of 24:17!

Run for Sight is the largest annual event for the Delta Gamma Center for Children with Visual Impairments. The mission of the Delta Gamma Center for Children with Visual Impairments is to help children who are blind or visually impaired reach their full potential through family-centered and



## Sequence exhibits at ISPE CaSA Golf Tournament



**Carolina-South  
Atlantic Chapter**

On May 18, 2015, Sequence exhibited at the 2015 ISPE Golf Tournament at Prestonwood Country Club in Cary, NC. Sequence sponsored one of the challenging par 3 holes; proceeds from the event went to the Me Fine Foundation.

The mission of the Me Fine Foundation is to provide hope to critically ill children treated by Children's Hospitals in North Carolina and their families through financial assistance, emotional support and necessary resources.

