



"PUTTING THE QUALITY IN QUALITY COMPLIANCE"

Sequence Spotlight

Oct. 2014

ISSUE HIGHLIGHTS

"Oh my how we've grown!"

Commence merciless cheek pinching!

It has been awhile since the last Sequence newsletter so there are plenty of developments to discuss. Some big changes such as our new home office, new website, and new St. Louis branch as well as continued growth in our client base, team members and offerings.

We've also had some smaller but also important developments such as the implementation of software packages such as Noverant for web training & compliance, Open Air for timesheet & expense tracking, Discoverant for process analytics reports (and so much more) and Netsuite for enhanced customer relations management. Also, we can't forget about the WOW factor for client visits such as our 22nd century (yes it is that high tech) conference room and in house lab space with batch vessel (or beer fermenter depending on who you ask).

We have also had a corporate rebranding to Sequence Quality Compliance Services in order to highlight our offering of all services

related to maintaining the highest level of cGMP compliance. There have also been some internal restructuring of the employee career path to allow room for additional advancement opportunities. These new roles include Sr. Manager, Manager, Principal Consultant, Sr. Consultant, Consultant II, Consultant I and Technician / Specialist.

Not to be left out we have finally had the need to put together the Sequence ping pong ladder after a leadership shakeup left a potential power vacuum with far reaching consequences. Be forewarned, if you can claim the title of King Pong you will have numerous challengers waiting to put you back in your place but stay strong and crush all who would dare question your paddle prowess.

Each one of these developments could probably fill a full newsletter but we have to pack it all into one so we have to keep most of it short and sweet (look forward to more in-depth breakdowns in future additions!)



St. Louis Expansion

Sequence is heading west! We have expanded our geographic reach with our newest expansion to St. Louis. California here we come!

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GSK Partnership

Sequence has signed on to perform calibration and monitoring for sample refrigerators used by pharmaceutical sales reps out of their home offices.

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The Dream Team

The Sequence family has expanded a lot since this photo was taken. Sometimes growth is chaotic for a young organization but the leadership team here has taken a very pragmatic and measured approach to make sure we don't scale beyond our means. Our means keep increasing rapidly though as word spreads about the quality we consistently deliver so it has been hard to keep up with demand for top talent. The Sequence approach of recruiting through personal reference has served us well however as shown by the following key anniversaries;

10 year

David Brewer

9 year

James Irons

8 year

Rob Hazle, Mark Levanites, Dylan Clark, Michael Hall

7 Year

Chad Cleveland, Gilbert Portela

6 year

Sara Abu-Zayed, Sachin Patel

5 year

Carl Johnson, Ragi Sanghvi

<5 year

Too many to list because of how fast we are growing! Congratulations everyone!

October Birthdays:

Coy Triplett, Rob Hazle, Chris Wallace, Samir Patel. Happy birthday!!

DID YOU KNOW?

Sequence has grown more in terms of number of employees in the past 3 years than it did in the 7 years prior to that?



Nothing says good job like a bit of the bubbly

PARTY TIME, EXCELLENT!!

Sequence kicked off 2014 with its holiday party at Sparians in Raleigh for some friendly competition on the bowling lanes as well as the opportunity to refuel dreams of a 300 game with dinner and drinks (I'm glad we all remembered to stretch after eating, there's no excuse for a season ender while on the lanes).

The best part of the night though was bringing everyone who has been on various client sites throughout the area together in the same room for a chance to get to know our fellow colleagues and their partners a little better. There were certainly some new faces but even with the people you know well it never seems like there's enough time to catch up on everything going on both personally and professionally so it was a welcome opportunity to mingle.

After a few cutthroat rounds of bowling and a spontaneous ping pong tournament Mike Putnam took the stage to highlight the amazing progress we have made in the past year as our organization has grown to new

heights with additional partnerships, new service offerings and a seemingly ever growing team of experienced professionals in the quality compliance field.

While the nuances of the speech might have been lost on those who were still lamenting over their numerous gutterballs the overall message was abundantly clear, the future of Sequence is bright thanks to all our hard work and that is certainly something we can all raise a glass to!



Obviously you're not a golfer...



THE TIDBITS



Batch Vessel

The recent acquisition of the W.H.E. BioSystems batch vessel will allow for demonstrations of Discoverant tools for tracking and analysis of process conditions (also in the works, the latest batch of Sequence Saison)



King Pong

Shown here is Mike "Powerball / Big Dog / El Jefe" Putnam crushing it against Rob "Boss Hawg" Hazel as James "Ironman" Irons watches in disbelief. The title stood proudly on Mike's desk shortly thereafter.

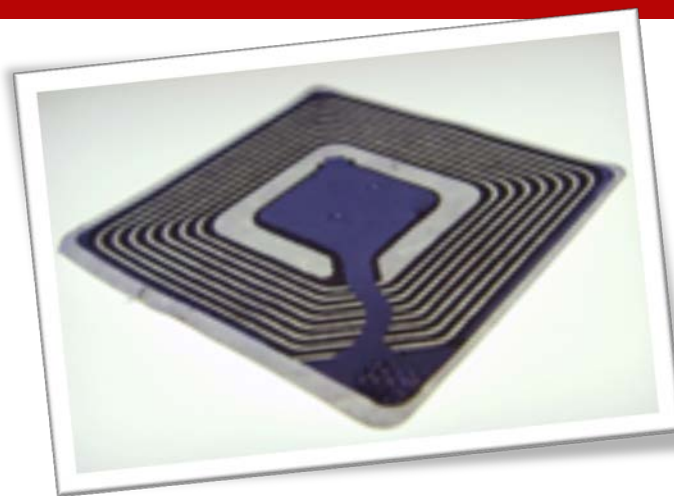
FAST (AND USELESS) FACTS

60%

60% of the time it works every time

90%

Working here is 90% mental, the other half is physical



RFID labeling is the holy grail of product identification

Serialization

by Matt Brawner

Serialization of your prescription drugs must be implemented by January 1st, 2015! Will you meet the deadline?

The US Drug Quality and Security Act (DQSA) was signed into law in 2013. Title II of DQSA, Drug Supply Chain Security Act (DSCSA), outlines the critical steps to implementing serialization. Two dimensional (D2) product codes and an interoperable database system will be required to identify and trace certain prescription drugs. The system is intended to improve patient safety by reducing the risk of illegitimate products in the supply chain, from manufacturer to pharmacy.

Many organizations implementing serialization are coming to realization that the road to DSCSA compliance has a unique set of challenges. Chief among them are the many areas of competency required to implement serialization. For example:

- Manufacturers are typically organized to execute packaging equipment and Information Technology (IT) projects using separate functional groups. Serialization requires these groups to work together to deliver the best compliance solution, even when equipment and IT validation procedures differ.
- Packaging equipment is typically made serialization capable by adding printing

and print verification (vision) components provided by a separate serialization vendor. Depending on your documentation approach, this has the potential to double the number of lifecycle documents required to qualify any one machine. Additionally, design, commissioning, qualification, and maintenance efforts must now be managed considering contributions from two vendors rather than one.

These are only two examples of how serialization will require companies to redefine their ways of working. Having successfully implemented serialization systems around the world, Sequence is well position to help you capitalize on the opportunities, and avoid the pitfalls of serialization. We would welcome the opportunity to strengthen your compliance system by helping with the successful implementation of your serialization solution.



Employee Spotlight

(a.k.a. **the hotseat!**)



Employee Details (no, not him ↑)

Name: Jill Schmitt

Nickname(s): Schmazee

Current Project: Line 36 Expansion at Novo Nordisk

Validation Team: Equipment and Utilities Services

Representing Sequence since: July 2013

Q: What were you doing before joining Sequence? Working full time for a Sequence client in Maryland as the supervisor of the document control department. This included launching a new electronic document management system and becoming the system administrator.

Q: How did you end up at Sequence? Dominic Leuci III sat across from me and one day I turned and asked, "Is Sequence hiring?", he of course said yes and I forwarded my information to him. Later I found out that he said yes because my husband was the head of site security and carried a gun at work every day (at least that is the story Dominic tells)!

Q: What has been your favorite client project as a Sequence employee so far?

My favorite client project has been the Line 36 Expansion project at Novo Nordisk. I have had

the chance to work with many other Sequence employees and enhance my knowledge of IT and automation qualification. Plus, we have a lot of fun every day!

Q: If you weren't at work right now, what would you be doing? Realistically, I would be curled up on the couch catching up on DVR shows or watching trashy reality TV while posting pictures to my dog Stan's Instagram (@mrstanagram).

Q: What is your favorite weekend activity? My favorite weekend activity is searching for North Carolina's best food and drinks. From local breweries to not so local donut shops, my weekends are usually delicious!

Q: What is your favorite vacation spot? I think the people you are with have a huge influence on how great a vacation spot is. My favorite spot is anywhere I've gone with my husband, but our tour of Ireland was probably my most favorite.

Q: What are your favorite food / beverage / dessert? Did I mention donuts earlier? Yeah, they are pretty much the best food on earth. I'm looking forward to trying my hand at the Krispy Kreme Challenge in 2015!

Q: What is your favorite movie and TV show? Movie: Willy Wonka and the Chocolate Factory (and not that crap with Johnny Depp). TV Show: Really digging The Mindy Project currently.

Q: What do you listen to during your daily commute? My 6-8 minute commute doesn't allow for much listening but I love listening to morning drive radio; Elvis Duran and the Morning Show, The Bobby Bones Show

Q: What is your favorite music genre? I really like all kinds of music. I gravitate towards 50s classics for long car rides but enjoy belting out country and pop tunes while in the shower.

Q: What is your favorite sport and/or athlete? I love me some hockey! Go Red Wings! I don't have a favorite athlete but I met Steve Yzerman at a Kroger store and have his autograph.

Q: What fictional character do you most relate to? Dr. Mindy Lahiri on The Mindy Project. She is a strong, smart and driven female who often finds herself in quirky situations.

Q: What celebrity do people say you look like? I've been told Jennifer Lawrence.

Specifically in her role as Katniss Everdeen in the Hunger Games. The daughter of a friend of mine saw the Katniss action figure in the store and remarked, "LOOK! It's Aunt Jill!"

Q: Name one or several of your personal heroes. One of my heroes has always been my mom. She has made a lot of sacrifices in her life for my siblings and me. She stayed at home to raise us and taught us all great and important life lessons. I definitely got my feisty personality from her, and I hope I also received her compassionate heart. She was very supportive of all my crazy endeavors and taught me that I could be anything I wanted to be!

Q: Who is your favorite historical figure and why? George H. W. Bush. In 3rd grade we were learning to write formal letters and I wrote to him. He wrote back and also sent along a book about the Bush family. Now, I really admire his love of funky socks!

Q: If you could go back in time to one day in history, what day would it be? I would love to see my parents on their wedding day. Every once in a while we hear stories about when they were first married, but to be there and see them on that day would be really special.

Q: What is your favorite quote or saying? "Let me in, I'm starving!" – Augustus Gloop, Willy Wonka and the Chocolate Factory

Q: Tell us one thing that no one at Sequence knows about you. I used to be really good at acrobatics. I learned how to do a back handspring in my back yard with no training!

Q: Tell a funny Sequence-related story if you can. Funny stories happen to me all of the time. They usually involve me telling a story and making some ridiculous sound effect that is accompanied by a gesture.

Home Sweet Home

Sequence recently got a big upgrade with the relocation of our corporate headquarters to the Gateway center business complex off of Aviation Dr. in Morrisville.

The facility started out as a blank slate so the project involved floor to ceiling renovation. From foundation to flooring, walls, insulation, wiring, carpet, tile, and of course a sweet A/V system).

No stone was left unturned, and while some may have seen that as an insurmountable challenge the Sequence team saw it as an opportunity to put our own signature touches on the facility and set the new standard for sexiness at the gateway centre.

This whole place feels like something out of Tony Stark's workshop with the automatic lights and sinks, drop down projection screens, sleek workspaces and

a server room that would make the NSA jealous.

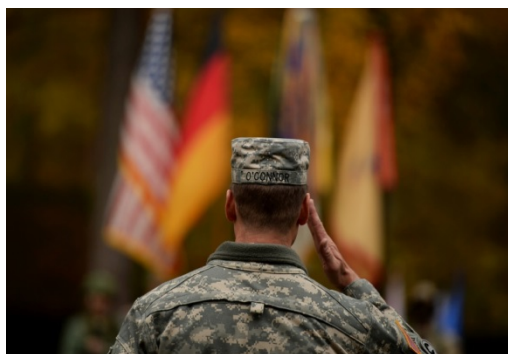
No one knows what the future for Sequence will bring but what I can say for certain is that we are heading there in style.

DID YOU KNOW?

If you set off the security alarm you better have Chad on speed dial because that lady on the other end of the line wants her password and she wants it NOW! (she also doesn't seem to appreciate it if you tell her she has a beautiful voice)



THANK YOU TO ALL WHO SERVED



Veterans Day 2014

Sequence would like to thank all the veterans currently with the company. Your service and sacrifice is greatly appreciated. The courage and leadership you have shown continue to inspire.



Sequence St. Louis

Greetings from St. Louis! The land of 2nd rate BBQ & football teams

A Note from David Brewer

We are currently in the midst of an important project with Mallinckrodt at their US headquarters in Hazelwood, Missouri located just outside of St. Louis. We are fortunate to have someone as experienced as Bill Cagle leading the effort to assess Mallinckrodt's IS Quality System and how the IS department staffs and manages projects. This project is instrumental in defining the long-term success of the Sequence Midwest office. That said, we would not be in this position if it were not for the hard work of Dylan Clark, Dominic Leuci III and Craig Morgan. Those three guys have exceeded expectations even under tough circumstances. Thank you!

Official Press Release

(St. Louis, Missouri, August 19, 2014) Sequence, Inc., an industry leader in the field of quality & compliance solutions for pharmaceutical, biotech & medical device manufacturers is opening a third office location in the "Gateway to the West", St. Louis, as a result of demand by clients to provide cost effective solutions to industry. The new location, which opened this month, allows Sequence to better serve new and existing customers in the Midwest.

Establishing a St. Louis office provides Sequence a hub to support customers in St. Louis, Kansas City, Indianapolis, Chicago, and the entire Midwest corridor as well as provide opportunities to reach other regulated industries. "This is an important move for Sequence as it ensures we continue to provide local support to clients and strategic business partners. It also allows Sequence to expand our footprint into other regulated industries throughout the Midwest" said Mike Putnam, President and CEO of Sequence, Inc.

Sequence relocated key members from their North Carolina headquarters to launch the St. Louis office and currently has initiatives to recruit top local talent in all areas of life sciences quality and compliance consulting. "For some time now, a Midwest presence has been a crucial component of our expansion goals," said Daniel Santarsiero, Director of Business Development. "We look forward to the opportunity to partner with clients and form long-term relationships that result in life saving drugs and devices being delivered to patients worldwide."

AROUND TOWN



Highlight St. Louis

St. Louis is a center of medicine and biotechnology. The Washington University School of Medicine is affiliated with Barnes-Jewish Hospital, the fifth-largest hospital in the world. The two institutions operate the Alvin J. Siteman Cancer Center. The School of Medicine also is affiliated with St. Louis Children's Hospital, one of the country's top pediatric hospitals. Both hospitals are owned by BJC HealthCare. The school's Genome Sequencing Center played a major role in the Human Genome Project. St. Louis University Medical School is affiliated with Tenet Healthcare's St. Louis University Hospitals and SSM HealthCare's Cardinal Glennon Children's Hospital. It also has a cancer center, vaccine research center, geriatric center, and a bioethics institute. Several different organizations operate hospitals in the area, including BJC HealthCare, SSM Health Care, Tenet and Mercy Healthcare.



There's always next year, right guys? Guys??

Our Digital Home

Sequence underwent a rebranding that began in April 2013 and as part of that rebranding a new website was launched in February 2014 to present the new direction of the company from our previous Sequence Validation Services to our currently more rounded Sequence Quality and Compliance services. The new logo was originally designed by a firm called 99designs in May 2013. Following the design Sequence hired ClickOptimize to help design and develop our new website. Sequence went through



numerous content creation and review meetings with ClickOptimize before the site was finally finished but the end result

was a big upgrade for our branding and interface.

Some new features that were implemented in the site include FDA & EU news updates from RSS feeds through a lightbox display. Also, you can now easily access form pages from internal SOPs using the forms/checklists tab on the main portal.



THE SPORTS PAGE



By: Shannon Cox, sports reporter

spot on the rankings is heavily sought after real estate. Needless to say, there has been a whirlwind of challengers vying for the title of King Pong and all of the accolades that come with the crown. Although the SPPL (Sequence Ping Pong League) has debuted to overwhelming positive reviews it is not without controversy. Commissioner Vinay Kolluru has had to respond to reports of PEDs, corked paddles and even match fixing. Although he could not be reached for comment his representatives assure this reporter that he is doing everything in his power to protect the league. As a knee jerk reaction to the allegations a set of league rules was rapidly drafted in order to reduce the media fallout.

Football

The pirates are off to a strong start with a 5-1 record, the the only loss coming at the hands of the Gamecocks. The highlight however was probably when they annihilated the Tarheels 70 to 41. The Wolfpack had a strong 4-0 start but after a crushing loss to the #1 seminole they have been on the decline losing their next two to go to 4-3 overall.



Ping Pong

Rankings are constantly in flux ever since Chris FitzGerald came into the office from the field and dethroned standing champion Rob Hazel. Then throw in the surprisingly ping pong adept management staff and the top



Pirate pride

GSK Partnership

Beginning in May 2014, Sequence was tasked by GSK with the responsibility of providing deployment and monitoring support for over 800 Panasonic refrigerators. Calibration of the refrigerator's temperature sensor is performed remotely utilizing FusionLive software. FusionLive provides regular temperature updates to ensure the refrigerator is operating within the required temperature thresholds. If the temperature violates the required thresholds, an alarm is created and GSK sales representatives are contacted and notified of the incident. Sequence then provides the necessary troubleshooting techniques to solve and fix the problem. Sequence has gone over and beyond by managing daily communication between GSK management, inVentiv Health management, Panasonic, JCI, and eControls, while providing QA



oversight for the entire project. Communication and organization skills were enhanced internally by developing a customized platform (NetSuite) to utilize for all information gathered during incoming alarms and phone calls. Also, success with GSK refrigerator installations lead to the opportunity to work with inVentiv Health to assist with installations as well. Sequence's unrivaled performance during this project has led to multiple alternate

proposals, inclining the company to take on a greater leadership role and ultimately, a closer partnership with GSK.

DID YOU KNOW?

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

CAUSE FOR CELEBRATION!



It wouldn't be a party without cake!

It was a beautiful day when the Sequence tailgate team rolled into town to celebrate the completion of the refrigerator installs for the GSK project.

It was also a good opportunity for some well-deserved R&R and the team rose to the challenge in prime fashion.

After some fierce competition on the cornhole courts the teamed turned its attention to the burgers and other goodies that grillmaster Jeff Price had been working up.

Follow up was a GSK cake to wash it all down with sugar induced coma soon after. Great job team!!

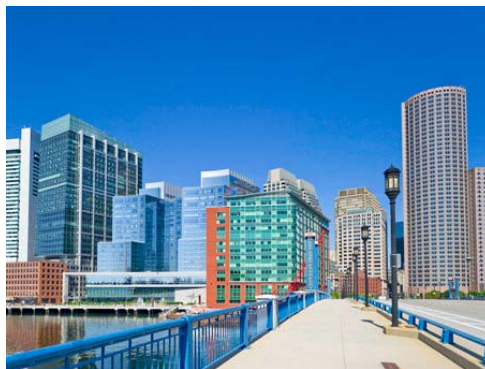


The Pirate Crew, AARRRRRRRR!!



Chad Cleveland showing us how it's done. What form!

Boston Means Business



Home office set right on the harbor next to the impressive boston skyline

As the leaves turn and the temperatures start to drop up here in the northeast, Sequence opportunities and business is finally starting to heat up. It has been almost two years since the opening of the Boston office and although the business growth has been slower than expected the groundwork has been laid and is starting to pay off.

Since the beginning of 2013 we have completed the following projects:

- EAM Upgrade Project completed by Ada Scheid at Biogen (completed)
- Reichert AR200 Digital Handheld Refractometer validation completed by Chad Cleveland and Armando Coronado for Biogen, Cambridge Manufacturing

- Medical Imaging Repository Upgrade for Biogen (completed)
- tranSMART Implementation Project for Biogen (completed)
- iPACS Implementation Project for Biogen (completed)

Current Projects being worked on are the following:

- GMS Discoverant Project Management, John Phillips at Bristol Myers Squibb, Syracuse, NY
- Empower Upgrade Project, Mark Levanites at Biogen, Cambridge
- Reichert AR200 Digital Handheld Refractometer Validation, Armando Coronado for Biogen QC Laboratory

Future Business:

Thanks to the many years of hard work and establishing great relationships that Sequence management and employees did and continue to do at Biogen, RTP that is going to pay off with a lot of



Our window washer probably making a killing!

work and additional head count for us at Biogen Cambridge next year. We already have one major project and 2-3 additional headcount approved for 2015 and another project in the works as we speak.

Plus, with the addition of John Phillips and the great work he is doing at BMS, Syracuse and the contacts he is making the arrow is pointing up here in the Northeast for Sequence. Recently, John traveled to BMS, NH and had some great meetings and made some excellent contacts.

Finally, Thanks again for the continued support!!!

-Northeast Sequence Team



Sequence Spotlight

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