



President's Message



Lisa Kerner

Welcome to the 25th Anniversary for the ISPE CaSA Chapter! This is an exciting year for our Chapter and it goes without saying – we have hundreds, if not thousands, of members to thank for our success. For starters, I would like to recognize ISPE CaSA Chapter's Past Presidents who helped us achieve this milestone. Their dedication and passion to support life sciences and the Chapter's

mission led us to where we are today. Having served on the Chapter Board of Directors for the past five years, I am truly honored to begin my second term as your Chapter President and have my name associated with this amazing group of leaders.

Patricia Lewis	1992-1993	Vince Miller	2004-2005
Bert Carter	1993-1994	Roy Snipes	2005-2006
Jeffrey Sieranski	1994-1995	Martin Rock	2006-2007
Brenda Carroll	1995-1996	Jim McGlade	2007-2008
Jeff Odum	1996-1997	Jacqueline Roth	2008-2009
Gary Reichelt	1997-1998	Mark Mathis	2009-2010
Mark Sawyer	1998-1999	Scott Billman	2010-2011
Jane Brown	1999-2000	David Brande	2011-2012
Marita King	2000-2001	Jennifer Lauria Clark	2012-2013
Cheryl Tucker	2001-2002	Matt Gilson	2013-2014
Bo Crouse-Feuerhelm	2002-2003	Heather Denny	2014-2015
Alan Jones	2003-2004	Lisa Kerner	2015-2016

Over the past 25 years, the ISPE CaSA Chapter has grown to one of the Society's largest and most active Chapters, and was awarded ISPE's prestigious Chapter Excellence Award in 1997, 1998 and 2000. CaSA also received the Chapter of the Year Award in 2008, 2007, 2006, 2003, 2001, 2000, 1998 & 1997. At the ISPE Annual Meeting in October 2014, the CaSA Chapter was recognized by ISPE with the Affiliate-Chapter Award for Innovation and Society Support. These are very high honors for our Chapter! For everyone that has contributed to CaSA's success, thank you for being a part of something amazing!

As we continue our journey, your Board of Directors have been working throughout the summer to develop plans for the upcoming year and we have many exciting education and networking events in the works!

We'll kick things off with our Annual Planning Meeting on September 8th from 2:30-5:30 pm at Prestonwood Country Club in Cary. At this meeting, we'll introduce you to new Board members and provide an update of Chapter happenings for the coming year. And, in true CaSA Chapter fashion, we'll have the opportunity to network with fellow members and friends in the industry at the cocktail reception beginning at 4:30 pm. If you would like to get involved or re-engage, this is the place to be!

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The CaSA Chapter has eight very active committees looking for volunteers. If one of the following piques your interest, then please be sure to join us September 8th or visit our website to learn more - <http://ispe-casa.org/ispe-casa-committees>

- Education Committee
- IT/Social Media Committee
- Life Sciences Technology Conference Committee
- Membership Development Committee
- Networking Committee
- Newsletter Committee
- Student Affairs Committee
- Young Professionals Committee

It's going to be a great year celebrating 25 years of the ISPE CaSA Chapter! With the support of our membership, board of directors, volunteers and sponsors, it is my hope to re-engage our members, recharge our events and continue to grow the ISPE CaSA Chapter. Please join us! Together we will do great things!

Lisa Kerner

President, ISPE CaSA Chapter

Re-Engage. Recharge. Grow.

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Membership Corner

REMINDER: ISPE-CaSA Jane Brown Scholarship Program

The ISPE-CaSA Chapter has established a scholarship to encourage students who seek a career in the life sciences industry. The ISPE-CaSA Chapter Jane Brown Scholarship will be awarded to an eligible CaSA Student Chapter member. Application information will be announced in the October Newsletter. This award will be announced at CaSA's **2017 Technology Conference** event at the Raleigh Convention Center in March. 🏠



CaSA COMMITTEES 2016

Education

Rachel Leahy

Newsletter

Rich Stanfield

IT/Social Media

Justin Rothwell, PE

Technology Conference

Amy Lineberry, CPIP

Student Affairs

Marisol Patiño

Membership Development

Mark Davies

Networking

Kevin Debbs, CPIP

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Mariessa Perez



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Membership Corner

Networking Committee

By Kevin Debbs, Networking Committee

Upcoming Networking Events

September Therapeutic Thursday

- ATL –
 - o Thursday September 15
 - o Time: 4:30 - 7:30
 - o Location: The Brass Tap
 - o Sponsored by CAI
 - o Address: 4505 Ashford Dunwoody Rd, Atlanta, GA 30346, USA
- RDU –
 - o Thursday, September 29
 - o Time: 5:30-7:30
 - o Location: TBD

Oktoberfest 2016

- Date: Thursday, October 13
- Time: 5:30 – 8:30
- Location: Koka Booth Amphitheatre
- Cost: ISPE Members: \$40.00
Non-Members: \$50.00
Young Professional Members: \$30.00
Students Chapter Members: \$25.00
- Sponsorship Opportunities:
 - Band Headliner Sponsor: \$1,500.00 (1 Sponsor Only)
 - Pub Class Sponsor: \$1,200.00 (1 Sponsor Only)
 - Craft Beer Sponsor: \$1,000.00 (1 Sponsor Only)
 - Gold Sponsor: \$750.00 (2 Sponsors Available)
 - Silver Sponsor: \$500.00 (4 Sponsors Available)
 - Bronze Sponsor: \$250.00 (Unlimited Sponsors)
- Food, Drink, Entertainment and Networking Opportunities: Provided!
- Note: More details to come soon via the weekly E-blast.



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Membership Corner

2017 Technology Conference Update

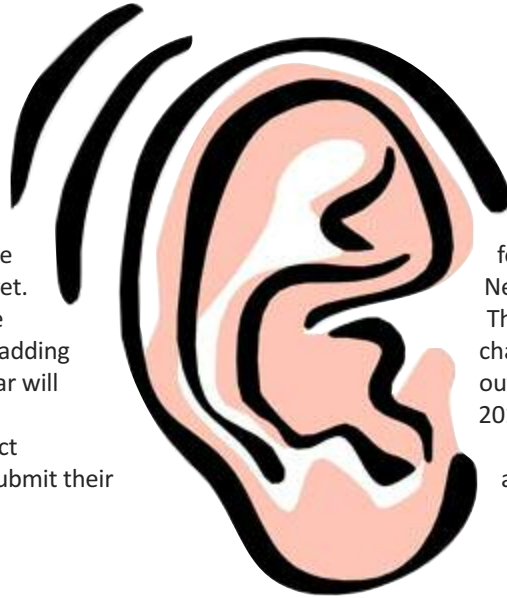
By Amy Lineberry, CPIP, ISPE CaSA Technology Conference Chair

The committee is in full planning-mode and working on presenting the best Technology Conference yet. Next year's Conference will be on March 14th 2017 and we are planning to have two educational tours on March 13th. Be on the lookout for information on these tours soon!


We Are Listening!

We have reviewed the comments received from the attendees and exhibitors at the 2016 Conference and are working on improvements! We hope that 2017 will be your best experience yet. We have improved the floor plan for the exhibit area to add more tables, we are adding more coffee and water, and new this year will be a phone/tablet charging station.

Our website is nearly ready for abstract submissions! Everyone will be able to submit their



abstracts and session ideas through the website this year, which should make things more seamless for everyone. The planning for the Keynote Address, Charity Donation and Networking Reception are also underway! The website will be launching soon for you to purchase tables and sponsorships. Keep an eye out for our weekly eBlast for more updates on the 2017 Technology Conference!

We look forward to seeing you March 13th and 14th!! 

Student Affairs

by Marisol Patiño

School is back in session and students are returning to their regularly scheduled ISPE activities. A total of 10 students have been selected to attend the Annual Meeting in Atlanta on September 18 - 21. Two of the students, NCCU undergraduate student Tiffany Nguyen and NCSU graduate student William Kish, will be representing CaSA in the student poster competition. The Annual Meeting is a great opportunity for students to network with professionals beyond their geographical area and to attend educational sessions featuring current industry trends and topics. We will be featuring their experiences in the newsletter following the conference.

If you are interested in becoming a student mentor or are interested in being a guest speaker at one of the local student chapter meetings, please contact ispecasasac@gmail.com.



**10 Students Have
Been Selected To
Attend The
Annual Meeting
In Atlanta ...**

Membership Corner

Young Professionals New Committee Chair

by Mariessa Perez



Mariessa Perez

Hello everyone, I would like to introduce myself as the incoming 2016-2018 Young Professionals Committee Chair. I have been active member with ISPE since 2013, holding an officer position as the President and Secretary at the Campbell University Student Chapter. I look forward to leading the committee to bring the young professionals of the ISPE-CaSA chapter fun yet profitable events throughout my term. The Young Professionals committee supports the ISPE-CaSA chapter at various events throughout the year, such as the ISPE-CaSA Annual Technology Conference and the Golf Tournament, as well as host our own social networking even in the area. If you are interested in joining the Young Professionals committee or volunteering at any ISPE-CaSA events, please send us an email at youngprofessionals@ispecasa.org. 🏠



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Gravimetric Feeding In Continuous Oral Solid Dosage Processing

*By: Andrew Christofides, P.E., IPS-
Integrated Project Services, LLC*

The OSD pharmaceutical industry is in the midst of a revolutionary shift from batch to continuous manufacturing. This was demonstrated in April 2016 by the FDA's historic approval of a change from batch to continuous production for Janssen's Prezista (darunavir), medication for the treatment of HIV-1 infection. To ensure the successful implementation of continuous pharmaceutical processing, it is incumbent on pharmaceutical engineers to understand its unit operations, the most critical of which is feeding.

Gravimetric (loss-in-weight) feeders set the mass balance and throughput for a continuous OSD process. Feeding accuracy and response time are arguably the most important performance criteria affecting the ability of a continuous manufacturing system to maintain a controlled state of operation.

A loss-in-weight feeder generally consists of an inlet hopper with flow assist, load cells, a variable speed product conveyor system, and integral controls that regulate conveyor speed to maintain constant feed rate, in weight per unit of time. Loss-in-weight feeders replace the traditional weigh/dispense operation in a batch pharmaceutical system. In continuous manufacturing, an array of feeders is arranged to simultaneously feed ingredients into a continuous mixer at a proportional feed rate, defined by the product recipe.

Loss-in-weight feeders may be charged via gravity, vacuum transfer, or manually. Gravity filling is simple and convenient, but requires room height that is not always available. Vacuum transfer is a viable solution in areas with low vertical clearance, but height in the equipment stack up must still be considered for

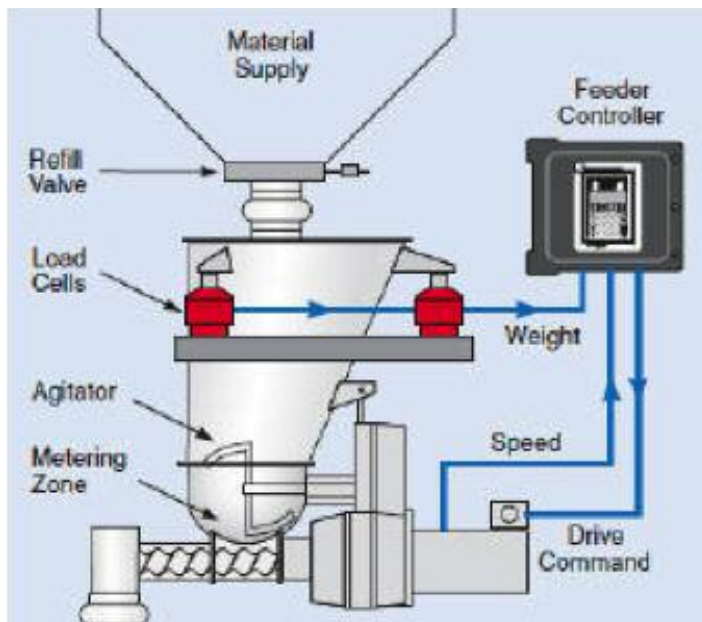


Figure 1. Typical Loss-in-Weight Feeder
(Courtesy of Coperion K-Tron)

vacuum receivers, which will be mounted directly atop feeder inlet hoppers. In order to achieve rapid refilling of feeder hoppers, vacuum transfer systems convey materials at high speeds over significant distances. The collision that occurs when material enters the vacuum receiver can adversely affect feeder performance if the receiver and feeder inlet hopper are not properly isolated. Manual charging is often employed for active ingredients or excipients used in very small quantities, such as lubricants.

Loss-in-weight feeders will almost always gravity feed the unit operation immediately downstream, therefore, feeders will typically reside on an elevated platform. It is critical that loss-in-weight feeders are mounted in such a way that their supports are isolated from potential disturbances, such as operators walking on platforms, or the aforementioned movement of an upstream vacuum receiver during refilling. Even the slightest disturbance, such as air movement from a nearby ventilation system, can adversely affect the performance of highly sensitive load cells in a loss-in-weight feeder.

Special provisions must be taken to protect operators if feeders are used to handle potent compounds. Feeders may be fitted with containment valves and spray devices to wet product contact surfaces prior to disassembly for removal from the system or at the cleaning station.

Loss-in-weight feeders will typically be cleaned out of place in a remote wash room. Feeders must be disassembled for cleaning, so that difficult to access product feed screws and hopper flow aids can be cleaned thoroughly. Access must be provided around feeders to allow for assembly of feeder arrays, operator access, and disassembly and removal at the end of a production run. This assembly and disassembly of feeder arrays often results in undesirably long setup and changeover times. Preassembling feeder arrays in a more modular fashion, on a solid, mobile base, may represent an opportunity to minimize the durations associated with these nonproductive activities.

Feeders set the capacity of a continuous manufacturing operation. Optimizing their setup and performance may be the most important measure a pharmaceutical engineer takes to ensure the overall effectiveness of a continuous OSD process. •



*Andrew Christofides, P.E.,
Lead Engineer,
Process Architecture
at IPS-Integrated
Project Services*



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Carolina-South Atlantic Chapter

Advertising Opportunities in ISPE-CaSA 2016 Electronic Newsletter

Advertising Opportunities in ISPE CaSA 2016 Electronic Newsletter

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

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

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

You may choose one of the special offers below (**pro-rated for partial-year advertising**):

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

We hope you will take advantage of these opportunities and advertise in the 2016 ISPE CaSA e-newsletter.

To reserve a placement of your ad for the remainder of 2016 please contact the ISPE-CaSA Headquarters at 919-573-5442 or via e-mail at info@ispecasa.org. **Deadline for 2016 advertisements, starting in the October 2016 issue is October 10th.**

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

Full-color business card-sized ads (3.5" x 2") may contain your logo or other artwork. Artwork should be sent directly to newsletter@ispecasa.org.

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


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

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Please submit any and all technical content to

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EDITORIAL POLICY

Articles should be written for technical professionals in the pharmaceutical, biotechnology, and medical device industries. The author is responsible for the accuracy and correctness of all statements contained in the manuscript (ISPE Carolina-South Atlantic Chapter assumes no liability.) Manuscripts should be submitted with a brief, three to four sentence synopsis of the article, as well as a brief biographical statement about the author that includes educational background, title and job affiliation, job responsibilities and major areas of accomplishment.

A word to the ISPE CaSA Newsletter advertisers:

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