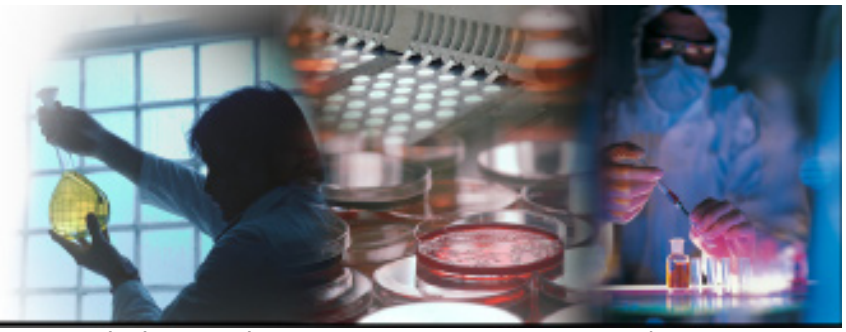
Carolina-South Atlantic Chapter
ENGINEERING PHARMACEUTICAL INNOVATION



Volume 17 · Number 2 Engineering Pharmaceutical Innovation SPRING/SUMMER 2010

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Technical Article Submissions

Publication Opportunities Exist in the Following Areas

- Innovative Technology
- Automation Solutions
- Operational Excellence
- Critical Utilities
- Commissioning and Qualification
- Process Development
- Oral Solid Dosage
- Facility Design
- Contract Manufacturing
- Regulatory Affairs
- Project Delivery
- ... and many more!

Articles should be written for technical professionals in the pharmaceutical, biotechnology, and medical device industries. The author is responsible for the accuracy and correctness of all statements contained in the manuscript (ISPE Carolina-South Atlantic Chapter assumes no liability.) Submission of technical article does not guarantee publication in the eNewsletter. We reserve the right to edit and select all entries. Articles that promote a specific product or company will not be accepted.

Editor's Note

Spring is always a busy time for ISPE CASA. We have been slammed with recent networking and educational events. Inside this issue you will find write-ups from many of these events, as well as several white papers from local members.

The Membership Committee scored again with Casino Night, it was certainly a night to remember! The Programs Committee reached outside to other communities during the Roche Tour in Florence, SC. Our biggest event of the year occurred in March, the 17th Annual ISPE CASA Life Sciences Technology Show.

As you browse this newsletter, keep in mind that the Communications Committee is always looking for new members, as well as technical article submissions. Don't forget that we have plenty of advertising space for your company, and that we distribute to over 1400 members every quarter.

If you have questions or comments on this newsletter or its contents, please contact me directly using the ISPE Directory, located on the website. I look forward to seeing you at upcoming local events, as well as at the 2010 Annual Meeting!

Warm Regards,

Megan Crum
Communications Committee Chair

ISPE Carolina-South Atlantic Chapter
ENGINEERING PHARMACEUTICAL INNOVATION

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- **Amy Lineberry,** *Students*
- **Blake Derrick,** *Young Professionals*
- **Alan Tucker,** *Tech Show*

Chapter Announcements

Event	Location	Date
Energy Management Forum	Novartis Campus Holly Springs, NC	16 September 2010
ISPE CASA Fall Gala	The Umstead Hotel and Spa Cary, NC	30 September 2010
Joint ASME BOE Event	TBD	October 2010

Welcome New Members!

Manoj Agrawal
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Jamil Barnville
Travis Barr
Michael Barrett
Thomas Beaird
Susan Beckert
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Kinjal Desai
Joshua Dills
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Jalesha Dunn
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Victoria Miller
Christopher Moore
Arya Morman
Morgan Morrison
Jeff Morton
Bradley Mosall
Tom Mulligan
Srinath Muppalaneni
Ken Murillo
Lamar Murriell
Musoki Mwimba
Nicholas Myszak
Maikhahn Nguyen
Ian Njoroge
Cayla Noble
Rania Nouh
Adam Oliver
Ron Olson
Isaac Ounda
Jeffrey Overman
James Overton
Lee Page
Hadiyah Parker
Margie Parker
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John Peart
Leotrice Pegues
Christopher Perry
Leslee Petersen
Dennis Plante

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Carolyn Primeaux
Mike Pritzlaff
Shreya Purohit
Chanel Rabon
Norah Ritter
James Robbins
Patrick Rogers
Monica Rose
Robin Roxas
Bethany Ruggiero
Mohit Sahoo
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Jessica Taylor
Precious Taylor
Martinique Thomas
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William Tyson
Paul Utt
Jim Viane
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Laura Watkins
Maxwell Webber
Jackie White
Susan Wickens
Allison Williams
Janifer Williams
Chanel Wilson
Lori Wilson
Ursula Wilson
Shawn Windley
Chris Woods

ISPE CASA Visits the Roche Carolina Inc. Facility in Florence, SC

By: **Martin E. Rock, PE, JD, LEED-AP**
OMNI Professional Environmental

Location, Location, Location . . . Due to the location of Roche Carolina Inc., near Florence, South Carolina, we were able to accommodate ISPE-CASA Chapter members from *five* states: Florida, Georgia, North Carolina, South Carolina, and Tennessee. A total of 55 of our members (our attendance limit) made the journey on April 8, 2010 from as far away as Jacksonville, Florida and Bristol, Tennessee to join in this event.

On behalf of the Chapter, a special thank you goes to Bert Miranda, RCI Engineering Manager; Kim Slattery, Senior Administrative Assistant; and RCI President Frank Cox for hosting our group. They worked closely with our ISPE-CASA volunteers, and the event proceeded very smoothly.

Thanks also to Vince Miller and Jacqui Roth, both past presidents of the Chapter, for their service in expressing our initial interest to Roche management several months prior to the event during an in-person meeting in Florence. The results of this meeting were a summary of the discussions and a preliminary agreement on the agenda for the event.

About Roche

Headquartered in Basel, Switzerland, Roche has been discovering and providing healthcare products for over 110 years. Roche employs over 80,000 personnel worldwide, and Roche is the world's leading supplier of prescription drugs for cancer treatment. Roche is also the world leader in in-vitro diagnostics, supplying a wide range of diagnostic instruments and tests for rapid and reliable disease detection and monitoring.

As the world's largest biotech company, Roche has brought many successful drugs to market. These include drugs for cancers, viral infections, metabolic and central nervous system disorders and inflammatory diseases.

Xeloda®, (Capecitabine, TP-activated) one of the products manufactured at the Florence plant, offers an oral treatment option in breast and bowel cancer, and this drug has shown indications in cancers of the stomach and pancreas. Xeloda® is an orally administered (tablet form) chemotherapeutic agent used in the treatment of these metastatic breast and colorectal cancers. Capecitabine is a prodrug, that is enzymatically converted to 5-fluorouracil in the tumor, where it inhibits DNA synthesis and slows growth of tumor tissue. Xeloda® recently celebrated a milestone of the one millionth patient treated.

In March 2009, Roche and Genentech announced a merger agreement under which Roche acquired the outstanding publicly held interest in Genentech for a total payment of approximately US$46.8 billion. Genentech in the USA and Chugai in Japan provide Roche with broad access to innovation, and Roche invests heavily in the research and development of new drugs and diagnostic products. Five of these products or their intermediates are manufactured at the Roche Carolina plant in Florence.

Roche is also a major player in the battle against H1N1 influenza. In response to the increased WHO pandemic threat level, Roche scaled up production of Tamiflu to

approximately 33 million treatment courses per month, and Roche is now able to supply up to 400 million packs annually, if required.
The RCI Florence plant produces Tamiflu intermediates and API and helped meet the challenge of the dramatic increased demand for Tamiflu resulting from the global H1N1 threat.

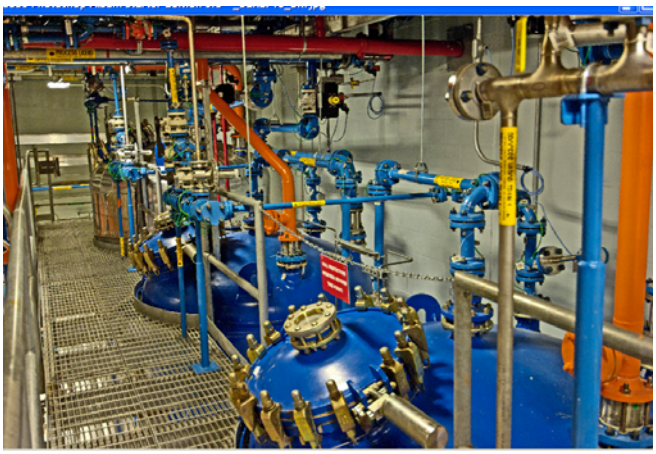
Roche Florence Plant

Roche Carolina has had a process development and bulk active ingredient manufacturing facility on the 1,400-acre (567 hectare) site in Florence, South Carolina since 1995 (groundbreaking in 1992) when the facility started production with only 20 employees relocated from the Roche US headquarters in Nutley, New Jersey.

Roche invested $650 million to build out a 100,000 square foot pilot plant and 14 other buildings became operational in June 1996, with 350,000 square feet of manufacturing plant coming fully operational in 1999. In 2007, over $60m was invested in the installation of a multipurpose production unit in an existing manufacturing building. The total capital invested to date is $800 million.

The Roche Carolina (RCI) facility manufactures the active pharmaceutical ingredients (API) for Xeloda® (capecitabine) [cancer treatment] and Tamiflu® (oseltamivir phosphate) [flu medicine]. The facility also produces the PEG reagent for Pegasys® (peginterferon alfa-2a) [hepatitis C treatment] and Mircera® (methoxy polyethylene glycol-epoetin beta) [renal anemia]. In addition, RCI performs a milling step for Xenical® (orlistat) [weight-loss drug].

According to the company when the first plant was constructed, the building, the utilities and the heating and cooling transfer system were purposely oversized for the job. This makes expansion at Florence much easier. Roche has developed only about 200 acres (81 hectares) of the 1,400-acre Florence campus, so there is still ample room for expansion.



In addition, the first plant at Florence has highly automated manufacturing operations that were designed with a high level of flexibility in mind. This allows the company to change over manufacture to new chemicals with no major capital investments and also to integrate new expansions into the existing operation.

Roche Carolina focuses on process development for the Swiss parent, as well as the supply of clinical trial materials. It has contributed to the development of manufacturing protocols for a number of Roche's leading brands.

Those who attended the tour also could sense the cooperative spirit of the RCI personnel. The staff at this site “gets it” – they work together as a team. RCI has a strong 3-year apprenticeship program modeled after the “Chemikant” system, and the facility has won the Roche Responsible Care Award for 10 consecutive years. RCI also has won an award for South Carolina Manufacturer of the Year, the American Chemistry Council Energy Efficiency Award, and the Silver Shingo Award among others. Thanks again to Roche Carolina for an excellent tour and a well-received Chapter educational event.

16th Annual ISPE CASA Golf Tournament

By: **Heather Denny, Membership Committee Chair**

With 136 golfers, the 16th Annual ISPE CASA Golf Tournament was a sold out event. On Monday, May 10th players came out to Devils Ridge Golf Course in Holly Springs to enjoy a cool spring morning. As golfers were registering, a few even mentioned that it may be a little too cool, but the day progressed into a warm, overcast North Carolina day, perfect for golf.

New to this year's tournament was the Million Dollar Shoot Out. Four golfers earned the opportunity to make one shot and go home a Millionaire. While we all saw the YouTube video, proving that it is possible at Devil's Ridge, no one went home with a Million Dollars on the 10th. Other contests that provided the ability to convert skills into winnings were the $10,000 Putting Challenge, Hole-In-One Opportunities for a Car, Airfare, Flat Screen TV, and Calloway Irons. We did not forget those "Just for Fun" golfers as more that 25 raffle prizes were drawn while golfers enjoyed an afternoon buffet including ice cream sundaes.

Team awards were presented based on flights.

A special thanks to all of the sponsors and teams that support this event.

As we enjoy the success of this years golf tournament it can not be done without stopping to remember Todd McCulloch. As prior Membership Committee Chair and current member Todd took the responsibility for organizing and planning the 16th Annual ISPE CASA Golf Tournament. Just as he had in previous years, he spent many hours creating new challenge opportunities for an exciting and great event. Todd's passion for golf and the ISPE CASA Chapter were never more obvious than watching him on the morning of one of our golf tournaments. Todd will be missed but his presence will be with us as we plan and look forward to next year's golf tournament.

Mark your calendar for Monday, May 2, 2011, plans are already underway for the 17th Annual ISPE-CASA Golf Tournament to be held at Prestonwood Country Club.

16th Annual ISPE CASA Golf Tournament Sponsors

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Sequence Validation Consulting Services
Yonkers Industries
DRWA Mechanical Engineering
Burkert Fluid Control Systems
Cooper Electrical Construction
RGD Project Management
Vantage Consulting Group

IPS: Breakfast and Logo Gift
CRB: Lunch and Logo Gift
A.N.D. Consulting: Million Dollar Shoot Out
O'Brien & Gere: $10,000 Putting Challenge
PCI: Hole in One "Car"
Total Facility Solutions: Hole in One Airfare
Getinge: Hole in One "Flat Screen TV"
Mangan: Hole in One "Calloway Irons"
Vantage Consulting Group:
Cart/Sign/Scorecards

Chromatography Workshop

"What's Wrong with My Column?"

By: **David Knorr, Programs Committee Chair**

On Tuesday April 27, Al Williams, Applications Manager at GE Healthcare (formerly Amersham Biosciences) presented "What's Wrong with My Column? Expected and Unexpected Behaviors in Chromatographic Operations" to the ISPE CASA chapter at the N.C. State BTEC. For those that remember, Al spoke with members of ISPE CASA in November, 2006 and this time he proved to be as popular as ever as the event was attended by over 50 area professionals.

Al stressed the importance of being prepared for unexpected behaviors in chromatography systems. This means being able to capture as much data as possible about the column and its packing including volume matrix and pressure/flow curves. Al went on to explain how to examine a chromatography system set-up; which often includes chromatography skids, piping, tubing, and valves; and how to determine their effect on commonly used packing criteria such as asymmetry and HETP.

Al then presented a series of chromatograms which resulted from various operational errors and how those errors caused the chromatogram deviate from the expected chromatogram. He then discussed common column packing problems, environmental factors and how to avoid system effects.

Al concluded with a discussion of column screens and incomplete cleaning of the screens and their effect of expected flow rates. A question and answer session was held followed a networking session with hors d' oeuvres to conclude the event.

CASA Members Win Big at Casino Night

By: **Heather Denny, Membership Committee Chair**

With the current 100 degree temperatures, it may be hard to remember February 6th when we were gambling on the potential of snow that would have affected the 2nd Annual ISPE CASA Casino Night.

The Membership Committee upped the stakes and held a tremendous event. Held at The Capital City Club in the Progress Energy Building in downtown Raleigh, 120 attendees could look out from the 21st floor and see the night life on the streets below while enjoying hors d'oeuvres, which included Mediterranean Shrimp and Goat Cheese, Vegetable Tempura, Asian Stir Fry along with cheeses, fruits, and antipasti. Trying their luck at the tables, guests had the opportunity to play craps, roulette, blackjack, and Texas Hold'em. As the night progressed the stakes got higher and some serious gaming was going on.

Our top money winner received a night at The Umstead, in Cary, along with a gift certificate for breakfast at Heron Restaurant in the hotel. The second and third money winner received a gift certificate to Second Empire and a gift certificate to the Angus Barn. This event would not have been possible without the generous support of our sponsors. Thank you to our Premiere Sponsors CRB and McDonald York Building Company. Also to our table sponsors Wesco, Bahnson Environmental Specialties, NNE Pharmaplan, SPI, Avid Solutions, PCI, and Commissioning Agents Inc. We look forward to seeing you next year.

ISPE & BTEC Joint Career Fair and Poster Competition

By: **Amy Lineberry, Student Committee Chair**

I would first like to thank Marcelo Anderson, Winnell Newman and the entire BTEC group for another hugely successful ISPE/BTEC Career Fair. We again had more than 200 students interviewing for jobs and internships with various companies from the area including the FDA. Several students walked away with a second interview and offers.

We also held our annual Undergrad and Graduate Poster Competition. We again had a strong group of competitors with 10 students competing. I have included the abstracts of the winner for each category. Thank you to all those that participated. The two winners won an all expenses paid trip to the 2010 ISPE Annual Meeting in Orlando, FL to compete at the International Level.

Congratulations to Juan Cueva of NCSU, Undergrad Winner.

Inhibitory Effect of Silkworm Extract on Alpha-Glucosidase Activity and Postprandial Blood Glucose in Mice

Abstract: The inhibitory effect of silkworm extract on alpha-glucosidase activity was determined through an *in vitro* enzymatic assay. In addition, the effect on postprandial glucose concentration was analyzed in mice. Silkworm larvae extract (SLE) was prepared with 50% ethanol and assayed with alpha-glucosidase enzyme from baker's yeast. The Km value for maltose was 50.5 mM. When SLE was added to the enzymatic assay, a competitive reversible pure inhibition was observed with a Ki value of 0.064 mg/ml (~2.2E-2 mM). Furthermore, the effect on blood glucose concentration in mice BALB/c was examined after an oral treatment with both SLE and a commercial brand of acarbose. After 30 minutes of oral administration, the increment of postprandial glucose was diminished 75.9% with a dose of 0.05 g/kg of acarbose, 54.9% with a dose of 0.08 g/kg of SLE, and 85.1% with a dose of 0.4 g/kg of SLE. In brief, SLE is an effective alpha-glucosidase inhibitor and reduces hyperglycemia conditions in a dose dependant manner. SLE and other silkworm larvae food derivatives have the potential to contribute positively to diabetes mellitus prevention and control if used as an alternative dietary supplement.

Congratulations to LeAnna Pearson of NCCU, Graduate Winner.

Use of In-process Analytics in Measuring Chromatographic Transitions to Evaluate Column Integrity

Abstract: The current testing methods for evaluating column health, integrity, and lifetime is to equilibrate the column with buffer, inject a spike solution, and slowly flow the spike solution through the column. The result is the measurement of HETP (height equivalent to the theoretical plate), and asymmetry. This method is not only time consuming but also can only assess the column health after a run takes place. By developing in-process system that analyses individual chromatographic transitions, the purity and yield of a protein could be significantly enhanced. This enhancement would be through the measurement of the health of a column as well as the integrity of the resin and its affinity for proteins. The analysis would allow for the evaluation HETP and asymmetry, immediately after packing and throughout the column lifetime, this would allow for a substantial increase in the amount of time that resin is used. By increasing the amount of time that resin is used and by knowing that optimal amounts of protein are being acquired both time and money would be saved. This real time analysis platform would require using transition analysis and principle component analysis which can prevent a bad column from passing and a good one from failing. In order to achieve this, the evaluation various chromatograms at lab scale is required in order to identify the optimum transitions for evaluation. The impact of transition analysis would be to offer a superior alternative to the current QA/QC method of HETP pulse test, as well as to increase protein yield and column lifetime. Any process changed during protein purification would yield a change to product purity and allow for the engineering of better medicines, as well as a better QA/QC validation tool.

17th Annual ISPE CASA Life Sciences Technology Show

By: **Shelley Preslar, 2008-2010 Tech Show Committee Chair**

The 17th Annual ISPE CASA Life Sciences Technology Show was held on Tuesday, March 23rd, 2010 at the RBC Center in Raleigh, NC. This was the third year in that venue, providing yet another successful event.

There was record registration and attendance this year. Between pre-registered attendees and walk-ins, there were over 650 people who came to this year's event. For the second year in a row, the show hosted a job fair. This year there were 13 companies that were represented, and they brought 28 representatives with them to talk with potential candidates. Local Operating Companies such as Merck, Talecris, Biogen Idec, Covidien, Novartis, NovoNordisk and DSM brought their listings of open positions. Exhibiting were 163 vendors of all types, providing services to the local Pharmaceutical and Biotech industry.

Hans Engel, Ph.D., President & CEO of DSM Pharmaceuticals, Inc was our first keynote speaker in this venue, presenting "The Role and Benefits of Pharmaceutical Contract manufacturing in the 21st Century and the Challenges of Increasing Complexity of Supply Chain." Throughout the day, many presentations from owners and vendors provided our attendees with multiple opportunities to learn about current trends and hot topics within our industry. Our Project Management Community of Practice (PM CoP) held a training session, "PM People's Court: Equipment Vendor Management" which was very well received. Educational events were spread out in the arena to provide plenty of opportunities for the exhibitors and the attendees to network.

Staying within the format of previous years, a well-filled day of learning and networking ended with a networking reception for all exhibitors, attendees and ISPE representatives. The food was fantastic, and the reception was well attended.

Thanks to all of you for continuing to support such a critically important event to our chapter.

Technology Show Photos

Mechanical Polishing Produces Residue on Stainless Steel Surfaces

By: **Daryl L. Roll, P.E.; Astropak Chief Technology Officer**

Have you ever wiped a vessel and found that the wipe had excessive black debris?

This is common on mechanically polished vessels, especially when they have not been properly prepped and cleaned. This discoloration on the wipe is classified as polishing debris consisting of ground-in stainless steel particles and abrasive residue. The residue is a thin film not generally visible on the surface and its removal can be problematic since it consists of very fine particles (metallic debris from sanding/polishing, abrasives, and other compounds or polymers) that are well attached to the surface.

Cleanliness evaluation of new equipment including vessels, process equipment and components is recommended prior to FAT testing or installation. Additionally, the condition of surfaces in new equipment and systems for pharmaceutical processing meeting the requirements of ASME - BPE should be documented.

INSPECTION

Inspection and sampling of mechanical polished surfaces is performed with the use of a clean room wipe and alcohol. First, scrub the surface with light to moderate pressure using an alcohol wipe over an approximately one square foot area. Next, inspect the wipe visually and/or under magnification to initially evaluate the severity and physical characteristics of the residue. The residue can appear white to light gray in color, or more commonly, dark gray to black. If excessive residue is encountered, the wipe can be evaluated with advanced analytical techniques to identify the metals or organic compounds present. ICP-MS (Inductively Coupled Plasma – Mass Spectrometry) and EDX (Energy Dispersive X-ray) are used to identify the inorganic elements (metal oxides) present on the wipe from the surface residue. FTIR (Fourier Transfer InfraRed spectroscopy) is used to identify any organic compounds present in the residue.

TESTING RESULTS

The testing results of vessels over the past 5 years are presented below to describe the typical components found in the residue. These tests were often the result of the appearance of rouge on the surface of the vessel or the appearance of a wipe from the equipment surface that was considered excessively colored. The analyses of the wipes are summarized in Attachment "A", from highest to lowest average concentrations. The risk of this film on the surface can be categorized as inhibiting the cleaning and passivation treatment, potentially available for release into the process or product fluids, or a source of rouge and corrosion products.

The elemental analyses lead to the following conclusions. The most prevalent elements (iron and chromium) are from the stainless steel particles present on the surface from polishing (sanding) operations. The second most prevalent group (calcium, sodium, potassium and magnesium) of elements are from process fluids or water. Silica (silicates) is found at a similar level of concentration and is one of the more common abrasive media components used in polishing operations. Other abrasive elements including aluminum are also seen at lower concentrations. The last group of elements includes manganese (often present on the surface of stainless steel) and metals found in low concentrations in stainless steel (such as copper, molybdenum, zinc and titanium). Phosphorus is sometimes found on the surface (generally from cleaners or from the stainless steel). Carbon is not quantitatively evaluated since the wiping material is composed of mostly carbon.

Organic analyses of the surface residues show a low level of oils and greases, waxes, esters, phthalates, and assorted polymers. These are compounds that can be found in polishing processes and some from the actual wipe. As in all this testing, a blank (clean) part of the wipe is processed in addition to the colored or residue laden section for comparison. The variance in the blank analyses and the variability in the residue analyses due to the low (ppm) levels of the contaminants only yield qualitative results.

REMEDIATION TECHNIQUES

Removal of these films have been attempted in a number of ways, including hand wiping with an alkaline cleaner, electrochemical cleaning (flash electropolishing) and high pressure washing with particulate removal chemistries. Results vary based upon the condition of the surface and the technique employed. Electropolishing of the surface has been shown to effectively remove both the surface contamination and the damage layer often associated with mechanically polished surfaces. Hand wiping removes the majority of the residue, but can require multiple treatment efforts with hot water washing cycles between wiping efforts. Pressure washing or the use of particulate removal chemistries is generally only marginally successful, unless combined with additional mechanical cleaning efforts.

SUMMARY

Analysis of wiping of product contact surfaces is a method to determine characteristics of potential residue or contamination. The residue from wipe samples show that it is mostly stainless steel particles and oxide compounds generated from the mechanical polishing with lower levels of abrasive compounds and water or process fluid residues. Each project presents a different level of contaminants based on existing conditions and polishing or cleaning techniques employed on the equipment surfaces. Sampling and testing of the residue will indicate the source and guide you in the proper treatment technique to be used.

Attachment "A"

ELEMENT	AVERAGE CONCENTRATION	SOURCE
Iron	Very High	Stainless steel particles / rouge
Chromium	High	Stainless steel particles
Calcium	Moderate	Water or process fluids
Sodium	Moderate	Water or process fluids
Silica	Moderate	Abrasive media
Potassium	Low	Water or process fluids
Magnesium	Low	Water or process fluids
Nickel	Very Low	Stainless steel particles
Aluminum	Very Low	Abrasive media or SS surface
Manganese	Very Low	Stainless steel surface
Zinc/Phosphorus/Copper /Molybdenum /Titanium	Trace	Water / Abrasive / Stainless steel

Very High - 20% ± 15%
High - 15% ± 10%
Moderate - 10% ± 5%
Low - 5% ± 5%
Very Low - 2% ± 2%
Trace - 1% ± 1%

CASA Goes To Court – Project Management COP

By: **Keith Gibbs and Jim McGlade**

Court was in session at the recent ISPE CASA Vendor Technology Show on April 23rd. The Project Management Community of Practice presented a unique presentation format simulating a legal court case. The session was titled, "PM People's Court: Equipment Vendor Management" and featured expert defense panels representing biopharmaceutical owner companies and industry equipment suppliers. The format also included a neutral, unbiased judge who proceeded over the hearing and rendered a final verdict. The two panels began the session with opening statements which outlined their "Points of Contention" with the opposing panel. Following the opening statements were a series of rebuttals which included poignant refutation from both panels.

Each panel addressed equipment supplier and owner related issues commonly experienced in a typical project lifecycle including the RFP/Pre-Bid, Post-Bid/Award/Fabrication, and FAT/Delivery/Start-Up phases. The hearing ended with each panel delivering closing statements that further reinforced their position. After a short recess, the honorable judge rendered a verdict supporting the owner's case, primarily on the weight of the regulated nature of this industry and the ultimate goal of patient health and product safety and efficacy. However the judge made it clear that both panels were guilty of practices detrimental to the success of a project, and both panels presented important issues that should be considered if an owner/supplier relationship is to be successful.

Following the hearing, the audience (jury) was involved in an interactive discussion which expanded on many of the points presented in the hearing. A repeated theme throughout the session was the need for more face-to-face interaction. It was expressed that despite its many perceived efficiency gains, our dependency on technology has resulted in less interaction and knowledge transfer. This decrease in personal interface has lessened the opportunities for project teams to resolve issues prior to their escalation.

The following are post-hearing comments from the esteemed panel members, judge.

Gordon Leichter – Belimed – Representative on Supplier Panel

"My name is Gordon Leichter and I was fortunate enough to be invited to participate as a "Supplier" representative on the panel for this session. As a sales and marketing professional with many years of experience providing capital equipment within our industry, this was an excellent and fresh opportunity to candidly approach a rather touchy topic in an open forum. My take away from the session was that there was agreement from both sides on the issues faced by both the provider and purchaser; and that open communication, and clear and concise definitions of scope of supply are key to a successful project and relationship."

Stephen Errico – Eisai – Representative on Owner Panel

"My name is Stephen Errico, and I served as one of the session participants. In my current role as Director of Parenteral Operations for Eisai, Inc., as well as previous capital project execution roles, the success of a project and future operations depend on the purchase and delivery of long lead process equipment. What this session taught me was that there is a critical need to improve the communication between the operating company (or owner) and the equipment supplier. The first step towards improved communication is scheduling of a detailed requirements review meeting before the official award. The operating company could schedule

this meeting with the potential award winner to insure there is complete alignment before the award is made. There are too many times that key gaps are discovered immediately after the award which negatively impact the business relationship and creates a lack of trust between both parties."

Scott Sobolewski – Custom Equipment Solutions – Representative on Supplier Panel

My name is Scott Sobolewski, and I am one of two owners of Custom Equipment Solutions, a traditional multi-line Manufacturers' Representative agency. Having worked for Pfizer back in the late 1980's as a process/project engineer, it reminded me how demanding on time and resources a major capital project has become, and how much more complex and demanding things have become from a regulatory/cGMP/FAT/validation standpoint. The main point I wanted to make to the panel and audience was that face-to-face human interaction between vendors and end-users is key to the success of a capital project, and should not be replaced completely with electronic bidding processes, internet meetings, and conference calls. I happen to feel that while these electronic helpers are necessary, a lack of focus on human interaction ultimately drives costs up overall.

Ramon Ruiz– Merck – Representative on Owner Panel

Ramon Ruiz is a Senior Process Engineer with Merck in Durham, NC.

“The most important take always I learned from the Vendor team was:

Owners must spend more time in the bidding process and improve communication so Vendors can quote projects more accurately; leading to less changes downstream.
Owners should be more flexible when process is not well defined up front so if there any changes both parties can handle those w/o trust issues.
Provide continuous and honest feedback during the process so both parties grow long term.”

The Verdict - A Call to Arms

Ray Scherzer – The Judge

My name is Ray Scherzer. I served as the Judge in the Peoples Court. Listening to both sides of this argument was very enlightening. There seems to be a great opportunity for us, as an industry, to blend the ideas from both sides of the very traditional vendor/owner challenges expressed in this session to create an even more effective project delivery system. This would take a bit of effort and more trust between our companies to break some existing barriers, but there is no doubt that it could be done. Wouldn't it be nice to see our CAPEX reduce, our schedules get shorter while quality improves. The conditions seem right for change; let’s see if we can lead it.

What is next for the CASA PM COP?

The audience suggested that the interactive, panel discussion format be continued at future events, and possibly explore the relationship between Owners and Design firms at the next session. The court may be adjourned, the judge may have spoken, but the issues on existing projects are still there, and as the Spanish philosopher George Santayana most famously said, “Those who cannot remember the past are condemned to repeat it.”

Young Professionals Join for Camaraderie and Career Advancement

By: **Ken Murillo**

My first encounter with the Young Professionals Committee was at a trendy, downtown restaurant near NC State University. I was invited by the committee co-chairs to dine with them and other possible committee entrants and learn more about this upcoming group. It was their kick-off meeting, and they had chosen this cozy locale to meet and mingle with anyone interested in joining. Let me describe the night to you…

I am late coming in. I am directed to a private room to the side of the restaurant by the hostess. I thank her and gingerly stroll in. Amide the dim lights and background din of chatter, I notice that I had missed the initial generous sharing of hors d'oeuvres and even more generous sharing of business cards. I see an open seat at the far end of the table and head straight for it. I almost make it to my destination undetected, but my attempt at a stealthy entrance was sabotaged by a warm welcome, "Hi! My name is Dacie. What's yours?"

"Ken." I answer, trying to hide the guilt in my voice.

"Well, it's finally nice to meet you!" Dacie is one of the committee co-chairs. We had corresponded solely by email until this point.

"Please have a seat. We are just getting acquainted before the waiters come for our orders." I respond with thanks and take my seat. I am quickly greeted by Blake. He co-chairs the committee with Dacie. He fills me in on the agenda for the evening.

Before our food arrives, we go around the table and introduce ourselves. I initially think this round of introductions as being rather customary, but I quickly find out that within this seemingly homogenous crowd of chicly dressed young people come a variety of backgrounds, interests, and ambitions. But, one reoccurring theme resurfaces again and again: the desire to advance their professional careers and to broaden their network.

From this initial encounter and an interview via email with Dacie and Blake, I learn much about the purpose and goals of this new committee and how they are similar to and different from the numerous and well developed student chapters of ISPE.

Students seeking careers in the pharmaceutical, biotech, and medical device industries have excellent opportunities for networking, mentorship, and professional growth through their local student chapters of ISPE. However, once these young fledglings leave the nest of their educational institutions and student chapters of ISPE, and begin seeking employment, or even from within their newly acquired jobs, they may find a gap that was once filled by the warm camaraderie and opportunity of their former student chapter.

Until now, these young professionals have had to rely upon themselves to develop their own networks and often miss out on the industry-wide perspective offered through their former student chapter. Now, to bridge that gap, we have the Young Professionals Committee (YPC) of ISPE-CASA! The Young Professionals Committee is a forum to provide unique opportunities for young professionals to network, socialize, foster mentorship, and share ideas with their peers to promote career development in the pharmaceutical, biotech, and medical device industries. The YPC was formed to help bridge the gap between college student chapter members and experienced professionals that currently make up the majority of active participants in the ISPE. Particularly for CASA, the presence of strong student chapters in the area lends itself to forming an equally strong network for young professionals.

Right now, YPC is seeking motivated individuals to join their core leadership group committed to planning, organizing, and marketing events that would appeal to young professionals in the CASA chapter. The committee also seeks to establish a group of individuals that regularly attend events and help spread the word to fellow colleagues, friends, and classmates. In the long run, the vision for the committee is to continuously build a cross-functional network of young professionals that become members of ISPE. So, if you are interested in joining, email casayoungprofessionals@gmail.com or join the group on LinkedIn.

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