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2012 Edition

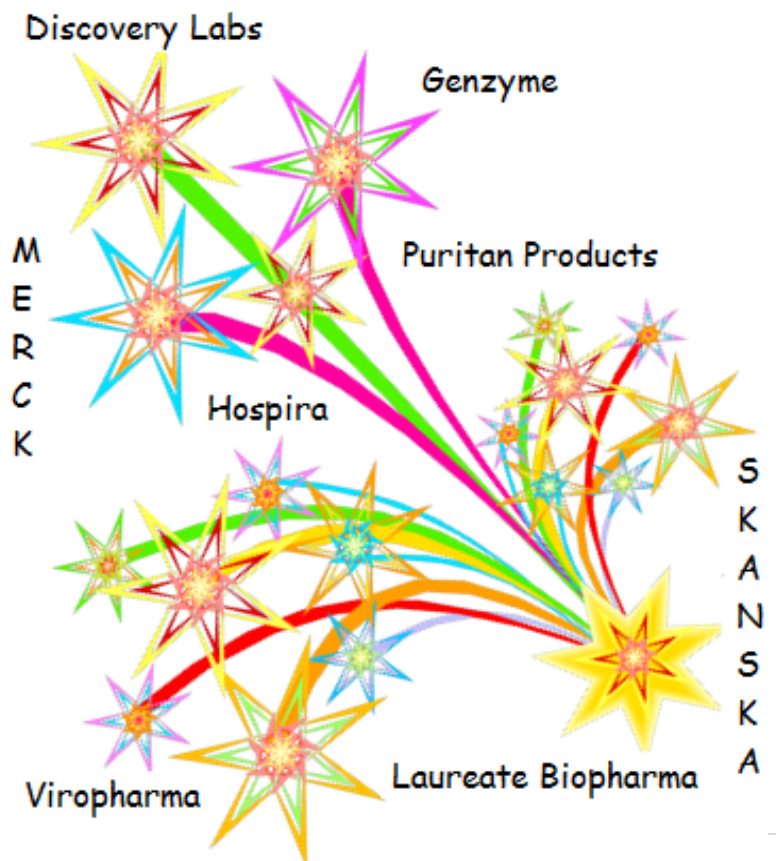


♥ ♥ ♥ ♥ ♥ ♥ ♥ ♥

*We would like to congratulate
Dominic Perazza who recently got
engaged in April of 2012. He and his
fiancée, Roxanne, are very happy!! No
date has been set as of yet!*



Celebrating New Clients!



CTG Welcomes!

It has been a while since our last newsletter and a few new faces have decided to try the CTG way!

ON THE NEXT NEWSLETTER!!!!

SPECIAL MENTION ABOUT PETE GRAU FOR HIS PRESENTATION!!!!

Brian Diaz

Omar Miah

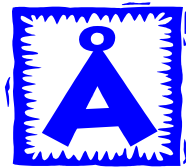
Phil Mumford

Rebecca O'Connor

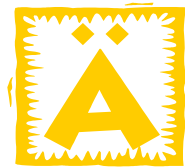
Peter Bossman



nother



nnoying



cronym



"Club Penguin Improvement Project", while this is true, the answer which best relates to CTG is "Certified Pharmaceutical Industry Professional". This certification is offered through the ISPE and is an intensive program focused on pharmaceutical manufacturing from development through production. Hank Bryant is currently attending this demanding course and will soon be certified as only 1 of approximately 12 in the North Carolina region.



☞ JANUARY ☞

Dave Fletes - 4 Years as an EE
 Steve Rose - 7 Years
 Kelly McBrearty - 9 years
 Kevin Earyes - 11 Years
 Chris Lee - 1 Year
 Mike Holub- 1 Year as an EE

☞ FEBRUARY ☞

Luis E Hernandez - 1 Year as EE
 Chris Patten - 7 Years

☞ MARCH ☞

Pete Grau - 7 Years
 Paul Mayer - 5 Years

☞ APRIL ☞

Matt Ostrowski - 4 Years
 Pete Swartz - 9 Years
 Barry Keister 9 Years

☞ MAY ☞

Mike Drexel - 1 Year as EE

☞ JUNE ☞

Dave Bixby - 1 Year
 John Lindros- 9 Years
 Ray Taylor - 1 Year

Contractors

☞ January ☞
 ATS

☞ February ☞
 Crimaldi - 9 Years
 Vista - 11 Years
 Cassels - 9 Years

☞ June ☞
 Nelson - 13 Years

Where is...?

Integra

Dante Mojares
 Luis Hernandez
 Mike Kiper
 Rob Williams
 Jenna Eicherly
 Mark Serafin
 Bernard Vista
 Jeff Moulic
 Don Mojares
 Omar Miah
 Phil Mumford
 Brian Diaz

Puritan

Dominic Perazza

RMS

Brett Pacheco
 Kyle Freund

Skanska

Sean McDonald
 Harry Koons
 (Precis)

Sanofi Pasteur

Pete Grau
 Jenny Jones
 Jamey Crimaldi
 Dennis Work
 Barry Keister
 Jeff Moulic
Novartis
 Dominic Perazza
 Chris Lee
 Steve Rose
 Nick Leuci
 Brandon Sessoms
 Hank Bryant

GSK

Dave Bixby

Merck

Kelly McBrearty
 Kevin Earyes
 Peter Swartz
 Alan Pratt
 Mike Holub
 Chris Patten
 Ray Taylor

Janssen

Ela Szymanka
 Sam Moyerman
 Paul Mayer

Imclone

Jay Cassels

Genzyme

Mike Earyes
 Matt Ostrowski
 Dave Fletes
 Adam Owens
 Travis Moore
 Luis A Hernandez

Laureate

John Lindros

Hospira

Peter Bossman

ViroPharma

Dan Lobb
 Dom Perazza
Discovery
 Don Nelson
 Brett Pacheco



MAY	Moyerman	13-May
	Moulic	25-May
JUNE	Nelson	6-Jun
	Dante Mojares	5-Jun
	Freund	25-Jun
	Eicherly	29-Jun
JULY	Fletes	11-Jul

PENNSYLVANIA PROJECT UPDATES



By early January 2012, after having lost Mike Earyes but before having lost three of our key CTG resources (Matt Ostrowski, Mike Holub, and Chris Patten) we had completed the execution of an additional 6 critical systems and drafted summary reports for all systems completed to date.

Since then, the team that remained has been constantly challenged to meet project schedule and budget, while also accepting responsibility for the development and execution of an additional 15 systems and their summary reports. At this late juncture, we are in the home stretch for closing out all 48 effected change controls, and all datapacks and summary reports for the project. Countless sleepless nights were experienced along the way and heroic efforts were forthcoming from all involved.

We tip our hat to the many CTG resources involved over the course of the project that are ultimately responsible for the project's success to date.

Many Thanks to:

Jamey Crimaldi
Mike Earyes
Kyle Freund
Pete Grau
Luis Hernandez
Mike Holub
Jenny Jones
John Lindros
Paul Mayer
Kelly McBrearty (home office support)
Travis Moore
Jeff Moulic
Becky O'Connor (home office support)
Dave O'Keeffe (BioK)
Adam Owens
Chris Patten
Bob Sciascia (Costanza)
Dan Suchecki
Dennis Work



A new client to CTG, Puritan Products is a specialty chemical formulation company in Allentown PA. Currently they manufacture their products without the need to follow GMP however they would like to venture into this arena. Puritan is in the infancy stage of understanding GMP and have asked CTG to help them get started. They have asked CTG to prepare a site validation master plan as well as IOQ/PQ documents for a USP grade water system that was previously "qualified" but was clearly lacking with respect to meeting GMP standards. Alan Pratt and Dominic Perazza have been working with Puritan to identify gaps as well as generation of all the necessary documents to bring the water system to a qualified state.



We are continuing our work on the Requalification Program at Malvern. CTG is working with Janssen on enhancing their production through Project Endure and the optimization of Clean in Place and Steam in Place procedures for the Harvest Hold, Media Prep and Hold, and Downstream Processing Suites.



A new client to CTG, Viropharma is a global biotech company (with its US headquarters in Exton, PA) that focuses on developing and manufacturing smaller, niche products. The majority of Viropharm's products are manufactured through a third party and CTG has been asked to provide general C&Q guidance with respect to a new filling line that Viropharma has purchased for an international third party manufacturer. CTG has been tasked to develop a project validation master plan as well as develop the PQ for the integrated line. Additionally, there is potential for CTG to develop and execute the process validation for the product/line also.



We landed the Whale! CTG was recently awarded to not one, but two large validation projects at the Merck WestPoint, PA site. A team of seven people will be supporting the PQ efforts of the VAQTA manufacturing facility and the Vaccine Sterile Supply (VVSS) facility renovations. The work will require approximately two years of Validation efforts for their systems which includes; autoclaves, CTUs, waste inactivation, HVAC, DHO, chromatography, columns and plenty of cleaning Validation! We have been welcomed by many including completion and this site is home to over 8,000 employees, so there is lots going on there, we are already getting additional request!! Good luck team!!



CTG was recently awarded the commissioning project for the "Workplace Transformation Project" which Skanska is responsible for. This project is the renovation of four buildings at the J&J Springhouse location. Due to our previous work with J&J, we were asked to bid and with the help of Precis Engineering, we won! Sean is the main person involved with this unique project as it is definitely different from our typical C&Q. The work is almost entirely non-GMP! Typical work consists of observing the installation and walk down of system P&IDs. The job is just getting underway and things are progressing nicely.

NEW JERSEY PROJECT UPDATES



The Integra Facilities Engineering Department, supported by **Bernie Vista, Mark Serafin, Don Mojares, Jenna Eicherly Phil Mumford, Omar Miah, and Brian Diaz** are in the process of renovating several ISO Class 7 manufacturing areas, including installation, commissioning, and qualification of a new HVAC air handling unit and HEPA filtration system, as well as upgrades to building utility systems such as clean compressed air, DI water, electrical and natural gas. The group is also supporting the implementation and qualification of new computerized preventive maintenance and calibration management systems.

The Integra Product Development Engineering Department, supported by **Luis Hernandez, Dante Mojares, Rob Williams, & Mike Kiper** is in the process of developing and executing cleaning validations for the entire Building 105 manufacturing facility. The group also supports the day to day needs of the site, including equipment and process qualifications/requalification's.

CTG supports all aspects of documentation and compliance for these projects, from initiation to completion. These projects are critical to facility and process improvements, as well as FDA warning letter response.



Jay Cassels continues to support the Cleaning Validation group in all aspects, from writing/executing various protocols from cycle development through performance qualification for BB50 Suite 2 to ongoing Cleaning Verifications, Product Changeover, Bag Studies and Cleaning Monitoring throughout all production areas. we recently have been assigned to work with the engineering group to handle cleaning validation aspects of new initiatives for optimization of all glassware washers and wash stations.



Currently we have **John Lindros** supporting Laureate in Princeton New Jersey; a leader in biopharmaceutical contract development and manufacturing and experts in process development and cGMP production of therapeutic proteins, including monoclonal antibodies and Fc-fusion proteins. Projects include CTU's, Warehouse, PQs of Tube welders and sealers, addendum qualification of Remote Environmental Monitoring system, Qualification of Steam-In-Place (SIP) of filtration skids and multiple test scripts addressing related change controls.



Brett Pacheco and **Kyle Freund** are at Roche Molecular Systems in Branchburg, NJ supporting the engineering department. They are assisting in the C&Q of several filling and labeling systems used for the packaging of test kits. These kits are used in the newest generation of diagnostic test platforms that Roche has developed for the diagnosis of blood-borne illnesses.



Discovery Labs is in the process of remediating gaps within the existing validation of all systems which support the manufacturing of their products. In support of this effort, CTG has been awarded the project to perform all the revalidation of the identified systems. This project is testimony to our staff as the point of contact at Discovery used to work for a competitor!

CTG SOUTH UPDATES



CTG currently has one person working at the Hospira, Clayton NC site. **Pete Bossman** recently began a validation and remediation project there involving a multitude of laboratory systems and equipment. We recently met with the validation and remediation staff at the Hospira, Rocky Mount NC site to discuss support for their on gong projects. We are currently assembling a team to present to the client to help fulfill their needs. Hopefully more to come with Hospira.



CTG currently has 4 employees at the Novartis, Holly Springs site. **Steve Rose** is supporting Fill Finish activities and requalifications. **Chris Lee** is working on completing cleaning validations studies and also supports Fill Finish requalification activities. **Hank Bryant** recently began a new document review and support role for the site. Brandon continues to support the Micro QC department and because of his many skills, is often called over to help the Validation team!



The Pernambuco Biotech Plant project officially kicked off in March both here in the US and in Brazil. Site grading has begun at an accelerated pace in hopes that it can be completed before the rainy season arrives in Mid June. The first equipment bid packages are being drafted and issued so that the long lead item fabrication can start. From the C&Q side, the drafting of the validation master plan is in full swing as well as initial testing of a new protocol generation system. Once this system is up and validated it is the intent to possibly start electronic execution of protocols which should be interesting. FATs are expected to start at the end of this year and the first half of 2013. Commissioning activities for the modular manufacturing building will start summer of 2013 in Charleston SC with the intent of delivering to the site at the end of 2013. Site commissioning activities will start end of 2013.

The highlight of the project so far has been navigating the Brazilian business climate and the challenges it presents and could ultimately decide the success of this project. Even some our Brazilian colleagues scratch their heads sometimes.



CTG currently has one employee fulfilling validation and automation engineering needs at the GSK, Zebulon NC facility. **Dave Bixby** is working on the configuration and re-validation of an oral dosage automated inspection system. He recently finished his responsibilities as a validation specialist for an electronic batch record system at the same location.

MASSACHUSETTS



Manufacturing challenges due to regulatory approvals have led Genzyme to implement a Remediation Plan. To support their efforts, CTG has been requested to provide consultants for the C&Q effort of their cell culture manufacturing suite. Currently five people have joined the effort at the Allston site and will be working with Genzyme to meet the goals of the crucial supply chain for this critical product used for the treatment of the rare disease called Gaucher. This new client has opened the gates for CTG to expand into the New England area!

STEAM QUALITY TESTING

Mike Drexel has been busy! SQT continues to grow for CTG. In 2011, CTG executed SQT at over 20 different client sites, covering more than 65 test locations, adding several new SQT clients along the way. The prospects for continued growth in 2012 are even greater. As the need for SQT service expands in both the US and Canada, CTG continues to work to maintain the well-earned reputation as the go-to service provider in the industry. SQT provides an excellent way to expand CTG's client list and gain prospective CQV business.

Term Time!!

Orphan Drug:

The FDA grants Orphan Drug status to one company for a drug that is believed to substantially increase the life expectancy of the treated patient for a particular disease. This excludes other companies from receiving an FDA license to produce a similar drug for a finite period (usually 7 years), thereby allowing the company producing the drug to recuperate their R&D expenses.

**Please remember
timesheets are
due every
TUESDAY by
10am to Kelly
and Rebecca!!!**

IN THE SPOTLIGHT: DAVID BIXBY

★ **What are you doing when you're not working?**

- Responsibilities of being a dad and getting stuff done around the house. Exciting stuff, eh?

★ **What's your favorite food?**

- Indian, followed closely by Italian.

★ **What's your beer of choice?**

- Hoppy pilsners. I try them all.

★ **If you could have dinner with any famous person live or dead, who would it be?**

- ESPN's Chris Berman

★ **If you could have one super power, what would it be?**

- Ability to fly.

★ **What's your biggest pet peeve?**

- Drivers remaining in the far left lane of a multi-lane highway driving slower than those to their right, gabbing away on their cell phone completely oblivious to other drivers having to weave around them.

★ **What place would you most like to travel to that you've never been before?**

- The Moon

A Letter from the Editor

Thanks once again to everyone who contributed to this edition of the newsletter. It would not have been a success without you! Many new faces have come and gone since our last issue but we are now through a transition and plan to remain committed to the idea of having a Newsletter every Quarter! As I have stated in past issues the intentions are to help all of you realize the company you work for is based upon a close-knit family atmosphere with all individuals understanding your place in this industry... You Are Not Alone! Also, please note we will be sending these newsletters electronically--- Welcome to the 21st century!! As always your comments are greatly appreciated and if you have advice or suggestions to improve upon our current newsletter, do not hesitate to reach out to me. We are looking for volunteers to submit an article. If you have an idea and would like a chance to publish it, here is your chance!

TRIVIA ANSWER...

The cola tree (*Cola acuminata*) produces caffeine-rich nuts that is extracted from coca to produce the main ingredients of Coca Cola. The cola tree is native to West Africa, but it also grows in Jamaica, Brazil, and India

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CTG WORKSEARCH



Calibration
Thermocouples
Hoods
Deprogenation
Kaye

Conductivity
Formaldehyde
Laboratory
Stablization
ValProbe

Qualification
Decontamination
Bacharach
Deviation
Verification

Profilometer
Cleanrooms
Datalogger
Lethality
Temperature

2012 Invoicing & Expense Schedule

Invoice	Weeks Ending		Received By	Paid
	Start	End		
January	2-Jan	29-Jan	10-Feb	29-Feb
			15-Feb	15-Mar
			29-Feb	30-Mar
February	30-Jan	4-Mar	10-Mar	30-Mar
			15-Mar	16-Apr
			30-Mar	30-Apr
March	5-Mar	1-Apr	10-Apr	30-Apr
			15-Apr	15-May
			30-Apr	31-May
April	2-Apr	29-Apr	10-May	31-May
			15-May	15-Jun
			31-May	29-Feb
May	30-Apr	3-Jun	10-Jun	29-Jun
			15-Jun	16-Jul
			30-Jun	31-Jul
June	4-Jun	1-Jul	10-Jul	31-Jul
			15-Jul	15-Aug
			31-Jul	31-Aug
July	2-Jul	29-Jul	10-Aug	31-Aug
			15-Aug	14-Sep
			31-Aug	28-Sep
August	30-Jul	2-Sep	10-Sep	28-Sep
			15-Sep	15-Oct
			30-Sep	31-Oct
September	3-Sep	30-Sep	10-Oct	31-Oct
			15-Oct	15-Nov
			31-Oct	30-Nov
October	1-Oct	4-Nov	10-Nov	30-Nov
			15-Nov	14-Dec
			30-Nov	31-Dec
November	5-Nov	2-Dec	10-Dec	31-Dec
			15-Dec	15-Jan
			31-Dec	31-Jan
December	3-Dec	30-Dec	10-Jan	31-Jan
			15-Jan	15-Feb
			31-Jan	28-Feb

2012 Summer Picnic

CTG would like to plan a Summer Picnic at the Brandywine Picnic located in West Chester, PA. There will be Tubing, paddle boats, canoeing, a Moon bounce, Carnival Midway of Games, gazing zoo, horseshoes, rides and slides, a rock climbing wall and miniature golf. Not to mention all the food you can eat! The date is still being discussed but it will most likely be one of the following:



August 18th
August 25th



<http://www.picnic.com/>

A Letter from the President

Since the last newsletter (Spring 2011), CTG is again in a very dynamic period. Over the last few months we have been transitioning personnel from two very large projects, which has been extremely challenging. I am extremely proud at how we have diversified with new clients in our CTG South and North locations. This diversification has aided us to transition from the large jobs to smaller jobs and still maintain our workforce. From my standpoint, this has happened due to the past success of our organization and the promising future outlook that our clients have in CTG. This has all happened without much input from me due to my work at Genzyme. It is a true testament that CTG is functioning at an extremely high level at all levels! As we have in the past, we are in a position to have the strongest business growth in CTG's history. With the expansion of CTG South and, coupled with strong growth in clients in New Jersey, Pennsylvania and Massachusetts, it is anticipated that this will be our biggest year to date at CTG. I continue to be impressed with our new clients and our growth at our core clients sites. Our name recognition in the industry is at an all-time high and we are recognized as a large player in the industry.

We have continued to focus on our home office organization and I have routinely heard good things from all personnel in the field with regard to home office support. I believe the focus that we put into the home office structure and organization has really paid off to make us a first-class consulting business with an emphasis on employees.