



# 2013 PDA ANNUAL MEETING

*Modern Sterile Product Manufacture –  
Exploring Best Practices and Seeking New Approaches*

**April 15-17, 2013**

The Peabody Orlando | Orlando, Florida

[www.pda.org/annual2013](http://www.pda.org/annual2013)

Exhibition: April 15-16 | Workshop: April 17-18 | Course: April 18-19



## Facilities and Engineering Interest Group

- Implementing Single Use Systems
  - Advantages:
  - Flexibility
  - Quick Change Over
  - Lower Capital Costs



## Facilities and Engineering Interest Group

- What are key advantages (\$\$\$)?
  - Reduced WFI/CIP/SIP
  - Reduced Validation (Esp. Cleaning)
  - But perhaps most importantly – have you ever build a building or a facility and the capacity forecast was way off the mark?



## Facilities and Engineering Interest Group

- Implementing Single Use Systems
  - Fears:
  - Extractables/Leachables
  - Leaks
  - Disposal/Waste



## Facilities and Engineering Interest Group

- What, then is the right choice?
  - Do you want to dip your toe in the water or dive right in?
  - If you are using silicone or thermoplastic tubing, or capsule filters, then you already have more than a toe in the water!



## Facilities and Engineering Interest Group

- Let's Talk about some of these fears:
  - E/L – did you know that arsenic and lead are extractables from Type 1 Borosilicate Glass?
  - Did you know that the clear majority of leaks encountered are with connections? Both traditional and single use?



## Facilities and Engineering Interest Group

- Disposal and Waste:
  - Supposed it is biocontaminated?
  - Do you have incineration facilities on-site?
  - Pound for pound, as much energy as gasoline?
  - Vendor recycle programs – is your intellectual or strategic intelligence vulnerable?



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# Facilities and Engineering Interest Group

- Questions and Discussion