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## Carolina-South Atlantic Chapter



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### INSIDE THIS ISSUE



President's Message .....	2
Board List .....	2

#### CHAPTER EVENT HIGHLIGHTS

18th Annual ISPE-CASA Technology Show .....	3
Reliability Excellence Review.....	5
YP Events Review .....	7
June 2011 Therapeutic Thursday.....	8
Lonerider Brewery Tour and Membership Drive.....	9



#### FEATURED CaSA EVENT

Durham Bulls Family Night Information and Registration .....	11
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#### TECHNICAL SECTION

3 Assay Development Rules for Tech Transfer. ....	13
Assessing Key Investment Strategies.. ....	15

#### UPCOMING EVENTS

Event calendar and education opportunities.....	20
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## Don't miss it!



**Annual CaSA Planning Meeting**  
Prestonwood Country Club, Cary, NC  
**Tuesday, August 23, 2011**



**Durham Bulls Family Night**  
Durham Bulls Athletic Park, Durham, NC  
**Friday, August 26, 2011**

# President's Message



David Brande

With summer in full swing and many of us just coming out of the dreaded summer shutdown schedule, I hope that you have been able to travel to the lake, the ocean, the mountains or your other favorite spots. Maybe for some of you just getting all of those end-less projects completed around the house is what has taken up your summer. Regardless, it is time to start thinking about the fall

and a "normal" schedule. When summer is about to end, that means a new year at CaSA is about to begin with opportunities to volunteer, become involved, and help plan the future of your industry. With the recent elections of the Chapter now behind us, the new Officers and Board members began their annual terms on August 1<sup>st</sup>. I look forward to a busy year with the newly installed Board.

First, let's talk about what a great year we had. Scott Billman led our Chapter through an unusual year with a change in management companies, a difficult and time consuming task. We hope that the changes you saw on a personal level were either unnoticed or maybe even improved. We work every day to best serve the Chapter. The Chapter officers met with our management company in late July to critique the past year and believe that we are beyond the steep portion of the learning curve and are confident that the Chapter will enjoy better service in the months forward. Please make your compliments or complaints known, to any of the Officers or Directors. It is important that the Chapter serve your needs and we need to know how well we are doing or how we need to change.

Our new Board will begin work on August 9<sup>th</sup> with our first meeting of the New Year, and high on our list of priorities is the Annual Planning and Membership meeting scheduled for August 23<sup>rd</sup>. The meeting will be held in the Grand Ballroom at Prestonwood Country Club in Cary, NC. If you do not have this scheduled on your calendar, I highly recommend that you do so today. The Annual CaSA Planning and Membership meeting is very important for two reasons: the opportunity to come and see the inner workings of CaSA and meet the Board members and management company representatives; and the presentation of the new strategic plan of ISPE given by Jane Brown. Jane has been involved, from a committee standpoint, in an in-depth study of current ISPE operations and how we should seek a new paradigm. Come hear Jane explain how the new ISPE of the future will operate and how this can affect you. For those of you new to CaSA, Jane Brown is a Past President of our own local Chapter, and Jane has also served as Chair of the International ISPE Board of Directors.

In closing, I would like to take this opportunity to say thank you to our three departing Directors at Large: Wes Robbins, Jim Murphy and Rob Hughes. We are grateful for their years of service to the Chapter and we cannot say "thank you" enough. As with any volunteer organization, we are only as successful as our volunteers. These three gentlemen have given untold hours of service and influence to the future of your Chapter.

I hope that everyone continues to enjoy this HOT summer and I look forward to seeing you at the Annual Planning and Membership Meeting on August 23<sup>rd</sup>.

*David Brande*  
Chapter President



**Carolina-South  
Atlantic Chapter**

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- Alan Tucker, Technology Show
- Blake Derrick, Young Professionals



# Chapter Event Highlights

## 18th Annual ISPE-CASA Technology Show

By Eric Mayer

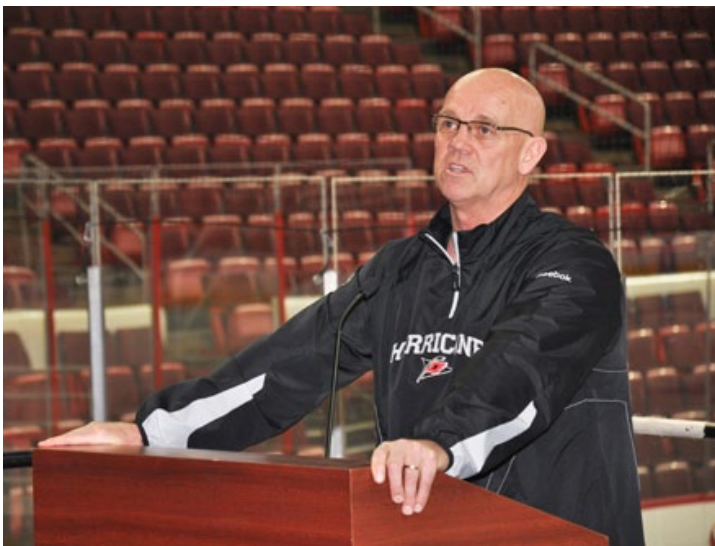
ISPE-CASA led the way in 2011 with The 18th Annual Technology Show at the RBC Center in Raleigh on April 5, 2011. The show is the Chapter's largest and most popular event. Once again, this year's show was received very well by the community with well over 1200 attendees.

The event featured 12 different speakers who offered technical sessions on compelling topics ranging from validation, quality by design, disposable process technologies, regulatory compliance, alternative production methods, HVAC, and electronic batch production records. In addition, Tom Rowe, assistant coach of the Carolina Hurricanes, gave an outstanding key note address in the arena with the ice rink and jumbotron serving as his back drop.

Karin Cleary, Director of Human Resources at Pharmaceutical Calibrations and Instrumentation, LLC (PCI), did an outstanding job at setting up a Career Fair at the event attracting 20 local operating companies that have positions open for new candidates. As with the show itself, this Career Fair was the largest in our 18 year history.

Once again the vendor community strongly supported the event with over 180 exhibit tables exhibiting and three exhibition vehicles parked outside the venue. ISPE-CASA recognizes and thanks the Show's Corporate Sponsors for all their support. They were STI, Burkett, IPS, PCI, Fluor, Hipp Engineering, Flanders, and Pharmsys.

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# Chapter Event Highlights

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After a long day of classes and learning, the event concluded with a wonderful networking reception at the Arena Club on the second level overlooking the ice. The reception was extremely well attended and all enjoyed delicious food and libations!

The Technology Show Committee of ISPE-CASA thanks our great community for making the show possible and looks forward to gathering again at the 19th annual show in the spring of 2012.



# Chapter Event Highlights

## Reliability Excellence — Held June 2, 2011 at the NC Biotech Center in RTP, NC

By Martin E. Rock, PE, JD, Past President 2006-07, ISPE Carolina-South Atlantic Chapter



oil condition, arcing, bearing wear, overheating and other parameters that can lead to the breakdown of capital equipment. They incorporate technologies such as vibration measurement and analysis, infrared (IR) thermography, oil analysis and tribology, and motor current signature analysis (MCSA).

### How would you like to see operating results like this?

- Lower your maintenance costs by 50%
- Reduce machinery downtime by 80%
- Increase your production by 25%
- Reduce overtime premiums by 70%
- Increase your profit by 40%

Do you follow a manufacturer's recommended maintenance schedule with your cars? The majority of car owners would prefer to spend a small amount on regular car care and maintenance rather than risk something wearing out or breaking, resulting in an expensive repair bill and possibly being stuck somewhere on the roadside. This is often referred to as preventive maintenance.

Studies at leading research institutes in the United States have found that a significant amount of the maintenance activity executed in American industry is not necessary. Predictive Maintenance enables plants to perform maintenance activities when actually needed based on equipment performance data, and not according to a set work plan. This saves the facility time and resources by eliminating shutdowns and servicing not actually required at that point in time.

This process has both management and technical components. Some examples of technical techniques for predictive maintenance include the following:

- Vibration PdM/RBM Programs
- Infrared Thermography Surveys
- Lube Oil Analysis Programs
- Acoustical Testing, Analysis and Design
- Ultrasonic Leak and Bearing Fault Detection
- On-site Dynamic Balancing

Predictive maintenance (PdM) systems and condition monitoring systems are used to predict equipment or component maintenance, and to monitor corrosion,



Vibration analysis systems apply the principle that all moving bodies produce sound waves. Predictive maintenance and condition monitoring systems that use infrared thermography measure the emission of heat. Oil analysis and tribology systems are used to monitor the friction, lubrication and wear of interacting surfaces in relative motion. Motor current signature analysis (MCSA) systems provide information about electrical faults caused by excessive motor starts or overloading.

### World Class Reliability Excellence

Some plants essentially operate in reactive mode (see top graphic). Maintenance is seen as a firefighting exercise of fixing things in a hurry without necessarily analyzing the root cause of the problem. Because things are fixed in a hurry, there is often considerable re-work, and since parts must be expedited and training is not adequate, the costs can also be high when operating in this mode.

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# Chapter Event Highlights

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An important step toward better management of these maintenance functions is incorporating total life cycle costs, including the costs of acquisition and the costs of ownership. Cost factors include the initial costs of the equipment, the efficiency & productivity of the equipment, the operation and maintenance costs, and the disposal costs. Understanding all of these cost factors allows plants to optimize total life cycle costs. This, in turn, leads to greater reliability and improved plant production rates.

From here, continuous improvement principles are used to align maintenance & reliability with the organizational metrics of high productivity, through the use of modern technology, utilizing life cycle costing, and including planning & scheduling systems. The equipment is improved and sustained over time, and the people are cross-trained so there is good bench strength.

Perhaps most importantly, there is now an ROI on maintenance & reliability. Improvements are realized due to factors such as reduced inventory costs, better labor utilization, less overtime premiums, reduced contractor costs, better control of capital investments, and more uptime and availability. All of these translate directly to the bottom line.

## Event Presentations

On June 2, 2011, ISPE Carolina-South Atlantic Chapter hosted four speakers on these important topics. The presentation slides and materials from these presentations are available at the Chapter website at the Presentations tab.



*Presenter Kevin Pait chats with Billy Morris, Retired executive with Bayer Corporation, And David Knorr, Chapter Programs Chair*

- **Ray Scherzer**, retired executive from GSK and chair of the Chapter's Industry Advisory Council (IAC), gave an interesting example from a Southwest Airlines incident. A fully loaded Southwest jet traveling at an altitude of 36,000 feet suddenly had an external sheathing failure causing rapid decompression inside the cabin.

What caused this problem? The takeoffs & landings were within limits, and the total hours were also within limits. But, this aircraft had experienced repeated turbulence and a number of rough landings. Ray then showed how this example translates into improved best practices in pharmaceutical facilities.

- **Kevin Pait, P.E.**, Director of Plant Engineering & Maintenance at Talecris (now Grifols), gave some tangible results from his experience at Talecris showing actual ROI from improved maintenance & reliability.

Kevin's presentation slides are not available for posting to the Chapter website, but Kevin has published an article in Pharmaceutical Engineering on this topic and this article is available at the Chapter website.

- **Quinton GoForth**, Principal Consultant with Genesis Solutions, provided an overview of Enterprise Asset Management and described the steps for moving from reactive mode to integrated alignment in enterprise mode.

Some of the same principles were described in both Quinton's and Kevin's presentations, but it was interesting to hear their different views from consultant and industry perspectives.

- **Michael Miller**, from RE Mason, described some basics about using vibration analysis for predictive maintenance. Michael also answered some questions about how vibration analysis compares and contrasts with other predictive maintenance technologies.

The various presentations seemed to integrate well to give the attendees some good information and maybe some new ideas to think about. Thank you to the presenters, attendees, our chapter management company, and to the Programs Committee for making another successful Chapter educational event.





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# Chapter Event Highlights

## “Invest in Your Future” and Other YP Events

By Blake Derrick, YP Committee Chair

The Young Professionals have received feedback in recent post-event surveys that indicated an interest in educational events that provide opportunities to learn about money management and financial planning, especially when beginning a career after college. In response to these requests, the Young Professionals held a Financial Planning Seminar at UNC Chapel Hill's Eshelman School of Pharmacy, on June 9th, 2011.

This seminar, titled “Invest in Your Future,” was attended by a large number of UNC pharmacy graduate students that had not previously been to ISPE events. Our guest speaker was Anna Lore, a certified financial planner with Women's Financial Partners, who gave an engaging presentation that covered an introduction to several relevant financial topics. Her presentation was extremely helpful, as she not only taught us some foundational concepts, but gave practical advice geared toward where young professionals should start and some common pitfalls to avoid. In addition to the seminar, all who came to the event were given a \$15 voucher which paid for access to an online-investing training course offered by the Learnvest website. Overall feedback was extremely positive, and we may look at offering a similar event again next year.



ering at a local restaurant, near the stadium, after the game. While some dates are yet to be determined, we plan to hold an educational event in late September or early October with guest speakers focusing on Leadership and Management or a technical discussion regarding various methods being used in vaccine production. Either way, look to hear about these topics in the upcoming year! We are also in the initial stages of planning an end-of-the-year event, in December, which will involve a tasting-tour at a local winery.

### Join ISPE

If you have an interest in joining ISPE as a Young Professional, would like to be added to our email list or to become more active in the planning committee, please contact us at [casayoungprofessionals@gmail.com](mailto:casayoungprofessionals@gmail.com).

## Other ISPE YP Events

### Therapeutic Thursday Brewery Tour and Membership Drive

For the month of July, the ISPE Young Professionals offered a special Therapeutic Thursday Brewery Tour and Membership Drive. The event took place on the last Thursday in July (the 28th), and was held at Lonerider Brewery in Raleigh. Special thanks go out to Bray, whose sponsorship enables us to provide appetizers and refreshments before and after the tour. This was an excellent opportunity for the CASA membership to join together to invite non-member guests, who got in for FREE, to hear about the benefits and features of ISPE membership. In addition, attendees heard details as to how Young Professionals can take advantage of ISPE membership at a reduced rate for the first four years after graduation. We encourage you to come out, relax, and enjoy catching up with your industry peers while also meeting some new “future” members.

### More events coming...

As for the rest of 2011, we plan to have more events starting in the early Fall. If you are attending the Durham Bulls Family Night in August, you should expect, soon, to hear details about a Young Professionals' gath-



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# Chapter Event Highlights

## June 2011 Therapeutic Thursday

*By Heather Denny, Membership Chair*

Per your request, we branched out in the month of June and visited the Carolina Ale House in Wake Forest, NC. Changing locations each month has diversified attendance. Even on a Thursday night before the holiday weekend, we had 15 members come out to network.

Therapeutic Thursday is on the last Thursday of each month to offer a venue for networking so members can expand their knowledge base and peer group. Appetizers are provided by our sponsor Bray. Go ahead and mark the last Thursday on your calendar, then watch for next month's location.

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*The CaSA ISPE Therapeutic Thursdays are proudly sponsored by Bray.*





# Chapter Event Highlights

## Lonerider Brewery Tour and Membership Drive

By Blake Derrick (YP Committee Chair) and Nancy Padgett (Membership Committee Chair)

The Lonerider Brewery tour was a highly successful networking event! Despite the withering heat, the ISPE Membership, potential new members, and Young Professionals came out in force on July 28, 2011 to tour the brewery. People could sample the Shotgun Betty Beer, indulge in happy hour goodies supplied by Bray, and enjoy being together. All in all, we had 52 attendees that made it out for the event. Our very own ISPE Young Professional, Dacie Edwards, gave the tour of the brewery and helped plan the event with the Young Professionals Committee. It was exciting to see CaSA ISPE members bring “future members” to an event. Young Professionals and CaSA Board Members distributed coupon code cards to non-members that provided a \$40 discount towards an ISPE Professional Membership. Although we don’t have official numbers, there were several attendees who indicated their intentions to become ISPE members.

Due to the limited space at Lonerider Brewery, we had to limit our registration and the sign-up process was closed one week prior to the event. This is the first time we’ve had such an overwhelming response during an event promotion, so we’ll definitely be planning similar events in the future. Many thanks again to Bray for sponsoring the food and playing an important part in making this event and other Therapeutic Thursdays a success.

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# Chapter Event Highlights

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## Featured CaSA Event

### Durham Bulls Family Night



**What:** CaSA ISPE Durham Bulls Family Night with After-Game Fireworks

**Where:** Durham Bulls Athletic Park, Durham, NC

**When:** Friday, August 26th, 2011  
6:00pm - 8:00pm Buffet open  
7:05pm Game starts

**Cost:** Adults \$15  
Children (3-10) \$10

(All fans 3 years and older require a ticket for entry.)

**Bring your family and come out and cheer the Bulls against the Charlotte Knights!**

Enjoy an evening in the DB Corral reserved exclusively for CaSA.

Ticket price includes buffet (hamburgers, hotdogs, fried chicken, macaroni and cheese, baked beans, and potato chips, Pepsi products, lemonade, and water) and game ticket.

Space is limited and will sell out fast so get your tickets soon. See registration form on next page.

**ALSO — Get your name out there by sponsoring the event. A great value, sponsorship is only \$300.**



**Carolina-South  
Atlantic Chapter**

# Durham Bulls Family Night

Durham Bulls Athletic Park, Durham, NC

Friday, August 26th, 2011

Registration		
Name & Guests		
Company		
Address		
City/State/Zip		
Phone		
Email		
Adults at <b>\$15</b> each                      Children (3-10yrs) at <b>\$10</b> each		
<input type="checkbox"/> My Company would like to Sponsor this event. <b>\$300.00</b>		
<b>TOTAL:</b> _____		
<b>Pay by Check or Credit Card</b> <input type="radio"/> Check <input type="radio"/> VISA <input type="radio"/> MasterCard <input type="radio"/> AMEX		
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# Technical Section

## 3 Assay Development Rules for Tech Transfer

By Stephen M. Perry, PMP®, President, Kymanox

At Kymanox, we get to see a lot of processes that are being developed for commercial approval. One of the biggest problems we come across on our projects is related to analytical assays. On fast-tracked tech transfer and scale-up projects, assay development—including qualification, transfer, and validation—are almost guaranteed to be rate-limiting for the overall project schedule.

Assays come in a lot of different flavors. Here is a short example list of some assays that we routinely deal with on our projects:

- pH
- Conductivity
- Purity by HPLC
- ID by IR-Spectra
- ID by ELISA
- Trace Heavy Metals Analysis by Titration
- Concentration by UV
- Cleaning Verification by TOC
- (Many others!)

We often see assays that are modified from their published USP compendial methods. Compendial assays are self-validating since they use internal controls and follow validated methods. These assays only need to be minimally qualified to support GMP manufacturing. So this leads to my first rule on assay development for successful technology transfer:

### RULE # 1: Follow Compendial Methods

*Use and explicitly follow USP compendial assays when they are available. Standards and methods from ASTM, ANSI, ISO, etc. may be acceptable substitutes if a USP compendial assay is not defined.*

The FDA is starting to crack down on companies who claim they are following compendial assay methods but are actually modifying the methods to suit their needs—or scientific urges—and are not validating the modifications. For example, a modification to “USP <791> pH” requiring a mandatory waiting or settling period outside the method parameters should be separately validated since this is a modification to the USP compendial method. In the Medical Device world, the FDA has even created a new form to ensure companies who reference compendial methods are following the methods exactly. This form is called Form 3654 and requires any method modifications to be clearly stated and justified.

Anyone doing R&D or Process Development should be trained to select and follow USP compendial assays whenever possible. This eliminates the need for stand-alone method validation and ensures assays can be outsourced and transferred with minimal time and cost.

The next problem we see related to assays is the eagerness to accept methods that only produce qualitative results (i.e., PASS/FAIL or attribute data). Ten years ago, this was not an issue; but in the 21st Century, it is imperative to utilize assays that yield quantitative (i.e., numerical) results. The main reasons behind this are Quality By Design (QbD) and ICH Q10. These universal quality principals and systems are rooted deeply in process characterization and understanding; quantitative analysis is simply more adept at characterization and understanding than qualitative analysis. Furthermore, executing QbD principles requires statistical-based science and risk management.

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# Technical Section

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At the end of the day, qualitative (i.e., PASS/FAIL) results provide a lot less information in comparison to their quantitative (i.e., continuous and numerical) counterparts. And once you start doing risk assessments and have to provide statistical rationale supporting those assessments, you'll quickly come to the same conclusion that assays which produce attribute (i.e., PASS/FAIL) data are a big handicap to fully implementing QbD.

As an example, we had a process validation exercise where we only had attribute data supporting critical quality attribute. All that we knew was that a contaminant level was below a specified threshold. Because we did not have continuous numerical data to statically and mathematically analyze, we required several more samples within each lot (i.e., batch) and more lots (i.e., batches) to sample. In the end, the lack of a quantitative assay cost the project hundreds of thousands of dollars in additional process validation runs and samples. In most cases where there is a need to demonstrate quality assurance at a specific confidence level, quantitative data can lower the number of samples required by ten-fold (i.e., 10x) as compared to qualitative (i.e., PASS/FAIL) data.

For processes in early development, we strongly recommend minimizing product quality and safety assays that yield only attribute (i.e., PASS/FAIL) data. Once the process is fully developed and the product is in late-stage development, there is usually very little time or resources available to make this assessment and improvement. This leads to the second rule.

## RULE # 2: Select Assays That Produce Numerical Results

*When developing and selecting assays for product quality and safety, as well as for in-process controls, avoid assays that yield only attribute (i.e., PASS/FAIL) data. Rather, select assays and methods that yield continuous numerical results so those results can be leveraged for statistical analysis which in turn can support the overall QbD quality approach.*

I'll skip to the third rule and provide more detailed rationale in a future post:

## RULE # 3: Minimize Assay Variability

*When developing assays, do everything possible to eliminate variability in the method.*

By minimizing variation, the assay becomes a much more powerful tool for making process improvements and detecting process changes. A lot of people are focused on assay accuracy; however, assay variability plays a much more important role in the realm of quality control and QbD. If you want more on RULE # 3, the following text book is an excellent resource:

*Six Sigma In The Pharmaceutical Industry: Understanding, Reducing, And Controlling Variation In Pharmaceuticals And Biologics* (Paperback, June 2007) by Brian K. Nunnally (Author) and John S. McConnell (Author)

Abbreviations used:

- GMP = FDA's Good Manufacturing Practices
- USP = United States Pharmacopeia
- ID = Identification
- ELISA = Enzyme-Linked Immunosorbent Assay
- TOC = Total Organic Carbon
- UV = Ultra-Violet
- R&D = Research and Development
- FDA = Food and Drug Administration

## About Stephen Perry

*Stephen Perry is the founder and president of Kymanox. He has well over a decade of cGMP biopharma manufacturing experience as a chemical engineer and project manager. Before starting Kymanox, Stephen had various leadership roles supporting successful scale-up, start-up and commercialization initiatives at Abbott Laboratories, Covance Biotechnology Services, Diosynth Biotechnology and Human Genome Sciences. Stephen graduated with high honors with a degree in Chemical Engineering from the University of Notre Dame. He has also studied at the graduate level at Purdue University.*



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# Technical Section

## Assessing Key Investment Strategies in the Pharmaceutical and Life Sciences Industry

White Paper written by Kelly Scientific Resources®, Kelly Services, Inc., and The Human Capital Institute

### Introduction

#### Assessing Key Investment Strategies in the Pharmaceutical and Life Sciences Workforce

In fall 2009 The Human Capital Institute® (HCI), a global professional association dedicated to the advancement of talent management practices and Kelly Services®, a leader in providing workforce solutions surveyed senior human resources executives in the pharmaceutical and life sciences industry.

The survey, supplemented with several hundred expert interviews, was designed to probe the talent management and recruiting practices of mid- to large-size pharmaceutical and life sciences firms. A variety of these organizations' talent management methods, best practices, and future plans were revealed accordingly.

Findings revolved around the following key questions:

- Management - How well is human capital being managed today in the pharmaceutical and life sciences industry?
- Investment - Where is the industry investing its scarce resources to achieve its human capital objectives?
- Assessment - Is the industry investing in and emphasizing the right strategies?

The following is a summary of key findings in the third of those three areas - **Assessment**.

This synopsis provides critical insights and inferences gleaned from the research, as well as high-level recommendations for enriching talent management practices across the pharmaceutical and life sciences industry.

#### How well are key investment strategies aligned?

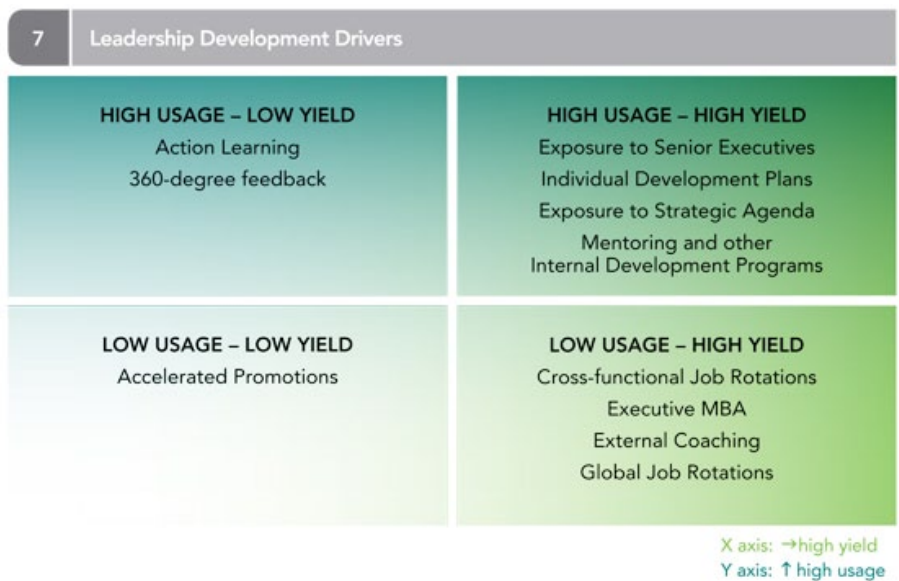
This information should prove valuable to industry HR and business leaders as they plan and prepare for the future in one of the country's fastest growing and most vital industries. Be sure to read parts one and two for additional observations on talent management in pharmaceutical and life sciences.

### Assessment

Is the industry investing in and emphasizing the right strategies?

**Insight:** Linking leadership development practices to human capital success

*The industry is experiencing solid success in its use of several HR and talent management techniques, but other opportunities remain largely untapped.*



Our research suggests that investment in areas such as exposing future leaders to senior executives and the strategic agenda and ensuring individual development plans are well utilized will yield solid returns in leadership development. In contrast, fewer within the industry leverage cross-functional rotations or external development programs for leaders despite the high returns such practices generate.

#### Key recommendations

Quite simply, we recommend that leaders in the pharma/life sciences industry focus on those areas that might yield above-average leadership development returns but are as yet under utilized. These practices might include the above-mentioned cross-functional rotations

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# Technical Section

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or external development opportunities such as an MBA program (Figure 7).

It should be noted that we do not recommend shifting assets from the high-yielding but well-utilized to a potentially high-yielding but under-utilized area. For example, our survey respondents generally were heavy users of three of the most effective tools in leadership development. These three practices—exposure to senior executives, individual development plans, and exposure to the strategic agenda—should not be considered expendable. Aside from the leadership development benefits, these practices also are among the most effective at driving positive company culture outcomes. So critical are these “basic” high-yielders that we believe organizations should consider “doubling-down” their investments in these areas while still looking for those under-utilized opportunities that might also offer an edge.

*The industry is experiencing diminishing returns in traditional HR practices such as 360-degree feedback and action learning programs for leaders.*

Unlike the preceding highly utilized but high-yielding practices, these practices appear to be over utilized in the industry from the standpoint of their below-average results in driving human capital success. While these practices, including 360-degree feedback and action learning, have proven successful in other industries, they are relative underperformers within the pharmaceutical/life sciences arena.

## Key recommendations

### Creating a constant performance feedback loop:

“We approached the performance evaluation process differently—no more annual reviews. Instead, we do monthly focused chats with our managers. No more having to get feedback only once or twice a year.”  
—Head of HR at a small pharmaceuticals company

As such, we recommend that leaders examine their own successes with these practices, though we do not recommend their abandonment. In the end, trade-offs always need to be made, and we believe that many companies will benefit from focusing more of their leadership development resources into the “high return” practices and away from the “low returners.”

## Insight: Linking general talent management practices to human capital success

The single most important driver of human capital success is the effective alignment of all talent owners—HR, line managers, and senior leaders.



Linking talent owners is more highly correlated with an increased Company Culture Score<sup>3</sup> than any single talent management practice (Figure 8). Of course, this notion of alignment relates to many elements of an organization, such as the previously reviewed company and employee values, beliefs, and behaviors. In general, there are areas for improvement in the general management of human capital that, if addressed, are likely to yield tremendous returns for organizations in the pharmaceutical/life sciences industry.

## Key recommendations

Thus, we recommend that a first (and most important) step to fully capturing the value of improved talent management is to ensure that talent management is integrated across all functions of an organization and not made an HR responsibility alone. In short, and consistent with all of the findings in this report, talent management must become the responsibility of all leaders in the organization (whether in the pharmaceutical/life sciences industry or elsewhere).

### An HR perspective:

“What works well is that HR is involved in the strategic aspects of the business. HR coaches managers [and] works on development.” —Head of HR at a small pharmaceutical company

We found unambiguous evidence to support the principle that the single most important driver of human capital success—and the strong company culture that drives and sustains it—is the effective alignment of all talent owners.



# Technical Section

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To do so, organizations must undertake what is often referred to as “HR transformation.” While not directly examined in this research, HCI and other organizations consistently have found that the majority of organizations continue to manage 21st century, knowledge-based workforces with industrial-age HR practices.<sup>4</sup> We believe that this approach does not allow an organization to maximize its potential, and in fact, in an era of hyper-competition, threatens its long-term viability.

In today’s workplace, HR simply cannot manage the workforce by treating employees as numbers on a computer screen. Instead, talent management requires a focus on the individual. Furthermore, integrated talent management must replace siloed HR to improve efficiencies and ensure that information from one area can be leveraged to inform decisions and actions across the entire organization and across the individual’s career lifecycle (Figure 9) within the organization.

policy, and ensuring that the “right” people are hired in the first place all rank in the top five in their level of use within the industry. However, all three rank in the bottom half of practices in their effectiveness (Figure 10 - next page). Thus, in addition to aligning and integrating talent management, organizations in the industry should also consider which human capital practices they are applying with the general workforce, and what kind of returns they are getting from those practices. It is interesting and somewhat perplexing that the “best practices” in which pharma/life sciences organizations are currently investing most heavily are among the least correlated with talent management success (Figure 10 - next page).

## Key recommendations

As with leadership development, we reiterate that companies should not stop investing in these methods, because they form a critical baseline.

However, other practices that are proving more effective and are currently under utilized (i.e., expanding on-boarding programs, targeted learning for pivotal positions, rotational and experiential job assignments) are, as shown in Figure 10, strongly linked to positive outcomes and may be better targets for increased funding.

***The power of preparation is often overlooked. Companies are not focused enough on preparing workers for key moments of transition: on-boarding and moving to jobs of increased responsibility.***

HR and line managers need to focus more on supporting new hires and workers—before and during their transition into each new job. Per Figure 10 (next page), only two of the general talent management practices ranking in the top five for their positive impact on human capital success are also among the five most used practices in the industry: *assessing performance and potential and line manager involvement (coaching, mentoring).*

## Key recommendations

Knowing current (and potential) performance levels is the first step in designing individual development programs to improve performance. In addition, assessing performance is just one of many

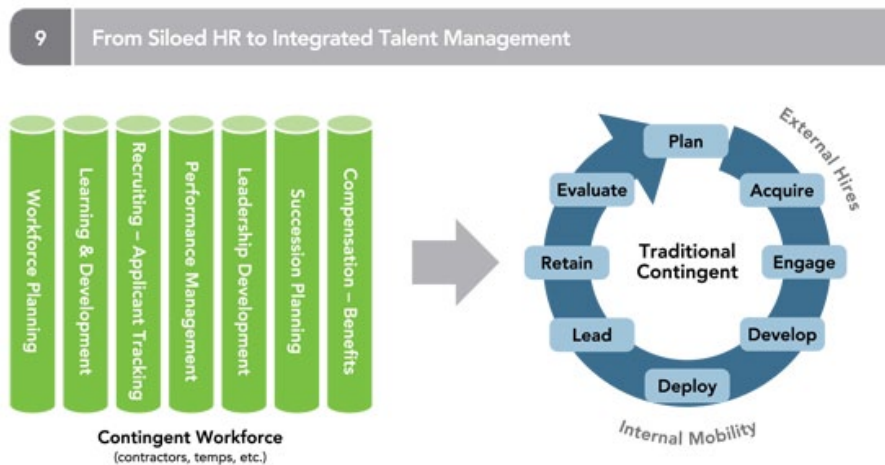


Figure 9 illustrates the difference between a siloed HR organization where contingent labor is managed separately from the traditional workforce and an Integrated Talent Management Organization that combines the management of the traditional and contingent labor forces.

***Some practices that are proving more effective, and that are currently under utilized, are good targets for increased funding.***

As with leadership development, some organizations are focused on traditional HR practices that do not always provide the greatest impact. Formal training programs, a promotion-from-within

### The contingent staffing firm as a strategic partner:

“Yes, we view our contingent labor partnership not as a transaction of ‘we need a talent now’ but more of a strategic partner ... they serve as a third-party partner to resolve short-term ... yet critical talent.”

—HR Executive at a large pharmaceuticals company

# Technical Section

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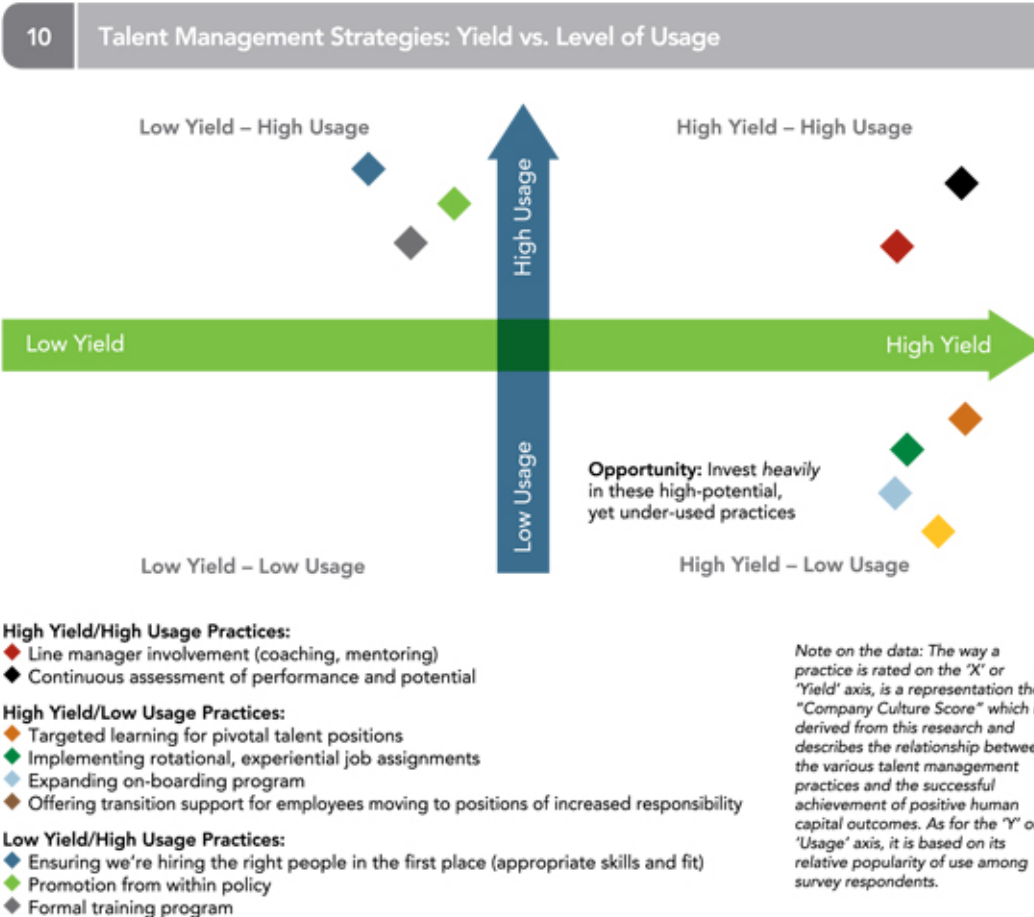
talent management practices that are improved with the active involvement of the line manager. Several HR and talent management practices are strong in the industry and should be maintained. However, most companies stand to reap significant benefits from investigating under-leveraged methods that yield high returns, particularly those highlighted in Figure 10.

## Conclusion

As highlighted in Parts 1 and 2 of this series on talent management in the pharmaceutical and life sciences industry:

## Management

- Companies should put systems in place today that will better prepare them for continued growth across the industry while global trends in talent expected over the coming decades demand change in sourcing and utilizing that talent.
- While most workers have a good impression of the industry, innovation is far less common than many might wish—it takes a highly creative and stimulating environment balanced with the uniqueness of globalization, Web-based connectivity, and in-silica development to utilize and retain top talent.
- Alignment between the values and beliefs of individual workers with corporate standards is strong across the industry—vital to creating a world-class talent management culture as employees are more and more in tune with societal responsibilities.



## Investment

- The foundations for better human capital management are in place, but many companies are currently under-utilizing an array of best strategic practices that show a high potential for success. How to deploy the workforce on a global basis, focused on skill set rather than job category, is the key to decreasing time and cost of product development to market.
- Closing the gap will require a much greater role for leaders throughout the organization, with responsibility for the workforce shared among HR, executives, and especially functional managers.

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# Technical Section

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Of all talent management practices embedded in the pharmaceutical and life sciences industry, one of the most proven, yet least utilized is simply in holding managers more accountable for retention practices and improvement. To address this trend, HR should select and develop functional managers that can carry much of the day-to-day challenge of talent management, and then leverage it aggressively. An obvious issue is to clearly recognize the values held most important to the differing demographics of the workforce balance with cultural uniqueness.

Our respondents believe in the core importance of both the traditional and non-traditional workforce. This will position the industry well as more and more of the workforce is comprised of contractors, temporary employees, remote workers, and other non-traditional talent. Like in other sectors, Human Resources in the pharmaceutical and life sciences industry must transform toward a new strategic approach to human capital management that corresponds better to the dynamics of today's workforce.

Vast changes have occurred in advanced economies over the past two decades and presently with the life cycle of products, yet many companies in the industry have failed to keep pace with modern talent management practices. Partnership with a leading provider of scientific workforce solutions can help the industry to adopt HR structures that support a holistic view of talent in the organization, as well as more integrated workforce solutions.



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- Annual CaSA Planning Meeting at Prestonwood Country Club, Cary, NC  
Tuesday, August 23 from 2pm - 5pm
- Durham Bulls Family Night at Durham Bulls Athletic Park, Durham, NC  
Friday, August 26, 2011 – begins at 6pm (see details on pg 11)

Details coming soon for the following events:

EVENT	MONTH
CaSA Fall Gala	October 2011
Energy Management Program	December 2011
Supply Chain and Lean Manufacturing Joint CaSA ISPE/APICS Event	January 2012
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