NEWSLETTER

January 2017

CHAPTER EVENTS

- Feb 16 – Networking Event – Morrisville, NC
- March 15 – Networking Event - Cary, NC
- April 03-05 - PDA Annual Meeting - Anaheim, CA
- April 19 – Dinner Meeting – Raleigh, NC
- May 17 - Southeast Spring Conference - Raleigh. NC
- June 15 – Networking Event - Clayton, NC

https://www.pda.org/chapters/north-america/southeast/calendar-of-events

CHAPTER NEWS

We have a very large chapter, spreading from Virginia to Florida to Mississippi and Kentucky. In today's environment people are very busy and receive too much meaningless communication. We have redesigned the newsletter to be a quick update of what is happening in the chapter. We are discontinuing original technical articles in the newsletter, and will be referencing interesting articles with some introduction so chapter members can decide if the article is interesting to them. We hope that you find reviewing this newsletter an effective use of your time, and benefit from membership in the PDA Southeast Chapter.

PERSONAL DEVELOPMENT
BY LAURIE SCAGGS

I recently took the Strengths Finder 2.0 test and read the follow-up sections of the book, and found it both enlightening and useful. StrengthsFinder 2.0 is published by Gallup Press. The #1 Wall Street Journal and #1 BusinessWeek bestseller features a personalized Strengths Insight Report, an Action-Planning Guide, and a web-based Strengths Community. This approach will help change your perspective of yourself, your co-workers, and your family, focusing on strengths rather than weaknesses. The cost of the test and associated book is low. Check it out!

http://www.strengths.gallup.com/110440/About-StrengthsFinder-20.aspx

PUZZLE FOR FUN

Since everyone should relax and have fun once in a while, here is a quick puzzle for you to test your knowledge of our industry and area.

www.crosswordhobbyist.com/229292

2017 CHAPTER OFFICERS

With the new year, there is a new group of officers:

- President – Renee Morley
- President-Elect – Austin Caudle
- Secretary – MaryBeth Panagos
- Treasurer – Ryan Phillips

https://www.pda.org/chapters/north-america/southeast/chapter-officers

SURVEY

The PDA Southeast Chapter Newsletter will be published quarterly. The point of this survey is to understand where our member's interest lie so we can meet your needs. If you have time, please take a few minutes to participate:

https://www.surveymonkey.com/r/VFYMXXS

FACILITY/ PRODUCTION
BY JOHN LEWIS

A recent factor in manufacturing in the Southeast is the expansion of Patheon by acquiring manufacturing facilities in North and South Carolina. They now have 3 manufacturing facilities in South Carolina producing small and large molecule API, and 2 pharmaceutical product facilities in North Carolina making sterile products and solid dosage forms. It is interesting to consider the different approaches for customer involvement in contract manufacturing.

http://www.biopharma-reporter.com/Upstream-Processing/Dedicated-or-condominium-Patheon-talks-biotech-capacity-models-at-BIO

MICROBIOLOGY
BY CRYSTAL BOOTH

Understanding container closure integrity systems, reviewing past observations, and following the regulations and guidance documents are excellent ways to establish a compliant container closure integrity assay. An article published in the American Pharmaceutical Review regarding container closure integrity testing describes recent changes to the United States Pharmacopeia (USP) <1207>, guidance documents, regulatory observations, common container closure methods, and provides recommendations on developing and validating a compliant container closure integrity test. This free article is located at

http://www.americanpharmaceuticalreview.com/Featured-Articles/239498-Understanding-Container-Closure-Integrity-Testing/

COMPLIANCE
BY NATHAN BLAZEI

FDA defines combination products as "therapeutic and diagnostic products that combine drugs, devices, and/or biological products". In recent years, the FDA has classified therapies administered by prefilled syringes under the purview of combination product regulations (21 CFR Parts 3 and 4). This new regulatory environment has made its way to developers and manufacturers of drugs and biologics, but there are many firms still working towards full compliance with the applicable medical device-related requirements of 21 CFR Part 820. In publishing its final guidance, the FDA has confirmed its expectations for industry.

Enforcement action is expected to increase for companies that are in a state of non-compliance during future inspections. It is recommended that companies review their compliance with the new guidance and consider remediation, where needed. A key area to focus on is the preparation of proper design history files (DHFs). Companies undergoing selection of container closure or administration device options should review the examples in the guidance for direction. Product development and regulatory affairs teams must work together early on to avoid missing key regulatory requirements for combination products, such as prefilled syringes.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM429304.pdf

HELP NEEDED

If you would like to help the chapter communications committee by authoring an article, or simply identifying a recent publically available article and writing an introductory paragraph; that help would be greatly appreciated. Please contact John.Lewis@dpsgroupglobal.com