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Operation Excellence – Peeling the Onion

By Rafi Maslaton, cResults President, rmaslaton@cresultsconsulting.com

In today's intense business environment, operation challenges such as inventory and cost reduction, cycle time reduction, improved efficiency and delivery consistency, quality systems streamlining, variability elimination and schedule adherence have been recognized by corporate leaders as imperative issues that need to be addressed.

Operation excellence has become an umbrella for many initiatives and approaches such as Lean Operation, Six-Sigma and Lean-Six-Sigma. All of these approaches aim at improving the overall operation performance and instituted a solid foundation for cultural changes to drive continuous improvement.

Like any problem solving methodology, the initial phase of discovery is like the peeling of an onion to better understand the contributors to the problem, collect the necessary data, perform the analysis, and determine the root causes that would lead toward a better understanding of the problem and help point toward potential solutions. Like the rigorous problem-solving approach of the five-step model known as DMAIC (Define, Measure, Analyze, Improve, and Control), by "peeling the onion" through appropriate data collection and analysis, a better project charter can be developed and focus efforts toward reaching the resolution faster and more effectively.

This article discusses the various components of operation excellence, and just like the peeling of an onion, many layers (or facets) will be exposed, including the major contributors and influencers that affect operation performance in the life science industry. Regardless of the approach to operation excellence that is chosen, similar operation challenges can be identified as outlined in this article. The magnitude of each of the operation excellence components varies based on each business type, yet each of the components requires a thorough analysis and focus.

1. Introduction

Some operation excellence challenges are typically found in the following areas:

- Poor planning and scheduling resulting in longer and unnecessary changeovers
- Lack of components and staffing deficiencies
- Changeovers and cleaning that take longer than the standard and fail QC when tested; packaging line configurations adding undesired constraints and complexity
- Products rationalization (too many non-profitable products which make packaging a nightmare)
- Lack of availability because too many lines are down when needed (corrective and preventive maintenance)
- Utilization and line speed optimization (getting 50% of the quoted speed by the vendor and using the line only 50% of the time)
- Labor efficiency and work methods contributing to already higher costs
- Quality systems and compliance resulting in poor deviation management
- Lack of structured root cause analysis and ineffective CAPA
- Material and logistics problems causing delays and operational structure
- Cumbersome roles and lack of accountability

As detailed, most cases result from a combination of many problems that contribute to the operational deficiency.

The chart below illustrates the various area of opportunities and affected areas that are critical to the overall operation excellence in the life science industries.

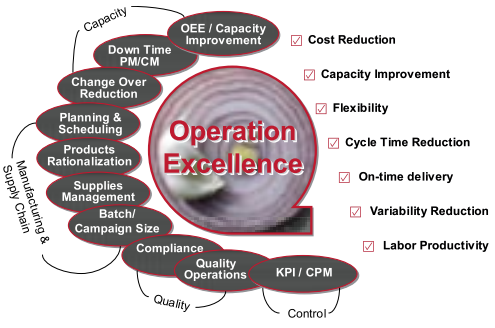

Figure-1:
Operation excellence contributors

(Continued on page 4)

A Message From the President

Hello Again. As this issue of *PharmaBulletin* goes to press, we will have completed three monthly meetings and getting ready for our annual Holiday Party at the NJ Meadowlands Racetrack. If you have not participated in an event, this one is guaranteed to be great fun and a wonderful networking opportunity.

I wanted to spend some time today discussing the state of the FDA these days and how our perceptions of the FDA guide our activities. In early October, an article was published in the NJ Star Ledger concerning the rather abrupt resignation of Lester Crawford as the head of the FDA. The article questioned the path that the FDA has been following during the past five years and wondered if politics were playing a greater role than sound scientific practices in the approval of pharmaceuticals. Surely, the VIOXX situation has contributed to the perception that FDA may be losing the battle of science vs. politics. Unfortunately, there is no easy answer and the press does tend to highlight the controversial issues, not the myriad of positive activities that the FDA is involved with on a daily basis. The FDA operates on a budget of 1.8 billion dollars and employs about 10,000 people. On the surface that seems sufficient to assure the public safety but we must remember that those 10,000 people are not only responsible for the assuring the safety and efficacy of new pharmaceuticals, they are also responsible for the ongoing monitoring and compliance of pharmaceutical facilities, the approval of all medical devices from sunscreens to heart monitors, veterinary drugs, cosmetics, radiation emitting devices and foods. They work with other government agencies such as the DEA to assure safe entry and use of controlled substances into the country and monitor pharmaceutical advertising activities. The FDA continues to raise the bar with initiatives such as PAT and QSIT. It has always been the drug, device, cosmetic and food research and manufacturing company's responsibility to comply with the laws and regulations put in place to protect the public health. Over the past couple of years, it seems like there is a strong initiative to do just enough which is often just not enough.

Are we, as members of the regulated community, really in support of the FDA? What is our culpability or are we blameless? I'd love to hear from you on this topic and look forward to continuing discussions.

Remember, we are an organization of individuals, and individuals can effect change that will truly benefit the whole. If you would like to volunteer; join a committee, write an article, facilitate a workshop or speak at a meeting. Let us know what you're thinking.

Please contact me or any of our Board or Committee Members to discuss how you can get more involved. You can also e-mail me directly at janit@omnival.com.

ISPE NJ Chapter Lunch & Learn Seminar Brochure

The New Jersey Chapter Education Committee is developing a Lunch and Learn Seminar Brochure.

The purpose of the brochure is to offer our ISPE Members a list of educational seminars that can be selected for in-house educational programs. To be considered for the Brochure, vendors must first submit their entire proposed seminar, including a detailed abstract, to the ISPE NJ Education Committee for review. The ISPE NJ Education Committee will review the seminars and abstracts. Those with educational content will be added to the Brochure. (Company promotional presentations and sales presentations are not considered for this listing). An abstract for each seminar accepted for the listing, along with contact information, will be added to the Brochure. Upon completion, the seminar Brochure will be distributed electronically to all Chapter Members as an educational programming resource. Additionally, the Brochure will also be posted on the Chapter's Web site.

Vendor Seminar Requirements:

1. Vendors are to submit an abstract and PowerPoint presentation of their proposed seminar to the Education Committee for review in either electronic or hard-copy (paper) format. A New Jersey Chapter Board Member will review the seminar for it educational content. Vendors may submit as many seminars as they would like.
2. Upon acceptance, the submitter will provide contact information for the seminar Brochure listing and agree to present the seminars as reviewed. Additional content/information can be added to the end of the seminar; however, the seminar must be presented as reviewed. Any changes to the seminar must be re-submitted to the Education Committee for review.
3. The Chapter will distribute only the abstract and contact information for arranging a seminar. Companies interested in the "Lunch and Learn" presentation will contact the seminar provider directly for an appointment.
4. Distribution of the presentation will be exclusively by the submitter. The Education Committee retains only a record copy of the presentation and the application submission.
5. The Seminar Brochure will be updated quarterly.

For additional details or to add your seminar to the Lunch and Learn Brochure, contact the Education Committee Chair, John Postiglione at JGPOST@VERIZON.NET. ■

Is It Time For A Completely Electronic Newsletter?

Well, it looks that way. In a follow-up effort to our initiative from last year, we have polled our membership regarding preferences for newsletter formats. We conducted two-surveys to maintain reliability. Both surveys asked for preferences regarding a hard-copy or electronic version, or both.

The first survey was published in the last newsletter and requested respondents to e-mail their preference. The second survey was e-mailed to the membership, requesting a reply-response. No responses were received for the first survey, which obviously invalidates the survey, but also points to the effectiveness of the hard-copy version.

The second survey produced 193 responses from 1713 members, which is a net 11.2% response. This is an improvement over the 141 e-mail responses to the initial survey that was conducted a year ago. The responses were as follows:

Hard copy only	**39**	**20%**
Electronic only	**103**	**53%**
Both versions	**51**	**27%**

Based upon the above results the Board of Directors has voted to discontinue the distribution of the hard-copy version of the *PharmaBulletin*. Though there was not a unanimous vote either way, there is enough of a bias to justify the difficult decision to initiate the change. Being a forward looking and technology driven organization, the Board of Directors feel that the move to a completely electronic format will allow for a more updated and useful tool for our membership.

The move to an electronic version of the newsletter will provide the following benefits:

- Reduction in paper waste.
- A cost effective move to full color.
- Hyper-links for contacts, references, and advertisers.
- Archiving and retrieval on the Chapter Web site.
- Timely distribution.

Respectively, this will be the last hard-copy version of the *Pharma-Bulletin*, which will be a true collector's item. Please look for the enhancements to the *PharmaBulletin* over the next coming year. As with the first step of this initiative, we will conduct a follow-up survey in a year from now to assure we are meeting the needs of our membership. Until then, please do not hesitate to send your comments or suggestions regarding the *PharmaBulletin* to me at gordon.leichter@pharmadule.com.

Thank you;
Gordon Leichter
Secretary
ISPE NJ Board of Directors

2. Peeling the onion

Let's start with the onion's peeling process in order to have a better understanding of how each of the contributors above effects operation excellence and leads into less desired performance measures.

OEE/Capacity Improvement

One of the key contributors to operation excellence is overall equipment effectiveness (OEE). The OEE is one of the tools used to assess both the tool performance and work methods of an area such as compression or packaging. Although OEE is focused on the equipment, for the most part the human factor plays a significant role in effective equipment operation. OEE is defined as the percentage of time that equipment is used to produce sellable products at the maximum machine rate. This measure of tool performance captures all equipment time consumed by the six biggest losses:

1. *Equipment Failure (Unscheduled Downtime)*
2. *Setup & Adjustment (Including PMs & Engineering)*
3. *Idling & Assists (Waiting for Operator, Minor Stoppages)*
4. *Speed Loss (Rework, Inefficient Batch Sizing)*
5. *Defects (Non-Fatal Defects)*
6. *Reduced Yield (Fatal Defects)*

The way OEE is related to operation excellence is clear, yet the relation between OEE / capacity to cycle time, one of the key pillars of operation excellence, is described as follows: Utilization and cycle time are related in such a way that if the line / work center is pushed to its highest achievable utilization, cycle time performance will most likely suffer (higher than desired). Therefore the pursuit of OEE improvement will enable the

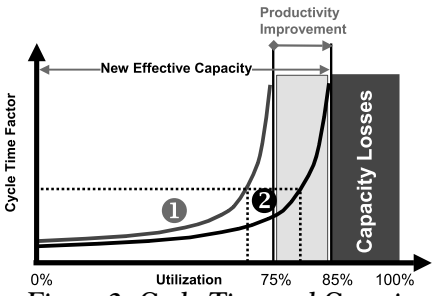

Figure 2: Cycle Time and Capacity Relation

curve to be moved (from (1) - red to (2) - black) and allow a shorter cycle time for a given throughput / utilization. Perhaps it can intuitively be assumed that the higher a line is utilized (one goal), the less desired, longer cycle time could be expected. The black curve (2) marks the new and improved operating condition where productivity improvement was applied. This results in reduced capacity loss in terms of higher available time, shorter and less frequent change over, and higher equipment speed. This curve is an illustration that clearly outlines the relation of cycle time to capacity improvement.

Down Time PM/CM

If we acknowledge the previous relationship between down time and its affect on OEE based on Figure-2, we can see that the capacity loss area is affected. By improving the overall availability of a given piece of equipment (assuming it is a bottleneck or close to bottleneck), then more can be produced, or improvement made to the cycle time by shifting the curve and extending the site capability to tolerate more throughput, while maintaining an acceptable cycle time performance. The goal regarding down time is to transition from an "As-Is" environment to a "Proactive" environment for a highly efficient and well-managed facility. Reducing the reactive management, improving the PM effectiveness, shifting focus to predictive maintenance, improving on wrench time and its effectiveness, will result in reduced change over and sets ups (performed by maintenance) and improve communications with operation and upgrade the training level.

Change Over Reduction

As one of the OEE components, change over and set ups provide a major operation excellence opportunity. It is even more significant when it comes to contract manufacturing or contract packaging sites, which usually experience more frequent changeovers. The ability to change over from one product / client to another is critical, and in many cases can become the most significant differentiating factor in a site capability to accept an order for a competitive price. Methods such as Single Minute Exchange Die (SMED) and various other Lean techniques help companies reduce their change over time. In addition, the planning and scheduling (which will be discussed later in this article) can be a major supporting tool to achieve operation excellence in this area. The ability to reduce the duration of activities on the critical path while optimizing the sequencing of a changeover is important; the ability to eliminate changeovers or significant changeover reduction via smart planning is a key factor in pursuing operation excellence.

Planning and Scheduling

Planning and scheduling at both the company level and at the site level present a significant challenge from different perspectives. The focus of this discussion is at the site level. It is important to real-

ize the effect of the release to the manufacturing line on the operation excellence performance. This can be shown using a simple equation that is based on Little's Law. This describes the relation between inventory levels, cycle time, and the release rate to the manufacturing line. Based on this law, cycle time is a function of inventory level divided by the number of lots (on average) that are introduced to the line.

Where N is the random variable for the number of jobs or customers in a system (inventory level), λ is the arrival rate at which jobs arrive (release rate), and T is the random variable for the time a job spends in the system, or cycle time (all of this assuming steady-state). Little's Law applies to any system, regardless of the arrival time process or what the "system" looks like inside.

$$N = \lambda * T \text{ or } T = N/\lambda$$

For example, if N = 40 lots and there are an average of 5 new lots every week (λ=5), then the expected cycle time (T) is 8 weeks. In other words, controlling the inventory level will determine the cycle time, assuming it is impossible to impact the demands / release requirement. Although it is a simple equation that may introduce planning as a simple function, in real life we typically see a lack of robust and accurate tools for planning and scheduling. Often lacking is accurate capacity modeling, limited inventory and cycle time tracking, and lack of awareness of the equipment availability that needs to be considered as part of the schedule. Other elements also come into play, such as forecast variability and frequent changes (daily), process variability (i.e., investigation closure time sometimes taking weeks), and raw material and packaging component availability. Other challenges include lack of true understanding of manufacturing, packaging and QC constraints, lack of understanding of true capabilities, and lack of visibility for the quality systems.

Products Rationalization

As we are move toward the heart of the onion, another critical layer is revealed related to a fundamental question in pursuing operation excellence. Are these products adding profit to our bottom line, and if not, is there a real business justification to continue to manufacture / package these products? An important analysis that can help isolate these products is equipment requirement vs. revenue. This chart can outline high capacity consumption products with relatively smaller revenue generation. This analysis will compare the revenue vs. the cost per product and can quickly help create a Pareto chart to isolate the unprofitable product.

Batch/Campaign Size

Lean manufacturing can be interpreted as requiring the reduction of batch size and run with a minimal campaign size (although one can argue that a run of 1 can include a few batches). Regardless of what may be suggested by one approach or another, the campaign size should be carefully defined as it has major impact on throughput in areas where a changeover is inevitable and consumes significant time compare to the run. Areas such as QC in instruments like HPLC may benefit from a campaign size of 4-6 samples. Packaging may benefit as well. Figure 3 shows the tradeoff between efficiency vs. cycle time as well as the diminishing return of a larger number of lots. The added efficiency gain is insignificant compared with the added cycle time in the two contradicting matrices. In order to achieve operation excellence we must pay attention and challenge opinion or the popular response of "always doing it this way," and use a fact-based approach to quantify the efficiency gain versus the added cycle time, for the n-1 batches that are accompanied by the first batch that arrives at the work center.

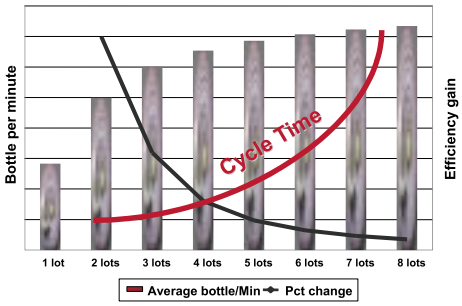

Figure 3: Campaign size effect

Quality Operations

Figure 4: Electronic Quality System

Quality operation includes laboratories, quality assurance, and all related quality systems. These areas can often provide a major opportunity for operation excellence initiatives. It is becoming increasingly apparent that quality systems are playing a significant role in the overall disposition of a batch, and therefore receive the most visibility nowadays.

(Continued on page 7)

NJIT Enhances Our Profession

In the late 1990's, a group of distinguished alumni of the New Jersey Institute of Technology, several professors currently serving on the faculty, and some invited guests met on the Newark Campus to plan the creation of a new set of courses intended to lead to the first Masters in Pharmaceutical Engineering in the nation. The group finally agreed that the primary objective of the program was and still is to educate professionals, and to provide them with the skills required to work in the pharmaceutical field, with particular emphasis on the engineering aspects of drug (chemical) manufacturing, pharmaceutical production, pharmaceutical development, and pharmaceutical operation.

The courses of study provide the intellectual climate and necessary tools needed to prepare students for positions and career advancement within this highly technical and highly regulated industry. Courses are taught by both full time and adjunct faculty from multiple departments such as Chemical Engineering, Industrial Engineering, Mechanical Engineering, Chemistry, Biomedical Engineering, Computer and Information Science, and Engineering Management.

Successful History

The program currently serves 120 degree and certificate pursuing students from industry. NJIT undergraduates who meet the rigorous qualifications can also take courses. A total of over 300 individuals have taken at least one course in the program. Their backgrounds are as varied as are employees in the Pharmaceutical Industry. They come to their studies possessing degrees in such diverse fields as electrical engineering, microbiology, mechanical engineering, biology, and chemical engineering. Students represent a virtual who's-who of the world reknowned Pharmaceutical and Biotechnology Industries in New Jersey. Merck, Wyeth, Hoffmann-LaRoche, Schering Plough, Sanofi-Aventis, Novartis, Pfizer, and Genzyme have all provided students.

One Industrial site where all four certificate courses (explained below) have been taught is Wyeth Pharmaceuticals in Pearl River, New York. Classes there ranged from 25-35 students and were run between 2002 and 2004. The educational efforts at Wyeth's Middletown Road site began when prominent NJIT Alumnus and program cofounder Joe Manfredi taught the the most basic of courses "Principles of Pharmaceutical Engineering". This course as well as many others was taught using original material as textbooks for many of these new and specialized courses are not available.

The testimonial of one successful graduate Harvey Weiner, a Senior Project Engineer in Wyeth's Vaccines Group is given below. (Harvey was originally trained as an Electrical Engineer.) Speaking of the Principles course described above, Harvey said "… Mr. Joe Manfredi, opened my mind and eyes to the endless new vocabulary and acronyms of the Pharmaceutical Industry. I consider myself very fortunate to have met Mr Manfredi at this turning point of my professional career." (A downsizing in his original manufacturing support position brought Harvey to Wyeth.)

Harvey continued "I'll never forget the feeling of renewed confidence I had while walking through a machine room the day after one of Mr Manfredi's lectures on pharmaceutical water systems. I was able to understand the process, and offer suggestions to help improve the water quality of a current manufacturing system."

Program Administrative Details

The NJIT MSPhEn Program is offered in two tracks:

Track 1: Process Development and Design for Drug Substance Manufacturing. Focus- Engineering aspects of chemical reactions and separation processes required for the manufacturing of active pharmaceutical ingredients (API or Bulk Pharmaceutical Chemicals).

Track 2: Process Development and Design for Drug Product Manu-facturing. Focus- Engineering aspects of processes required for the manufacturing of final drug products.

Students in both tracks are mandated to pass the following five core courses:

- PhEn 601 Principles of Pharmaceutical Engineering
- PhEn 603 Pharmaceutical Unit Operations
- Liquid and Dispersed Phase Systems
- PhEn 604 Validation and Regulatory Issues in the
- Pharmaceutical Industry
- PhEn 606 Pharmaceutical Unit Operations:
- Solids Processing
- PhEn 618 Principles of Pharmacokinetics and Drug Delivery

Track 1 students must further pass the following two courses:

- PhEn 612 Pharmaceutical Reaction Engineering
- PhEn 614 Pharmaceutical Separation Processes
- Track 2 students must further pass the following two courses:
- PhEn 602 Pharmaceutical Facility Design
- PhEn 605 Pharmaceutical Packaging Technology

For the Master's degree all students need to take nine (9) additional credits, six of which can be in the form of a Master's Thesis. A twelve credit Pharmaceutical Technology Graduate Certificate can also be earned involving PhEn 601, PhEn 603, PhEn 604, and PhEn 606 as listed above.

For Further Information Contact

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Operation Excellence – Peeling the Onion– *Continued from page 5*

Many of the observations cited by the FDA directly relate to the quality systems such as CAPA, deviation, and complaints. For some organizations, the quality systems are either a paper-based or hybrid system. They do not provide accurate and up-to-date information. Records get lost, or are hard to find. Applying an electronic quality system as seen in Figure 4, provides robust key performance indicators, and help to prioritize the pending documentation for review, increase accountability, and improve training and communications. These are some of the opportunities to help quality operation add value to operation excellence, and to help reduce the overall cycle time and improve on-time delivery. When peeling the onion even further, we reach the laboratories that are being asked to control Cost of Goods (COGs) and improve their efficiency and cycle time in the QC Labs. Issues such as lack of advanced planning and scheduling tools, inefficiencies related to work methods, reoccurrences of OOS and re-test, tight instrument capacity, and high-dedication, poor LIMS implementation are only few of the challenges. There is no silver bullet for these situations, and for QC it is not any different. The journey toward operation excellence requires following a robust problem-solving methodology such as DMAIC, or other available approaches, to help Pareto the potential initiatives and support the implementation of improvements.

3. The heart of the onion

As the list of operation excellence contributors is exhausted, let's review the following table. It outlines several initiatives (listed in the left hand column) that have been seen in various life science companies; the right columns list the expected impact on operation excellence, including the expected cost to implement these initiatives. It can be clearly seen that layout changes are usually the most expensive solution, while providing relatively low impact on operation excellence. Often, after performing value stream mapping the first temptation is to rip the layout and start all over. While perhaps it is feasible in a general manufacturing environment, this is not the preferred avenue to pursue when it comes to the life sciences industry. This leads to an important consideration when implementing Lean; to make sure that the team members have a full understanding of the industry regulations and constraints before rushing into a Kaizen event, VSM implementation, or other actions.

Area of focus	*Low Impact*	*Med impact*	*High Impact*
Corporate performance management (CPM)		$$	
Overall planning and scheduling		$$$	
Layout changes to improve material / people flow	$$$$$		
Improve forecast		$$	
Automation		$$$$	
Quality systems automation			$$$
Batch record release streamlining		$$	
QC planning and test allocation		$$	
Staffing level, shift structure, work method, standards		$$$	
Manufacturing paperwork and documentation errors			$$$
Overall Equipement Effectivenss (OEE)		$$	
MES Implementation			$$$$$

4. Summary

As can be seen from the examples above, no matter what approach is taken, whether it is Lean, Six Sigma, or Lean/Six-Sigma, the contributors to operation excellence are usually the same. In most cases operation excellence is resultant of a combination of many problems that contribute to the operational deficiency, requiring a coordinated effort between the various owners. The question that always needs to be answered is how to convert an ambitious concept into tangible lasting improvement. That is a topic that deserves an article by itself.

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(1) Hopp, W.J., and Spearman, M.L., *Factory Physics, Foundations of Manufacturing Management*, IRWIN, Boston, 1996.

(2) Ronald D. Snee and Roger W. Hoerl, *Leading Six Sigma*: A Step-by-Step Guide Based on Experiences at GE and Other Six Sigma Companies, 2003

(3) Rafi Maslaton, *Creating Manufacturing Excellence Through Cycle Time Reduction*, ISPE 2001

(4) Leachman, R., *Closed-loop measurement of equipment efficiency and equipment capacity*, ESRC 95-03/CSM-2, Department of Industrial Engineering, University of California - Berkeley, Berkeley, CA, January, 1997.

About The Author

Rafi Maslaton has more than 15 years of diversified experience in operations, manufacturing engineering, information systems, and business management issues for Fortune 500 firms. Prior to joining cResults he served as COO of Sparta Systems, the maker of TrackWise. Prior to working at Sparta, Maslaton was a senior partner at Operational Management Consulting, responsible for the Pharmaceutical and Biotech sectors. Over the last 15 years, Maslaton has managed projects for Fortune 500 clients such as: Abbott, Amgen, Baxter, Bausch and Lomb, Bayer, Centocor/OBI, C.R. Bard, Eli Lilly, Genentech, J&J, Novartis, Pfizer, Pharmacia, Roche, Schering-Plough, Teva and Wyeth, Agere Systems, Alpha Industry, Anadigics, HADCO, IBM, Intel, Lucent, Motorola, Nortel Network, Philips, Raytheon, and Siemens.

September 2005 Event

Water Purification – from the Basics to the Future of the Technologies

In September, the Chapter expanded the normal monthly presentation format to provide three presentations that covered basic to advanced information on water purification. John Postiglione of MECO started the event by reviewing the four main types of water contaminates (inorganic ions, organics, particles and microorganisms) and the methods used to measure them. He then touched on the current water purification technologies including filtration, reverse osmosis, ion exchange and distillation as well as an overview of the validation process for water systems.

The second part of the evening gave attendees, the owner, and vendor perspectives on water system design practices. John Postiglione reviewed how to develop the design of water systems and some of the configuration options. Peter Vishton of Wyeth Pharmaceuticals then discussed component selection and the advantages and disadvantages of the various water purification technologies. Peter also covered the start up and commissioning of water systems and detailed various case studies.

Andrew Collentro of Water Consulting Specialists took over for the last segment of the event on recent regulatory & cGMP developments for pharmaceutical water systems. Andrew recapped some of the latest changes to compendial monographs and some of the new technologies and applications that are leading to changes in the regulations associated with water systems.

If you would like to see a copy of John's and Peter's presentations, please check the New Jersey Chapter Web site upcoming events section at:

http://www.ispe.org/newjersey/upcoming.htm

Online Registration for Chapter Events:

Event notifications will continue to be e-mailed with ample time to register. The notice will now contain links to the event online registration site and to the ISPE NJ Chapter Web site. The traditional PDF event notice will be posted on the Chapter Web site for those who want to utilize the existing hardcopy registration process.

Amy Pries, Edward Alonso, Nandita Kamdar and Tom Bolan all from PS&S and Richard Panikiewsky from IPS (second from right)

Fred Lewis, Merck, Philip Sumner, Pfizer, Joe Manfredi, GMP Systems Inc.

Dragutin Stoicovici, Cozzoli Machine Company, Alexander Mitrovic, Novartis and Peter Zafonte, Trane

October 2005 Event:
Managing Your Energy Costs

The October event covered a subject that is currently making headlines across the country! The rising fuel costs have made energy conservation a hot topic. Michael Belikoff, of Paulus, Sokolowski and Sartor, provided an extremely informative presentation that started with an overview of the energy consumption patterns and cost trends in the United States. He then covered some strategies on how to start an energy reduction program including getting upper management buy-in, getting all of the various user groups involved and collaborating with others in the industry. He also discussed the Energy Star and Labs 21 programs that will help benchmark building energy consumption as well as the New Jersey Smart Start program that can provide funding for some of the cost reduction projects. Michael, with the help of several other speakers, then compared and contrasted the various power related equipment including battery and flywheel UPS mechanisms, sterling engine generators, and photovoltaic and other renewable energy sources.

The audience was also fortunate to hear from Farley Hunter, who is the Energy Manager for the Novartis East Hanover site. He provided some real world examples of some of his success in implementing an energy reduction program at Novartis and talked about some of the low hanging fruit that can be tackled to get quick wins to support the energy reduction efforts. One of the biggest quick fixes mentioned was the building management systems. The HVAC is a major power consumer and adding new control strategies can be easily implemented and yield high cost savings. Farley also discussed how important it is to accurately monitor energy usage. He stressed the usefulness of having an effective instrument calibration program to ensure you can determine how critical equipment like air handlers and chillers are running. Other approaches to finding energy savings included a robust preventative maintenance program including vibration analysis to identify and correct improperly running equipment as well as shifting to low differential pressure air filters and installing occupancy sensors and more efficient lighting systems.

Overall, between all the speakers, the entire night was loaded with methods to reduce facility energy costs. If you would like more information on some of the methods discussed, please see Michael's presentation which can be downloaded at the New Jersey Chapter Web site upcoming events section at:

http://www.ispe.org/newjersey/upcoming.htm

October Speakers

John Postiglione, MECO, Peter Vishton, Wyeth and Andrew Collentro, Water Consulting Specialists Inc.

James Berry, Camp Dresser & McKee Inc and Daniel Matias, Perrigo Pharmaceuticals

I've Been Thinking.....Why Should I Hire You?

By: Don Sutaria

Many of you may be thinking..... Should I change jobs soon, possibly moving to a growing pharmaceutical or biopharmaceutical company which would be best suited for my career and talents?

Did you ever consider the question: ***"Why Should I Hire You?"*** or ***"Tell Me About Yourself!"***

The answer to this question can become the cornerstone in hiring or promoting you. It is your chance, and possibly the one and only chance, to reach your goal for capturing a position. It is an open invitation to give the questioner a ***30-60-90-120-Second Sound Byte: Your Personal Infomercial.***

Ask any seasoned job hunter and he will tell you that you have not really lived until you master the ***Two-Minute Pitch***. It is no time to be modest about your achievements.

What do we mean by this?

If you have a succinct summary statement in your resume, you can use that as a springboard for your infomercial. By varying the length, mood and the tone, you can use this pitch in social settings like cocktail parties or formal interviews.

You may need to write out your pitch and practice its delivery until it appears completely natural and spontaneous, not canned! Always tailor the speech to your audience. The first few words which you utter are the most important, because they can immediately tell your professional level from them.

You are not being invited to tell your personal life story. You need to talk only about your professional work experience at this stage, in reverse chronological order. You must know a lot about the company you are interviewing, their needs and the requirements of the position. There is a multitude of innovative ways of finding out this information, based on your initiative.

Here is a **sample** of an infomercial for the position of a **Vice President, Pharmaceutical Engineering and Technology.**

"I have extensive technical and executive experience in pharmaceutical companies and consulting firms. I have demonstrated leadership skills in the development of long-range growth plans and supervision of projects up to $300MM, involving 100 people. Through business process reengineering, I have optimized human resources, increased productivity and reduced costs in domestic and international multiplant operations. In addition, I am also proficient with computer systems.

Industrial experience in operating companies includes ten years at ABC Pharmaceuticals and seven years at Alpha Biotech. Five years were spent consulting with the Harvard Healthcare Group.

My areas of expertise are business process reengineering, project management, plant modernizations, strategic planning, pharmaceutical manufacturing technology, validation, new plant design and construction, facilities maintenance, barrier isolation technology, manufacturing and packaging of sterile and non-sterile dosage forms, cost reduction and profit improvement programs, current good manufacturing practices, and technical and managerial training of professionals.

In one case, I was instrumental in completing the construction and validation of a $30MM, 120,000 sq. ft. manufacturing facility for injectables in the USA within 18 months and obtained Food & Drug Administration approval.

In another case, I was the project leader for engineering a 100,000 sq. ft. oral solid dosage and injectables, hormones and steroids, narcotics plant in Japan, costing $40MM.

A sampling of job titles includes Group Director of Engineering and Maintenance, Director of Pharmaceutical Manufacturing Technology, Project Director, Chief Engineer, Manager of Validation, Manager of Engineering, and Senior Management Consultant.

My academic background includes an advanced degree in Management from Columbia University, a Master's degree in Industrial and Manufacturing Engineering from Kansas State University and a Bachelor's degree in Mechanical Engineering from the University of Ponca.

In addition, I have continued education through specialized courses, served on various committees of professional organizations, published several articles, and conducted seminars and courses. I am a Member of the International Society for Pharmaceutical Engineering and Parenteral Drug Association. I am a licensed Professional Engineer and was also inducted into International Who's Who of Professionals."

Our attention spans are getting smaller and smaller because of the bombardment of our senses by the media. People are accustomed to 15 and 30-second sound bytes. Unless you make it interesting enough, 120 seconds is a long time. Engage the listener by using buzzwords. A friendly, conversational tone is appropriate. Bring in a couple of relevant examples, which illustrate problem-action-result orientation.

Besides business attire, when delivering your pitch, you need to smile. It makes you seem to have friendliness, competency and confidence. In other words, the personal chemistry seems so right. Always remember that hiring is also an emotional decision, not just a rational one!

If you really want a job, let your body language show it. Everything else being equal, the person who will finally get the job or the promotion will invariably have a couple of X-factors in his/her favor. These are a Positive Mental Attitude and Enthusiasm, because they really go MAD (Make A Difference).

Don Sutaria is President of CareerQuest, a Career Counseling and Executive Coaching organization, with offices in New Jersey and New York. He has written several articles for ISPE over the past 15 years and served on various committees, since its inception. CareerQuest's specialties include counseling of international professionals, Generation X, career changers, free lancers, consultants, mid-career executives and people over age 50. He can be reached at don@careerquestcentral.com or (908) 686-8400. The Web site is www.careerquestcentral.com and the weblog is http://careerquestcentral.blogspot.com.

New Jersey Chapter – Schedule of Events 2006

Date	Time	Event	Location
Wed Jan 11, 2006	4:00pm-8:00pm	Modular Technology	Holiday Inn, Somerset, NJ
Wed Feb 8, 2006	4:00 pm-8:00 pm	R&D at Universities Disposable Components Regulatory Issues	Holiday Inn, Somerset, NJ
Wed March 8, 2006	4:00 pm-8:00 pm	Nanotechnology	Cambrex Tour North Brunswick, NJ
Wed May 10, 2006	Starts 1:30pm	Golf Outing	Farmstead Country Club Lafayette, NJ
Thurs June 15, 2006	9:00am-6:00pm	NJ Chapter Day	Holiday Inn, Somerset, NJ

Refer to the New Jersey Chapter Web site
http://www.ispe.org/newjersey for the latest Schedule of Events.

2006 ISPE International Events

2006 San Francisco Classroom Training Series
6-9 February 2006
The Intercontinental Mark Hopkins
San Francisco, CA

INTERPHEX Puerto Rico
16-17 February 2006
Puerto Rico Convention Center

2006 Tampa Conferences
20-24 February 2006
Grand Hyatt Tampa Bay
Tampa, FL

2006 NJ Classroom Training and GAMP Americas Forum
13-17 March 2006
The Westin Governor Morris
2 Whippany Road
Morristown, NJ

Welcome New Members

David Arcury, *Dynalene Inc.*
Mr. Robert A. Ayello, Jr.,
Stevens Institute of Technology
Mr. Christopher D. Balducci, *Purdue Frederick*
Douglas Bartus, *KMPT (Krauss Maffei)*
Mr. Sebastian Beyer, *Werum America Inc.*
Melvin Blum
Mr. Steve Bolke, *K&G Power Systems*
Ping Chang, *Schring Plough*
Mr. Michael A. Chiti,
Bristol-Myers Squibb
Van Ekambaram, *URS*
Donald Eng,
Stevens Institute of Technology
George Feller, *Heinen Drying, Inc.*
Mr. JR Gandolfo, *K&G Power Systems*
Boyenoh T. Gaye,
New Jersey Institute of Technology
Shmuel Gorodetsky,
United Lubavitch Yeshiva
Peter Heyman, *Heyman Consulting*
Kremena A. Ivanova,
Stevens Institute of Technology
Mr. Jeffrey Jackowski, *GeneraMedix*
Stacey A. Johnson, *Wyeth*
Maharaj Kaul, *Wyeth*
Mr. Michael Klapal, *Warner Chilcott*
Edward Lawson,
GE Water & Process Technologies
Joseph F. Masiello, *Stantec Consulting*
Thomas May, *sanofi pasteur*
David McKenna,
Grantek Systems Integration Inc.
Randy Nelson, *Sartorius BBI Systems*
Joseph Pastorello, *Kos Pharmaceuticals*
Kalpesh Patel, *JM Hyde*
Mr. Raymond Powers,
KOS Pharmaceuticals Inc.
Dr. William G. Randolph, III,
Global Pharma Supply Group
Ramkumar Rayapureddy,
Schering-Plough Research Institute
Natalia J. Schmidt,
Stevens Institute of Technology
Ankur J. Shah,
Stevens Institute of Technology
Andrew H. Shelofsky,
Schering-Plough Research Institute
Mr. Michael S. Solamon,
Feldmeier Equipment Inc.
Mark J. Tattoli, *Forest Laboratories*
Mr. Christopher J. Voisinet,
American Pharma Partners
Ms. Kimberly L. Wallbank, *Wyeth*
Joseph B. Walsh Jr., *Technip BioPharm*
Brian Yates, *Northeast Controls, Inc.*
Themistoklis Zacharatos, *Wyeth*
Mr. Pete Zafonte, *Trane*

The ISPE New Jersey Chapter 2005/2006 Board of Directors

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	Tom Malone, *Bristol-Myers Squibb*, (609) 252-3876, temalone@patmedia.net
Immediate Past President	Bob Ranard, (609) 497-3922, *TCPI*, (609) 216-3866, rar@ranard.com
Chapter Manager	Lorraine Gallo, *Paulus, Sokolowski and Sartor*, (732) 560-9700, manager@ispenj.org

2005-2006 Chapter Committees

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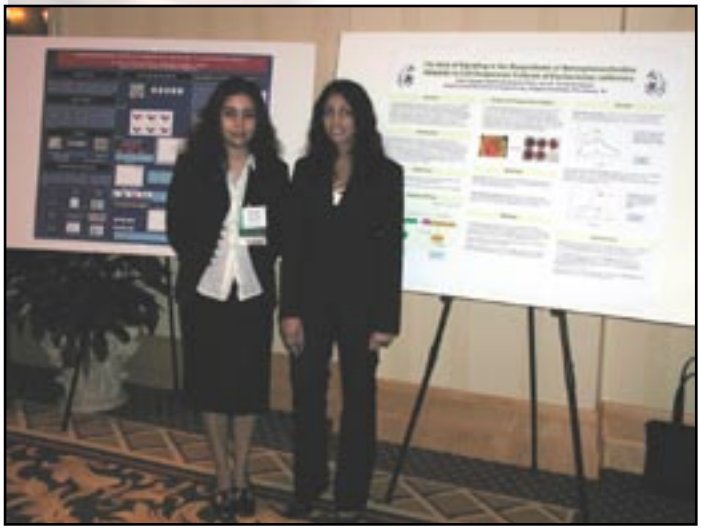
If you are interested in assisting on a committee, please contact Jim Livolsi or the committee chair.

The Student Corner

Students Compete in Annual Meeting Poster Competition

Nisha Sosale (undergraduate) and Patricia Portillo (graduate) competed at the ISPE Annual Meeting International Student Poster Competition in Scottsdale, AZ. They represented the ISPE NJ section and joined 12 other poster presenters. As international finalists, they were all winners of local Chapter poster competitions held earlier in the year. Nisha was an undergraduate chemical engineering major (graduated May '05) at Rutgers University and Patricia is currently a graduate student at Rutgers.



Patricia Portillo (left) and Nisha Sosale (right) with their posters at the ISPE Annual Meeting Poster Contest

The ISPE Stevens Student Chapter held its first event of the semester on October 19, 2005.

(left to right) Rebecca Apruzzese, Trishna Saigal – President, Brad Horton – VP, Tom Malone – Student Affairs Co-Chair, and Richard Berkof – Faculty Advisor.

Twenty students, with majors in biomedical, chemical and mechanical engineering, as well as chemical biology attended the event. Tom Malone, Co-Chair of the New Jersey Chapter Student Affairs Committee, presented a general overview of the pharmaceutical industry, including the process of drug development and trends in the U.S market, followed by a discussion of possible career paths. Malone also explained the benefits and resources available to Student Members of ISPE for those who were new to the organization. The e-board hopes to continue to spark student interest and have more events to learn about the pharmaceutical industry. Visit the Student Chapter Web site at http://www.stevens.edu/ispe/.

ISPE New Jersey Chapter Funds Student Projects

The ISPE Student Chapter at Rutgers University was awarded a $2,000 grant by the New Jersey Chapter for development of advanced instrumentation and control of a fermentation system. The project will explore alternative schemes for data acquisition and remote process control of a batch fermentor using a web-based browser. The primary objective of this study is to explore various alternative methods for running experiments over the Internet. The Rutgers Student Chapter greatly appreciates this support of our project relevant to the pharmaceutical industry.

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What's Inside