



NATIONWIDE QUALITY &amp; COMPLIANCE SERVICE PROVIDER

# Sequence Spotlight

## March 2015

ISSUE HIGHLIGHTS

## Oh! The Places You'll Go!

Oh! The places you'll go! Bring back memories? Maybe you remember your mom or dad reading this classic Dr. Seuss book to you as a child. Like me, maybe you think back on reading the story to your own child during the nighttime bed routine. Either way, I'll bet it brings back precious memories for many of a time you knew there was so much ahead to experience. Such is the case with a company born 13 years ago this March. Your company, Sequence!

From its fledgling years as a start-up computer validation firm to today where over 100 industry-leading professionals perform the gamut of quality, compliance, engineering and technical services, Sequence has begun to spread its wings and soar to greater heights. Among the many exciting accomplishments of 2014 was commissioning the Sequence Compliance Center, forming an Automation Engineering group, and investing in technologies to enable growth and sustainability of our company. The hard work and dedication sown by each of you in 2014 will reap rewards for many years to come. Whether you contributed by providing outstanding services to

clients or by simply referring a new hire to the company, you made a positive difference and I thank you.

2015 is sure to bring many more exciting opportunities. As we strategically position Sequence to serve clients with both centralized and regional support models, organizational growth and exceptional quality of service will remain the top priorities. To maximize our potential, each of us will need to pursue the next big opportunity. We will need to think of ways to utilize our experience and expertise to leverage growth to exponential proportions. Whether you are a seasoned veteran of Sequence or new to the company, make no mistake that you have the ability to impact our direction and success as much as anyone.

So...be your name Buxbaum or Bixby or Bray or Mordecai Ali Van Allen O'Shea, you're off to Great Places! Today is your day! Your mountain is waiting. So...get on your way!

Sincerely,


**Baxter**

### Another Door Opens

Sequence has completed an acquisition with a local Automation Engineering/CQV firm that is currently working with Baxter in Covington (GA). This acquisition positions Sequence with the ability to now offer engineering services.

Page 5



### Google Pharma?

In 2014 and into 2015, internet giant Google has begun converging on the pharmaceutical market.

Page 9



### Making a Name

As Sequence enters 2015 and continues to strengthen its nationwide brand, the client list and headcount continue to grow.

Page 10

# Holiday Celebration!

Everyone working out of the Sequence office on Dec. 19, 2014 celebrated the holidays with lunch from Smokey's BBQ with all of the fixings. Everyone also brought in a gift to participate in a White Elephant (something no one wants) gift exchange.

There were some interesting gifts, including a RC Car, tabletop drum set, and the most popular gift, a bull horn. It was a great way to enjoy some good food and fellowship for the Holidays!



## Changing the Face of Men's Health

In honor of Movember, Sequence employees participated in a mustache growing contest in December 2014. Congratulations to the winners!

The Movember Foundation is the leading global organization committed to changing the face of men's health, and has funded over 800 programs in 21 countries that are saving and improving the lives of men affected by prostate cancer, testicular cancer and mental health problems.



**THE MAGNUM:** The participant with the most full, exquisitely groomed, manly mustache reminiscent of Tom Selleck on Magnum PI.

**Winner (Pictured Left):** Brian Stonebraker



**THE E-TRADE BABY FACE:** The participant with the least amount of mustache growing ability (must attempt to grow one).

**Winner (Pictured Center):** Sam Watson



**THE CHARLIE CHAPLIN:** The participant with the most stylish mustache reminiscent of Charlie Chaplin.

**Winner (Pictured Right):** Jamie Moore





## Employee Spotlight



**Name:** Jonathan Wood

**Nickname(s):** Jonnywood, JDub, Flea

**Title/Dept:** Senior Manager, Engineering Services

**Current Project:** Program Covington at Baxter

**Representing Sequence since:** Dec. 31, 2014



**Q: What were you doing before joining Sequence?** Operations Manager with PharmaE, supporting Baxter Covington.

**Q: How did you end up at Sequence?** Long story, but after years of various conversations, the timing was just right. Several Sequence employees were former colleagues.

**Q: If you weren't at work right now, what would you be doing?** Surfing, playing guitar, or hanging with the family.

**Q: What is your favorite weekend activity?** Chasing kids, playing music, surfing, or watching the Wolfpack lose ball games.

**Q: What is your favorite vacation spot?** Costa Rica.

**Q: What are your favorite food / beverage / dessert?** Chicken burritos, Sun Drop, and cheesecake.

**Q: What is your favorite movie and TV show?** Movie - Rocky IV and TV show - Nashville

**Q: What do you listen to during your daily commute?** All kinds of music.

**Q: What is your favorite music genre?** Can't be just one... rock, country, pop punk, and contemporary Christian.

**Q: What is your favorite sport and/or athlete?** Football and Russell Wilson / Philip Rivers... typical NC State fan answer.

**Q: What fictional character do you most relate to?** Rocky.

**Q: What celebrity do people say you look like:** Some guy on the Vampire Diaries.

**Q: Name one or several of your personal heroes.** My mom; she is the most encouraging and supportive person in the world.

**Q: Who is your favorite historical figure and why?** Wright Brothers; their invention allows me to get back home to my family much quicker.

**Q: If you could go back in time to one day in history, what day would it be?** One particular Sunday late in the summer when I was 12 or 13 years old, there was a hurricane off the coast of North Carolina that produced absolutely perfect waves. I've been taking trips and chasing hurricanes ever since trying to find waves like that to surf.

**Q: What is your favorite quote or saying?** "Never give up!" – Jimmy V (editor's note: another typical NC State fan answer)

**Q: Tell us one thing that no one at Sequence knows about you.** I was very shy as a kid up until 12 years old. I've spent the last 24 years telling everything that I observed haha.

**Q: Tell a funny Sequence-related story if you can.** Mike Putnam came to visit the Baxter site and when he left, I caught a ride with him to a restaurant. I left my laptop bag in his rental car and he left early for the airport. I called him to tell him just to leave it at the rental car place until I got there the next day. No one would take the bag since they thought it had a "bomb". He decided to leave it with some random airport guy that called me 10 times to ask me where I was and I better come get it ASAP. It turned into a suspense thriller for the next two hours and I finally got it back. I paid the guy a tip and we have spoken a few times since then. Crazy night... it's a much better story told in person.



# Breaking New Ground with Sequence

*In December 2014, Sequence completed an acquisition agreement with a local Automation Engineering/CQV firm. The integration of these engineers positions Sequence with the ability to offer Engineering services such as Commissioning and Automation Design to existing and future clients. The addition also allows Sequence to pursue engineering opportunities in industries outside of pharmaceuticals/biotech such as energy and transportation.*

**Submitted by Jonathan Wood, Senior Manager, Engineering Services**

Sequence Engineering was awarded a Professional Engineering license on January 5<sup>th</sup> of this year and we are extremely excited about the opportunities and challenges that the future will hold. The Engineering Business unit is currently supporting the new Baxter green-field project in Covington, GA.

Resources have been providing various services to Baxter since July of 2013 including: DCS and MES Functional Specification development for all process areas, FAT support for BAS Utilities, Design reviews for DCS software on a DeltaV platform, SOP development (Engineering and Qualification), Commissioning Plan development, Commissioning test plan development/execution, and alarm strategy development.

The project has presented many challenges due to the vast amount of design revisions and tight schedule constraints. A project of this magnitude requires great communication to be successful, especially considering the amount of contractors and full time staff working towards the same goal of a successful start-up.

Sequence resources have participated in many departments and continue to work together to mitigate the risks associated with the evolving equipment and software design.



## Baxter

### *Big Facility, Big Opportunities*

Baxter's Covington site is a more than \$1 billion, state-of-the-art manufacturing facility, and will cover more than 1 million square feet.

The integrated campus includes three main manufacturing components, as well as support components such as warehouse and utilities buildings, administrative facilities and laboratories.

Construction is expected to finish in 2016. Licensing and ramp-up activities leading up to commercial production will begin in early 2015 and continue through 2017. The plan is for the site to be fully operational by early 2018.

The new plasma fractionation facility will bring Baxter additional capacity for testing, purification and fill and finish for its biologic medications, include immunoglobulin therapy for patients with immune deficiencies and albumin products, which are primarily used as plasma-volume replacement therapy in critical care, trauma and burn patients.

The project is expected to create a total of 1,500 full-time positions in Georgia and more than 2,000 jobs in total across multiple U.S. locations.

# A Puerto Rican Christmas in Georgia

**Submitted by Dave Brewer, Senior Manager, Quality Programs & Compliance and IT Quality Services**

The day started off with a simple plan. Travel down to Covington, Georgia, briefly meet with our newest Client (Baxter), deliver NEO training to our new team members in the Engineering group, and head back to the airport. After arriving early that morning, Carl Johnson gave me a call to inform me the Engineering group was going singing later that night and that he had committed me to join them. Almost in passing, he mentioned something about a parranda.

My curiosity was piqued at that point. Arriving earlier than anticipated that day gave me time to meet the Engineering team for lunch and have a chance to get to know them. Gauging their excitement, I realized this parranda thing was going to be a bigger deal than I anticipated. Jonathan Wood explained his team worked with a large contingent of Puerto Ricans at the Baxter site and had forged some great friendships over the last 18 months.

For those new to the Puerto Rican culture, a parranda is when a small group of friends gather together to "asaltar" or surprise another friend. It's the Puerto Rican version of Christmas caroling. Most parranderos play some sort of instrument, either guitarras, tamboriles, güiro maracas, or palitos. Everyone sings. A parranda tends to be more secular than religious even though many of the traditional aguinaldos (Puerto Rican Christmas songs) retain the holiday spirit. The parranderos arrive at the destination and then very quietly gather by the front door. At a signal all start playing their instruments and singing. The parrandas

usually begin after 10pm in order to surprise and wake the sleeping friend. The parranderos are invited in and refreshments, music and dance follow. Of course we don't surprise unsuspecting victims. The parranderos are given plenty of "hints" beforehand by the homeowner so they are ready to receive a parranda. Back to the story...

Jonathan, and his team, targeted a few friends for the "asaltar" later that night, Maria and Johanna & Rafy. We all gathered at Jon Robertson and Forrest Brown's house to get the "instruments" which consisted of pots, pot lids and various utensils then piled into Justin Cook's diesel dually. Jon and Forrest both drew the short straw, so they



climbed in the bed of the truck. Keep in mind, at this point it is 11:00 PM and no more than 35°F. Needless to say, Jon and Forrest were very cold riding down the road for 30-40 minutes total. We pulled into Maria's neighborhood and instantly noticed an inordinate number of law enforcement cars parked in the driveways. For those not familiar with the decibel level of a diesel dually, you can be assured that no one will ever sneak up on you driving one. Being uncertain of the exact address, we slowly circled the neighborhood until we finally settled on the house we thought belonged to Maria. The combination of the large law enforcement



presence and smaller patio homes made it seem like everyone could hear us. Jonathan cranked up the Bluetooth speaker he brought to play Christmas carols and we started banging the pots and pot lids. The level of noise even surprised us. After a few minutes of noise and no response from inside, we decided it was best that we fled the scene and headed for our next asaltar before the law enforcement officer next door took us downtown.

We pulled into Johanna and Rafy's driveway around 11:40. Jon and Forrest had to feel like a popsicles after the 20 minute ride. We wasted no time firing up the music and banging the pots. A minute later, Johanna turned on the upstairs bedroom light, walked to the window and peered down at us with a huge smile. Johanna ran downstairs to welcome us into their home and the fun really started. We spent the next two hours hanging out in the kitchen "playing" music as Johanna cooked homemade empanadas and Rafy played along with his guitar. Jonathan Wood even started playing one of Rafy's guitars at one point as we progressed into singing classic 80's songs. White Lion got a lot of play that night!

Jon and Forrest were happy to learn about the truck bed lid Justin Cook had for their ride home. The guys were a little warmer, but the truck bed must have seemed like a coffin.

That night in Georgia showed me the fun and excitement that the folks in the Engineering group bring to the people they work with and is another reason everyone is so excited about them joining Sequence.





## GSK Partnership Update

Submitted by David Foster, Consultant II, Lab Compliance Services

Sequence partnered up with GSK and InVentiv Health to provide deployment support for approximately 1000 Panasonic refrigerators in May of 2014. The next phase of the project was to set up a program to monitor all installed refrigerators. Sequence remotely monitors all of the refrigerator units from the Sequence RTP Compliance Center utilizing the GSK provided/hosted LabAlert system. LabAlert has been an ideal setup due to its ability to monitor, trend, report, and notify Sequence and GSK personnel of current and historical refrigerator conditions. The LabAlert monitoring and support program ensures GSK/InVentiv refrigerator units are properly managed and that performance data is systematically reported on a routine basis.

Once LabAlert notifies Sequence monitoring team of an alarm, a Sequence support engineer will attempt to contact the sales representative via email and/or phone to troubleshoot the issue. To manage alarms and out-of-specification data occurs, Sequence has organized a customer relation tool to document the cause of the alarm and the steps taken to resolve the issue. Each alarm and out-of-

specification data are documented and sent to GSK/InVentiv for review.

In response to Sequence's great success with providing deployment and monitoring support for over 800 Panasonic refrigerators, GSK has accepted Sequence's proposal to annually calibrate each Panasonic refrigerator. Sequence has developed a process in which the sales representative will be guided through the annual calibration by a Sequence representative over the phone.

Sequence will prepare an annual calibration package in the Sequence Compliance center and then send it to the sales representative. The package will include a temperature probe, preventive maintenance tools and a visual aid packet. The visual aid packet has been prepped with detailed steps for the sales representative to follow with a Sequence representative over the phone.

Sequence has taken the leadership role in instructing the representative through the annual

### DID YOU KNOW?

GSK is the world's sixth-largest pharmaceutical company after Johnson & Johnson, Novartis, Hoffmann-La Roche, Pfizer, and Sanofi?

calibration, providing good documentation practice for each completed calibration, and handling any calibration support issues.

The deployment support project started in May of 2014 and from there Sequence has developed the project into a three parts: Deployment, Monitoring and Calibration Support. As our partnership with GSK strengthens, we were able to gain trust and develop a leadership role for the overall project. It is a huge success for Sequence to show we can handle a nationwide project from our Compliance Center here in Raleigh, NC.



## Top Blockbuster Drugs of 2013-2014

Ranking	Drug	Manufacturer	Sales
1	Abilify	Bristol-Myers Squibb	\$7.2 billion
2	Humira	Abbott Labs	\$6.3 billion
3	Nexium	Astra Zeneca	\$6.3 billion
4	Crestor	Astra Zeneca	\$5.6 billion
5	Enbrel	Amgen	\$5.0 billion
6	Advair Diskus	GlaxoSmithKline	\$5.0 billion
7	Sovaldi	Gilead Sciences	\$4.4 billion
8	Remicade	Janssen	\$4.3 billion
9	Lantus Solostar	Sanofi Aventis	\$3.8 billion
10	Neulasta	Amgen	\$3.6 billion

Source: Web MD

Timeframe: July 2013 - June 2014



# Discovering Discoverant

Submitted by Ragini Sanghvi, Principal Consultant, Software Management Services

Ragini Sanghvi, Project Lead for BIOVIA Discoverant Enterprise Manufacturing Intelligence (EMI) system at Biogen Idec, manages programming / configuration / validation services to support integration of Biogen Idec commercial and clinical product data in Discoverant. For this project, Ragini and her team of Sequence, Inc. experts provide Discoverant support to build/modify, validate, and implement Discoverant hierarchies at Biogen Idec. These hierarchies are used to input and collect data from numerous site data sources.

This project includes scope change assessments, design and development/modification of PRIMR Book Templates, PRIMR Pages, and associated parameters (Tags, Descriptions, Data Types) and Hierarchy configurations for integration of DeltaV, Labware LIMS, Nautilus LIMS (Stability), OPM (Raw Materials), PI and PRIMR data sources. The project also includes design and development of source database views, context views, historical data insertion statements and investigation for moderate/major impacts.

For more information about Discoverant, utilize the link below:  
<http://accelrys.com/products/process-management-and-compliance/accelrys-discoverant/>.

 **Discoverant**<sup>®</sup>

 | The 3DEXPERIENCE Company

## biogen idec

### WHAT IS DISCOVERANT?

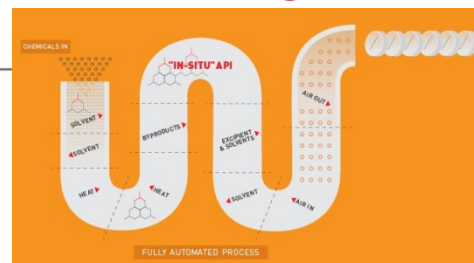
Discoverant is a validatable Process Management Informatics (PMI) application that integrates powerful ad-hoc investigational analytics with a unique data modeling technology. The software provides real-time, on-demand data access, analysis and reporting of manufacturing and process development data on-demand by the end users themselves, reducing supply chain costs by making manufacturing process outcomes more predictable and by:

- Accelerating process development for faster commercialization
- Integrating data modeling with powerful analytics
- Providing collaborative data access and reporting
- Transforming paper records into actionable information

The application provides on-demand access to all data types from all sources for all users—regardless of functional area or geography—for analysis and reporting.

- Process and Product Monitoring
- Data Analysis ( InVision)
- Dashboarding and Reporting
- Data Aggregation and Contextualization ( Nexus)
- Paper Records Data Management ( PRIMR)

## Continuous Integrated Manufacturing



Pharmaceutical manufacturing has been performed using product batches for over a century.

While most other manufacturing industries use continuous operations combined with advanced process control and automation, the pharmaceutical industry has mostly relied on fixed recipes to product batches. This practice results in very long and expensive processes that have been supported by high gross margins. In contrast, the development of novel manufacturing technologies has the potential to transform the current “batch manufacturing” process into a “novel” integrated continuous manufacturing (ICM) process.

This vision for the future of pharmaceutical manufacturing uses the concepts of continuous flow, end-to-end integration, a systems approach, and an integrated control strategy. The vision was initially validated by a team of researchers at the Novartis MIT Center for Continuous Manufacturing, who designed and constructed a small scale prototype system to demonstrate that pharmaceuticals can be produced continuously in a fully integrated manner with automated control. In this way, raw materials can be transformed into finished tablets without interruption (24 hours a day), with the active ingredient being synthesized in situ without isolation.

This approach opens a new manufacturing paradigm for the pharmaceutical industry with drugs being delivered to patients much quicker, at significantly reduced cost, and with consistently high quality.

Source: Pharmaceutical Manufacturing  
<http://www.pharmamanufacturing.com/articles/2014/integrated-continuous-manufacturing/>



# Recruiting the Next Wave of Leaders

Sequence Management recently participated in a CET (College of Engineering and Technology) Career Networking Day on February 11<sup>th</sup>, 2015, at East Carolina University's Murphy Center.

This networking event offered the unique opportunity for Sequence to engage with ECU faculty and students. The event was open to all undergraduate and graduate students, including those pursuing a degree in the fields of computer science, engineering, construction management, and technology systems.



## Google™

*In 2014 and into 2015, internet giant Google has begun converging on the pharmaceutical market.*

### biogen idec

In January 2015, it was reported that Google X is partnering with Biogen Idec, the multiple sclerosis drugmaker, to expand its venture into medical research. The duo will study environmental and biological contributors to the debilitating disease's progression.

Google and Biogen will use sensors, software and data analysis tools to collect and analyze data from individuals who have multiple sclerosis (MS). The companies aim is to explore why MS progresses differently in each patient.

Multiple sclerosis affects an estimated 2.3 million people worldwide.

Source:  
<http://www.healthcareglobal.com/tech/1803/Google-Biogen-Idec-Unite-to-Bring-New-Research-to-Multiple-Sclerosis>

## converging on Pharma?

### abbvie

In September 2014, it was reported that Google Inc. 's Calico LLC life-sciences company is partnering with AbbVie to develop treatments for age-related diseases.

Under the new partnership, Calico and AbbVie will each invest up to \$250 million, and potentially another \$500 million each, to confront conditions like cancer and neurodegenerative disorders. The companies said they would share costs and profits from the collaboration equally.

Calico will build an R&D center in the San Francisco Bay area, and will oversee early drug development and the early stages of human clinical trials for drugs. AbbVie will help Calico identify, design and conduct early-stage research, and has the option to manage late-stage drug development and marketing of any drugs that pass through the early stages of trials.

Source:  
<http://www.wsj.com/articles/google-abbvie-announce-research-partnership-1409764830>

### NOVARTIS

In July 2014, it was reported that Novartis is teaming up with Google to develop "smart" contact lenses that would help diabetics monitor their blood-sugar levels or restore the eye's ability to focus.

The device for diabetics would measure glucose in tear fluid and send the data wirelessly to a mobile device. The technology is potentially life-changing for many diabetics, who prick their fingers as many as 10 times daily to check their body's sugar production. Diabetes affects an estimated 382 million people worldwide.

The second element of the Google agreement is centered on presbyopia, in which ageing eyes have trouble focusing on close objects. Novartis hopes the lens technology will help to restore the eye's ability to focus, almost like the autofocus on a camera.

Source:  
<http://www.reuters.com/article/2014/07/15/us-novartis-google-ceo-idUSKBN0FKOU320140715>

# Making A Name

*As Sequence enters 2015 and continues to strengthen its nationwide brand, the client list continues to grow. The below diagram displays the current active clients by business unit.*

## Software Management Services

- Becton, Dickinson and Company
- Biogen Idec
- Bristol-Myers Squibb
- Dassault Systems Biovia Corp
- Regeneron
- Samsung Biologics
- Shire
- Novartis

## Quality Programs & Compliance

- Novartis
- Mallinckrodt
- Patheon Manufacturing Services LLC

## Lab Compliance Services

- Biogen Idec
- bioMerieux
- GlaxoSmithKline
- Hospira
- Pfizer
- Bayer CropScience
- Eisai
- inVentiv Health



## IT Quality Services

- Biogen Idec
- Patheon Manufacturing Services LLC
- Grifols
- Hospira
- Novartis
- Mallinckrodt
- Hospira
- RAI Services Company
- Dyneema, LLC
- Bristol-Myers Squibb
- Novo Nordisk

## Engineering Services

- Grifols
- Baxter
- Pfizer

## Technical Services

- bioMerieux
- Fresenius Kabi
- GlaxoSmithKline
- Hospira
- Novartis
- Novo Nordisk
- Patheon Manufacturing Services LLC
- Xellia Pharmaceuticals

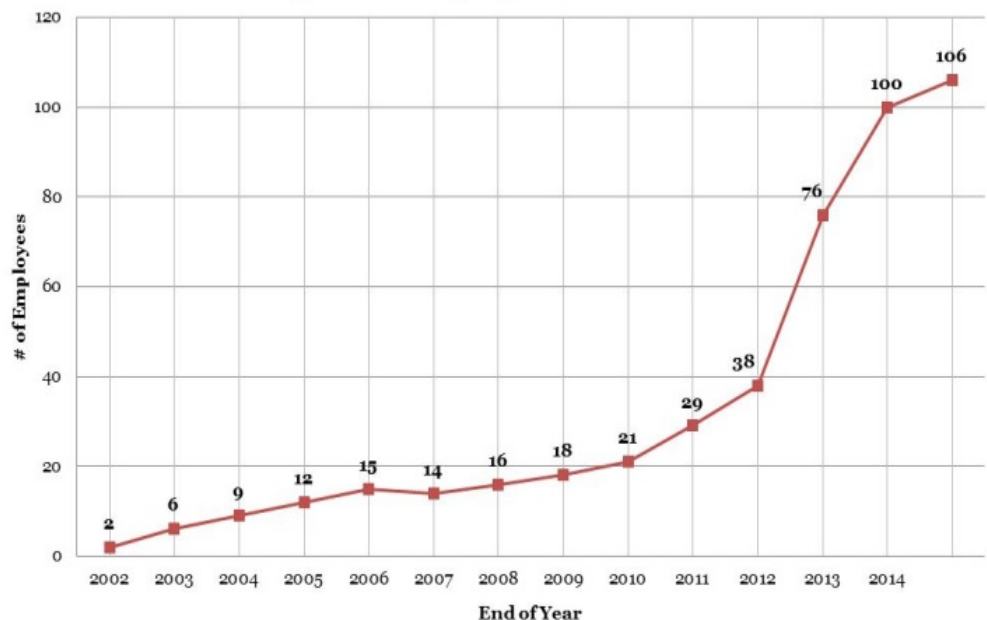
## MOVING ON UP!

Displayed to the right is a graphical illustration of the company's employee headcount since 2002. Since 2010, our company has expanded 500%!!

Sequence plans to continue its unprecedented growth in 2015, as it works to expand into new industries and geographical markets.



## Sequence Employee Head Count





# 2014 Sequence Timeline in Review

2014 was a big year for Sequence as an organization. The below timeline highlights major events/accomplishments during the calendar year.

