



NATIONWIDE QUALITY & COMPLIANCE SERVICE PROVIDER

Sequence Spotlight

August 2015

ISSUE HIGHLIGHTS

Hard Work Pays Dividends

As summer nears its end, Sequence continues to stay hot with exciting new service offerings, a new office, new facilities, new support staff, and new client projects. As you know, we opened the doors to the Compliance Center in March 2014 and we instantly began seeing the benefits of having our own base of operations.

So much so that at the beginning of July 2015, the Business office (consisting of Senior Management and other Office Support personnel), along with the Software Management team were forced to expand into a new location (pictures on page 3). We are now located one block away on the third floor of the main high rise building at the entrance of our office park in Gateway Centre. This expansion was necessary to make room for the growing Remote Monitoring Services and Engineering teams.

Another Business Unit that worked out of our Compliance Center and has impacted our need for more space is the Software Management team led by James Irons. This team of highly skilled specialists supports projects from the east coast of the United States all the way around the world to Korea! Can you guess if its North or South Korea?

We are seeing tremendous growth in other areas of the company as well. This is a direct result of the outstanding work of all Sequence teams at our various client facilities. To name only a few, Baxalta in Covington Ga. has recently asked Sequence

to support their Lab Qualification effort. Patheon, in Greenville NC, continues to request more and more resources, and our Midwest Office has seen an increase in opportunities from new clients like Monsanto and AAI to existing clients like Mallinckrodt and Catalent.

I'm out of breath just typing this exciting news and there is MORE! Carl Johnson is moving forward with his vision of expanding the Engineering & Technical services business unit to include Integration Services. The Integration team will be led by long time Sequence friend and successful automation solutions provider Mill Kram. Mill, along with Andre Webb (another automation controls expert) will head up the system integration and automation controls facility located in Greenville NC (more news about this service offering to come).

There are so many exciting things happening at Sequence that I can't put them all here, but you can read more about them on the following pages, on the Hub, and as updates occur on the News & Events page on our website. With 2016 growing closer by the minute, it amazes me how much has been accomplished already. I can only imagine where we will be 12 months from now.

Sincerely,



Sequence's Newest Additions

As Sequence continues to grow as an organization, so does our family. This feature focuses on the new additions to our Sequence families.

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Expanding Way East

As Sequence's Software Management group continues to grow, so does its geographical reach, as members of the team have made several visits recently to South Korea.

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Greater Raleigh Chamber of Commerce

Another Year, Another Honor

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

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Newest Additions to the Sequence Family

As Sequence continues to grow as an organization, so does our family.

Pictured are the newest additions to the Sequence family. Congrats to all!

Dax Carter Braswell

Son of Rick Braswell
DOB: 04/05/2015



Harper Kate Foster

Daughter of David Foster
DOB: 04/10/2015



Madelyn Noelle Wood

Daughter of Justin Wood
DOB: 01/17/2015



Nolan Patrick Murphy

Son of Mark Murphy
DOB: 04/08/2015



Cody Benjamin Cook

Son of Justin Cook
DOB: 04/07/2015



Kingsley Xian

Son of Gary Xian
DOB: 04/20/2015



Waverly Jade Sanchez

Daughter of Jamie Sanchez
DOB: 05/22/2015



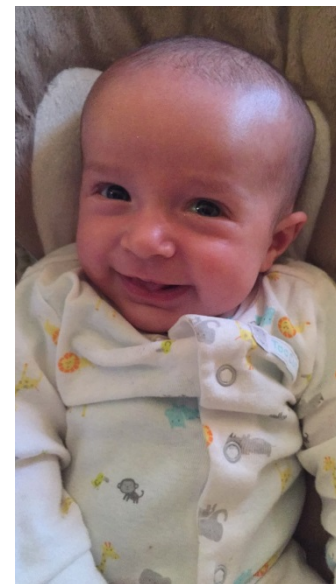
Isabelle Sophia Coronado

Daughter of Armando Coronado
DOB: 04/23/2015



Griffin Buck

Son of James Buck
DOB: 03/16/2015



Sequence Expands Into Supplemental Office

As Dan Santarsiero mentioned on the front page, the Business office (consisting of Senior Management and other Office Support personnel) has moved into a new location.

The supplemental office is located one block away on the third floor of the main high rise building at the entrance of our office park in Gateway Centre.

The need was identified in February of this year; after identifying the space and performing a minor face lift, team members moved in July.

This expansion was necessary to make room for the growing Remote Monitoring Services, Engineering, and Software Management teams.



Sequence Family Night at the Ballpark

Sequence closed out the summer with a night at a Durham Bulls game on August 20, 2015.

Sequence employees and their families enjoyed a great night at the ballpark as the Bulls played host to and beat the Toledo Mud Hens, 9-1.

The night included a 2-hour all-you-can-eat buffet including fresh grilled hamburgers, hot dogs, crispy fried chicken, fresh baked macaroni & cheese, potato chips, and baked beans.



Software Management in the Far East!

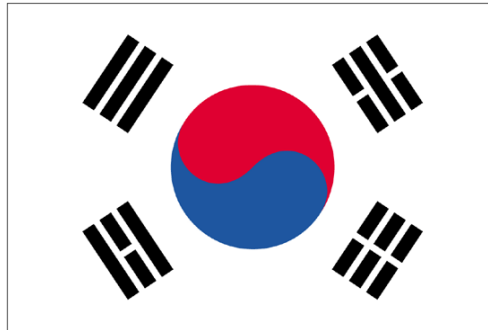
Submitted by James Irons, Senior Manager, Software Management Services

Sequence's Software Management Services group has had an exciting year. One of our most interesting and exciting projects has been working with a third-party manufacturer in Incheon, South Korea.

Sam Watson and I traveled to the site for 16 days in late February and March to kick-off the project, and boy was it windy and cold! The trip was very successful, and we got to see some cool sites as well, including the Incheon Landing Operation Memorial, War Memorial of Korea, do some shopping in Seoul and even eat at a fish market that was, according to our host, "older than America".

Our group has been back twice since and are heading back for a final trip for this project in August for on-site training. Our Korean colleagues have really appreciated all of Sequence's hard work and are keeping us on as a long-term commitment.

Since the Korean kick-off, we have also expanded our footprint in Asia. We are currently developing a Discoverant Hierarchy for a Bristol-Myers Squibb site in Shanghai, China.



Employee Spotlight



Name: Eric Borries

Nickname(s): They called me Boris in college. After a few drinks, my friends couldn't pronounce my last name and it kind of stuck.

Title/Dept: Manager, Lab Compliance Services

Current Project: PM for Win 7 Upgrade at Biogen, GSK Tanzeum remote monitoring, BioMerieux Performance Solutions

Representing Sequence since: The first time I worked for Sequence was for a year and a half back in 2012. I came back last August when I realized the grass really wasn't greener.

Q: What were you doing before joining Sequence? I can't remember. My mind has blacked out the 18 months before I most recently joined Sequence. It was a dark, dark place. Please don't make me talk about it.

Q: How did you end up at Sequence? Chad [Cleveland] made me an offer I couldn't refuse.

Q: If you weren't at work right now, what would you be doing? Hanging out on the lake.

Q: What is your favorite weekend activity? Wakeboarding!

Q: What is your favorite vacation spot? Hamanasi Dive Resort in Belize. We've been there twice and almost didn't come back the last time. Our goal is to move there one day and start up a snow cone shop called Slushy Balls.



Q: What are your favorite food / beverage / dessert? Mexican food / water / pie.

Q: What is your favorite movie and/or TV show? Sherlock. I'm not usually a BBC guy but Cumberbatch and Freeman are awesome in this show.

Q: What do you listen to during your daily commute? Sports radio.

Q: What is your favorite music genre? Nothing beats 80's Alternative Rock.

Q: What is your favorite sport and/or athlete? NFL – Denver Broncos and John Elway. Current favorite is Peyton Manning, as long as he can keep walking on and off the field.

Q: What fictional character do you most relate to? Bill the Cat. So misunderstood.

Editor's Note: This is Bill the Cat.



Q: Name one or several of your personal heroes. Hiro Nakamura because his name is hero.

Q: Who is your favorite historical figure and why? Antonie van Leeuwenhoek because he's the father of Microbiology and has an awesome name.

Editor's Note: What. A. Nerd.

Q: If you could go back in time to one day in history, what day would it be? I'd like to go back to the day when this questionnaire was written so I could delete this question.

Q: What is your favorite quote or saying? Gotta wanna needa getta hava Bojangles!

Q: What celebrity do people say you look like: Steve Buscemi.

Editor's Note: This picture is actually Steve Buscemi and not Eric Borries.



Q: Tell us one thing that no one at Sequence knows about you. I have a twin sister. No, we're not identical and she looks nothing like Steve Buscemi.

Q: Tell a funny Sequence-related story if you can. Ok, when I was working for Biogen about ten years ago, we hired Sequence to help out with some CTU and lab instrument validations. One day, the lab was super busy and one of the Sequence guys walked into my office and asked if I could train him on gowning so he could have access to the lab. The guy looked like he was 12 years old, maybe, and even though it was the last thing I wanted to do, I did the training because I knew this guy was very persistent and wouldn't stop until I did it. When I was done, I wondered to myself where Sequence found this child labor to work in our labs. Well, a few months later someone told me that the "kid" was Mike Putnam, the President of the company. That was when I really started rethinking my career choices and life decisions.

Growth Continues with Win 7 Upgrade at Biogen

Submitted by Tushar Bhagat, Principal Consultant, Lab Compliance Services

Sequence has been providing Biogen with analytical instrument validation (AIV) services for almost 6 years now. The AIV project is a continued collaboration effort by Sequence and Biogen to ensure all instrumentations/equipment are validated, decommissioned and upgraded based on business demands.

In 2014, Biogen decided to initiate a global change across 3 sites (RTP, Cambridge, Mass, and Hillerod, Denmark) for implementing Windows 7 OS to all applicable QC instruments. Sequence's long term onsite presence led us to the opportunity of providing additional validation services to support this new global Win7 upgrade initiative.

The Win7 upgrade team consists of 2 Project Managers, one for each facilitating site (CAM and RTP) along



with 8 validation consultants and 2 dedicated QA consultants. The scope of the Win7 project consists of change assessments, global change controls and upgrading QC instrument workstations from Win XP OS to Win 7 OS along with instrument software upgrades. There are over 80 instrumentations that need to be upgraded globally across 3 sites by the end of 2015 for the Win 7 project.

Additional Sequence resources were added in May (2 CAM and 1 RTP) after the labs were over loaded with validation activities. This has become one of biggest projects for the Laboratory Compliance business unit.

With over 12 consultants and counting, the AIV and Win 7 upgrade projects has given a lot of exposure to the Sequence brand across 3 Biogen sites. With all the resource additions in the Boston area, we went from 1 member to 6 for the Boston Sequence office.

QUICK INSIGHT

The average cup of coffee contains more than 1000 different chemical components, none of which is tasted in isolation but only as part of the overall flavor.



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



Reminder: the Hub can be accessed from www.SequenceQCS.com by logging into Employee Resources. Once there, you will have access to various company links that include benefits information, training, organizational chart and general job descriptions, time and expenses, phone directory, etc. Also, we recently added an Internal Forum and Media section!

Check Out the Hub

Test Yourself: GxPs

As you know, GxP is an acronym commonly used in the drug, device, or biologic industry to describe a collection of regulations, guidance, and industry standards employed in several aspects of drug development and commercialization, including manufacturing, nonclinical research, and clinical research. Take a few minutes to test your knowledge.

Question #1 (True/False): The Food, Drug, and Cosmetic (FD&C) Act, which ensures that safe and effective products are sold in the market place, was created as a direct result of a Penicillin incident in 1945.

Question #2: Institutional Review Board review and approval must be obtained prior to which stage in the development of a new product?

- A) Clinical Study
- B) Manufacturing
- C) Design
- D) Non-Clinical Study



Question #3: Which phase of a clinical study involves up to several hundred subjects afflicted with the condition being studied in order to explore effectiveness, risks, and side effects?

- A) Phase 1
- B) Phase 4
- C) Phase 3
- D) Phase 2



Question #4 (True/False): 21 CFR Parts 210 and 211 contain the GMPs for drug products.

Question #5: Which regulations were created to promote the quality and validity of the test data that result from a non-clinical study?

- A) GMPs
- B) GxPs
- C) GLPs
- D) GCPs

Answers: Q1: False, the FD&C Act was created as a direct result of an Elixir of Sulfanilamide incident in 1937 Q2: A) Clinical Study Q3: D) Phase 2 Q4: True, 21 CFR Parts 210 and 211 contain the GMPs for drug products Q5: C) GLPs

SEQUENCE MAKES AN IMPRESSION AT GSK



Our president Mike Putnam recently received this email from a client, regarding our efforts as part of the Tanzeum refrigerator monitoring program. Great job to all those involved!

As we are concluding the end of our first "Refrigerator Recalibration" phase with Sequence assuming ownership of those related duties, I felt that we, GSK, were long overdue in thanking you for not only a job well done, but also for the manner and professionalism in which the job was done. This has been, without a shadow of a doubt the most customer-centered company with whom I have ever had the pleasure to work.

From day 1 to the present, there has been no obstacle too great for Sequence to overcome. GSK shared a vision of a novel cold chain sampling program that would ensure only the highest quality of products would be promoted and delivered to our HCP's. Sequence took that vision and with the most amazing teamwork strategies I have ever witnessed turned it into a viable reality. In case you were never told, our "Tanzeum Project Team" received its highest honor with being recognized on the President's Roll of Honor and we owe a great deal of that to Sequence.

There are far too many on your payroll to thank by name, some of whom I've had the pleasure to work with and some that were "behind the scenes" that I have never met, but I would like to say a special thank you to David [Foster], Chad [Cleveland], Ashley [Rasavage], and Carman [Pericozzi]. Their willingness to persevere through all of the highs and lows of putting a novel concept into motion was, and continues to be, beyond remarkable.

There are many compliance concerns on my plate every day, but one of them is not the livelihood of the Tanzeum refrigerator monitoring program. Your staff at Sequence has provided GSK a level of confidence that is unmatched and I personally wanted to extend a most sincere "thank you" for the amazing efforts of your most innovative and hard-working staff.

Michael Jones
Compliance Manager at GSK

Sequence Kickball Fights Through Injuries

Submitted by Jill Schmitt, Manager, Quality Programs & Compliance

As you all know, Sequence sponsored a kickball team in the City of Raleigh Adult Kickball League this spring. There was much momentum heading into the season with a roster full of eager kickballers! We started with 25 active roster participants and had good turnout for our first 2 practices.

The early season rain outs should have been an omen of what was to come! We played the season (which was about 10 games due to rain outs) and ended with a 2-9 record and were eliminated in the second round of the end of season tournament.

This stat does not paint the full picture of the season! We had 2 on the injury reserve list before season play got started! And the injuries kept coming, as there was a season ending knee injury during game 2 and numerous pulled hammies and groins throughout the rest of the season!

In the end, the active roster dwindled to 11 active players (some of which were mid-season recruits).

A good time was had by all and one particular sentiment was shared at the end of the season from Elvis Moyer, "I hope all those who participated appreciate the new thread of teamwork and camaraderie we Sequence kickballers have now experienced above a singular emphasis on a score count/scoreboard."

DID YOU KNOW?

Kickball, originally called "Kick Baseball", was invented around 1917 by Nicholas C. Seuss, Supervisor of Cincinnati Park Playgrounds, in Cincinnati, Ohio. Starting around 1920, kickball was used by physical education teachers to teach children the basics of baseball.



Establishing A New Relationship with INC Research

Submitted by Jill Schmitt, Manager, Quality Programs & Compliance

INC Research is a full-service clinical research organization (CRO), providing the full range of Phase I to IV clinical development services for the world's pharmaceutical, biotech and medical device industries. They operate on six continents!

Sequence and INC Research began their relationship when INC Research found themselves in need of a computer system validation program. Jason Hodges, Principal Consultant, has been working with INC since March to evaluate their current system and provide a comprehensive computer system validation program for them.

A unique challenge of this project is INC Research has grown rapidly in the last few years through mergers and acquisitions. Each organization integrated into the INC family brought with it their own legacy computer systems and philosophy for computer system validation (CSV).

Jason has completed his evaluation and is in the process of drafting and reviewing the CSV program documents with the client stakeholders. A recent meeting with the client indicated that they were very pleased with the Sequence approach to CSV and they look forward to changing the INC CSV philosophy.

QUICK INSIGHT

Aspirin went on sale as the first pharmaceutical drug in 1899, after Felix Hoffman, a German chemist at the drug company Bayer, successfully modified Salicylic Acid, a compound found in willow bark to produce Aspirin.



Sequence Helps Expand Production for Insulin Products

Submitted by Carl Johnson, Associate Director, Engineering and Technical Services

Sequence consultants have been working on the Line 36 project since March 2014. Currently, Sequence has 10 consultants working together for different tasks associated with the project. Personnel on the project include: Carl Johnson, John Hartman, Jill Schmitt, Brian Stonebraker, Dominic Leuci, Dominic Leuci III, Regan Sigler, Daniel Kim, Ryan McNamara, and Billy Pope.

Line 36 project will expand Novo Nordisk's manufacturing capacity for insulin products. Line 36 project contains a Formulation and Storage suite, a filling suite (Washer / Tunnel, Filler, and Vision System), and a washer / sterilizer. The control system used for Line 36 project is iFix SCADA and is used for control for Formulation and Storage suite, filling, and washer / sterilizer.

Resources have been providing services for specification development, Validation Plan development, FAT development/execution, FAT support out of country (Germany and Italy), Commissioning test plan development/execution, IQ/OQ/PQ of equipment and automation. Resources have participated in all aspects of the Line 36 project and continue to grow knowledge.



Featured Service: Sequence Monitoring Center



The Sequence Monitoring Center supports clients across all 50 states and is experienced in the installation, configuration, calibration, validation, quality oversight, and monitoring support of products, equipment, and facilities. Through our client dedicated support module, our 24 hour call center, and our ability to provide vendor management, quality oversight and remediation, we are able to provide our clients a complete solution for monitoring support and compliance.

In addition, the Sequence Monitoring Center provides customized data analysis and reporting to help turn raw data into meaningful information. Sequence will work with clients to define reporting and trending needs to ensure the client gets the information required to meet project demands.

For more information, refer to <http://www.sequenceqcs.com/remote-monitoring/>

Top 10 Pharma Companies by 2014 Revenue

#1 **Johnson & Johnson**

#5 **SANOFI**

#9



#2 **NOVARTIS**

#6 **MERCK**



#10 **GILEAD**



#3 **Roche**

#7 **gsk** GlaxoSmithKline



#4 **Pfizer**

#8 **AstraZeneca**



Source: <http://www.fiercepharma.com/special-reports/top-15-pharma-companies-2014-revenue-johnson-johnson-1>

Recent Industry News

First 3D-printed drug approved by FDA

For the first time ever, the U.S. Food and Drug Administration has approved a 3D-printed drug. The prescription pill, Spritam levetiracetam, will be used to treat certain types of seizures in epilepsy patients.

The drug's manufacturer, Aprelia Pharmaceuticals, says it makes the oral medication through a three-dimensional printing process, which builds the pill by spreading layers of the drug on top of one another until the right dosage is reached.

This technique allows the pill to deliver a higher dosage of medicine -- up to 1,000 milligrams -- while being porous enough to dissolve quickly. These attributes can be particularly beneficial for patients who have a hard time swallowing their medication, and miss doses of treatment, the company says.

For the full story, refer to <http://money.cnn.com/2015/08/04/technology/fda-3d-printed-drug-epilepsy/>

Big Pharma-Produced Cannabis Is Likely Coming to the U.S.

For those hoping that Big Pharma could still be blocked from the medical cannabis scene there is bad news: the deal is done. Look for the first naturally-derived, Big Pharma-produced cannabis product to be on the market by the first half of 2016, perhaps even sooner.

Epidiolex is a liquid formulation of pure, plant-derived cannabidiol (CBD) manufactured by the British company, G.W. Pharmaceuticals. It is currently on the FDA Fast Track and has entered its final Phase 3 study for pediatric epilepsy disorders such as Dravet's and Lennox-Gastaut's syndromes with results scheduled for the first quarter of 2016.

Barring an unlikely catastrophic finding, there are plenty of signs that Epidiolex will breeze through this final stage and will thus have cleared

the FDA's testing requirements. For any other drug the remaining details would be purely administrative but Epidiolex is derived from cannabis and that puts a few more hurdles in the way before marketing can begin. There are, however, plenty of signs that government officials are literally paving the way for this new player.

For the full story, refer to http://www.huffingtonpost.com/alice-oleary-randall/medical-cannabis-issue-th_b_7925956.html

Glaxo Rehires Executive Investigated as a Whistle-Blower

GlaxoSmithKline announced recently that it had rehired a former executive whom the company once suspected of being the whistle-blower in a scandal at its Chinese operations.

The decision came after a devastating period in China for the British pharmaceutical giant. Two years ago, investigators in China detained senior executives and sales managers. Eventually, five senior executives were convicted and the company was fined nearly \$500 million for bribing doctors, hospitals and others to bolster sales in China.

The company has acknowledged widespread misconduct in China and pledged to revamp the operation. In a recent news release, Glaxo acknowledged only that the executive, Vivian Shi, whom the company investigated over making accusations of fraud and corruption, had rejoined the company.

For the full story, refer to http://www.nytimes.com/2015/08/05/business/international/glaxo-rehires-executive-linked-to-whistle-blowing.html?_r=0



Mallinckrodt amps up hospital business with \$1.3B Therakos buy

Mallinckrodt has made its second buy of the year--and the company believes it's the perfect match for its first purchase.

The Irish drugmaker agreed to fork over about \$1.33 billion to investment firm The Gores Group for immunotherapy maker Therakos in a deal that should bolster its hospital offerings. Therakos specializes in extracorporeal photopheresis, a form of therapy approved to treat symptoms associated with a form of lymphoma.

The acquisition fits "hand-in-glove" with Mallinckrodt's (SMNK) previous deal--a \$2.3 billion purchase of Ikaria that brought it access to a respiratory med for babies in neonatal ICUs.

Mallinckrodt can reach out to medical establishments already using that treatment--dubbed INOmax--to help build demand for Therakos' devices, which they forecast could haul in \$500 million or more per year.

For the full story, refer to <http://www.fiercepharma.com/story/mallinckrodt-amps-hospital-business-13b-therakos-buy/2015-08-10>

QUICK INSIGHT

About 99.9% of your DNA is exactly the same as everyone else's. The other 0.1% codes for all of the differences that make us unique.

Humans shares about 98% of their genes with chimpanzees, 92% with mice, 76% with zebrafish, 51% with fruit flies, 26% with thale cress (a type of weed), and 18% with E. coli bacteria.



Making A Name

As Sequence 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

- AstraZeneca
- Baxalta
- Becton, Dickinson and Company
- Biogen
- Bristol-Myers Squibb
- Dassault Systems Biovia Corp
- Hospira
- Novartis
- Samsung Biologics
- Shire

Quality Programs & Compliance

- INC Research
- Novartis
- RAI Services Company
- Talon Labs

Lab Compliance Services

- American Snuff
- Bayer CropScience
- Baxalta
- Biogen
- bioMerieux
- Eisai
- GlaxoSmithKline
- Hospira
- inVentiv Health
- InvivoSciences
- Performance Solutions
- Pfizer
- RAI Services Company
- RJ Reynolds (RJRT)



IT Quality Services

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

Engineering Services

- Baxalta
- Grifols
- Pfizer
- Robert E Mason & Associates

Technical Services

- Becton, Dickinson and Company
- bioMerieux
- Catalent
- Fresenius Kabi
- GlaxoSmithKline
- Grifols
- Hospira
- ITW Medical
- Novartis
- Novo Nordisk
- OSO Biopharmaceuticals
- Patheon Manufacturing Services LLC
- Xellia Pharmaceuticals

Your Opinion Matters!

Have any recommendations for the next newsletter or want to learn what you can do to help, please contact Dylan Clark or Dan Santarsiero!

