ISPE® | Carolina-South Atlantic Chapter *presents*

LIFE SCIENCES TECHNOLOGY CONFERENCE

MARCH 14, 2017 | 10:00 AM - 7:00 PM
RALEIGH CONVENTION CENTER

RALEIGH, NC

25 YEARS 1992-2017
ISPE® Carolina South Atlantic Chapter

ISPE® | Carolina-South Atlantic Chapter

presents

LIFE SCIENCES TECHNOLOGY CONFERENCE

MARCH 14, 2017 - RALEIGH, NC

Monday, March 13, 2017

4:00pm-8:00pm	**Exhibitor Entrance for Set-Up** *RCC Front Entrance at Salisbury Street, or Loading Dock off Lenoir Street*
4:00pm-8:00pm	**Exhibitor Registration & Set-Up** *Level 4 – Ballrooms A, B & C*
5:00pm-8:00pm	**Talk & Tour at Catalent**
5:00pm-8:00pm	**Talk & Tour at Medicago**
4:30pm-7:00pm	**Exhibitor Reception & Student Poster Display** (Judging starts at 6:00pm) *Level 4 – Ballrooms A, B & C*

Tuesday, March 14, 2017

7:00am-8:30am	**Exhibitor Entrance for Set-Up** *RCC Front Entrance at Salisbury Street, or Loading Dock off Lenoir Street*
7:00am-8:30am	**Exhibitor Set-UP** *Level 4 – Ballrooms A, B & C*
7:00am-8:30am	**Exhibitor Registration** *Level 4 – Ballroom Lobby*
7:30am-9:30am	**Past Presidents Breakfast** (by invitation only) *Glass Room*
7:30am-9:30 am	**Continental Breakfast** *Level 4 – Ballroom Lobby*
8:30am-5:00pm	**Exhibit Hall Open** *Level 4 – Ballrooms A, B & C*
8:00am-5:00pm	**Attendee Registration** *Level 3 – Salisbury Street Entrance*
9:00am-10:00am	(206) NC BIOMANUFACTURING & PROCESS DEVELOPMENT: Allogeneic Cell Therapy Vaccines for the treatment of Cancers
9:00am-10:00am	(301A) IP COP: Revolutionary Medication Management
9:30am-9:45am	**General Session Kick-Off** *Rooms 302 A, B, & C*
10:00am-10:45am	**Educational Sessions I** *Level 3 Classrooms, Rooms 302 A, B & C* • (206) NC BIOMANUFACTURING & PROCESS DEVELOPMENT: Allogeneic CAR-T Cell Therapy Manufacturing • (301A) IP COP: 3D Printing in Pharmaceuticals – Patient-Specific Care With Shortened Supply Chain • (301B) MANUFACTURING OPERATIONS: Engineering Human Competency: The First Step Toward Operational Excellence • (302 A, B, & C) WOMEN IN PHARMA: Women Influencing the Industry – A Local Perspective on Developing Your Journey • (303) DEVICES & EQUIPMENT: CLEANING: Strategies for Cleaning and Cleaning Validation that Minimize Downtime for Product Changeovers • (304) FACILITY OF THE FUTURE: Rapid Compounding of Drug Substances into Semisolid Matrices – One Patient at a Time • (306C) FDA: Using Statistical Analysis in place of re-qualification testing for CTUs • (402) STUDENT/YOUNG PROFESSIONAL CAREER DEVELOPMENT: Traveling Down Your Career Path – Lessons Learned Along the Way
11:00am-11:45am	**Educational Sessions II** *Level 3 Classrooms* • (206) NC BIOMANUFACTURING & PROCESS DEVELOPMENT: Nanoparticle and Microparticle Manufacturing Using the PRINT® Platform: Enabling Novel Products in the Life Sciences and Beyond • (301A) IP COP/CROs: Delivering Superior Service to Clinical Sites and Patients • (301B) ENGINEERING: Enhancing Compliance Through Innovative Approaches to Commissioning & Qualification/Validation (CQV) of Automation, Facilities, Utilities & Equipment Systems used in Biologics Manufacturing • (302 A, B, & C) WOMEN IN PHARMA: Women Influencing the Industry: A Local Perspective on Developing Your Journey • (303) DEVICES & EQUIPMENT-CLEANING: Feasibility Testing, Cycle Development and Validation Guidance of VHP Low Temperature Surface Terminal Sterilization for Pharmaceutical Packaging Process • (304) FACILITY OF THE FUTURE: Seeing the future – A Review of the ISPE 2016 Facility of the Future Conference • (306C) SERIALIZATION: Lifecycle Approach to Serialization Process Qualification • (402) STUDENT/YOUNG PROFESSIONAL CAREER DEVELOPMENT: Enhancing Your ISPE Experience
11:30am-1:00pm	**IAC Executive Luncheon** (by invitation only) *Room 307*
11:30am-1:00pm	**Lunch for Attendees, Exhibitors and Guests** *Level 4 – Ballroom Lobby*
1:10pm-2:00pm	**General Session-Keynote Address & Recognition of ISPE-CaSA Past Presidents** *Room 302 A, B & C*
3:00pm-3:45pm	**Educational Sessions III** *Level 3 Classrooms* • (301A) IP COP: Investigational Products and the Academic Health Care System – A Dynamic Integration • (301B) ENGINEERING: How to Structure the Execution of the World's Largest Biotech Project • (303) INFORMATION MANAGEMENT SYSTEMS: Data Security in the Cloud for Life Sciences • (304) FACILITY OF THE FUTURE: Transitioning from Low to High Density Mammalian Cell Culture Clarification within Existing Manufacturing Infrastructure • (306C) BIOTECH: From College to the Real World: How Our Senior Projects Prepared Us for Biotech Facility Design • (307) DEVICES & EQUIPMENT-CLEANING: Optimizing Plant Performance with Unique Mixproof Valves • (402) STUDENT/YOUNG PROFESSIONAL CAREER DEVELOPMENT: Data Integrity 101
5:00pm-7:30pm	**Evening Reception** *Level 4 – Ballroom Lobby*

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Special Thanks to Our Corporate Sponsors

Welcome to the 24th Annual ISPE-CaSA Life Sciences Technology Conference

The ISPE Carolina South-Atlantic Chapter Technology Conference Committee is pleased to present the 24th Annual ISPE-CaSA Life Sciences Technology Conference at the Raleigh Convention Center in beautiful downtown Raleigh, N.C.

On behalf of the committee, I would like to welcome you as we celebrate and enjoy our chapter's largest annual event.

We are fortunate to have with us Nick Valvano, from the Jimmy V Foundation as our keynote speaker. The Jimmy V Foundation has awarded over $170 million to fund cancer research. Please be sure to purchase raffle tickets, bid in the silent auction or purchase additional chips for Casino Night to support The Jimmy V Foundation.

Throughout the day, please take advantage of the many opportunities you will have to visit with a vast array of exhibitors, participate in leading edge training sessions, and explore opportunities for young careerists, who represent the future of our profession.

One of the most valuable aspects of this Technology Conference is the opportunity to network with the best talent our industry has to offer and to enjoy greeting longtime colleagues, while making new connections.

Be sure to visit our CaSA Pavillion area, where our corporate and manufacturing exhibitors are eager to showcase their latest products and to update you on their most recent developments. This year we have a variety of manufacturers represented.

Your interest and participation, personal involvement, and continued desire to learn more about the life sciences industry has enabled ISPE-CaSA to grow successfully, and we are proud to present our industry's best and brightest speakers, exhibitors, and participants at this Technology Conference and other ISPE-CaSA events. Whether you represent a manufacturer, a service provider, industry supplier, or you are joining us as an individual attendee, we are so excited you are here.

Over the last two decades, ISPE-CaSA has developed outstanding educational programs, and this year is no exception. Thanks to the hard work and vision demonstrated by the Education Subcommittee, led by Jennifer Clark, we are pleased to introduce a diverse panel of pharmaceutical and biotech company representatives, as well as suppliers and service providers to lead our classroom presentations today. These local, national, and international leaders are responsible for implementing innovative technologies, compliance, and quality standards, and they are poised to give you the latest industry updates.

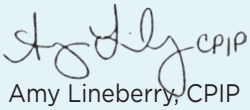
When the educational programs end, and the exhibits wind down, the conference is still far from over. We have scheduled plenty of time for you to meet up with your colleagues to discuss your favorite program sessions, exchange business cards, and make plans to stay connected.

As the conference concludes, the ballroom lobby will come to life with the Casino Night, back by popular demand, featuring heavy hors d'oeuvres and a cash bar. Be sure to end your day of exhibit touring and class participation by visiting and socializing with your friends and colleagues.

The Technology Conference Committee would like to thank the ISPE-CaSA Board of Directors, led by Chapter President Lisa Kerner. We appreciate our board's guidance and are grateful to those directors who have also served on our conference committee. They bring continuity and consistent quality to our event. I would also like especially to thank Jim Hubbard; Jim's help with the Conference has been invaluable to the Committee and me. More than a dozen members of the Tech Conference Committee have provided countless hours to planning, organizing, and recruiting speakers and to producing this conference. I am grateful for their service and commitment to the Conference. As I complete my last year as Chair I know the Conference is in very capable hands.

Each year we strive for improvement over our previous conferences, and we make sure to repeat our successes. Please complete the online survey we offer and let us know your thoughts and ideas. Comments and suggestions are your way to give us feedback and guidance for planning future events. Our goal is continually to improve your experience as an exhibitor and as an attendee.

Thank you for your support and participation, and don't forget to enjoy the conference.



Amy Lineberry, CPIP
2017 Committee Chair

Join Us in Celebrating CaSA's 25th Anniversary

A message from ISPE-CaSA President Lisa Kerner

On behalf of the ISPE-CaSA Board of Directors, welcome to our 24th Annual Life Sciences and Technology Conference, where we offer our signature expo featuring the pharmaceutical industry's latest, cutting-edge technology along with presenters who will offer insights into the latest industry innovations.

We are also celebrating the CaSA Chapter's 25th Anniversary and today we honor our past presidents for their substantial donation of time and talent through the years. ISPE-CaSA is one of the nation's top chapters, thanks to the visionary leadership and hard work of our past presidents.

Our conference and trade show continue to grow. We especially are pleased to welcome a number of manufacturing partners, giving you a chance to network with representatives of some of the most exciting pharmaceutical companies in the United States.

In addition to a full complement of business partners on our trade show floor, a variety of corporations have contributed to the success of our conference through generous sponsorships and overall participation.

We are happy to announce our charity partner this year is the V Foundation for Cancer Research, founded by ESPN and legendary basketball coach Jim Valvano. Coach Valvano, who died of cancer in 1993, had a dream – to achieve victory over cancer. Now in its 24th year, the V Foundation has awarded over $170 million in cancer research grants nationwide and has grown to become one of the premier supporters of cutting-edge cancer research funds.

This year's conference brings you more topics than ever before. Together we will explore the Facility of the Future, Women in Pharma, topics in Devices and Equipment, and Biomanufacturing & Process Development. In addition, we are offering special programming for students and young professionals.

During today's events, we invite you to engage with your friends, colleagues, industry representatives, and expert speakers.

We offer you an opportunity to refresh your knowledge base and explore new ideas and processes through our enlightening educational sessions, and we hope you will find opportunities to grow your business and reach your career aspirations through the professionals you meet, the classes you attend, and the lessons you learn.

ISPE-CaSA's Annual Life Sciences and Technology Conference may be our largest and most far-reaching event, but it is not our only program. Your CaSA committees, along with the board of directors, are dedicated to building excellent educational programs and networking opportunities all year long.

If you are not a member of ISPE-CaSA, we encourage you to join our chapter and experience the best of what we have to offer. We are pleased to welcome representatives from ISPE's national headquarters who will be happy to share the benefits of membership at a global level.

I personally want to thank our conference chair, Amy Lineberry, and the entire Technology Conference Committee for the great job they have done to produce this exciting event. The committee, along with our staff has spent hundreds of hours preparing for the conference, and they continue to raise the bar to reach ambitious goals benefiting our entire organization and the industry we represent.

The ISPE-CaSA Technology Conference provides an excellent foundation for you to network, expand your knowledge, and improve your business.

Thank you for joining us, and I hope you enjoy the day,

Lisa Kerner
President, ISPE-CaSA Chapter

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25 YEARS 1992-2017

ISPE® | Carolina-South Atlantic Chapter

Thank you past presidents for your dedicated leadership and valuable contributions to the success of ISPE-CaSA!

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ISPE-CaSA Past Presidents

Leadership ♦ Service ♦ Dedication

Heather Denny	2014-2015
Matt H. Gilson	2013-2014
Jennifer Lauria Clark, CPIP	2012-2013
David E. Brande	2011-2012
Scott Billman	2010-2011
Mark Mathis	2009-2010
Jacqueline L. Roth	2008-2009
James W. McGlade	2007-2008
Martin E. Rock, PE, JD	2006-2007
Roy Snipes	2005-2006
Vince R. Miller	2004-2005
Alan F. Jones	2003-2004
Bo Crouse-Feuerhelm, CPSW	2002-2003
Cheryl L. Tucker	2001-2002
Marita A. King	2000-2001
Jane R. Brown	1999-2000
Mark J. Sawyer	1998-1999
Gary E. Reichelt, PE	1997-1998
Jeffery N. Odum	1996-1997
Brenda S. Carroll	1995-1996
Jeffrey J. Sieranski	1994-1995
Bert A. Carter, PE	1993-1994
Patricia Lewis	1992-1993

ISPE-CaSA Education Event Talk and Tours

Provided by:

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Catalent is the leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products.

medicago

Medicago is a leading clinical-stage biotechnology company that uses proprietary plant-based technologies to rapidly develop and produce novel vaccines and antibodies.

Thanks to Catalent and Medicago for their hospitality and informative tours.

Special Thanks to these Companies for their Generous Sponsorships of our Talk and Tour Events

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Session Descriptions

BIOTECH

3:00PM - 3:45PM

From College to the Real World: How Our Senior Projects Prepared Us for Biotech Facility Design

306C

Kevin Ventura, Process Engineer, CRB

Bryan Raborn, Process Engineer, CRB

Allan Bream, Lead Biopharmaceutical Specialist, CRB

When finishing your final semester of Chemical Engineering, it can be difficult to envision how hours of Organic Chemistry problem sets, Thermodynamics tutoring and a Senior Design project will translate to the professional world. However, in your first three years of designing Biotech facilities, you'll learn that all those late night study groups and hard work truly paid off.

As Young Professionals in the Biopharmaceutical industry, you're not only fortunate to have colleges and universities investing resources in state-of-the-art engineering education, you're graduating into a field that offers multiple technical and leadership opportunities. Asking good questions, finding a mentor and participating in professional organizations can prove to make all the difference.

DEVICES AND EQUIPMENT – CLEANING

10:00AM - 10:45AM

Strategies for Cleaning and Cleaning Validation that Minimize Downtime for Product Changeovers

303

John Hyde, Founder / Principal Consultant, Hyde Engineering + Consulting

Changeover for multiproduct organizations can be, if conducted without a holistic view of operations and product profiles, very time consuming and cost intensive. By drawing from the FDA's process validation guideline and addressing the cleaning process in a staged fashion, the necessary information for the development of a data-driven, efficient, cost effective changeover plan can be acquired.

11:00AM - 11:45AM

Feasibility Testing, Cycle Development and Validation Guidance of VHP Low Temperature Surface Terminal Sterilization for Pharmaceutical Packaging Process

303

Juha Mattila, Senior Product Manager, STERIS FINN-AQUA

This topic describes applications and operating principles of VHP (Vaporized Hydrogen Peroxide) low temperature sterilization for sensitive drug product applications, but concentrates on the process implementation steps principle, and provides guidance for feasibility testing, load cycle development and validation of such process.

3:00PM - 3:45PM

Optimizing Plant Performance with Unique Mixproof Valves

307

David Summers, ESE Commercial Manager – Valves, Equipment Division, Sanitary, Alfa Laval Inc.

Roger J. Ashton, Valve Systems Specialist, Equipment Division, Sanitary, Alfa Laval Inc.

We will discuss the use of mix-proof technologies and how to apply them in creative ways for the hygienic treatment of product manufacturing and development. Using an integrated approach, an appropriate intrinsically safe mix-proof valve system will maintain production efficiency while reducing capital costs and potential harm to the pharma product manufacturing process.

Session Descriptions continued

ENGINEERING

11:00AM - 11:45AM

Enhancing Compliance through Innovative Approaches to Commissioning & Qualification/Validation (CQV) of Automation, Facilities, Utilities, & Equipment Systems Used in Biologics Manufacturing

301B

Brian Urban, Associate Director, Quality Systems & Enterprise Management, Biogen

Robert Smith, Sr. Manager, Automation, Biogen

Tolga Musa, Associate Director, Process Engineering, Biogen

We will be presenting a new approach to commissioning and qualification/validation (CQV) for facilities, utilities, and process equipment systems in biologics manufacturing. This approach will target scientific methodologies intended to broaden the risk profile of CQV. The approach will be driven by a risk versus benefit profile (as outlined in ICH Q9 (Quality Risk Management), which will clearly define how most effectively, efficiently, and compliantly to enhance CQV activities for a new facility. The possibilities include the application and implementation of continuous verification through real-time control and monitoring of critical functionality for facility, utility and equipment systems. Essentially supporting how the biologics industry can enhance its position in providing novel therapies – through innovative CQV approaches, while maximizing the assurance of quality and compliance.

3:00PM - 3:45PM

How to Structure the Execution of the World's Largest Biotech Project

301B

Carsten Nicolai Petersen, Director, NNE

Gary Lohr, Project Director – Site Support and Deputy Site Head, Novo Nordisk

Case story from the ongoing Novo Nordisk DAPI US Project in Clayton, NC. This presentation describes how the project is structured into Work Packages with Work Package Descriptions for each sub component. How all schedules, cost, risk, etc., is broken down according to the same structure to enable efficient execution of 50 sub-projects instead of one large project. The presentation also describes how all the Work Packages are coordinated via Interface Agreements and how some Work Packages have a more central and overall coordinating role! IT WORKS WELL – IF SET UP RIGHT.

FACILITY OF THE FUTURE

10:00AM - 10:45AM

Rapid Compounding of Drug Substances into Semisolid Matrices – One Patient at a Time

304

Rick Lawless, Associate Director, Strategic Programs, NC State BTEC

Edison Hudson, CEO and Co-Founder, Panacea BioMatx, Inc; CTO & Founder, Panaceutics, Inc.

The current paradigm for cGMP manufacture of approved small molecule drugs involves centralized facilities that produce large batches of tablets, capsules, liquids, or topical ointments. The methods employed in this type of production are capital intensive and result in large inventories of drug products at each dosage level. Nonstandard dosages and/or formulations prescribed for unique medical situations are allowed under Section 503A of the Food Drug & Cosmetic Act (FDCA), but the pharmacies that compound these products typically use manual operations that are slow and susceptible to human error. In this session, we'll present a technology that uses automated equipment located at or near the point-of-care to compound individualized blends of drug substances, dietary supplements, flavorings, and/ other excipients in semisolid matrices. These personalized formulas are expected to be particularly effective for children, senior citizens, and anyone on a daily regimen of multiple drugs.

11:00AM - 11:45AM

Seeing the Future – A Review of the ISPE 2016 Facility of the Future Conference

304

Jim McGlade, Science Market Leader, BHDP Architecture

Robert Chew, President/CEO, CAI

Phil McDuff, VP, Global Engineering, Biogen

How will pharmaceutical manufacturing facilities be different in the future? Is the traditionally "slow-to-change" industry really on the cusp of revolutionary advancements? Answers to these questions will begin to take shape at ISPE's first Facility of the Future Conference being held on November 13-14, 2016.

This presentation will provide the attendees with a "Cliff Notes" version of the conference. The conference theme, "Innovating the Facilities of the Future – What's Next?", will highlight new manufacturing technologies recently

implemented or being planned by many of the industry's largest companies. The conference program includes a diverse array of industry experts who will share their best practices and benchmark solutions.

3:00PM - 3:45PM

Transitioning from Low to High Density Mammalian Cell Culture Clarification within Existing Manufacturing Infrastructure

304

Matthew Westoby, Associate Director, Biogen

Increasing cell culture densities and productivities are placing a larger burden on downstream clarification due to higher levels of solids and other impurities. Facilities and equipment designed for lower density mammalian cell culture may now have to handle cell culture processes in excess of 40 million cells/ml. To accommodate this challenge, solutions need to be identified and implemented while minimizing capital investment and impact to a facility. In this presentation, we describe an innovative approach where a centrifuge was modified to accommodate either an intermittent discharge or continuous nozzle based centrifuge design within the same processing skid. Implementation of the modified system is demonstrated at 15kL manufacturing.

FDA

10:00AM - 10:45AM

Using Stastical Analysis in Place of Re-qualification Testing for CTUs

306C

Gavin Wendel, Senior Validation Specialist, Pfizer

During a 2013 MHRA routine GMP inspection of the Pfizer Sanford site, the following observation was issued regarding controlled temperature units (CTUs): "The thermometric assessment of cold storage devices was deficient in that there was no periodic requalification plan in place." At this time new CTUs were qualified for use following their installation, but afterwards the monitoring of temperature and other environmental conditions was solely performed by the DeltaV distributed control system, which monitors environmental conditions in a single, fixed place. Re-qualification testing following the initial qualification method was not performed. Having received this observation, it was quickly concluded that performing re-qualification testing on nearly 200 CTUs was both impractical and prohibitively costly. Instead, a method was developed and implemented whereas DeltaV data collected was evaluated using statistical analysis to look for signs of system degradation where only those CTUs which exhibited signs of decline were tagged out-of-use and retested.

INFORMATION MANAGEMENT SYSTEMS

3:00PM - 3:45PM

Data Security in the Cloud for Life Sciences

303

Jeff Miller, IS Department Manager, Avid Solutions, Inc.

Cloud-based computing offers significant advantages over traditional private data centers for business applications. These advantages include: (1) massive scalability, (2) ability to rapidly increase and decrease computer resources as needed, (3) typically a "pay as you go" contract philosophy that allows you to pay only for the resources you use, and (4) user self- provisioning of resources as needed.

However, one of the big questions is: 'How secure is the cloud computing environment?' Life Sciences companies in particular are extremely sensitive about their process and manufacturing data due to regulatory compliance and proprietary drug substances. As a result, these companies have been very slow in adopting cloud-based computing for their business operations. However, more and more companies are establishing data warehouses and performing data analytics on their manufacturing information. As this wave of Big Data proliferates, the advantages of cloud computing become ever more valuable.

Session Descriptions continued

IP COP

9:00AM - 10:00AM

Revolutionary Medication Management

301A

Ali Abdulhay, Full Stack Engineer and COO, Digidose LLC

With WiFi/4G and Bluetooth compatibility, the digidose pill dispenser and home health hub boasts an array of features and the ability to store up to a 90 day supply of 8 different medications for dispensing in both clinical and home environments.

10:00AM - 10:45AM

3D Printing in Pharmaceuticals – Patient-Specific Care With Shortened Supply Chain

301A

Peter Denmark, Director of Sales - Americas - MCAD, Envisiontec

This topic provides an understanding of 3D printing and the market. Gain insight into how 3D printing touches the pharmaceutical industry and its affect on the supply chain.

11:00AM - 11:45AM

Delivering Superior Service to Clinical Sites and Patients

301A

Greg Hottell, Director, GSK

Ensuring high service levels to clinics and patients in a highly uncertain environment places a strain on any clinical trial supplies organization. A recent survey by CenterWatch Monthly (March 2015) has highlighted that performance among Pharma sponsors is varied with some of those sponsors scoring higher marks. This session explores how one sponsor (GSK) was able to significantly improve its performance from the 2013 survey and achieve top-tier results in 2015. The session includes (1) an overview of the CenterWatch survey and a summary of results, (2) specific examples of improvement activities undertaken at GSK, and (3) an overview of lessons learned during the improvement journey.

3:00PM - 3:45PM

Investigational Products and the Academic Health Care System – A Dynamic Integration

301A

Gregory Westby, Clinical Compounding Pharmacist, Duke University Health System

This presentation will give an overview of the management of investigational products (IP) used for clinical research within an academic health care system. Accreditation standards and institutional polices will be reviewed to support the unique pharmacy practice niche of the Investigational Drug Service (IDS) while adhering to good clinical practice, United States Pharmacopeial Convention (USP) guidance, and state and federal regulations. Essential IDS services and current challenges will be highlighted. Examples of investigational products and respective safety concerns as well as collaborative strategies for IP packaging and masking will be reviewed.

MANUFACTURING OPERATIONS

10:00AM - 10:45AM

Engineering Human Competency – The First Step Toward Operational Excellence

301B

Richard Tree, Vice President, Commissioning Agents, Inc.

Shane Kelly, Maintenance Systems Manager, Shire

It seems obvious to the average reader that competent humans are necessary to achieve operational excellence. Unfortunately, in the life sciences industry, many companies tend to focus on simply maintaining minimum levels of proficiency rather than on improving human competency. Greenfield startup projects are particularly susceptible to not meeting the minimum standards needed to start up a facility because they often have to staff their operation with a wide range of competencies and experience - all the while dealing with construction-related problems that tend to take center stage day in and day out. What steps should a firm take to avoid problems of human competency? This presentation includes lessons learned from a recent Greenfield project.

Session Descriptions continued

NC BPD

9:00AM - 10:00AM

Allogeneic Cell Therapy Vaccines for the Treatment of Cancers

Room 206

Jeff Hutchins, PhD - Chief Scientific Officer and Senior Vice President of Preclinical Development, Heat Biologics, Inc.

Heat Biologics, Inc. is developing whole cell therapy products as immunotherapies for the treatment of cancer. Heat Biologics' ImPACT™ technology transforms living allogeneic human cancer cell lines into miniature osmotic pumps that continually secrete cancer antigens in order to activate and educate the patient's own immune system to better recognize and destroy cancer cells. Immune response data obtained during our Lung Cancer (NSCLC) and Bladder cancer (MIBC) clinical trials strengthen support for the vaccine mechanism-of-action and clinical proof-of-concept for antigen specific immune activation. Although the development of live cell therapies represents a different set of challenges for CMC compared with therapeutic proteins and traditional vaccines, Heat Biologics' off-the-shelf and ready-to-use technology offers a straight forward CMC development pathway through to registration and a cost-effective commercial platform.

10:00AM - 10:45AM

Allogeneic CAR-T Cell Therapy Manufacturing

206

Kim Nguyen, Director, Process Development, Precision Biosciences

Manufacturing of cell-based therapies (e.g. CAR T-cell products) is not new, but in comparison to monoclonal antibodies the field is in a much less evolved state. The paradigm of "the process is the product" is still largely the case, as better analytical methods to characterize products and to understand how processing conditions may impact the product are needed. An absolute need exists to decrease manufacturing costs to enable these breakthrough therapies to reach more patients. Process intensification to shorten process durations and increase manufacturing efficiency is required. Extensive use of automated systems can help to achieve lower manufacturing costs while also reducing lot-to-lot variability. Precision Biosciences' current manufacturing strategy for allogeneic CAR-T cells will be presented, along with future thinking on bioanalytics, decreasing COGs, process intensification, and automation in CAR-T cell biomanufacturing.

11:00AM - 11:45AM

Nanoparticle and Microparticle Manufacturing Using the PRINT® Platform: Enabling Novel Products in the Life Sciences and Beyond

Room 206

Derek Schorzman, Executive Director, Manufacturing Sciences, Liquidia Technologies, Inc.

Description: Over the next decade, nanotechnology has the potential to influence virtually every aspect of our lives, including our energy, food, water, buildings, and medicines. However, in order to realize this broad potential, robust, cost-effective, regulatory-friendly manufacturing technologies will be required. Through its novel technology platform and expansive intellectual property, Liquidia is poised to be a leader in the development of nanotechnology-based healthcare products and a catalyst for the growth anticipated across this industry. By leveraging fabrication techniques from the semiconductor industry, Liquidia has the ability to rapidly design and manufacture precisely engineered particles of virtually any size, shape, or composition. This unique ability to precisely engineer particles enables scientists to explore new product frontiers that, until now, have otherwise been out of reach. Using the company's proprietary PRINT® Platform, Liquidia is creating precisely engineered vaccines and inhaled therapeutics that address critical unmet patient needs.

SERIALIZATION

11:00AM - 11:45AM

Lifecycle Approach to Serialization Process Qualification

306C

Wendy Haines, PHD, Project Manager, Mangan Biopharm

John R. Hodge IV, Project Manager, Mangan Biopharm

The ultimate goal of serialization is prevention of counterfeit or altered drugs from entering the market by securing the supply chain from which products are produced. Each unit sold will have a standardized numerical identification (SNI) accompanied by e-Pedigree certification. The serialized data will also be available to regulatory bodies. This process should provide accountability across supply chains for items used to manufacture drug products.

There are challenges in the development of a serialization program related to the increasingly blurred lines between manufacturing systems and IT systems. Companies that have kept these areas distinct may face unexpected

scenarios in the integration of line-level equipment to enterprise-level off-site networks.

Companies need to evaluate current business state and supply chain relationships: determine handling of data management, how an item will be tracked and traced, and be proactive about serialization needs.

Come hear several successful serialization implementation case studies for major pharmaceutical/ biotechnology companies.

STUDENT/YOUNG PROFESSIONAL CAREER DEVELOPMENT

10:00AM - 10:45AM

Traveling Down your Career Path - Lessons Learned Along the Way

402

David Yarley, Director of Training and Development, Fujifilm Diosynth Biotechnologies

As you travel down your career path, you will discover that technology will change, but what carries you down the path will be a maintaining of your personal integrity and your ability to develop and sustain communication, learning and adapting skills. This presentation will present ways of developing these skills within the pharmaceutical industry. Other related skills will be discussed such as the ability to work as part of a team, keeping abreast of regulations, knowing the proper route to make changes, respecting others' roles and responsibilities, continuous learning and the importance of gaining experience in operations (manufacturing). If you are beginning your journey fresh out of school or making a career change from another industry, you should find these lecture topics both beneficial and timely.

11:00AM - 11:45AM

Enhancing Your ISPE Experience

402

Ken Ewan, Leadership Coach, KME Leadership, LLC

The Young Professional's COP consists of those born between 1980 and 2000, commonly referred to as Millennials. They will soon represent the largest chunk of the American workforce and make up a significant component of the membership and future leadership of ISPE. Regardless of whether our members are leading a technical team, a capital project, an internal company initiative, a committee, or a chapter of ISPE, their growth, both as technical contributors and as leaders, will have an impact on the success of the Society. The ability of these young professionals to take advantage of education and networking opportunities like the Tech Show can be enhanced with guidance from experienced professionals. This discussion will help the young professionals understand the opportunity and develop a plan to optimize their personal investment in ISPE.

3:00PM - 3:45PM

Data Integrity 101

402

Marisol Patino, Process Engineer, Sartorius Stedim Biotech

Data integrity has always been critical in the manufacturing of GMP compliant pharmaceuticals and medical devices but has gained much momentum over the last several years. The FDA released a guidance just last year around the fundamentals of data integrity, highlighting its importance. Join an interactive session geared towards students and entry level professionals in the pharmaceutical industry.

WOMEN IN PHARMA

10:00AM - 10:45AM and 11:00AM - 11:45AM

Women Influencing the Industry: A Local Perspective on Developing Your Journey

302ABC

Christa Myers, Senior Pharmaceutical Engineering Specialist, CRB

Jennifer Lauria Clark, Executive Director of Strategic Development, Commissioning Agents, Inc.

Heather Denny, President and CEO, McDonald York Building Company

Addie Anderson, StrengthsFinder Coach; Lead Process Engineer & Project Manager, Associate, CRB

Megan Crum, Plant Engineer, Maintenance, Biogen

Cathy Middleberg, Pfizer

"I know a little something about a woman in a man's profession," was presumably first spoken by Queen Elizabeth during her reign from 1558 - 1603. Now, however, a growing number of women are making their marks in the biopharma industry, paving the way for generations to come so that people won't think "man" when they hear the word "engineer."

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Speaker Bios

Ali Abdulhay

Ali Abdulhay is a Full Stack Engineer and COO of Digidose LLC

Addie Anderson

Addie Anderson is a certified Gallup StrengthsFinder Coach and her top 5 strengths include: arranger, relator, analytical, responsibility and harmony. In addition to leading CRB's StrengthsFinder efforst, Addie has served as a Project Manager and Lead Process Engineer for 16 years. Addie has extensive knowledge with scaling ultrafiltration and depth filtration equipment, and specifying and procuring process modules. Recent project experience includes managing facility upgrades for ethanol-based processing, studies on hydraulic and vaccum systems and dust collection, and several small projects including fermentation, recovery, purification, chemistry and buffer distribution modifications.

Roger J. Ashton

Roger Ashton has 48 years' experience in beverage, dairy, food, pharmaceutical and personal care industries and is tenured with Alfa Laval's valve division. Throughout his career, Roger has worked with many types of valve systems and applications with innovative companies which include Tri-Clover and G&H Products Corp. For 24 years, Roger's main focus at Alfa Laval is mix-proof and diaphragm valves, the process and mix-proof valve applications. Since the mid 1990's, he's been instrumental in bringing Alfa Laval mix-proof valve models to market in conjunction with Alfa Laval's research and development teams in Kolding, Denmark. Roger holds a degree in Mechanical Design from Gateway Technical Institute and is based in Kenosha, WI.

Allan Bream

Allan Bream has more than 30 years of engineering and manufacturing experience including 25 years in the biotechnology industry. His expertise encompasses large-scale bacterial fermentation, mammalian cell culture, vaccines, downstream processing, protein purification and immobilization, and GMP facilities design, operations and assessment.

Allan's facilities experience includes all phases of process design including master planning, conceptual and detailed design, construction services and equipment procurement across the United States, Puerto Rico, Europe and Asia. His experience also includes BL2-LS and BL3-LS facility design projects.

Robert Chew

Robert Chew is President and CEO of Commissioning Agents, Inc. Commissioning Agents is a leader in helping companies achieve faster project delivery and higher levels of performance and reliability from their GMP-regulated manufacturing operations. The company has operations in North America, Europe, and Asia.

Robert is an internationally recognized consultant to the pharmaceutical and biotechnology industries, focusing on capital project delivery, manufacturing operations, and regulatory compliance. Over the past two decades, he has spoken at international conferences in the US, Europe, Asia, and South America to promote innovation in GMP-regulatory compliance and operational excellence. He is a member of the Global Pharmaceutical Manufacturing Leadership Forum. Mr. Chew served on ISPE's International Board of Directors from 2004 – 2007 and was the society's 2008 Member of the Year.

Robert began his career as an US Naval Officer, serving on a nuclear submarine. He has a B.S. in Chemical Engineering from Case Western Reserve University, and is a registered Professional Engineer.

Megan Crum

Megan Crum has eight years of experience supporting Biologics, Fill Finish and Bulk Operations. She is currently a Plant Engineer at Biogen in RTP, holding responsibilities for Utilities and HVAC within the Maintenance Organization. Previously, Megan held Engineering and Facilities Management roles at Merck in Durham, N.C. She has experience in root cause analysis, regulatory compliance, equipment reliability, process optimization, predictive maintenance technologies and project execution. Megan first joined ISPE as a student in 2008 and has remained active in the local chapter. She holds a B.S. in Biological Sciences from North Carolina State University, and was the first recipient of the BTEC Biomanufacturing Minor, specializing in Downstream Operations.

Peter Denmark

After graduating from Wake Forest University, Peter Denmark went on to earn a master's degree in exercise physiology from Furman University, and an MBA from Eastern Michigan University. Throughout it all, Peter has always had a strong interest in the medical sciences. At EnvisionTEC, he found a company that was a world leader in 3D bioprinting with its 3D-Bioplotter series. EnvisionTEC's robotic additive manufacturing technology — the Viridis3D RAM 123 — also falls under Peter, where it's currently being offered in the marketplace to bring sand molds and cores for the foundry industry.

Speaker Bios continued

Heather Denny

Heather Denny is the President and Chief Executive Officer of McDonald York Building Company, a Triangle-based General Contractor, founded in 1910. Heather has built her career at McDonald York. In 2010, she became the fifth President, and the only non-family president in the company's history. In 2013, she was named CEO. She is known for her problem-solving capabilities, consensus team-building skills, clear communication style, and commitment to active community service.

Heather is passionate about serving the community and helping others. She is actively involved in many professional and non-profit organizations, and serves in leadership roles within a majority of these groups. Heather chooses volunteer organizations that are both professionally and personally meaningful; that allow her to make a significant impact within the community. Currently, her activities include board positions with NC State's Civil Construction and Environmental Engineering (CCEE) department's advisory board, the Carolina South Atlantic (CASA) Chapter of International Society for Pharmaceutical Engineering (ISPE), Union Bank, the John Rex Endowment, Fostering Bright Futures, and the City Club of Raleigh. Additionally, she is the chair of the Triangle Area Chapter of the American Red Cross.

Heather has received numerous awards including, "Top 50 Business Leaders to Watch," by the Triangle Business Journal; Engineering News Record's, "20 Under 40"; Triangle Business Journal's,"40 Under 40"; CREW Network's, "20 Under 40"; Triangle Business Journal's, "Women in Business"; and Business Leader Magazine's, "Women Extraordinaire".

Heather is a graduate of North Carolina State University with a Bachelor of Science in Civil Engineering.

Ken Ewan

Ken Ewan is an executive coach and facilitator. He brings to coaching and consulting 45+ years of experience in the chemical, biotechnology, and pharmaceutical fields. Ken has held senior level positions at Genentech, MedImmune, Amgen, Skanska USA Building, GlaxoSmithKline, and DuPont in engineering and project management. Ken enjoys working with technical and creative professionals and leaders. He works with leaders to explore new ways to view situations, individuals, possibilities, and to develop new approaches, plans, strategies and actions. Ken believes in the power of coaching to be transformational for leaders, leading to unforeseen possibilities, and higher levels of achievement and growth, both professionally and personally.

A 25+ year member of ISPE - International Society of Pharmaceutical Engineering, Ken has held international leadership roles having chaired both the Education Committee and the Professional Certification Commission. At the local level, Ken was on the Board of Directors for ISPE Chesapeake Bay and for ISPE CaSA. Ken is currently serving on the Board of Directors of three companies: PCI-LLC, a leading provider of calibration, instrumentation, consulting, and commissioning services within the Life Sciences industry, Tunnell Consulting, Inc., a provider of Strategic, operational and technical solutions for biotech and pharmaceutical organizations, and WithersRavenel, Inc., a full-service civil and environmental consulting engineering firm.

Ken is a graduate of Clemson University in South Carolina and Drexel University in Philadelphia in Architecture and has a post-graduate certificate in Leadership Coaching from Georgetown University. He is a member of the International Coach Federation and holds the credential of Associate Certified Coach (ACC).

Wendy Haines, PhD

Dr. Wendy Haines has 19+ years of experience in both the research and biopharmaceutical arenas, encompassing process design, analysis, validation, project/protocol management and scientific writing. She has successfully integrated herself in both the research and commercial areas of business. Wendy has been a long standing member and active participant within ISPE and has held integral roles of responsibilities that have helped shape our local, national and international rules and guidelines and she is currently the CaSA Chapter Vice President.

John R. Hodge IV

John Hodge has 12+ years of experience in Validation and Automation Engineering in the field of pharmaceutical manufacturing. He has completed Serialization, Building Management System, and Virtualization projects by combining the roles of Validation Specialist and Automation Engineer to deliver fully developed, integrated, and qualified systems to Mangan's clients. John believes that acting as a single point of contact for developing, documenting, implementing, and verifying system changes can accelerate project schedules and reduce risk of gaps.

Greg Hottell

Greg Hottell is a Director in the Clinical Interface team at GSK, where he is responsible for the cost-effective, patient-focused supply of investigational product for GSK's pharmaceutical development portfolio. Since joining GSK in 2011, Greg implemented an end-to-end planning platform for clinical supplies, helped redesign GSK's approach to clinical supply blinding and unblinding risk management, was a core team member for the Investigational Material Supply strategic planning initiative, all while consistently delivering top-tier performance with on-time supply of investigational product to patients.Greg has been a Supply Chain professional since 1999, most recently holding positions of increasing responsibility at

Speaker Bios continued

Eli Lilly & Company and Fisher Clinical Services prior to joining GSK. Greg has a diverse background in the Pharmaceutical Industry spanning roles that include clinical trial materials management, demand planning, site inventory management, IRT utilization, drug product supply planning, temperature excursion management, study drug expiry dating extensions, customer service, operations planning & scheduling, and procurement. Greg holds a bachelor's degree in Operations Management, an MBA, and is a Certified Fellow in Production and Inventory Management (CFPIM) through APICS.

Edison Hudson

At Panacea BioMatx, Edison Hudson led the design of a novel automated compounding machine and the launch of GMP operations to produce personalized dietary supplements. Prior to co-founding Panacea BioMatx, he led several technology and robotics companies, including iRobot, and RedZone Robotics. He has over 16 patents in machine design, control systems, machine vision, robotic algorithms, and semiconductor processes. He was a Morehead Scholar in physics and computer science at the University of North Carolina, studied artificial intelligence at Oxford University, UK, and received an MBA from Duke University.

Jeff Hutchins, PhD

Dr. Jeff Hutchins oversees Heat Biologic's research efforts, with over 24 years of research and clinical development experience from both large pharmaceutical and biotechnology companies. Most recently, Jeff served as Vice President of Preclinical Research for Peregrine Pharmaceuticals, Inc., a biopharmaceutical company developing therapeutics to fight cancer and infectious diseases. Jeff was responsible for building out the research program for Peregrine's lead product candidate, bavituximab, a chimeric monoclonal antibody designed to target phosphatidylserine. Prior to joining Peregrine in 2012, Jeff served as Vice President, Preclinical Development at Inhibitex Inc, which was acquired by Bristol-Myers Squibb From 1991 to 2000, Jeff held several senior scientist positions in Discovery Research at Burroughs Wellcome and Glaxo Wellcome, with a visiting professor appointment at Rush Medical College. Jeff earned a B.S. in Biology from Oral Roberts University, a Ph.D. in Biomedical Sciences from the University of Texas, Health Science Center at the M.D. Anderson Cancer Center and conducted postdoctoral training in the University of Southern California's Department of Microbiology at the Norris Cancer Center. Jeff's publications and patents span the fields of oncology, infectious disease, osteoarthritis and immunology.

John Hyde

John Hyde is Chairman and Founder of Hyde Engineering + Consulting, Inc., a firm of 220+ engineers and scientists, founded in 1993 and specializing in process engineering, process and equipment validation, and compliance consulting for biopharmaceutical and pharmaceutical manufacturers. Hyde Engineering + Consulting, Inc. have operations in the United States, Europe, Singapore, and India.

For nearly two years before the formation of Hyde Engineering + Consulting, Inc., John was Senior Project Engineer with Synergen, a biopharmaceutical research, and manufacturing company located in Boulder, CO. His work at Synergen included design, start-up, and validation of key process systems and the overall responsibility for the cleaning validation programs for the firm's large scale and clinical manufacturing facilities. From 1982 to 1992, John was Manager, Process Design with Seiberling Associates, Inc., an engineering firm specializing in the design and start-up of biopharmaceutical, food, and beverage process systems and the application of CIP technology.

John has presented papers at numerous engineering conferences and short courses on topics including biopharmaceutical process systems design, automatic cleaning system design and implementation, and control system design for pharmaceutical processes, and he has published numerous articles on these topics. He, as a member of the PDA Subcommittee for Biopharmaceutical Cleaning Validation, contributed two chapters to a book on the subject, and he has also contributed a book chapter on PAT as applied to CIP operations. John is a member of the editorial board of the Journal of Validation Technology and he has been a regular speaker at conferences presented by Pharma Conference, the Institute of Validation Technology (IVT), the International Society of Pharmaceutical Engineers (ISPE), the American Institute of Chemical Engineers (AIChE) and other professional societies. John has also provided training to FDA CBER personnel on cleaning and cleaning validation practices. He holds Bachelors degrees in Food Science and Business Administration, and a Masters degree in Food Engineering, all from the Ohio State University.

Shane Kelly

Shane Kelly is the Maintenance Systems Manager at Shire in Social Circle, GA. He received his B.S in Chemical Engineering from the University of Louisville, before beginning his career in pharmaceutical manufacturing. During his 18 year career, he has worked for several biopharmaceutical companies ranging from small-scale biologics to large-scale plasma fractionators. He has been involved with two substantial green-field pharmaceutical builds; responsible for Engineering design, plant startup and operations establishment on the client side. Shane is an avid reader and enjoys hunting, gardening and beekeeping. He currently resides in Social Circle with his wife Dana and daughter Isabella.

Speaker Bios continued

Jennifer Lauria Clark, CPIP

Jennifer Lauria Clark, CPIP is the Executive Director of Strategic Development for Commissioning Agents, Inc., where she is responsible for business development, their key account management program, commissioning and qualification planning, protocol development and execution, project startup and coordination, consulting support among other duties. She has over 11 years of experience in regulated industries. Previously she held positions at Yonkers Industries where she provided services for Merck, BD, GSK, Biogen and others. Jennifer has been a Member of ISPE for more than 12 years and actively involved in the Society's local and international activities. She is Past President of the ISPE CaSA Chapter, is a member and Past Chair of ISPE's Young Professionals Committee, and a past member of ISPE's Pharmaceutical Engineering Committee. Currently Jennifer has just finished a four year stint as a Director on the ISPE International Board. She has a degree in Industrial Engineering from North Carolina State University. Jennifer earned her ISPE CPIP designation in 2012.

Rick Lawless

Rick Lawless is a manager and instructor at the Golden LEAF Biomanufacturing Training and Education Center (BTEC) at NC State University. As an independent consultant, he also provides GMP expertise to emerging companies such as Panacea BioMatx. Prior to joining BTEC in 2006, Rick accumulated more than 20 years of industry experience with companies such as Eastman Kodak, Johnson & Johnson, and Wyeth. He was involved in the start-up of four biomanufacturing facilities and has managed several GMP production units that manufactured commercial quantities of clinical diagnostic products and vaccines. He received a BSE in Chemical Engineering and BS in Microbiology from University of Michigan - Ann Arbor, and a MBA from State University of New York at Buffalo.

Gary Lohr

Gary Lohr has been with Novo Nordisk since 2005 when he joined Novo Nordisk site Clayton as the Validation Project Leader for the first major expansion project at the Site that included Aseptic and Finished Production. Gary assumed responsibility for operations of the newly installed FlexPen® manufacturing lines and Finished Production Process as Shift Manager in 2007.

Starting in 2010, he became responsible for establishing the FlexTouch® capacity in the US as the Senior Project Manager for PDS290 Phase 3&4. In 2012, Gary accepted the role of Director, Production Support.

Since the announcement of the Diabetes API, US project in August 2015, Gary has held the position of Project Director – Site Support and Deputy site head. Gary is the community face of the project as first contact with state officials and local regulators.

Juha Mattila

Juha Mattila is Senior Product Manager for STERIS FINN-AQUA Sterilization systems. He joined STERIS in 2000 and has over 16 years of experience in the design, development and product management of pharmaceutical and research process equipment, including several years in Research and Development for STERIS FINN-AQUA products and systems. He has worked with several clients in the designs and installations in Europe, North America and Asia, is an active conference presenter, and has contributed as author/co-author for articles in professional journals. Juha is a member of ISPE Nordic Board of Directors, PDA, and Finnish Biosafety Network.

Phil McDuff

Phil McDuff currently works for Biogen as the Vice President of Global engineering. In that role, he oversees the process engineering, automation and validation, maintenance, and instrument/controls functions for the company. He has been with Biogen for 13 years, working in multiple areas of engineering. During his tenure at Biogen, he has contributed to increasing facility capabilities within Biogen's production facilities to up to 10 times their design basis and has been instrumental in establishing design and operation principles that reduced microbial contamination rates to below industry standard. Prior to Biogen, he worked at Roche Vitamins as a process/product engineer supporting multiple unit operations and process tech transfers. He received a BS in Chemical Engineering from Auburn University and has held various roles in engineering for over 22 years.

Jim McGlade

Jim McGlade is a Science Client Leader with BHDP Architecture. Jim's focus is on helping clients solve their facility challenges to support their strategic goals. Jim has more than twenty-five years of professional experience in the science industry. Jim's background includes all phases of project services including marketing/business development, client leader, programming, planning, design integration, contract negotiations, developing construction documents, and construction administration. Jim is registered architect and a Leadership in Energy and Environmental Design (LEED) Accredited Professional. Jim is a Past-President of the ISPE Carolina-South Atlantic Chapter, Past-Chairman and current member of the Facility of the Year Awards Committee, and current steering committee member of the Project Management Community of Practice.

Speaker Bios continued

Catherine (Cathy) Middelberg

Catherine (Cathy) Middelberg is a Principal Validation Engineer at Pfizer's clinical and commercial launch manufacturing facility in Sanford, NC. Cathy has over 35 years of engineering experience, with 30 years spent in the pharmaceutical and biopharmaceutical industry. She is currently an instructor and course developer for the Validation Academy and the Bionetwork of Wake Technical Community College. Cathy also volunteers at Middle Creek High School as a member of the Engineering Advisory Board. She is a past member and chair of ISPE's Pharmaceutical Engineering committee. Cathy holds a Bachelor of Science in Chemical Engineering from the University of Cincinnati.

Jeff Miller

For more than 20 years, Jeff Miller has led world-class programs in the fields of process automation, machine automation and electrical design. He has consulted with Procter & Gamble, Dannon, DHL, Kroger, Toyota, Ford and others to optimize their manufacturing and operations. His primary focus is on promoting data flow vertically and horizontally to those within an organization in order to positively affect quality, efficiency and profit. This translates to delivering the right data, to the right people, at the right time, so that they can make the right decisions. With a degree in electro-mechanical engineering from Miami University and several years spent as a cryptologist in the military in Naval Intelligence, he has vast experience in manufacturing execution systems (MES), information solutions, custom software development, and is a thought leader for the Industrial Internet of Things (IoT).

Tolga Musa

Tolga Musa is the Associate Director of Process Engineering at the Biogen, RTP, NC facility. Tolga holds a Chemical Engineering degree from the Georgia Institute of Technology and a Master's degree in Business Administration from the University of North Carolina, and is registered as a Professional Engineer (state of GA).

Christa Myers

Christa Myers is a Senior Pharmaceutical Engineering Specialist at CRB with more than 20 years of experience providing clients with insight as to how innovative technologies apply to process and facility designs. Her involvement starts with the strategic concept and continues through construction and startup of projects. Building on her years as an operator, Christa has used her first hand approach and understanding to assist her clients in designing facilities and equipment – each facility being unique, with different drivers, different products and different dosing mechanisms. With 20+ years of operating and designing filling equipment experience, Christa has been instrumental in many fill finish projects—both retrofits and new construction.

With an extensive background in the design of fill-finish facilities, chemical kilo labs, pilot plants, API research and manufacturing facilities, bulk pharmaceutical chemical facilities, highly hazardous compound containment, and biotech process facilities, Christa's broad range of expertise benefits her clients in the design of their facilities.

Kim Nguyen

Kim Nguyen currently heads the Process Development team at Precision Biosciences, focusing on the scale-up and manufacturing of allogeneic CAR-T cell therapeutics. She received her AB in Chemistry from Princeton University, her PhD in Chemistry from Columbia University, and subsequently completed a postdoctoral fellowship with Ian McNiece at the University of Miami focused on both the scientific and regulatory aspects of preclinical process translation and clinical cGMP scale-up of MSC, dendritic cell, and HSC cultures. Subsequently Kim joined Terumo BCT in Lakewood, CO and served as Principal Scientist and Senior Manager for Cell Processing R&D, focusing on the development of automated platform technologies for cell and gene therapies. She also currently serves as an Affiliate Investigator at Blood Systems Research Institute in San Francisco, CA.

Marisol Patino

Marisol Patino just recently joined Sartorius Stedim Biotech as an Integrated Solutions Sales Manager for the southeast US. In her role, she provides process support for the design of large scale bioprocesses and custom bioprocessing solutions. Previously, Marisol worked as a Process Engineer at Fujifilm Diosynth Biotech, a contract manufacturer. She was responsible for downstream technology transfer and process validation. Other roles have included learning specialist, supporting manufacturing training, and bioprocess technician. She is currently the Chair of the ISPE-CaSA Student Affairs Committee and serves on the ISPE International Young Professionals Committee.

Speaker Bios continued

Nic Petersen

Nic Petersen has over 20 years of international Project Management expertise and has executed large scale capital projects in USA, Denmark, Indonesia, Ireland, and China. Nic joined NNE in Denmark in 1996 as a Project Manager and has participated in several of the large Novo Nordisk expansions around the world and is very familiar with the Novo Nordisk way of executing large projects.

From 2000-2004, Nic headed the partnership between NNE and Fluor where the team executed two large Construction Management projects in Europe. Starting in 2007 Nic opened NNE's office on the US West Coast based in San Francisco and transferred to the NNE US HQ in RTP in 2010 where he has held positions as Director of South East, Project Director, and Director of Project Governance.

Nic is currently supporting the new Novo Nordisk DAPI expansion in Clayton to help apply well-proven Project Execution methodologies and to coordinate the NNE team's role as Owners representative.

Bryan Raborn

Bryan Raborn is a Process Engineer at CRB with three years experience. Bryan graduated from North Carolina State University with degree in Chemical Engineering and had participated in the design of several biotech facilities.

Derek Schorzman, PhD

Dr. Derek Schorzman holds the position of Executive Director, Manufacturing Sciences, at Liquidia Technologies, Inc. He has been a key contributor to the research, development, and implementation of the continuous PRINT® nanoparticle fabrication platform since joining Liquidia in 2006.
Prior to joining Liquidia Technologies, Dr. Schorzman conducted research and development of biomedical devices for diabetes care and ophthalmic materials, while at Becton Dickinson and Bausch & Lomb, respectively. Dr. Schorzman served a post-doctoral appointment at UNC Chapel Hill, received his Ph.D. in Chemistry from Virginia Commonwealth University, and a B.S. in Chemistry from Utah State University. He holds 31 U.S. patents and has authored six publications.

Robert Smith

Robert Smith is the Sr. Manager of Automation Engineering at the Biogen, RTP, NC facility. Robert holds an Electrical Engineering degree from the University of North Carolina at Charlotte.

David Summers

With more than two decades of international business experience in the food and beverage process and pharmaceutical equipment industry, David Summers ecently transitioned from Alfa Laval Kathabar in New York where he focused on liquid and dry desiccant dehumidification systems for food and pharma. David brings a wealth of knowledge to Alfa Laval and to its customers with an effective ability to cultivate trust and rapport and works with Transfer Technologies as Alfa Laval's Commercial Manager – Valves, Sanitary Equipment Division in the United States. He's tenured with Alfa Laval in Australia and The Netherlands and is multilingual in English, Dutch, German and Friesian. Educated in Australia, David holds a Certificate III in Engineering from RMIT University, diplomas in Media Studies from the Australian College of Journalism, and a degree in International Business from The University of New England's Graduate School of Business. He also holds Graduate Certificates in Project Management and Marketing with Villanova and Tulane Universities. He's a member of ASHRAE engineering society and is based in Tampa, Florida.

Richard Tree

Richard Tree is a hands-on senior consultant with 33 years of leading maintenance, reliability, commissioning, and performance improvement teams. His leadership has consistently strengthened the client's bottom line by improving efficiency and eliminating waste. He leads a team that develops unified strategies to help clients improve Overall Equipment Effectiveness (OEE) through enhanced human performance and asset management practices. A lean operations expert, he is personally credited with the lean transformation of 9 manufacturing sites, mentoring over 34 manufacturing sites in advanced lean operations, and designing and implementing asset management strategies at 15 manufacturing sites.

Richard's leadership roles began in the US Navy, where he was responsible for operations, training and staff performance, maintenance and quality of power generation, propulsion, and cooling systems on four nuclear-powered submarines. He was hand selected by the Director of Naval Sea Systems Command, Reactors to lead the initial manning, testing and commissioning of a first-in-class nuclear submarine with a never-before operated and tested nuclear reactor. His leadership and success led to numerous commendations. He has held several key operations leadership roles in manufacturing companies prior to joining Commissioning Agents, Inc.

Richard is currently working toward a PhD in Operations Management, at the University of Texas Arlington where his research has focused on Behavioral Operations and Statistics. He holds an MBA from Southern Methodist University and a Bachelor of Science degree in Information Technology from Columbia College.

Speaker Bios continued

Brian Urban

Brian Urban is the Associate Director of Quality Systems & Enterprise Management within the Corporate Quality organization at the Biogen, RTP, NC facility. Brian holds a Chemical Engineering degree from North Carolina State University as well as being a certified Six Sigma Black Belt.

Kevin Ventura

Kevin Ventura is a Process Engineer with four years experience. He is a graduate from North Carolina State University, majoring in Chemical and Biomolecular Engineering with a minor in Biotechnology. Since joining CRB, Kevin has been involved in the design of several biotech and life science projects.

Gavin Wendel

Gavin Wendel is a Senior Validation Specialist with Pfizer. With a BS degree from Virginia Tech he has worked for 15 years in the pharmaceutical industry. For the past 11 years he has worked at the vaccine manufacturing facility in Sanford, NC in various roles including validation, project management and clinical manufacturing. He is currently responsible for equipment qualifications and board of health commitments for the areas of sterilization, lyophilization, cold storage and warehousing.

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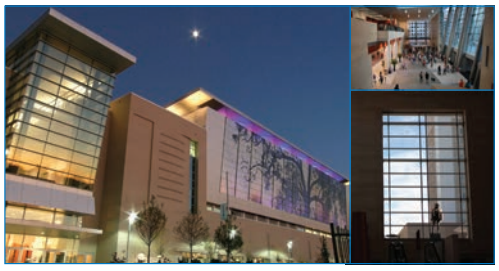

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Gregory Westby

Gregory Westby is a clinical pharmacist and student preceptor at Duke University Hospital. He received his pharmacy degree from the University of North Carolina at Chapel Hill and his Master's in Clinical Research from Campbell University. During his 27 years at Duke, he has worked in both the inpatient and outpatient settings and serves on Duke Hospital's Sterile Preparations Oversight Committee. He spent 15 years in the Investigational Drug Service Pharmacy collaborating on government, industry and investigator sponsored research projects. This collaboration has included IND submissions, pharmacy manuals, and the development and implementation of masking and packaging strategies for investigational products. Currently, he works with the Duke Compounding Facility as a quality assurance and compounding pharmacist. Greg has served as a primary reviewer for the Duke University Health System IRB since 2003. He has received "Patient Care" and "Medication Safety" awards and has interests in medication safety, quality assurance and regulatory affairs.

Matthew Westoby

Matthew Westoby is the Associate Director of Protein Purification Development at Biogen with over 15 years of process development experience in both technical and managerial roles. He has contributed to the development of 25 biopharmaceutical programs and has extensive experience across all phases of drug development. Matt has an established track record of innovation, resulting in implementation of multiple new technologies throughout Biogen's manufacturing infrastructure and establishment of a high productivity purification platform. Matt recently served as the technical lead for the Biogen-MIT Biomanufacturing 2020 Program exploring alternate expression systems and novel downstream technologies to drive disruptive innovation in biologics production. Matt has a B.S. in Chemical Engineering from The University of California at Davis and a MBA from The University of California at San Diego.

David Yarley

David Yarley serves as the Director of Training and Development for Fujifilm Diosynth Biotechnologies USA, Inc., located in Morrisville, North Carolina. Fujifilm Diosynth Biotechnologies is a contract manufacturing organization (CMO) that produces bulk active pharmaceutical ingredients (APIs) using fermentation and cell culture processes. Prior to this position, he served as the Director of Bioprocess Training at the BioNetwork Capstone Center located at the NCSU BTEC facility and in management positions in technical support, marketing, and manufacturing at Ajinomoto AminoScience LLC. David received his MS degree in chemical engineering at the University of Virginia and his BS in chemical engineering at North Carolina State University.

Exhibitor Company Descriptions

ABEC

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Access Orchestrate

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Rod Schregardus

Access Orchestrate production planning & scheduling software ensures improved communication between departments, giving planners, technicians and operators a single version of the plan that is consistent and without ambiguity. Used for day-to-day scheduling, capacity planning and what-if analysis, Access Orchestrate has helped Pharmaceutical and Bio-pharmaceutical companies improve throughput, efficiency, yield and utilization.

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ASEPCO

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BE&K Building Group provides integrated construction services for biotech and pharma, healthcare, higher education, advanced manufacturing, aerospace, food and beverage, and commercial clients. Over the past 30 years, BE&K Building Group has put in place more than $2.5 billion of biotech, pharma and life sciences projects including new construction, expansions and renovations. We provide in-depth understanding of current Good Manufacturing Practices and regulatory compliance requirements.

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Beckman Coulter Life Sciences is dedicated to empowering discovery and scientific breakthroughs. The company's global leadership, world-class service and support delivers sophisticated instrument systems, reagents and services to the life science researcher as well as manufacturing process monitoring equipment enabling new discoveries in biology-based research and development. A leader in particle counting, centrifugation and flow cytometry, Beckman Coulter has long been an innovator in particle characterization and laboratory automation.

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Steven Robinson

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Biogen

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David Smith

Through cutting-edge science and medicine, Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases. Founded in 1978, Biogen is a pioneer in biotechnology and today the Company has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first and only approved treatment for spinal muscular atrophy, and is at the forefront of neurology research for conditions including Alzheimer's disease, Parkinson's disease and amyotrophic lateral sclerosis. Building on its heritage in biologics, Biogen also manufactures and commercializes high-quality biosimilars.

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BioPharma Systems

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BioPharma Systems provides high level sales and engineering knowledge assisting our clients and principals with a unique approach to applications and equipment solutions. Our principals include Esco Technologies, (Downflow Booths and Isolators), Bausch Advanced Technologies (Vial, Syringe and IV bag filling and closing systems), Fedegari Sterilization solutions and ChargePoint split butterfly valves. Also featured are PalPharma Materials handling equipment and PBSC Clean room components.

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jenkinsagt@aol.com
Dave Jenkins

Premier supplier of high-quality process equipment to the Pharmaceutical, Bio-Pharm, and Laboratory markets. Products: pure and clean steam generators; cGMP and laboratory steam sterilizers; cGMP terminal sterilizers; Lytzen Class 5 and 7 depyrogenation ovens and granulate dryers; laboratory dry heat ovens and incubators

BTEC at NC State University

238, 239

850 Oval Dr
Raleigh, NC 27695
919-513-2195
cpsmith4@ncsu.edu
Chris Smith

The Golden LEAF Biomanufacturing Training and Education Center (BTEC) is a unique, cross-disciplinary instructional center that provides education and training opportunities to develop skilled professionals for the biomanufacturing industry. It also provides bioprocess development and analytical services to a wide range of customers from academia and industry.

Burkert Fluid Control Systems

804

11425 Mt. Holly-Huntersville Road
Huntersville, NC 28078
704-504-4440
Curtis Bares

Burkert Fluid Control Systems is a global system solution provider in the fluid handling industry. Our focus is on reliability and innovation, with the goal of creating lasting and effective results for the customer. Our manufacturing expertise encompasses process control and automation in a consultant system minded approach. We bring this wide range of knowledge to the hygienic and biopharm industry for the purpose of offering: improved automation, product yield, CIP and steam handling, an active role in the various process safety, and aiding our customers in areas of desired improvement.

Burns Engineering

216

10201 Bren Rd. East
Minnetonka, MN 55343
952-567-6414
jwigen@burnsengineering.com
JeffWigen

Burns Engineering manufactures high performance temperature measurement products and engineered solutions for temperature critical processes in the pharmaceutical, biotech and metrology markets. We design custom solutions that meet your unique temperature measurement needs for safety, process efficiency and product quality. Products include RTDs, Secondary SPRT's, Thermocouples, Thermowells, Temperature Transmitters/Indicators and NVLAP accredited (Lab Code 200706-0) Calibration Services.

Burt Process Equipment - Hamden, CT

225

100 Overlook Drive
Hamden, CT 06514
203-287-1985 Ext. 223
Billelliott@burtprocess.com
Bill Elliott

Burt Process Equipment is a full service manufacturer and supplier of world class industrial products and engineered systems to a wide range of industries and markets. Burt Process engages in services ranging from efficient and reliable distribution of products to fully integrated design, manufacturing and installation of complex process systems. Our core values focusing on partnerships with our customers and suppliers are as prevalent today as they were when Bill Burt founded the company in 1970.

BWT Pharma & Biotech Inc.

203

417-5 South Street
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508-485-4291
Robert.vecchione@bwt-pharma.com
Bob Vecchione

BWT Pharma & Biotech is a global pharmaceutical and biotech equipment / solution supplier for USP, WFI, Pure Steam, and Ozone and Heat Distribution/Sanitization Systems. Having production facilities and offices in Marlborough Ma. USA, Europe & Asia. BWT has been active in the water purification market for 70 years and the is a market leader and turnkey Supplier in the production of pharmaceutical waters and Steam for Critical Utilities. BWT Group is one of the largest Water Treatment companies in the world employing more than 3,300 people worldwide.

Exhibitor Company Descriptions continued

Camfil

333

1 N. Corporate Drive
Riverdale, NJ 07457
647-289-1592
Matthew.Crouch@camfil.com
Matthew Crouch

Camfil Farr is the world's leading air filtration supplier to the Life Science Industry. Our clean air solutions protect people and processes: custom supply and exhaust housings, autoscan (in-place) systems, unique high temperature HEPA filters, wide range of HVAC filters and contained process dust collection. Our LCC (Life Cycle Cost) and CREO (Clean Room Design Standards & Energy Optimization) software platforms can be used to optimize filter life and reduce energy costs.

Carolina Mechanical Services, Inc.

219

5100 International Drive
Durham, NC 27712
919-477-7100
chris@carolinamechanical.com
Chris, Bradley

Carolina Mechanical Services, Inc. provides support to the pharmaceutical, biotech, medical, and food/dairy/beverage industries. Our services include engineering, design/CAD modeling, fabrication, CNC machining, high purity piping/custom fabrications/skids, passivation, electro-polishing, custom air systems, automated equipment, and installation services. Our products are developed for use in cleanrooms and cGMP facilities.

Carotek, Inc.

132

911 Applenook Ct.
Wake Forest, NC 27587
704-844-1100
pete.tollens@carotek.com

Pete Tollens Carotek is a process automation instrumentation distributor with offerings serving the sanitary/hygienic and industrial markets.

Central States Industrial (CSI)

122

2700 N Partnership Blvd
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417-831-1411
417-860-0051
curtise@csidesigns.com
Curtis Elkins

CSI distributes, designs, and manufactures processing equipment for the high purity industries, including pharmaceutical, biotech and personal care. CSI's large inventory of fittings, pumps, valves, tubing, and instrumentation offers in-stock solutions to meet your needs. CSI also maintains the world's largest inventory of piping and components in corrosion-resistant superalloys AL-6XN® and Hastelloy® C-22®.

cGMP Validation L.L.C.

325

7930 W. Kenton Circle
Huntersville, NC 28078
704-965-8954
chris.gillikin@cgmpvalidation.com
ChristopherGillikin

cGMP Validation was established in 1997 as a full service validation/compliance firm offering services for the pharmaceutical, bulk pharmaceutical, animal health, biotechnology, biologics, medical device and medical diagnostic industries. cGMP Validation specializes in the preparation and execution of validation IQ/OQ/PQ protocols, compliance documentation for equipment, utilities, processes, laboratory instruments, and computer systems.

Charter Medical Ltd

256

3948-A Westpoint Blvd
Winston-Salem, NC 27103
336-768-6447
Lexan Lhu

Charter Medical, Ltd., is an ISO 13485 certified and FDA registered manufacturing facility. Charter Medical has a 25 year history of creating high-quality, single-use products and serves the bioprocessing, cell therapy and medical device industries. Focus is on designing and supplying solutions for cell growth, frozen storage and biological fluid handling. Charter Medical is committed to providing quality products and services with a staff dedicated to exceeding customer expectations.

Clark Nexsen

806

CLARKNEXSEN

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pokeefe@clarknexsen.com
Pat O'Keefe, AIA, LEED AP BD+C

Founded in 1920, Clark Nexsen is an award-winning firm with a reputation for excellence in the design of pharmaceutical research and manufacturing facilities that is known worldwide. Within the past six years, the firm has designed more than 2,000,000 SF of complex research environments. Located in 10 offices throughout the Southeast and Mid-Atlantic, Clark Nexsen is a full-service architecture, engineering, lab planning, and interior design firm.

Cleanseal Door Systems

258

5848 N. 95th Ct.
Milwaukee, WI 53225
414-464-6200
Jason Faries

Cleanseal Door Systems manufactures a comprehensive line of swinging, sliding, roll-up, fire rated and custom doors for controlled environments. With styles designed to meet requirements ranging from GMP to Class 1, Cleanseal provides complete door systems including a full range of panel choice, hardware selection, frame and interlocking designs.

Cleansol

222

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ed@fluenta.us
Ed Perez

Passivation & Cleanroom insulation services

Coastal Instruments, Inc

310

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Burgaw, NC 284725
910-259-4485
sbruce@mfchelp.com
Bruce Benson

Coastal Instruments is a Mass Flow Controller sales and service company formed in 1980. Accredited to ISO/IEC-17025 by A2LA, we service and sell (re-manufactured) MFC's/MFM's from all manufacturers including newer digital devices as well as older legacy devices. We can calibrate all digital MFC's currently manufactured, and offer replacement devices for your older equipment. on the web at WWW.MFCHELP.COM

Exhibitor Company Descriptions continued

Commissioning Agents, Inc.

8

9813 Adlie Drive
Wake Forest, NC 27587
919-696-2335
jennifer.clark@cagents.com
Jennifer Lauria Clark, CPIP

We help our customers design, deliver, operate and maintain quality-critical manufacturing (GMP related) or mission-critical facilities. Our engineering, technical and consulting services encompass all aspects of operation: equipment, automation, process, human performance. The result is a superior level of operational performance and reliability.

CPC (Colder Products Company)

266

1001 Westgate Blvd.
St. Paul, MN 55114
919-468-7228
bob.schulze@colder.com
Bob Schulze

CPC (Colder Products Company) is the leading provider of quick disconnect couplings, fittings and connectors for plastic tubing.

CRB

10

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Lisa Kerner CRB is a global service provider of engineers, architects, constructors and consultants driven to deliver the right solutions to life science and advanced technology clients. Founded in 1984, we have grown to a team of more than 900 passionate professionals in 14 offices throughout the country. CRB's single-minded focus on putting our clients' interests first – every day, on every project – defines us as a firm.

Cross Instrumentation

251

4400 Piedmont Parkway
Greensboro, NC 27410
919-437-6201
phil.mckinney@crossco.com
Phil McKinney

Cross Company Instrumentation, you will be working with industry leaders in applying solutions that measure, analyze, control, and safely operate your processes.

DCI, INC

316

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320-257-4378
ldgunderson@dciinc.com
ScottKloetzer

DCI-Biolafitte leads the biotechnology equipment industry in the design and production of top-quality bioreactors and fermentors. From benchtop units to industrial-scale systems, DCI-Biolafitte benefits from the design and engineering expertise that comes from decades of being a trusted biotech solutions provider. We feature a wide variety of bioreactors, fermentors, retrofit, and custom-built biotech solutions.

DMP Corporation

115

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Chris Ameo

DMP is the premier provider of integrated wastewater treatment solutions. For over 45 years, we have been dedicated to helping our industrial customers solve their most difficult water treatment issues. At DMP we take the worry out of wastewater by: Getting you into compliance and helping your stay in compliance (5-year performance guarantee), saving you money and helping you use water more efficiently.

Dur-A-Flex, Inc.

330

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kevins@dur-a-flex.com
Kevin Stephens

Dur-A-Flex, Inc. is a family owned, manufacturer of high-performance, resinous floor and wall systems. With over 50 years in business, Dur-A-Flex puts emphasis on its ability to continually deliver innovative products to the coatings industry as well as unmatched levels of customer service to its contractor base. Named one of the "Best Places to Work in CT" five times by the Hartford Business Journal-sponsored awards program, Dur-A-Flex considers its people it's most valuable asset. For more information on Dur-A-Flex floor and wall systems, please visit www.dur-a-flex.com.

Dycem

138

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Alun Jones

Dycem is a world leading manufacturer and supplier of polymeric contamination control floor solutions for critical environments and clean rooms.

East Carolina University

237

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James Parker

ISPE Student Chapter, East Carolina University

Ellab Inc.

346

303 E. 17th Ave.
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Harry Glendinning

Ellab is the leading manufacturer of complete thermal validation equipment and on-site services in North America. We are devoted to increasing consumer safety by providing the most accurate and reliable measurements possible. Ellab's validation products measure a variety of parameters such as temperature, humidity, CO2, pressure and more. Ellab's validation consultants provide commissioning and qualification services of chambers and processes related to pharmaceutical and biotech production, including but not limited to lyophilization, stability and sterilization.

Exhibitor Company Descriptions continued

Energy Services from Duke Energy

4

400 S. Tryon Street
Charlotte, NC 28285
704-382-7973
Roger.Paules@duke-energy.com
Roger Paules

Do you have Backup Generators, UPS units, Switchgear, Chillers or Lighting Systems that need to be replaced or expanded? Duke Energy's Energy Services team designs, installs, owns and maintains electrical, mechanical and backup power systems as a managed service. We own electrical and mechanical systems allowing you to focus on your core business. Our services are available to any customer in the USA. We are glad to sponsor this event as a way to say thank you to the CaSA customers that we already partner with. Visit our booth # 4. Finally visit our website at www.duke-energy.com/energyservices

Enterprise System Partners

807

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Durham, NC 27703
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Kevin Henning

Enterprise System Partners (ESP) is a leading global consulting and project engineering company – supporting manufacturing IT solutions for the life science industry since 2003. We offer specialist support and consulting services exclusively for manufacturing and supply chain operations in biotechnology, pharmaceutical and medical devices, with core focus on Manufacturing Execution Systems (MES) and serialization. Our specialist consultants and engineers have the expertise to support the concept, planning, vendor selection, design and implementation of the entire manufacturing systems landscape from process automation to the enterprise layer (level 0-4).

Eppendorf NA

336

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800-645-3050
David.m@eppendorf.com
Mike David

Eppendorf is a leading life science company that develops and supplies bioprocess instruments catering to microbial and cell culture applications. The product range includes DASGIP and New Brunswick Bioprocessing systems and software solutions. The product portfolio includes Stand-Alone, Parallel and Single-Use systems with working volumes from 60ml to 2,400L all from one source, Eppendorf.

Evolution Scientific, Inc.

118

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Chris Stoeckel

Evolution Scientific is a registered VOSB, ISO 9001 comprehensive technical service provider to the pharmaceutical biotech, medical device, and other regulated industries. Scheduled and unscheduled service with response times often within the same day or next day. We're located in Pennsylvania and servicing clients throughout the U.S. We provide vendor consolidation, fast response, minimized downtime, custom tailored solutions, cost savings, controlled quality services, superior customer service, cGxP trained, ISO registered.

Excellis Health Solutions

278

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New Hope, PA 18938
215-919-0144
wmh@excellishealth.com
Wes Hyman

Excellis Health Solutions, LLC is the undisputed leading provider of strategy and implementation consulting services within the Life Sciences and Healthcare Industries on a global basis. Founded in 2010, Excellis is privately held and has over 400+ years of combined industry experience in the Life Sciences, Pharmaceutical, Healthcare, Manufacturing and Consumer Package Goods fields.

Experis Engineering

277

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Charles Thomas

With seasonal peaks and fluctuating market demands, your industry requires exceptional workforce agility and quick access to the right talent and specialized solutions. That's what Experis delivers. We provide Professional Resourcing and Project Solutions to fit your business, whether you're looking for an interim design engineer, a project team for a critical initiative, or your next VP of Engineering. At Experis Engineering, we go further to find top engineering talent both contract and permanent positions. In fact, we place over 3.2 million hours of engineering talent each year.

Extract Technology

226

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PeterSchofield

Extract Technology are a leading worldwide supplier of containment and aseptic systems for the pharmaceutical, healthcare, biotech and chemical markets.

Ezi-Dock USA

154

246 Calef Highway
Barrington, NH 0
603-415-3625
amutz@ezidockusa.com
Andy Mutz

Ezi-Dock USA offers high containment (OEB5) powder transfer systems in both disposable and re-usable format to address the cost, maintenance and reliability challenges faced by pharmaceutical and biotech end users.

Feldmeier Equipment

151

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sjones@feldmeier.com
Stephanie A Jones

Feldmeier Equipment has become a respected supplier to some of the most elite companies worldwide in their respective trades. From pharmaceutical, biotech, and cosmetic clients to brewers and food, dairy, and beverage processing facilities, the Feldmeier name has become a trusted resource for quality, dependable stainless steel processing equipment.

Festo Corporation

142

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Christopher Navolio
mike.severino@festo.com
Mike Severino
508-294-3408

For over 40 years in the US and 80 years globally, Festo has been a positive force for manufacturers. Our passion is automation - creating intelligent automation solutions that transform the way people work, the way companies compete. Ultimately, it's about continuously stimulating progress. Our aim is to help our customers make their

Exhibitor Company Descriptions continued

products faster, smarter and more precise. Rather than surviving, they can thrive as industry leaders. And when our customers win, we win. We observe. We analyze. We inspire.

Flexicon Liquid Filling

159

37 Upton Technology Park
Wilmington, MA 01887
978-658-6168
peter.lambert@wmftg.com
Peter Lambert

Our peristaltic filling and capping solutions bring significant advantages to users as they scale-up from research to production fill/finish. Using our single-use asepticsu™ technology, our range of benchtop fillers/cappers, clinical scale semi-automatic filling systems and fully automatic production scale systems define simplicity and security in high purity liquid filling applications.

Flow Sciences, Inc.

311

2025 Mercantile Drive
Leland, NC 28451
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jhutson@flowsciences.com
Josh Hutson

Flow Sciences' mission is to provide containment systems for laboratory, pilot plant and manufacturing areas. The products are designed to protect operators from exposure to hazardous particulates and vapors while performing delicate operations. Flow Sciences, Inc. is focused on achieving the following goals for all of its enclosures: -maximized containment -ergonomic ease of use -high performance standards -minimal energy consumption -design flexibility The Flow Sciences' Team, with over thirty years experience in laboratory containment, is committed to finding containment solutions that meet your needs.

Fluenta Solutions

250

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ed@fluenta.us
Ed Perez

Distributor single-use components

Fluor

114

100 Fluor Daniel Drive
Greenville, SC 29607
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Beth.brown@fluor.com
Andrew Baird

Fluor's expertise covers the full range of planning, engineering, procurement, construction and advanced manufacturing services for new and existing facilities. With our proven capability to execute projects, Fluor's Life Sciences is a reliable solution to minimize risks when delivering new capital projects of any size - anywhere in the world.

FLW Southeast

247

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monty.monteith@flwse.com
Monty Monteith

FLW Southeast is an international supplier of Measurement Instruments & Control Systems to manufacturers in a wide range of industries. By combining world-class products, application expertise, and unsurpassed customer service, FLW Southeast enables its clients to increase manufacturing efficiency, reduce production costs, and improve product quality and value.

Fristam Pumps

300

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704-577-3366
kmeulemans@fristampumps.com
Ken Meuleman

Fristam Pumps USA designs and manufactures high-purity, high-performance stainless steel pumps, blenders and mixers. Our broad line includes centrifugal pumps for process, WFI and CIP supply; self-priming pumps for CIP return; positive displacement pumps for gentle product handling and dosing applications; and mixers and blenders for quick, consistent blending.

Fujifilm Diosynth Biotechnologies

13

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919-337-4400
Mark.yates@fujifilm.com
Mark Yates

Contract Manufacturing

Garlock

314

1666 Division Street
Palmyra, NY 14522
315-237-2330
mari.foley@garlock.com
Mari Foley

Garlock® seals help make life better for millions of people around the globe. They play an important role in assuring the safety of medications, food, beverages, cosmetics and many other consumer products. Process engineers and professionals working in Quality, Operations and Maintenance trust the Garlock family of companies to develop Pharmaceutical and Bio-Pharmaceutical industry sealing solutions for a broad range of applications, including hygienic pipework, reaction vessels, blenders and mixers, ultra-pure water systems, valves and pumps.

G-CON Manufacturing, Inc.

128

6161 Imperial Loop
College Station, TX 77845
979-431-0700
dpowers@gconbio.com
DennisPowers

G-CON Manufacturing provides the resources and experience to transform the industry by providing unmatched manufacturing flexibility in biologics, cell and gene therapy, pharmacy compounding and cleanroom labs. PODs, a fully integrated, autonomous cleanroom solution, are completely self-contained pre-fabricated mobile units offering a flexible, scalable, failsafe system for continuous process operation.

GEA North America

227

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844-432-2329
Michael.rohr@gea.com
Michael Rohr

GEA North America is a global specialist in solid and liquid dose technology. Our installations include batch and continuous granulation, drying, pelletizing and coating, contained materials handling, tablet compression, freeze drying, fermentation and liquid formulation, separation, homogenization and cell disruption. GEA also provides technical competence, test facilities for product development and process evaluation, project management, market-leading equipment, customer service and support.

Exhibitor Company Descriptions continued

Gemu Valves

275

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678-553-3400
hpetty@gemu.com
Heather Petty

GEMÜ Valves manufactures valves, measurement and control systems for all sectors of industry. GEMÜ is committed to the pursuit of quality and excellence in the development, production and manufacturing of engineered diaphragm valves. GEMÜ strives to consistently provide a level of service exceeding the expectations of customers. Every inquiry and order is carefully considered so the customer can be offered the most suitable GEMÜ product to match their requirements. GEMÜ's overriding philosophy is to ensure each and every customer contact is a quality experience.

Getinge La Calhene

343

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Vendome, PA 41102
(610) 241-5025
david.milligan@getinge.com
DaveMilligan

The DPTE® system is the core of the transfer system that La Calhène created over 50 years ago. The DPTE® system provides bi-directional containment without intermediate bio-decontamination.

GF Piping Systems

145

9271 Jeronimo Road
Irvine, CA 92618
714-731-8800
714-788-7042
paul.galvin@georgfischer.com
Paul Galvin

GF Piping Systems provides high-quality piping systems, featuring recirculating lab faucet AquaTap and Fuseal lab waste piping system. Plastic pipe and fittings, valves, actuators, rotameters, fusion joining technology, secondary containment, flow monitoring and process control instrumentation.

Gill's Process Control Inc.

157

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Rocky Mount, NC 27804
252-977-9391, Ext. 221
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John Gill

Gill's Process Control Inc. provides quality, comprehensive validation, compliance and technical services to the pharmaceutical industry. We are experienced in automation, equipment, HVAC, Utility, Facility, Lab, IT validation projects and offer a variety of services to meet the needs and budgets of our clients. We look forward to serving you through commissioning and qualification during your next project. www.Gillsprocess.com for more information.

groninger USA L.L.C.

156

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Matt Clifton

groninger designs and manufactures fill/finish processing lines for pharmaceutical and cosmetic industries. Our core competencies are customized turnkey aseptic liquid processing lines which include; cleaning, sterilization, filling and closing of vials, eye drops, syringes, and cartridges.

Hallam-ICS

218

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Natasha Yaryna

Toxic Gas Monitoring Systems, Process Control and Plant Automation, Commissioning and Validation, Arc Flash and Electrical Safety, Mechanical, Electrical and Process (MEP) Engineering

Hamilton Company

267

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Reno, NV 55114
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dcarine@hamiltoncompany.com
Mark Recupero

Hamilton Company produces process sensors including pH, optical dissolved oxygen (DO), viable cell density, optical density, and conductivity. Hamilton Arc products replace traditional transmitters via placement of a microprocessor inside the sensor. Arc sensors measure more reliably and save on cost by communicating directly with the process control system. Our viable cell density instrument measures living cells in-line through capacitance based measurement.

Harrington Pure - SED North America

121

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815-609-3844
dreed@sed4valves.com
Doug Reed

Harrington Pure, a division of Harrington Industrial Plastics, has opened an office and warehouse in Raleigh, NC. This new branch offers SED Flow Control Aseptic Diaphragm Valves, ASME BPE tube and fittings, hangers, Exergy heat exchangers, Avco ball valves, hose assemblies and additional industry compliant quality products for the BioPharm and Industrial Markets. Harrington Pure has unparalleled stock, service and expertise with a team of BioPharm specialists and a knowledgeable sales staff.

Harrington Pure - SED North America - Harrington Industrial Plastics

120

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Doug Reed

Harrington Pure, a division of Harrington Industrial Plastics, has opened an office and warehouse in Raleigh, NC. This new branch offers SED Flow Control Aseptic Diaphragm Valves, ASME BPE tube and fittings, hangers, Exergy heat exchangers, Avco ball valves, hose assemblies and additional industry compliant quality products for the BioPharm and Industrial Markets. Harrington Pure has unparalleled stock, service and expertise with a team of BioPharm specialists and a knowledgeable sales staff.

Hipp Engineering and Consulting, Inc.

802

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919-755-1033
Cathryn Parsons

HIPP Engineering is a leading Engineering & Consulting firm in process and facilities design for cGMP/cGLP driven fields. We provide planning, budgeting, design, project management, construction support, and start-up services for all FDA, EMA, and MHW regulated industries.

Exhibitor Company Descriptions continued

Holloway America

107

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417-863-0077
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EGayer@HollowayAmerica.com
Evelyn Gayer

Holloway America – Custom stainless steel tanks, ASME pressure vessels, & components–Custom concepting/design/Finite Element Analysis (FEA)/engineering/machining/fabrication, from simple parts to complex machines–YOURSITE™ On-Location Services: fabrication, repair, retrofit/modification, and/or replacement of vessels & tanks, valves, instrumentation, controls, pumps, all performed at your location–Tank & pressure vessel remediation–Installation & startup assistance–Certified craftsmen—Seal-Break Pliers

HP Services

329

800 Scenic View Dr.
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dcole@hartcompanies.com
Don Cole

Cleaning, Passivation and Derouging Services

Hyde Engineering + Consulting

208

6260 Lookout Road, #120
Boulder, CO 80301
415-748-8753
Simon Forder

Hyde Engineering + Consulting is a leader in the engineering, commissioning and qualification of equipment and clean utility systems. Hyde is known for high quality expertise ranging from facility planning and design to training of client staff and regulatory personnel. Our in-depth understanding of global regulatory requirements allows Hyde to provide significant value to our clients on a global scale. Our team of highly skilled engineers and consultants are committed to our client's success.

Hydro Service & Supplies Inc.

306

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Research Triangle Park, NC 27709
919-544-3744, Ext. 324
kaustin@hydroservice.com
Katelin Austin

Hydro Service & Supplies provides a range of quality ultra-pure water systems. We combine innovative designs, high performance components, and superior materials of construction and precision manufacturing for ultra-high quality systems. Hydro serves the Pharma/Biotech, Electronics, Research, Academic, Medical, Food & Beverage, and Industrial markets. We offer engineering services, system fabrication, installation, start-up and commissioning, validation support, PLC programming, and reliable service support 24/7.

ICQ Corp

808

202 Sunstone Dr
Cary, NC 27519
401-440-2991
afarley@icqconsultants.com
Ashley Farley

Integrated Commissioning & Qualification, supplies services in the life science industry. Our services range from technical commissioning and qualification engineers to project management services. We focus on the commissioning effort in alignment with qualification, which can leverage many aspects of those efforts with complying to procedures and quality systems

IES Engineers

204

1720 Walton
Blue Bell, PA 19422
610-828-3078
jveve@iesengineers.com
Janet Veve

IES Engineers (IES) was established in July 1991 as a consulting firm specializing in environmental, health and safety compliance, OSHA compliance/training, industrial hygiene, process safety management , risk management, potent compound evaluations, and design/build of air and wastewater pollution abatement systems among other EHS services. Located in Blue Bell, PA, IES provides nationwide and international services to the Bio-Pharma, Chemicals, Food, Manufacturing, and Printing industries.

ILC Dover LP

229

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rosasp@ilcdover.com
Pedro Rosas

Since 1947, ILC Dover has provided engineered solutions to complex customer problems, serving the aerospace, personal protection and pharmaceutical industries. Known for production of space suits for NASA, ILC is a world leader in the use of high-performance flexible materials, allowing for unique solutions to meet customer needs. ILC's innovative products have been used on the moon, on Mars and around the globe. ILC Dover...creating what's next.

IMA Life North America, Inc.

214

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716-695-6354
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Bruce Houser A global supplier of automated processing equipment for vials, ampoules and syringes. Equipment range includes rotary and linear washers, depyrogenation tunnels, liquid and powder fillers, freeze-dryers, loading/unloading systems, cappers and labelers. We provide solutions for laboratory, pilot and commercial processing needs.

Industrial Automated Systems

135

4189 Dixie Inn Road
Wilson, NC 27893
252-237-3399
bsauls@ias-nc.com
Bryant Sauls

"Industrial Automated Systems (IAS) is a System Integrator that understands the critical challenges of manufacturing, including costs, time-to-market, and information management. IAS has expertise is in Process Control, Engineering Consulting, Controls Design & Implementation, Software Development and Data Collection Implementation, Electrical Contracting, Machine Vision (Cognex Certified), and UL508 Control Panel Design and Construction.

Exhibitor Company Descriptions continued

International Society for Pharmaceutical Engineering (ISPE)

244

600 N. Westshore Blvd., Suite 900
Tampa, FL 33609
813-960-2105
tryan@ispe.org
Tracey Ryan,

ISPE, the International Society for Pharmaceutical Engineering, is the world's largest not-for-profit association serving its Members by leading scientific, technical and regulatory advancement throughout the entire pharmaceutical lifecycle. ISPE is committed to the advancement of the educational and technical efficiency of its members through forums for the exchange of ideas and practical experience.

IPS

260

2803 Slater Road
Morrisville, NC 27560
919-460-6636
IPS@ipsdb.com
Mark Butler

IPS-Integrated Project Services LLC is a global leader in developing innovative and cost-effective solutions for the engineering, construction, commissioning and qualification of complex biopharmaceutical research and manufacturing facilities. With technical expertise spanning R&D to pilot-scale to large-scale production, we specialize in the technology, trends, and regulatory environment to successfully deliver capital projects and improve operations worldwide.

ISPE Carolina-South Atlantic Chapter

245

1500 Sunday Drive, Suite 102
Raleigh, NC 27607
919-573-5442
Membership@ISPE-CaSA.org
Mark Davies, Membership Committee Chair

ISPE Carolina-South Atlantic Chapter (ISPE-CaSA) is a not-for-profit volunteer society of technical professionals who apply their practical knowledge in the regulated pharmaceutical and medical device manufacturing industries. The Chapter is committed to the advancement of the educational and technical efficiency of its nearly 1300 members through forums for the exchange of ideas and practical experience. ISPE Carolina-South Atlantic is one of ISPE's more than 30 North American Chapters and worldwide Affiliates. ISPE-CaSA is one of the Society's largest and most active chapters.

ITT Engineered Valves

152

33 Centerville Rd.
Lancaster, PA 17603
717-509-2208
Miles Chamblee

ITT Engineered Valves offers superior hygienic process components for hygienic processing industries (Pharmaceutical, Bioprocessing and Fine Chemical). The Pure-Flo brand is synonymous with the highest quality, precision engineered hygienic diaphragm valves. Through both standard and custom valves, ITT is committed to providing the best quality and value for your unique flow-control needs.

J.A. King

263, 264

7239 ACC Blvd, Suite 101
Raleigh, NC 27617
336-268-0124
Doug.Ahrens@JAKing.com
Doug Ahrens

J.A. King is a third generation family business providing industrial measurement solutions in the form of Distributed Equipment, Engineered Solutions, Embedded and Calibration Services. J.A. King is a distributor of over 50 leading brands enabling us to provide the measurement equipment you need throughout your entire facility. J.A. King offers accredited calibration services with service plans tailored to your individual needs. We have a network of 14 state of the art, fully accredited ISO 17025 calibration laboratories covering 16 states. Our Engineering division can offer custom measurement equipment from micron to meter, microgram to Kilo heavy capacity batching and truck scales.

Jacobs

259

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Cary, NC 27518
919-859-5008
david.broughton@jacobs.com
David Broughton

Jacobs provides the following services to our pharmaceutical and biotechnology clients: Site Selection, Economic Development Incentives, Master Planning, Programming, Feasibility Studies, Engineering Preliminary and Detailed Design, Procurement, Owner's Agent, Construction Management - T&M, Lump Sum, GMAX, Commissioning, Qualification, Validation and Maintenance. Typical projects in these industries include laboratories, research and development facilities, pilot plants, bulk active pharmaceutical ingredient production facilities, large-scale biotechnology facilities, and secondary manufacturing facilities (administrative, packaging, warehouse).

JE Dunn Construction Company

206

1001 Locust St.
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816-474-8600
susan.bradt@jedunn.com
Susan Bradt

As the nation's 4th largest Science & Technology builder, JE Dunn's Science & Technology group constructs facilities such as biomedical and chemistry research, medical manufacturing, pharmacology, biotechnology, laboratory, and high contaminant spaces. JE Dunn has specific experience with advanced technology installation ranging from microelectronics, nanotechnology, aerospace, cleanrooms and renewable energy.

Jedson Engineering

307

8000 Regency Parkway
Raleigh, NC 27518
252-916-2811
Phillip DeMuth

Established in 1984, Jedson Engineering is a privately owned, full-service engineering, procurement, and construction management (EPCm) company that specializes in innovative and efficient pharmaceutical projects. From our headquarters in Cincinnati, Ohio and offices located throughout the United States and in Saudi Arabia, we deliver projects that improve your profitability and predictability.

K-Patents Process Instruments

130

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Herb Betts

Manufacturer of Process Instruments

KAYE

101

967 Windfall Road
St. Marys, PA 15857
814-834-9140
barry.harston@amphenol-sensors.com
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The Kaye product range is designed to meet the most demanding industrial requirements for process improvement, thermal validation and environmental monitoring in Pharmaceutical and Biotechnology Industries. Find out more about the next generation validation system the new Kaye Validator AVS. Check out Simplified Real Time Validation - wireless high accurate measurement of temperature and humidity with the new Kaye RF ValProbe II

Exhibitor Company Descriptions continued

Kalyx Scientific

123

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Craig Loudermilk

Kalyx Scientific specializes in cutting-edge, high-quality products for the Healthcare, Pharmaceutical, Biomedical, Biotech and University industries.

Kymanox

108

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Kevin C.Brown

Kymanox is dedicated to Ideal Knowledge TransferTM (IKT). Our industry experts provide technical services focused on: + Facility Conceptual Design + CQV for Facilities, Equipment, & Processes + FDA & EMA Submissions + 483 & Warning Letter Remediation + Medical Device Design Control & DHF Kymanox emphasizes process understanding and best-in-class documentation to set us apart from the competition. Our experienced team and proven toolkits help organizations achieve predictable success.

L.J. Star Inc.

272

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mcurnutte@ljstar.com
Mike Curnutte

L.J. Star is a leading supplier of process observation equipment including sight glasses, sanitary visual flow indicators, sanitary fittings and clamps; tank lights , camera systems and accessories including wipers, spray systems and timers. At L.J. Star, we stand behind our products and supply third party documentation of product performance claims and standards compliance, unlike other suppliers. We make you LOOK better.

LEWA-Nikkiso America, Inc.

249

132 Hopping Brook Road
Holliston, MA 0
508-429-7403
mmorse@lewa-inc.com
Marlis Morse

LEWA-Nikkiso is your global supplier for Biopharmaceutical systems utilizing a fully integrating supply chain. LEWA-Nikkiso is the leading supplier of metering pumps used in chromatography systems today. Using our advance fluid design and fabrication capability, we can provide a custom designed chromatography system with unmatched flexibility and accuracy. This advanced design is optimized for use with integrated buffer dilution incorporated into the system's footprints.

Lives International

137

99 Pine Hill Road
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Vlad Curtean

Lives International is an industry leading manufacturer and distributor of thermal validation equipment within the pharma and biotech industry worldwide.

M.G. Newell Corp.

150

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336-393-0100
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Mimi Cartee

M.G. Newell is a distributor and fabricator of sanitary processing equipment including hygienic valves, pumps, fittings and instrumentation.

Mangan Biopharm

205

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Brooks Fardy

Mangan Biopharm, a division of Mangan, Inc. is an employee-owned company delivering resources that provide best in class automation, compliance, and CQ&V services to the regulated Life Sciences industry. We provide total Lifecycle Engineering, including robotics, automation and controls system engineeering, GMP classified area manufacturing support, process engineering and complete commissioning, qualification, and validation of facilities, utilities, equipment, and processes.

Mar Cor Purification

153

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484-991-0220
mhoughton@mcpur.com
Mark Houghton

MCP is a leading provider of complete water treatment systems & services for the Life Science market. For over 40 years & over 1000 installations, we have been providing high-purity water solutions to companies in the pharmaceutical, cosmetics, medical device, food & beverage & dialysis markets. We have an extensive line of turn key High Purity Water systems & associated products & services, while providing proven filtration & disinfection technologies. Mar Cor Purification has one of the largest water treatment related technical & field support networks to support our installed systems with locations across the U.S. & Canada.

Mason-Grey Corporation

313

400 Galleria Pkwy
Atlanta, GA 30339
678-385-7470
Joseph Reini

The Mason-Grey Corporation provides engineering solutions and services to process industry clients in energy, metals, plastics, biotech, pharmaceutical, and other key process markets. Today Mason-Grey executes projects and provides services to the Fortune 500 and mid-tier companies from coast to coast. Mason-Grey employees live and work in support of our mission from Massachusetts to California. Mason-Grey proudly offers full benefits options to its employees including company paid medical insurance, a 401(k) with 4% company match, dental & vision programs, and paid vacation and holidays. Mason-Grey is headquartered in Atlanta, Georgia.

Exhibitor Company Descriptions continued

Masy BioServices

323

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978-433-6279
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Branden Morris

Masy BioServices' integrated suite of metrology, qualification, and offsite cGMP biorepository services helps life science companies improve the quality and accuracy of every step of the product development chain — from ensuring the accuracy of primary standards and measurement instrumentation, through qualifying manufacturing equipment and environmental chambers, to secure storage of samples and finished products.

MECO

340

501 Community Drive
Fuquay Varina, NC 27526
919-605-0044
Don Batot, MECO RSM

MECO manufactures made in the USA BioPharm USP Purified water systems including Multimedia, Carbon, Softener pretreatment, Ultrafiltration, Reverse Osmosis, Electrodeionization, UV, and Ozone equipment. MECO designs and builds Multiple Effect, Vapor Compression WFI systems, WFI storage/distribution, and Pure Steam Generators.

Merck

11

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Jeffrey Coles

For 125 years, Merck has been a global health care leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. For more information, visit www.merck.com

METTLER TOLEDO

246

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Dave Ferragamo

METTLER TOLEDO Process Analytics is a leader in process and pure water monitoring instrumentation used in pharmaceutical and biotech applications, offering systems for the measurement parameters of pH/ORP, dissolved oxygen, TOC, dissolved CO2, and conductivity. METTLER TOLEDO's innovation continues with the introduction of the 7000RMS analyzer for on-line microbial monitoring.

Michell Instruments, Inc.

131

319 Newburyport Turnpike
Rowley, MA 01969
978-843-7660
rose.barry@michell.com
Rose Barry

DewPoint, Relative Humidity and Oxygen sensing equipment

Miele Professional (Represented by Atlantic Technology Group)

147

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Midlothian, VA 23113
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jenkinsatg@aol.com
Dave Jenkins

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MilliporeSigma

268

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919-468-7228
Tom.Johnson@emdmillipore.com
Tom Johnson

MilliporeSigma is the U.S. life science business of Merck KGaA, Darmstadt, Germany. With 19,000 employees and 72 manufacturing sites worldwide, MilliporeSigma's portfolio spans more than 300,000 products enabling scientific discovery. MilliporeSigma has customers in life science companies, university and government institutions, hospitals and industry. More than 1 million scientists and technologists use its products. The company is committed to solving the toughest problems in life science by collaborating with the global scientific community. For more information, visit www.emdmillipore.com and www.sigma-aldrich.com.

MilliporeSigma

309

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james.brown@emdmillipore.com
James P. Brown

Research. Development. Production. We are a leading supplier to the global Life Science industry: solutions and services for research, development and production of biotechnology and pharmaceutical drug therapies.

NCCU-BRITE

236

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919-530-7717
njanvierderilus@nccu.edu

Natacha Janvier-Derilus Training and research that leads to satisfying careers in the life sciences industry is at the heart of North Carolina Central University's Biomanufacturing Research Institute and Technology Enterprise (BRITE). BRITE students may earn undergraduate or advanced biotechnical degrees in courses taught by seasoned scientists, many with recent industry experience. The 52,000-square-foot ultra-modern classroom and lab facility provides hands-on learning opportunities to create graduates who are job-ready in analytical technology, drug discovery, biomanufacturing and other fields.

Neutronics Inc.

209

456 Creamery Way
Exton, PA 19341
610-524-8800, Ext. 159
bob.maza@neutronicsinc.com
Bob Maza

With sensor capabilities ranging from percent down to ppb, Neutronics' oxygen analyzers, sample conditioning packages, and gas detection systems provide reliable process control and workplace area monitoring solutions, giving you the information you need to maintain a safe working environment, meet high quality standards, and keep your operations running smoothly.

Exhibitor Company Descriptions continued

New England Lab

317

300 Dominion Drive
Morrisville, NC 27560
888-635-2080
mpizzo@newenglandlab.com
Marc Pizzo

Our clients leverage our 25 years of laboratory furniture experience to make educated buying decisions. We take the time to understand our client's requirements, vision and budget and use this extensive experience to meet the project objectives. Our commitment to lab-tested quality spans our full product line of fixed casework, adaptable furniture, fume hoods and accessories. We understand what matters to you, take pride in our craft and products, and deliver service that makes your new lab right.

NNE

2

1101 Slater Rd.
Durham, NC 27703
510-410-4854
Andrew Quebbemann

NNE is an international company specialised in pharma engineering. We help pharmaceutical companies bring products to market by providing flexible, compliant and future-proof solutions. We have close to 2,000 professionals delivering global knowledge and best practices, all dedicated to supporting our customers globally and on local sites. Through focused pharma engineering we enable our customers to deliver on demand.

O3 Sterilization Systems by Burkert

320

11425 Mt. Holly-Huntersville Road
Huntersville, NC 28078
704-504-4440
Greg Love

Burkert has developed a patented ozone sterilization system to assure sterility with one's single-use disposable process. The system adapts to any manifold or connection configuration with its zone sterilization adapter system. Localized sterilization of single-use aseptic connection points provides SAL throughout a bioprocess production system. Detailed SAL electronic signature data at each connection point is stored in a central data storage system for validation.

Oceasoft

248

250 Phillips Blvd.
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201-213-8002
k.muro@oceasoft.com
KimMuro

Helping clients stay aware of their environments OCEASOFT designs, calibrates, and commercializes smart wireless sensors for monitoring physical parameters such as temperature, humidity, CO2 levels, and differential pressure for life science and agribusiness industries.

OEC Fluid Handling

207

140 Cedar Springs Road
Spartanburg, SC 29304
800-500-9311
Scott Rosenberger
srosenberger@oecfh.com

OEC Fluid Handling Inc., provider fluid processing equipment for the high purity market.

OPTIMA pharma

339

1330 Contract Drive
Green Bay, WI 54304
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920-983-3151
beate.gurr@optima-usa.com
Beate Gurr

Optima Pharma's designs and manufactures machinery in accordance with cGMP requirements for cleaning, sterilizing, filling, closing and assembly of syringes, vials, infusion bottles and cartridges for liquid, viscous and powder products, including freeze drying and clean-room technology.

Pacific Ozone

212

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brl@pacificozone.com
Brian Lowe

Pacific Ozone is the leading manufacturer of air-cooled ozone generators and packaged systems for industrial applications including precision dissolved ozone control, ozone instruments and UL control panels, response now service and over 9,000 installations worldwide

Parker domnick hunter

319

2340 Eastman Avenue
Oxnard, CA 93030
919-594-9822
bowen.carpenter@parker.com
Bowen Carpenter

Parker domnick hunter provides integrated bioprocessing solutions that speed up development times, increase efficiency and safety and enable reproducible quality. Incorporating SciLog®, we combine filtration, single-use fluid-handling systems and sensors and automated single-use solutions.

Patton's Medical

141

3201 South Blvd.
Charlotte, NC 28209
704-942-8904
pat.coyle@pattonsmedical.com
Pat Coyle

Laboratory Air and Vacuum Systems. Specialty High Purity Gas delivery systems and accessories.

Paul Mueller Company

210

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Springfield, MO 65802
417-575-9216
dgraham@muel.com
David Graham

The Paul Mueller Company was founded in Springfield, Missouri in 1940 and specializes in Stainless Steel solutions for processing industries worldwide. Delivering quality and innovation are hallmarks of the Paul Mueller Company and its over 1000 employees across the globe.

PCI, LLC.

6

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Raleigh, NC 27617
919-781-7787
919-417-2292
kcollins@pci-llc.com
Kakki Collins

PCI clients can select a comprehensive Instrument Asset Management program, or any combination from our menu of services to meet their specific laboratory, production and compliance needs. Our clients capitalize on the benefits of service continuity from a single provider while they focus on core business, avoiding strained resources and ineffective efforts to manage assets internally.

Exhibitor Company Descriptions continued

PDA Southeast Chapter

242

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Debora Steenson

The Parenteral Drug Association (PDA) is the leading global facilitator of science, technology and regulatory information. The PDA creates awareness and understanding of important issues facing the pharmaceutical and biopharmaceutical community and delivers education for the community. Founded in 1946 as a nonprofit organization, PDA is committed to developing scientifically sound, practical technical information and expertise to advance pharmaceutical / biopharmaceutical manufacturing science and regulation so members can better serve patients. PDA Southeast covers the following states: North Carolina, South Carolina, Virginia, Georgia, Tennessee, Florida, Kentucky, Alabama, Louisiana, Mississippi and Arkansas.

PEG Contracting

338

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Nikki Ricketson

PEG Contracting is a North Carolina based unlimited General Contractor that provides high-quality construction management services to the pharmaceutical industry. We are proud to be certified as a Service-Disabled Veteran-Owned Small Business (SDVOSB) with Veterans Affairs and Historically Underutilized Business (HUB) with the State of North Carolina.

PharmaSys, Inc.

163

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Mark Davies

PharmaSys, Inc. provides quality, compliance and validation services to the worldwide community of pharmaceutical, biotech, clinical trial and medical device industries. PharmaSys offers a wide range of services including computer validation, audit services, compliance training, commission, equipment/process validation and QA consulting. Please see our website for more information – www.pharma-sys.com.

Piercan USA Inc.

234

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San Marcos, CA 92069
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Madeline Herrmann

PIERCAN serves the global market for glovebox gloves. We have manufacturing sites in California and Normandy, France. We offer a vast variety of polymer gloves meeting the pharmaceutical, nuclear, microelectronic, and biomed markets. Our knowledgeable and dedicated staff are able to match the best polymer to your containment needs today.

PRI Bio

265

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314-602-1993
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Craig Morley

PRI Bio is an industry leader in biowaste treatment solutions. PRI Bio effluent treatment includes AutoFlow™ continuous flow sterilization (HTST); ThermoBatch™ batch sterilization; and ChemFix™ for chemical disinfection and pH neutralization. PRI Bio also offers the patented Thermal Tissue Digester™ for carcass sterilization and disposal. For more than 30 years, PRI has advanced the science in hazardous waste treatment systems with more than 3,000 units installed in over 35 countries worldwide.

PTI

224

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Oliver Stauffer

PTI is a leading manufacturer of non-destructive inspection technologies for high risk packaging applications. We offer solutions for package integrity testing, leak detection, container closure integrity testing, and seal integrity testing. PTI's inspection technologies are deterministic test methods that produce reliable and robust quantitative test data. Our technologies conform to ASTM and other regulatory standards. We specialize in offering our customers comprehensive solutions including test method development. Applications include vials, ampoules, auto-injectors, cartridges, blisters, empty and pre-filled syringes, pouches and flexible packaging, bottles & other rigid containers. PTI - Experts in navigating the new USP 1207.

Quadro Engineering Corp.

345

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Ricky Evans

Quadro Engineering Corp., an IDEX Material Processing Technologies Business Unit, is the originator of the conical screen mill. Quadro manufactures an innovative line of size reduction mills, fine grind mills, mixers, emulsifiers, powder dispersion units, high shear wet mills and security screeners for the pharmaceutical, food, cosmetic, chemical, biotech and associated industries.

Refine Technology, LLC

116

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973-952-0002
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ChrisBartlett

Refine Technology manufactures and provides a 1.5" Single Use Connector and custom tubing assemblies for high volume sterile fluid transfer in single use and hybrid stainless steel/single use bioreactor systems.

RE Mason and Associates

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Matthew Power

For more than 65 years, the R.E. Mason Company of the Carolinas has served the Carolinas with a large array of innovative process automation and asset management solutions. We are the authorized local business partner of Emerson Process Management, representing many of their industrial product lines, including Fisher Controls and Emerson Process Systems and Solutions.

RGD Project Management, Inc.

16

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919-674-2013
jdeloso@rgdinc.com
Jack Deloso

RGD Project Management, Inc.

RGD Project Management specializes in the construction of biotech and pharmaceutical facilities. Since the inception of our company over seventeen years ago, we have recognized the importance of hiring highly

Exhibitor Company Descriptions continued

qualified personnel and delivering high quality facilities. In addition to construction, RGD's services encompass the implementation of capital projects throughout the project lifecycle: feasibility analysis, estimating, logistics, engineering & design, commissioning and validation. We are involved from concept development to first production runs. Our services include owner's representation, site selection, constructability, procurement, contracting, safety, shutdown management, project scheduling, quality control, commissioning, and validation support and site readiness for your first sellable product.

Rodem Inc.

18

128 Rand Park Dr.
Garner, NC 27529
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kbingley@rodem.com
Kevin Bingley

Rodem offers much more than sanitary process equipment distribution. We pride ourselves on offering our customers industry leading knowledge and experience to assist you with every step of your sanitary process operations.

RoviSys

20

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daniel.mclaughlin@rovisys.com
Dan McLaughlin

As an independent automation organization and an approved system integrator for a wide range of control systems and MES platforms, RoviSys is well suited to meet the diverse needs of our clients. Our independence combined with our experience on multi-level projects results in efficiency and quality in the creation of functional specifications, instrument specifications, process documentation, electrical design, and system configuration.

Sani-Matic, Inc.

255

1915 S. Stoughton Rd.
Madison, WI 53716
800-356-3300
608-226-8523
chrism@sanimatic.com
Chris McNulty

Sani-Matic, Inc. delivers critical cleaning solutions to the pharmaceutical, biotechnology, nutraceutical, personal care, food and beverage industries through targeted engineering, automation programming and craftsmanship. The Madison, WI-based manufacturer offers a full line of equipment including Clean-In-Place (CIP) Systems such as the UltraFlow™ 45 and 110, Clean-Out-of-Place (COP) Immersion Parts Washers and cabinet washers including the TactiWash™, PharmiCab™ and IBC Wash. Sani-Matic's automated process cleaning equipment and Tactical Solutions system optimization program are designed to provide pharmaceutical manufacturers with a complete, validatable clean.

SaniSure

155

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336-264-3826
cadkins@stwcos.com
Chris Adkins

SaniSure is a leading global OEM supplier of custom innovative Single Use solutions — from R&D to Process Development to GMP sterile applications. SaniSure can help you design aseptic solutions for transfer, cell growth, sampling, mixing, filling and storage. Use our innovative products and solutions to reduce assembly time, eliminate cleaning validations, protect product integrity and decrease the risk of contamination.

Sartorius

232

5 Orville Drive
Bohemia, NY 11716
631-254-4249
Tim Drennan

As a total solution provider, Sartorius Stedim Biotech merges one of the broadest portfolios of single-use components, hybrid or traditional stainless steel systems, and services in the market. Our integrated solutions cover fermentation, cell cultivation, filtration and fluid management as well as purification and lab technologies. Visit booth # 232 to learn more about all Sartorius Stedim Biotech has to offer!

Seqirus

7

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919-577-5894
blake.derrick@seqirus.com
Blake Derrick

Seqirus is a subsidiary of CSL Limited, a global biotherapeutics company. Seqirus was established on 31 July 2015 following CSL's acquisition of the Novartis influenza vaccine business and its subsequent integration with CSL's existing influenza vaccine division, bioCSL. With extensive research and production expertise and manufacturing plants in the US, UK, Germany and Australia, Seqirus is a transcontinental partner in pandemic preparedness and a major contributor to the prevention and control of influenza globally.

Sequence, Inc.

12

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Morrisville, NC 27560
919-844-7171
dsantarsiero@sequenceqcs.com
Dan Santarsiero

Sequence, Inc. is proud to offer quality and compliance services for software, IT infrastructure, laboratory instruments, analytical methods, equipment, automation, processes, cleaning and utilities, as well as process optimization, laboratory software support, remediation, regulatory compliance services, engineering, commissioning, integration and system/facility startup across the United States, as well as internationally. We provide turn-key implementation and validation solutions for instrumentation and methods including the VITEK ® 2 Compact, VITEK MS® and BacT/ALERT® 3D through our partnership with bioMérieux. We also have specialized experience integrating process analytics systems such as Discoverant, as well as many other software solutions widely used in regulated industries.

Our partnerships, knowledge and experience with the systems, instruments, equipment and processes used throughout regulated industries allows us to offer related support and administration services for comprehensive compliance solutions

Siemens Industry, Inc

143

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Lori Foy

The Siemens Industry Sector (Erlangen, Germany) is the world's leading supplier of innovative and environmentally friendly products and solutions for industrial customers. With end-to-end automation technology and industrial software, solid vertical-market expertise, and technology-based services, the Sector enhances its customers' productivity, efficiency, and flexibility. With a global workforce of more than 100,000 employees, the Industry Sector comprises the Divisions Industry Automation, Drive Technologies and Customer Services as well as the Business Unit Metals Technologies. For more information, visit http://www.siemens.com/industry or http://www.usa.siemens.com/pharma

Exhibitor Company Descriptions continued

SKAN US, Inc.

220

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John Groth

SKAN, founded in 1968, is one of the pioneer companies in the field of cleanroom equipment and isolator design for the global pharmaceutical industry. Innovative products, customer-specific solutions and an efficient service organisation have led SKAN to become a global market leader and important partner for industry and research laboratories.

Solid Design Southeast, Inc.

228

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Jim Singer

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WIKA Instrument LP

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25 YEARS 1992-2017

APRIL 1991
Patricia Lewis led task team to create Carolinas Chapter

MAY 1991
Forming Chapter held first meeting, an FDA presentation

MARCH 1992
Carolinas Chapter signed Articles of Incorporation

OCTOBER 1992
First Vendor Show, which turned into the Tech Conference

DECEMBER 1992
CaSA grows to 100 members

1993
Developed the first Chapter Handbook, becomes prototype for all ISPE Chapters & Affiliates

NOVEMBER 1997
Carolinas Chapter wins Chapter of the Year Award for the first time

JANUARY 1998
CaSA grows to 500 members

NOVEMBER 1999
Carolinas Chapter wins excellence award for Chapter Management & Member Services for the first time

NOVEMBER 2000
CaSA Student Member wins the Inaugural International ISPE Student Poster Competition

DECEMBER 2001
CaSA reaches 1000 members

CONNECTING
PHARMACEUTIC

SPE® | Carolina-South Atlantic Chapter

2002

Southeast Chapter absorbed and current name adapted

FEBRUARY 2004

Tennessee added to the Chapter

NOVEMBER 2002

Jeff Odum, CaSA Past President, wins The Richard B. Purcy Distinguished Achievement Award

NOVEMBER 2006

Campbell University wins award for Student Chapter of the Year

NOVEMBER 2010

NC State University wins award for Student Chapter of the Year

NOVEMBER 2011

Jane Brown, CaSA Past President, wins The Richard B. Purcy Distinguished Achievement Award

OCTOBER 2014

Awarded the first Jane Brown CaSA ISPE Student Scholarship

SEPTEMBER 2016

CaSA Chapter hosts ISPE Annual Meeting in Atlanta, Georgia

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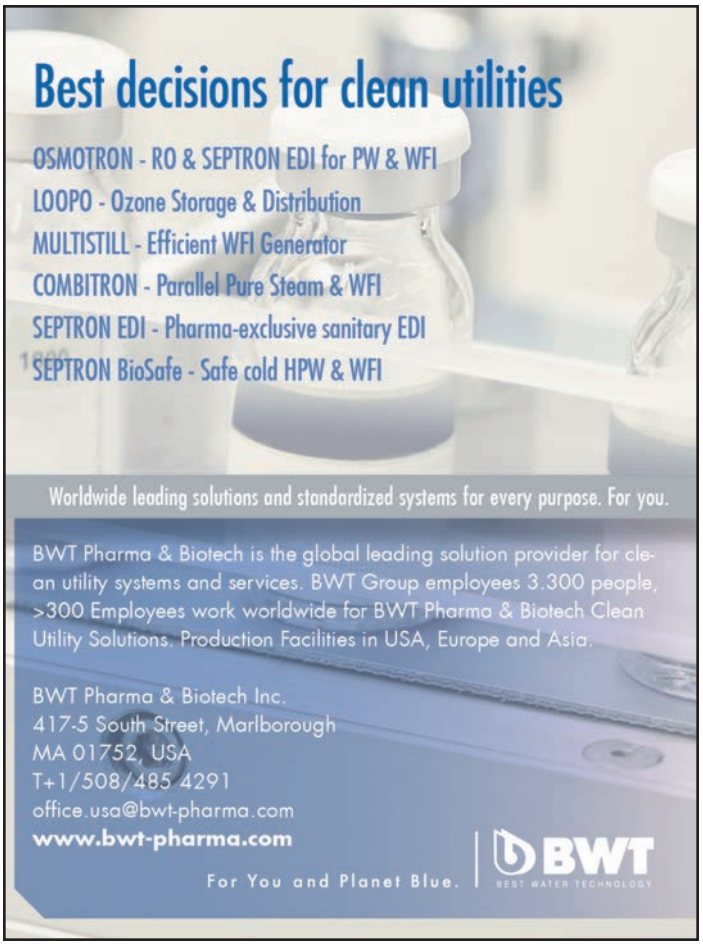

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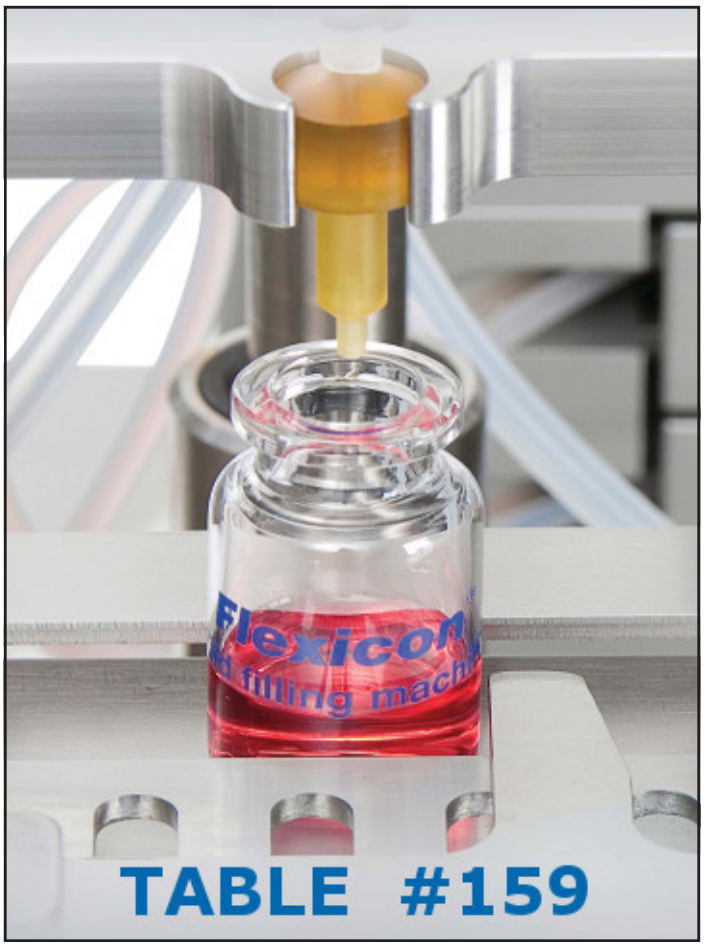


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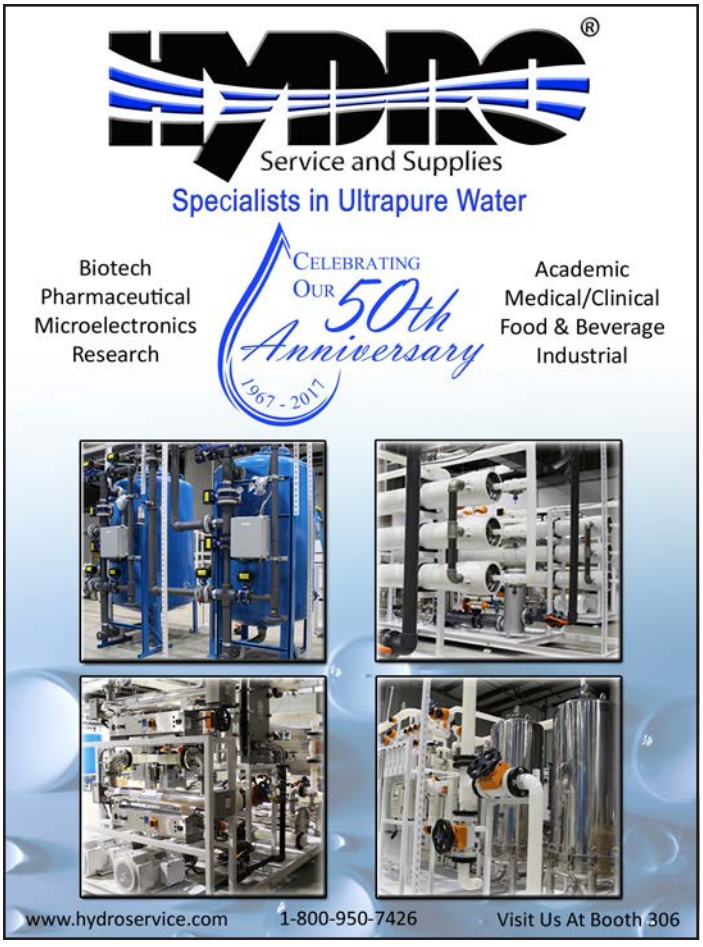

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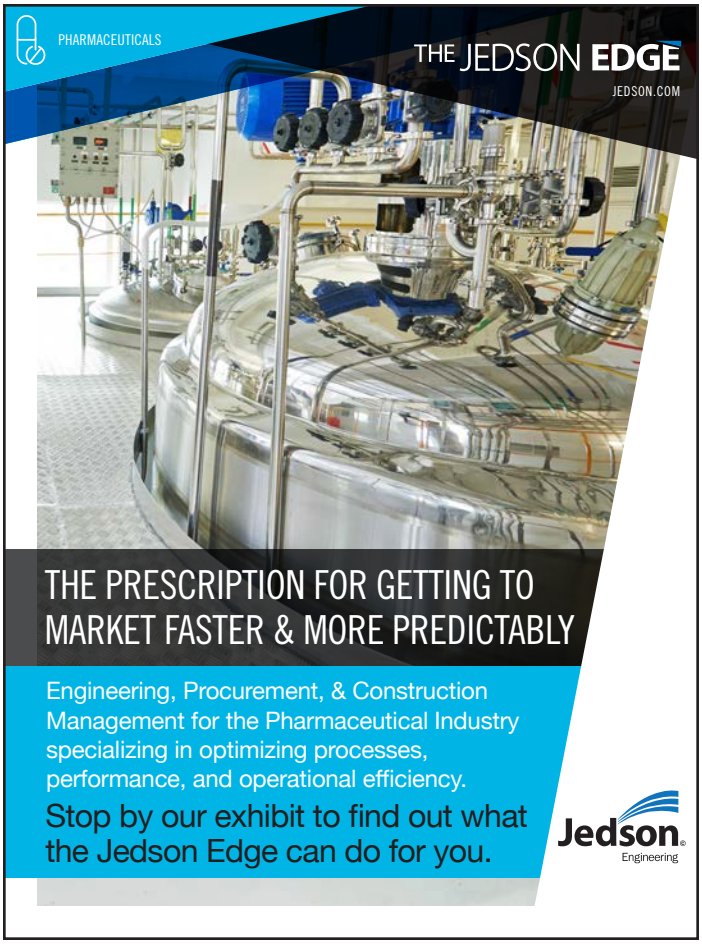

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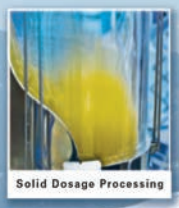
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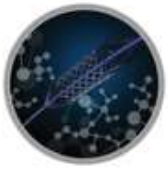

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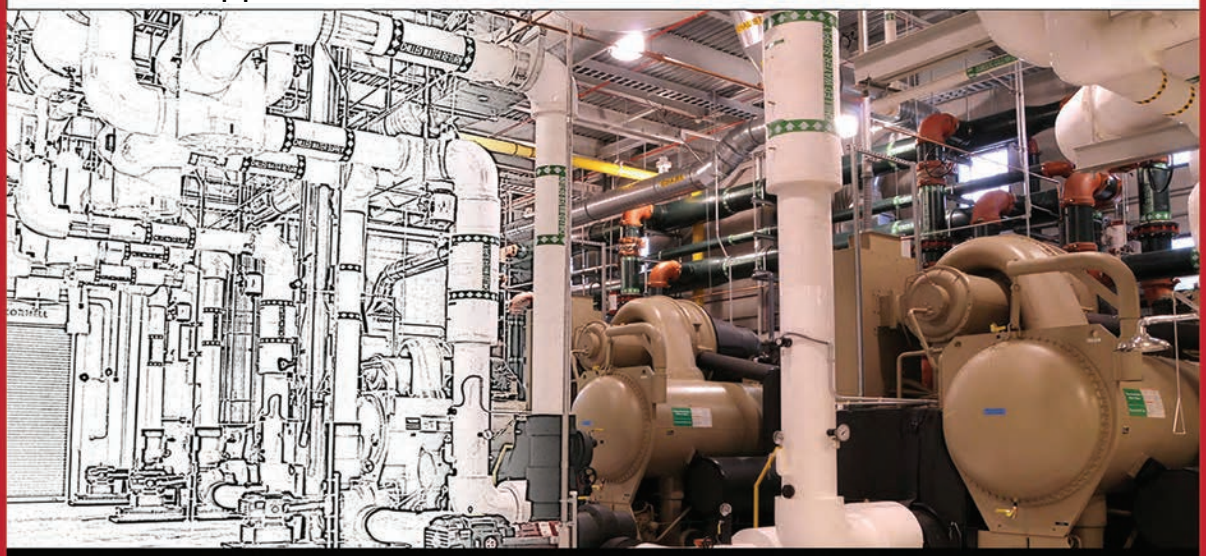

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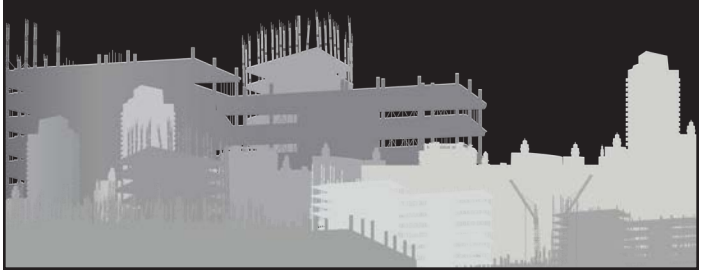

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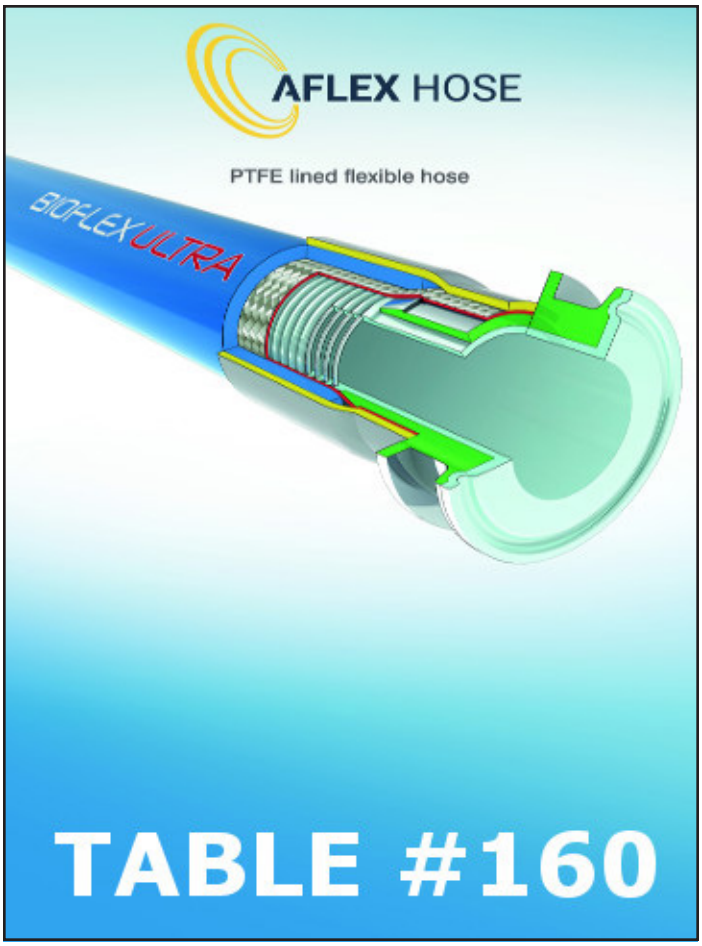

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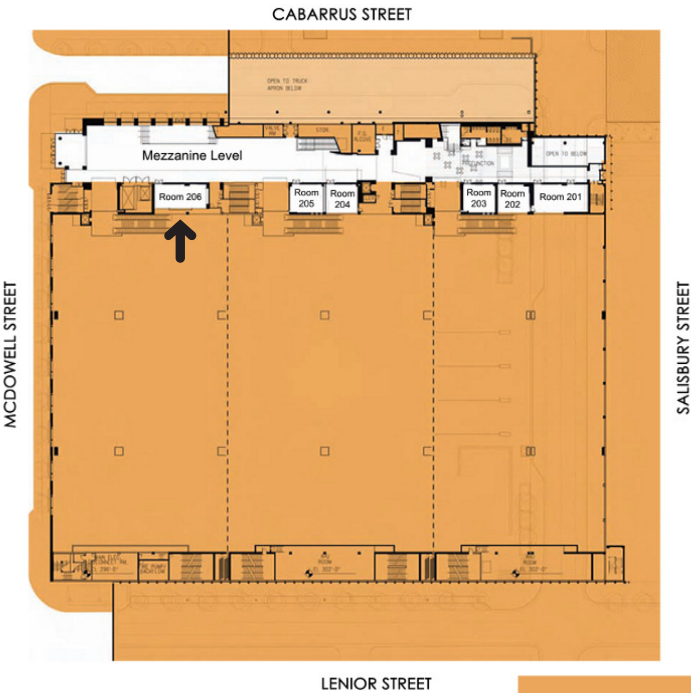
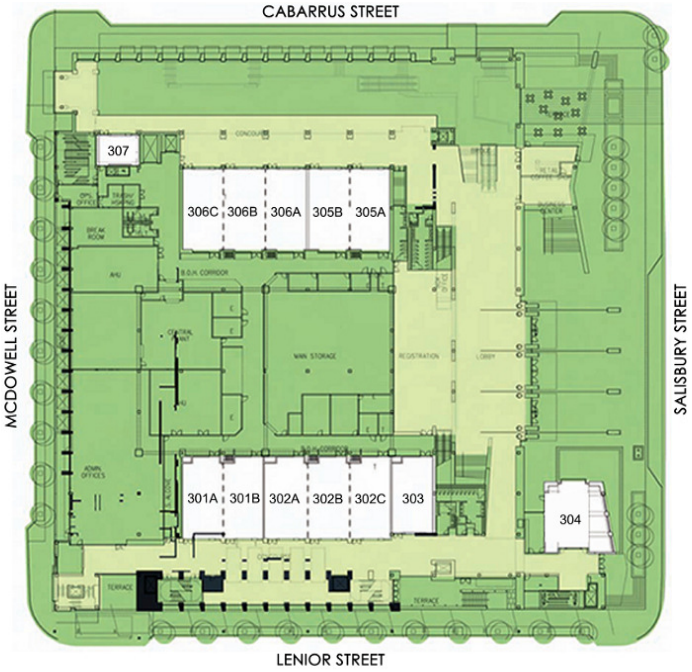
Miele Professional (represented by Atlantic Technology Group) 147
Pacific Ozone 212
Paul Mueller Company 210
STERIS Corporation 162
Wacco, Inc. 254

Meeting Rooms

200 LEVEL (Room 206)



300 LEVEL MEETING ROOMS



Ballroom Level (Room 402)

(across the hall & around the corner from Ballroom A)

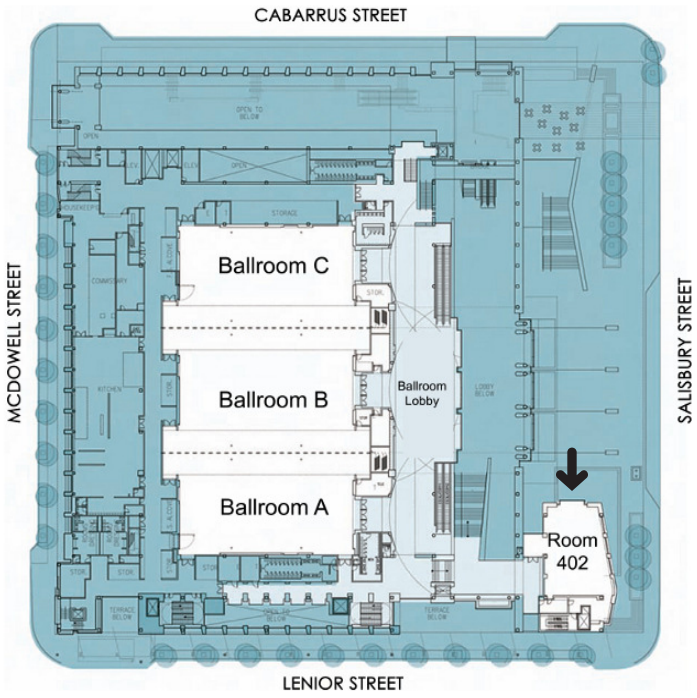
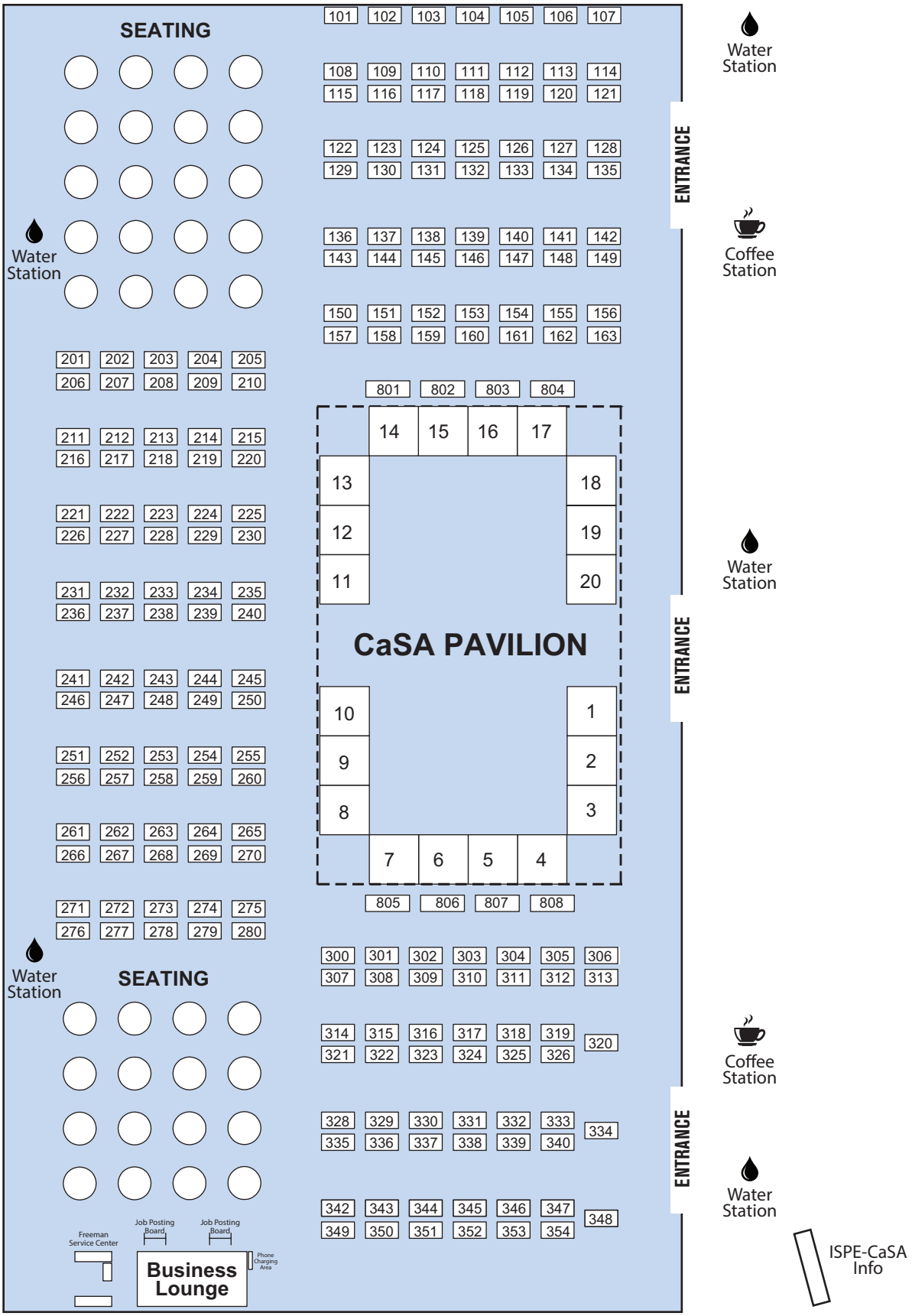


Exhibit Hall Floor Plan — Ballrooms A, B, and C



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(Chair)
Mangan Biopharm

Jim Hubbard
(Vice Chair)
AlfaNordic

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Chapter Management

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