ISPE
Connecting a World of Pharmaceutical Knowledge

Carolina-South Atlantic Chapter

CaSA News

Volume 21 • Number 6

December 2014

President's Message

Heather Denny

This time of the year, most of us stop and reflect on what we are doing with our lives and where we want to go. As I was sitting in traffic on a rainy night, remembering I needed to stop and write this newsletter article, I started to reflect on our industry, the area we live in and CaSA. Stepping back and looking at the industry as a whole, there have not been many weeks in 2014 that there was not an article about change in the pharmaceutical industry; mergers, sales of product lines, how companies are filling their pipelines, just to name a few. This is an industry in constant flux.

Closer in, you look at the CaSA area which includes North Carolina, South Carolina, Georgia, Alabama, Florida and Tennessee. There is a lot of industry change in our region; companies that are hiring and expanding, companies relocating functions to geographic locations, sales of facilities and product lines. These are all major impacts to our region and the people that are affected.

So what does all of this activity in the industry have to do with CaSA? With 1,200 plus members, CaSA is a network of industry professionals that is here to provide a platform of opportunities for you, whatever your circumstance in today's world. In addition, you have the outer network of ISPE which reaches around the globe. If you are a hiring manager looking to bring on the best in the industry, ISPE is the place to start. If you find yourself beginning a new job search, this is the place to start. If you just want to continue your education, there is no better place than ISPE.

How do you take advantage of this great network? Get involved. The start of the 2014-2015 CaSA year has seen huge successes. With a sell-out Young Professionals event at Biogen Idec, record number of attendees at Oktoberfest where we combined our annual planning meeting with our fall networking event, and high turnout for the Automation Forum, we have created momentum. Let's keep that momentum going as we turn the calendar to 2015. Planning is in full swing for the Technology Conference; soon, it will be spring and the annual golf tournament will be upon us, and many more activities. We've finally made some headway into Georgia with several Therapeutic Thursdays and for 2015, there are plans to expand with educational sessions.

Our network is strong and growing. Make sure to get involved and use the resources around you.

Heather Denny
President, ISPE CaSA Chapter

Featured Sponsors

INSIDE THIS ISSUE

Upcoming Events

Technology Conference - March 10, 2015 at Raleigh Convention

NCSU/ISPE-CaSA Career Fair - March 27, 2015 in Raleigh, NC Center

Tri-Sci Expo - April 11, 2015 at NC Museum of Life Sciences, Raleigh, NC

Golf Event - May 18, 2015 at Prestonwood Cary, NC

Membership Corner

$40 DISCOUNT NOW AVAILABLE FOR NEW INDUSTRY MEMBERSHIPS!

By Terence Morrison, P.E., LEED AP BD+C, ISA 84 SFS

$40 DISCOUNT NOW AVAILABLE FOR NEW INDUSTRY MEMBERSHIPS! Applications can be made online at www.ispe.org/join. Click on Join Now under Industry Membership, and enter **CASA2014** in the promotion code box. Please remember ISPE's Refer-A-Friend Program! Earn one free month of membership for every friend you refer. All the details are available at http://www.ispe.org/membership-referral-program

This discount is not applicable to Students, Young Professionals, Academics, and Regulatory Authority / Government as these all hold discounted memberships already.

If you have any question about ISPE or the CaSA Chapter, please contact me at membership@ispecasa.org.

Welcome New Members

New Members who joined October 7, 2014 through November 26, 2014

AnnieLloyd Nesbitt
Bianca J. Richardson
Dulce Lacson
Edwin Alston
Joanna M. Mularchik
Lauren Faulkner
Maria Guardiola
Mark C. Holland
Matthew Cooper
Matthew Jones
Michelle Maciejewski
Missy Bailey
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Joseph G. Cagassola
Justin Travis Moore
Kelly Boisvert
Michael J. Wourms
Ashley Fox
Donna M. Farago
Radeyah D. Howard
Faith Fraley
Maider C. Vang
Terrilee Odom
Vinishma Datta Nuthi
Paul Ginos
Sarah J. Peterson
Scott D. Smith
Sigma S. Mostafa
Ugochi Nwamara

22nd Annual ISPE-CaSA Technology Conference

By Amy Lineberry, CPIP, CaSA Technology Conference Committee Co-Chair

Exhibitor registration is now open for the 22nd Annual ISPE-CaSA Technology Conference!

Only four Corporate sponsorships and three Host sponsorships are left! Attendee registration is set to open in early January. The 2015 Conference is shaping up to be the best Conference yet, with high level education during the day and a Casino themed networking reception in the evening. Come and bring your co-workers for a great day of education and networking. We are looking forward to having everyone at the Convention Center on March 10, 2015. Please look for more details about the Technology Conference in future newsletters as we spotlight key features and information in each issue. In the mean-time, visit http://www.ispe-casa.org/2015 to register your company to attend or check out the details of the Conference. The conference is expected to be a sellout, so act fast.

Membership Corner

Carolina and South Atlantic Facility of the Year Category Winner for Project Execution

By ISPE

Grifols won the Project Execution category for their North Fractionation Facility, located in Clayton, North Carolina. The $340 Million project is a 150,000 SF expansion on their existing campus for Human Blood Fractionation.

The project enabled Grifols to update their bioscience process to more current standards through the use of closed processing in order to minimize human interaction and maximized the use of supplier-enabled innovation through a new disk stack centrifuge design and development of an automated bottle opener. The facility also incorporated a high level of automation to reduce human interaction (to two steps) and decrease process variability. The team incorporated process and equipment technology advances during the project while also looking for facility design technology advances (such as reduction of classified clean space and use of sustainability).

The project was executed using a culture focusing on the long-term goals of the project utilizing preplanning (from design to modularization of equipment to C&Q planning to startup of manufacturing operations).

Grifols Therapeutics, Inc.
North Fractionation Facility – Clayton, NC

Education Corner

Education Committee

By Jim Hubbard

COMING IN 2015:

Education events in the Atlanta/Covington area...planning is already in progress. For more information on sponsorship opportunities, suggestions for classes, or to join the Education Committee, please email Jim Hubbard at jhubbard@amts.com

NEW MEMBER:

Please join me in congratulating Gigi Fan as our newest member. Gigi came on board just after meeting her at the Oktoberfest event. She currently works with CRB as an I&C Engineer in their Atlanta office. We're all glad to have you on our team!

JOIN NOW:

The Education Committee is looking for more members in the Atlanta/Covington area to assist in developing a long term commitment to this locale. If you have a passion for education or mentoring your peers, please email Jim Hubbard at jhubbard@amts.com

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Carolina-South Atlantic Chapter

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Membership Corner

First Annual Jane Brown CaSA ISPE Scholarship Winner

By Wendy Haines, PhD, ASQ CQA

For the inaugural year of the Jane Brown CaSA ISPE Scholarship, we had a lot of applicants representing five of our different student chapters: Campbell, East Carolina University, North Carolina Central University, North Carolina State University, University of North Carolina, Chapel Hill. The judges all agree that we had a lot of amazing candidates and it was a tough decision to choose only one winner. CaSA invited all of our applicants to attend Oktoberfest, where Jane Brown would announce our scholarship winner. Ryan Boehm, of the University of North Carolina, Chapel Hill, was our winner.

Ryan is a graduate student pursing a PhD in biochemical engineering. Ryan, with the support of his advisor, Roger Narayan, started the Science Saturday outreach program, funded by the NC Space Grant. This program is aimed at teaching middle school and high school students about the opportunities and benefits of education and careers in STEM (science, technology, engineering, and math) fields. Once a month on Saturday mornings, university researchers from across the state share their research in an informal setting with students, teachers, and parents at the NC Museum of Natural Science.

Ryan is a past CaSA ISPE Graduate Student Poster winner and is the current treasurer at the UNC-CH ISPE Student Chapter. Ryan has nine first-authored papers and a total of 12 peer-reviewed publications. Ryan has a BS in biomedical engineering from North Carolina State University and is maintaining a 3.88 GPA in graduate school.

Thank you to our judges: Kathleen Cline, Jennifer Lauria Clark, Jennifer Parks, Natan Siegel, and Kevin Ventura. Please join me in congratulating our scholarship winner, Ryan Boehm.

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Student Corner

We're Moving!

By LeAnna Pearson

The Student Leadership Symposium is MOVING…. We will be integrating with the Technology Conference to be held on March 10th 2014. This is exciting so that we can now offer a Student and Young Professional Educational Track. This move is in an effort to work with other committees and with the success of the Technology Conference we could not think of a better pairing.

Tracks for the Young Professional and Student Educational Session at the Technology Conference are:

Morning: Take Control of YOUR Career! Developing a Career Plan and Sticking to it.

Evening: Intro to Project Management.

Call for Volunteers!

The Student Affairs committee is searching for a graduate from Virginia Tech to represent and lead their student chapter membership – Please send your information to info@ispeCaSA.org, subject line "GO HOKIES!"

Sponsors needed for 2015 Therapeutic Thursdays! A great way to get your company into the hearts and minds of the chapter membership – Please send your information to info@ispeCaSA.org, subject line "Cheers!".

OKTOBERFEST, OCTOBER 30

By CaSA Board

The ISPE Carolina-South Atlantic Chapter (CaSA) combined their committee recruitment session with the fall networking event, resulting in an Oktoberfest celebration! Oktoberfest was held at the Koka Booth Ampitheater and featured live music, food, and carnival games. Over 200 people, ranging from facility owners, to members, to service providers in the region attended.

The event was important for driving committee membership and included networking and socializing opportunities for the growing number of pharmaceutical industry professionals in the area.

Each CaSA Committee set up a table with fun and/or interesting material related to their committee. The tables were manned by committee members to provide information to the chapter membership about the committee and the kinds of activities that committee volunteers can and do perform in support of the chapter.

The event helped members interested in contributing to the Chapter as a speaker, committee volunteer, or as somebody willing to share a particular expertise by providing education, training, writing articles for the newsletter or planning the technical conference or local training events connect with the committees charged with these important activities.

The CaSA board would like to thank our sponsors for this event – without you, we would not have been able to enjoy such a fantastic evening!

Evolving from Craft Based to Procedure Based Maintenance
(With Special Emphasis in the Regulated Industries)

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Evolving from Craft Based To Procedure Based Maintenance

Abstract:

What does it mean to evolve from Craft Based Maintenance to Procedure Based Maintenance? The days of Journeymen and Maintenance Technicians being capable of fixing or troubleshooting anything they confronted is no longer a realistic expectation. Following detailed directions adds an element of expertise to those willing enough to follow the disciplined, precision, process-driven instructions included in detailed Work Instructions. Couple the challenge of maintaining more sophisticated, complicated, automated and robotic equipment with the demands of controlling the processes which support the manufacturing of pharmaceutical drugs, it is easy to see the criticality of an extreme level of control over the quality of the work accomplished. It is necessary to expand the focus of maintenance beyond that of restoring equipment functionality; maintenance and reliability practitioners must understand the potential impact of their work -- not just on the equipment and how it may affect the equipment reliability, but also on the product and process. This includes any potential impacts on the Safety, Integrity, Strength, Purity and/or Quality (SISPQ) of the product.

Detailed work instructions ensure a common approach, implementation, and results, driving a standardized maintenance strategy across a facility. Certainly, ensuring that this document is utilized appropriately remains a responsibility – and quite often a challenge -- for those managing Maintenance Technicians, as well as the Technicians themselves. The other significant challenge that this approach presents is the inherent demand of authoring these detailed Work Instructions. This paper speaks to the skills required to create the detailed Work Instructions so instrumental in documenting Procedure Based Maintenance, and how to do so without demeaning the Technician performing the work – while integrating the precision specifications, so often absent in work orders. As industry standards – especially in regulated industries – evolve from Craft-Based Maintenance to Procedure-Based Maintenance, technical writing skills will be critically utilized to produce high-level detailed Work Instructions. The presentation will provide tips and tricks to format, standardize, simplify, provide visuals and organize these technical writing skills into professional documents that inspire precision work by the Maintenance Technicians while ensuring standardization, common processes and regulatory compliance.

Introduction

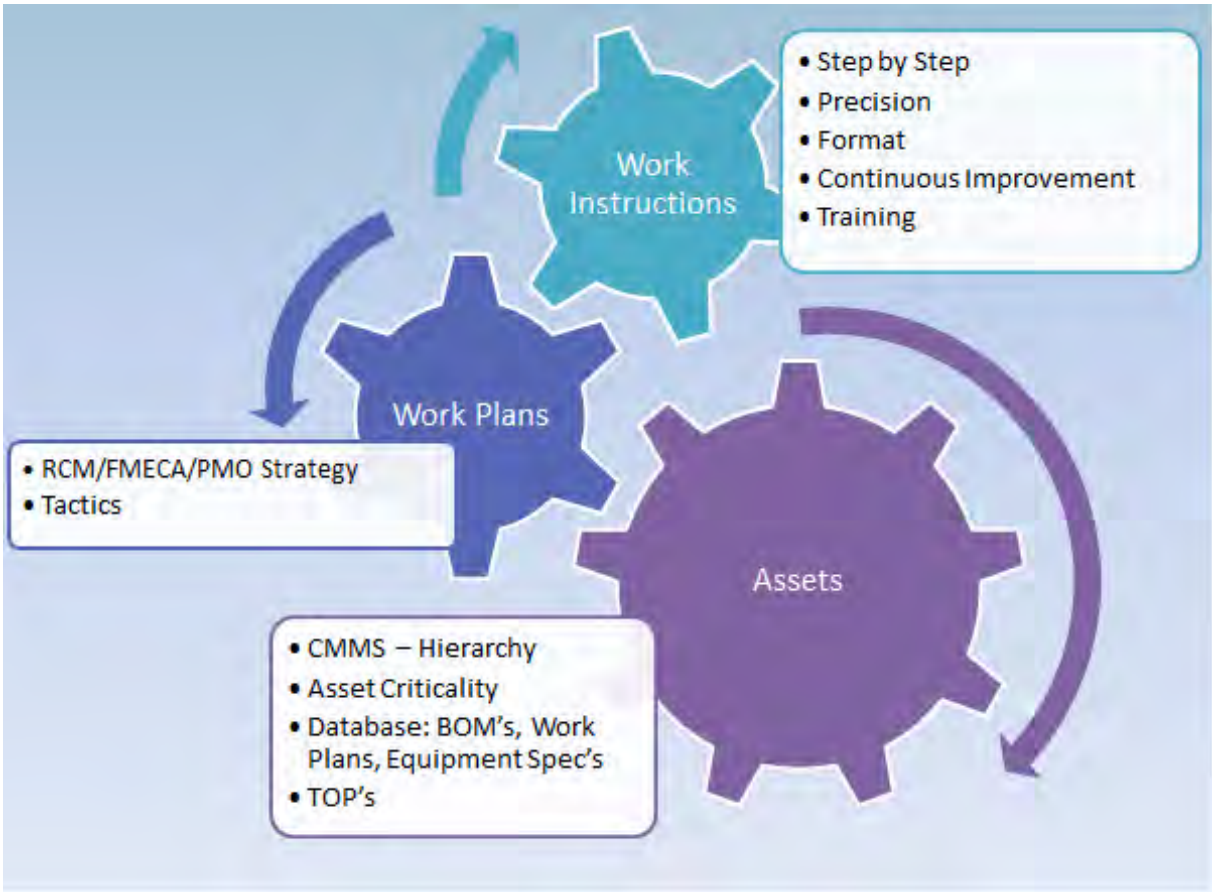
Many maintenance programs are craft-based, meaning that they are performed by Technicians or Journeymen with years of experience and a wealth of knowledge on the maintenance work to be performed and the capabilities and weaknesses of the equipment. A well-designed and carefully presented Maintenance Work Instruction and Training Program assists in the transition from a craft-based to procedure-based maintenance system. This strives to satisfy regulatory requirements (having documented procedures for maintenance work and the Technician training), however, in no way diminishes the necessity for talented Journeymen to execute the Work Instructions. The Technicians may not be accustomed to following a procedure or documenting the results. It is necessary for the author of these instructions to be sensitive to the fact that the Technicians may have never followed an SOP in the past – and even more so, may question the basic necessity of following one presently. They may feel threatened that every step of their job is documented, and perceive this procedure-based strategy as a negation of their expertise. With these considerations in mind, the style in which the Work Instructions are written can determine how the Technician receives the procedure. The approach the Maintenance Department takes and their response to the Technicians' feedback is critical to establish buy-in and a Continuous Improvement culture in a procedure-based maintenance department. Work Instructions ensure that precision work is repeatable and documented, and may help to cultivate a culture of inspiration within a regulated facility.

Regulatory Expectation

The days of FDA investigations that only look at the surface of the maintenance department are no more – historically, FDA Maintenance audits consisted of a check-over of the maintenance plan, PM program, and list of critical instruments. Now, the focus is a much more rigorous one: the FDA is actively looking at the maintenance and reliability programs of pharmaceutical and biotech manufactures with intricate detail. Well-documented asset logs of failures – with appropriate strategies implemented to prevent the failure in the future, a robust record of technician training – adding confidence that the implemented changes were executed appropriately, and lists of equipment specification, detailing the safety and efficacy of using such equipment, are areas of focus within this regulated industry that are fundamental to a successful maintenance program. This new level of regulatory control – documented through procedures, work plans, and training – ensures that the maintenance goal (controlled and precision work is being performed) has been achieved. Furthermore, regulatory investigations may delve deeper – probing for unplanned maintenance events due to failure and appropriate follow-up. It comes to no surprise that a robust maintenance program, meeting system owner and regulatory expectations, is one that is well-documented, controlled, repeatable, and traceable.

Procedure-based Maintenance

Writing detailed work instructions reduces human variation in maintenance activities and introduces new Technicians to the



standard requirements, and most evidently, this process demonstrates the level of control necessary in this regulated industry. These instructions act as a living document – with a level of flexibility necessary for continuous improvement. Beyond ensuring consistency in maintenance activities, standardized work instructions promote acceptance by following a standardized format and ensuring that important considerations, such as safety or environmental hazards, are not overlooked.

Maintenance SOP's, or Work Instructions, are written to compliment the training of the Technicians who are executing the contents of the Work Instructions, typically in the form of a Work Plan or Work Order. Typically, the Work Plan and/or Work Order are maintained as part of the Computerized Maintenance Management System (CMMS). These Work Instructions provide a connection between the Assets, the Work Plans, the CMMS and the training records of each Technician to work on these assets. The work plans provide the strategy for how each asset will be maintained, the tactical details required to ensure the control required in a regulated environment, and the reliability desired in the operations, maintenance and reliability departments. The Work Instructions give specific information regarding the maintenance to be performed. The integrated system helps to plan required maintenance and demonstrates the control and training required to meet the requirements of the regulatory agencies.

The CMMS is often used to link every Work Plan to an Asset or Equipment Record and each Work Plan and Work Order must have supporting Work Instructions. In addition to this, documented training records are required that demonstrate each Technician who performs work on an Asset has been trained to do so. This often includes a practical demonstration of performing the work prior to being qualified or certified on the given task(s).

A well-integrated, procedure-based maintenance and reliability system is one that is driven by precision work and documented in work instructions. The work plans, developed as a result of process investigations – as manifested in Reliability Centered Maintenance Plans or Failure Modes and Effects Analysis – drive the content of these instructions, and are reflective of an understanding of the unique asset or system and its given operating conditions. As industry standards evolve from Craft-Based Maintenance programs towards a procedure-based strategy, and as equipment and systems become increasingly sophisticated and complex, this well-integrated system will provide the fundamental groundwork to ensure that quality work is performed, accurately documented, and is compliant with regulatory requirements within such a tightly controlled industry.

Technical Writing

Greater business demand for improved performance & equipment reliability consequently drives the necessity for detailed, technical documents that provide maintenance instructions. Technical authorship of these work instructions may initially appear to be a daunting undertaking, but the resources necessary to create high-level work instructions are readily available within a pharmaceutical manufacturing facility, provided that the author knows where to look.

Before any ink meets paper, it is important, first, to define the expectations of the Work Instruction. The level of detail and organization are flexible, dependent on how the work instructions will be utilized, and also on the expertise of the intended audience. Understanding the appropriate structure and amount of explanation best suited for a facility's unique needs will determine the level of detail required of the text. Work Instructions may be organized in two different approaches: all work instructions pertaining to an asset may be included in one large index, or each procedure may exist in a standalone document. The first approach, where all instructions pertaining to an asset are kept in one location, may result in a rather cumbersome document – however, with this organization comes increased regulatory confidence in the maintenance strategy, and in those executing the work. The second strategy is not as popular within a regulated industry, as thousands of standalone documents may result from the separation of individual Work Instructions, meaning a significant amount of documentation to control.

There are at least two different approaches to writing Work Instructions. The free format, presented in paragraph form, is read like a book. This format is most familiar, and is therefore easy to follow. Each maintenance step is numbered, with the level of detail suitable for the subject matter included in each step. The table format separates text in columns, where each subsequent column may add another level of detail to the General Procedure. The first column may list the task to be performed (remove the belt guard, torque to X ft/lbs, etc.), with a picture or sketch in the third column. Photographs are a useful tool in either approach, and may be integrated throughout the procedure to help eliminate any confusion that may result from the written procedure. Pictures should be taken of the actual equipment to be maintained, with additional pictures or sketches depicting the exact location on the equipment to orient the Technician properly when performing the work.

Adequate preparation is fundamental in quality production. Research will be required in order to document the maintenance activity adequately and in sufficient detail. The information included in the procedure is equipment-specific, and gleaned from many sources. The bulk of information will come from manufacturer-provided Turnover Packages, and operations and service manuals.

The following sections should be represented in the Work Instruction:

1. Purpose/Scope:

1.1. The Purpose should describe why the document was written. Since the work instruction will be written for a specific piece of equipment and maintenance activity, these details should be included in the purpose of the maintenance activity.

➢ Free Style
– Text with supporting pictures

➢ Table Style
– Levels of detail depicted by column(s)

GENERAL

1. Inform the Control Room Operator that the compressor will be unavailable while inspecting.
2. Drain the intercooler and after-cooler moisture traps. Make a note to call Atlas Copco in for service if either one produces little or no water after being open for 20 seconds. This will mean that Atlas Copco needs to service the coolers and/or the moisture traps.
3. Check the readings on the gauges to make sure they are operable. See Figure 1
4. Check to see that the loading and unloading pressures are between the marks on the gauges. See Figure 1
5. Check to see that the return glycol temperature is between the marks on the gauge. This temperature will indicate the cooling efficiency of intercooler and after-cooler. See Figure 1
6. Check to see that the oil level is between the marks on the sight glass. See Figure 2

Figure 1 Check gauges

Figure 2 Check oil level

7. Inspect the compressed air piping inside the compressor for leaks using ultrasonic leak detection. See Figures 11-13

GENERAL

Step	Description	Notes	Pictures
1.	Post required permits.	Make sure permits are filled out and signed by operations. Perform safety task and TRACK. LOCK OUT TRY OUT! LOCK OUT TRY OUT!	
2.	Remove the belt guard and belts	Remove the belt guard. Loosen the jacking bolts on the motor and remove the belt. Hello Now I Can Change the Body of the Belt Guard Belt guard Jacking bolts	
3.	Remove the old sheaves	Loosen the bushing bolts and put them in the blank holes and remove the sheave. Loosen the allen screw and remove the locking color. Inspect the shaft for damage or corrosion. This can be done on both the pump and motor. Bushing bolts	

1.2. The Scope should describe what the document covers; equipment name and model number, description and use of the equipment and how the work instructions apply to that equipment.

2. Preparation Work

2.1. This includes scheduling with the equipment owner and notification of affected departments and groups such as the control room and operations prior to and following accessing the equipment and utilities to perform work depicted in the Work Instructions.

2.2. Document the process and procedure to achieve the required preparations for access to be granted and work accomplished.

2.3. Document in the preparation section all requirements for turnover of the equipment to maintenance and return from maintenance to operations.

3. Safety

3.1. This section could be called Health, Safety and Environment or some other similar heading. The work instructions must contain any known or anticipated safety hazards and the methods required to mitigate the hazard. Check the operations and maintenance manuals for any hazards specific to the equipment or the function to be performed.

3.1.1. Permits; list any permits required

3.1.2. PPE; list any required PPE

3.1.3. LOTO; ensure all necessary LOTO's have been implemented

3.1.4. Environmental Toxins; specify any potential environmental hazards and how to mitigate the hazard (wipe up spills, dispose of hazardous material properly (list where/how if known)), do not allow toxin to enter the drain system etc. Specific toxin must be listed and supporting MSDS's referenced.

3.1.5. JHA's (Job Hazard Analysis); reference the JHA's for the equipment. If no JHA's are available, utilize the JHA thought process to ensure all hazards are contemplated and reflected in the final document.

3.1.6. Automation; highlight any special provisions for work being done to equipment with interlocks, protective devices and other special safety considerations.

4. Materials and Equipment

4.1. List all the tools and materials needed to perform the task. These may include, torque wrenches, specific hand tools, rags, buckets, machine parts specific to the task etc.

4.1.1. Include all precision tools and equipment required to en sure precision techniques are applied.

4.2. List any equipment specific tools required for the task such as rigging, lifting devices etc.

5. Procedure

5.1. Provides the necessary details, and may be formatted to align with appropriate site-specific documentation.

6. System Turnover

6.1. List all steps to be performed before turnover of the system to the owner. This will include removal of all LOTOs, closing out any permits, ensuring all guards and other safety features removed during the course of maintenance have been replaced etc.

6.2. It may also include pressure-testing fittings, starting pumps and motors to ensure they are installed correctly.

7. Theory of Operation

7.1. It is strongly recommended to document the Theory of Operations supporting the Work Instruction or SOP. This provides in depth description of how the equipment works and can be helpful when Technicians are maintaining or troubleshooting the equipment.

7.2. The information for the theory of operation will come from the operations manual or perhaps the OEM's website. Some clients have a large collection of information on their websites dealing with their equipment and products. This can be a great source of information.

7.3. This section can be placed either in the body of the SOP or as an appendix.

8. Definitions

8.1. This section can be placed in the body of the SOP but is usually an appendix.

8.2. List the definitions of all acronyms and technical terms used in the SOP.

9. List of Spare Parts

9.1. This can be found in the turnover package or the results of an FMEA or RCM Analysis. It can be of use to the purchasing department or maintenance personnel when ordering parts. It can be helpful when writing the procedure to obtain the proper name for the replacement parts.

9.2. This section may be placed in the body of the SOP or as an appendix.

10. Roles and Responsibilities

10.1 This section is typically Client specific to ensure the SOP or Work Instruction is properly used for maintenance. This section should document the Owner of the document, Individuals responsible for implementing the contents of the SOP or Work Instruction and any special requirements to accomplish the work.

11. Appendices

11.1. The content of the Appendices can vary significantly and each Client will have their input.

11.2. One critical question is whether the Appendices will be considered a Controlled Document.

12. Documentation

12.1. Revisions including the date, reason for revision and approval process must be managed and maintained. Often this is at the end of the document prior to the Appendices.

13. References

13.1. All sources of information used to prepare the SOP or Work Instruction should be listed in this section.

Summary

Work instructions are to provide concise instruction to the maintenance personnel, while ensuring regulatory compliance and meeting the unique needs of the pharmaceutical manufacturer. Work instructions should not, however, be viewed as obligatory documentation to be executed in addition to everyday maintenance activities: these detailed work instructions should instill a culture of inspiration with a focus on precision work. Precision tools and techniques – that improve the Technician's skills and understanding of the work they are doing – should be integrated within the Work Instruction to cultivate this culture of inspiration within the facility. As procedure-based systems become more commonplace, and regulatory demands veer away from craft-based maintenance programs, the inevitable consequence will be the development of these detailed, repeatable Work Instructions. Developed as part of a robust maintenance plan, Work Instructions – incorporated with Technician Training and appropriate analyses to define the system-specific, critical maintenance activities – are fundamental in developing a successful maintenance program. In this highly-regulated industry, Work Instructions lay the groundwork for precision maintenance, and even in light of this tight control, Work Instructions may work to inspire those willing enough to follow.

Keywords

Asset Reliability
Best Practices
Culture Change
Compliance
Maintenance Employees
Employee
Living Program
Maintenance Improvement
Personnel
Performance
Performance Improvement
Practices
PM Effectiveness
Precision Maintenance
Proactive Maintenance
Productivity
Work Sampling
Workforce
Wrench Time
Utilization
Training
Skills

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Evolving from Craft Based To Procedure Based Maintenance

Marie Getsug is the Maintenance and Reliability Technical Lead at CAI. She was instrumental in launching and is currently the Chair of the SMRP (Society for Maintenance and Reliability Professionals) Pharma and Biotech SIG (Special Interest Group). She has been the Maintenance or Reliability Manager for four Fortune 100 Companies during 10 of her 25 years in Manufacturing. Marie is a manufacturing and supply chain professional with emphasis in reliability and experience leading high performance work teams and systems to excellence, demonstrating world-class results by building a culture of inspiration, motivation and collaboration. Marie excels with the opportunity for growth to lead change initiatives such as changing maintenance from reactive to proactive and building new processes or facilities. She thrives on changing the culture of a facility with Lean strategies like New Work Systems (NWS), Reliability Centered Maintenance (RCM), Theory of Constraints (TOC), and Total Productive Manufacturing (TPM), and sustaining manufacturing plants through innovation.

Marie holds a B.S. Chemical Engineering from University of Wisconsin, Madison and holds the following professional certifications:

- Certified Maintenance and Reliability Professional (CMRP), SMRP
- Certified Maintenance and Reliability Technician (CMRT), SMRP
- Certified Project Management Professional (PMP), PMI
- Reliability Centered Maintenance II Facilitator, Aladon Network
- Certified Thermographer – Level One, Infraspection Institute
- Certified Vibration Analyst – Level One, Mobius Institute
- Certified Machine Lubrication Technical – Level One, ICML

Patrick Wagner is a degreed biologist, and Project Manager with BCforward. His background is deeply rooted in the sciences, with undergraduate and graduate degrees in Biology from DePauw University and Purdue University. Now working to manage IT initiatives in regulated industry, Wagner's background in scientific investigation, paired with regulatory experience and an interest in technical writing have prepared him well for a pharmaceutical career.

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Carolina-South Atlantic Chapter

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The ISPE CaSA Chapter produces six e-newsletters per year. ISPE CaSA sends out the newsletters via e-mail and via Web link to all of our Chapter Members throughout the Southeastern U.S., which reach top-notch pharmaceutical, biotechnology, and bio-science professionals and managers. These newsletters are also posted on our Web site so your ad can be accessed by interested visitors to our site.

The cost for a full color business-card-sized ad is $750 per year. There is also the ability of positioning your ad on the front page of the newsletter for an additional $750 per year for six issues. Space limits the number of front page to only four, and is offered to the first four paid advertisers on a first-come, first-served basis.

Also, if you would you like to have your targeted customers go directly to your website by simply clicking on your ad; a hot-link can be added to your submitted ad file for an additional $500.00 for the entire year.

You may choose one of the special offers below: :

- $1,500 Full-color ad for six issues on the front page of each newsletter ($250/issue)
- $1,500 Full-color double-sized ad for six issues ($250/issue)
- $ 750 Full-color ad for six issues ($125/issue)
- $200 Full-color ad in 1 newsletter of your choice
- $500 Adding a hot link for directing customers to your website by a simple click

We hope you will take advantage of these opportunities and advertise in the 2015 ISPE CaSA e-newsletter.

To reserve a placement of your ad for 2015 please contact the ISPE-CaSA Headquarters at 919-573-5442 or via e-mail at info@ispecasa.org. Deadline for 2015 advertisers to be in the February 2015 issue is January 23.

You will be notified via e-mail or telephone when your advertisement has been accepted by the ISPE-CASA Newsletter Committee and asked to submit your advertisement digitally.
Full-color business card-sized ads (3.5” x 2”) may contain your logo or other artwork. Artwork should be sent directly to newsletter@ispecasa.org.

We ask that your text be no smaller than 12 pt so that the text is easily readable in the electronic format. PDF, JPEG, or TIF formats, are easiest for us to work with. Space is limited, sign up today!

Carolina-South Atlantic Chapter

Connecting a World of Pharmaceutical Knowledge

Electronic Media ISPE-CaSA.org

Now you can reach www.ispe-casa.org audience by advertising on our website. A limited number of advertising spots are now available so don't delay. Contact the ISPE Carolina-South Atlantic Chapter to reserve your space.
(Please note: ISPE-International-forbids website ads on our chapter's home page, so they are on subsequent web pages.)

To learn more about this opportunity, contact Penney De Pas, Chapter Manager, at 919-573-5442 or pdepas@ispecasa.org. If you are interested in signing up for the program, please complete the form and return to pdepas@ispecasa.org or fax 919-787-4916. Advertisements are sold on a first-come first-served basis.

SPECS OF ADVERTISEMENT:

Top Placement Ad 120 pixels wide by 240 pixels high; File formats accepted: .GIF, .JPG, .SWF
Bottom Placement Ad 240 pixels wide by 400 pixels high; File formats accepted: .GIF, .JPG

	12 months	6 months
240 x 400 Vertical Rectangle	$500	$300
120 x 240 Vertical Banner animated	$400	$250
120 x 240 Vertical Banner - non animated	$300	$200

- ☐ 240 x 400 Vertical Rectangle ad 6 Months, $300
- ☐ 240 x 400 Vertical Rectangle ad 12 Months, $500
- ☐ 120 x 240 Vertical Banner animated ad 6 Months, $250
- ☐ 120 x 240 Vertical Banner animated ad 12 Months, $400
- ☐ 120 x 240 Vertical Banner - non animated 6 Months, $200
- ☐ 120 x 240 Vertical Banner - non animated 12 Months, $300

Name: _____ Member #: _____
Company: _____
Title: _____
Address: _____
City: _____ State: _____ Zip: _____
Tel: _____ Fax: _____
Email: _____
PAYMENT TYPE: ☐☐Visa ☐☐MasterCard ☐☐AMEX
Or ☐☐Check (Payable to: ISPE-CASA)
Card #: _____ Expiration Date: _____
Cardholder Name (as it appears on card): _____
Cardholder Signature: _____

ISPE CaSA Chapter E-Newsletter Ads

Newsletter Ads Work for Your Business!

Our Chapter produces six e-newsletters per year, and we depend on the support of our advertisers. We send out the newsletters via e-mail and via web link to all of our Chapter Members throughout the Southeastern U.S.

That means you get targeted access to top-notch pharma, biotech, and bio-science professionals and managers. These newsletters are also posted on our website so your ad can be accessed by interested visitors to our site.

Best of all, the cost is only $750 for your full color, business-card-sized ad for six insertions. That's only $750 for targeted advertising in full color for an entire year!

Ask About HOT LINKS!!

Would you like to have targeted customers simply click on your ad and get right to your website?

A hot-link can be added to your ad, connecting readers directly to your company website for an additional $500.00 for a whole year.

If you are interested in advertising with the ISPE CaSA e-newsletter, please contact our Chapter headquarters at:

ISPE-CaSA
1500 Sunday Drive
Suite 102
Raleigh, NC 27607
919-573-5442
info@ispeCaSA.org

You will be notified via e-mail or telephone when your advertisement has been accepted by the ISPE CaSA Newsletter Committee and asked to submit your advertisement digitally.

Full-color business card-sized ads (3.5" x 2") may contain your logo or other artwork. Artwork should be sent directly to info@ispeCaSA.org.
We ask that your text be no smaller than 12 pt so that the text is easily readable in the electronic format. PDF, JPEG or TIF formats are easiest for us to work with. Space is limited, sign up today!

ISPE Carolina-South Atlantic Chapter Newsletter

1500 Sunday Drive, Suite 102, Raleigh, NC 27607
Tel: 1-919/573-5442 • Fax: 1-919/787-4916
rich.stanfield@cagents.com

EDITORIAL POLICY

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.) Manuscripts should be forwarded to a Member of the Communications Committee at rich.stanfield@cagents.com for review 30 days prior to publication. A brief three to four sentence synopsis of the article, as well as a brief biographical statement about the author that includes educational background, title and job affiliation, job responsibilities and major areas of accomplishment must accompany the article.

Got News?

Send it to: rich.stanfield@cagents.com

Entries should be brief and be of general interest to the readership.
Entries must include a name and telephone number for verification purposes.
We reserve the right to edit and select entries.

A word to the ISPE CaSA Newsletter advertisers:

Thank you all for your continued support. Without it we could not have the wonderful support staff to get our ISPE CaSA Members the news in such a timely and professional fashion. If you have updates to your advertisements or find any other error, please contact us so that we can serve you better.