



Large Molecule Technologies

- Cell Culture/Fermentation
 - Metabolite feedback control
 - In-Line Nova/NovaFlex/BGA
 - FTIR/NIR/Raman
 - Capacitance (cell mass)
 - In-process image processing
 - In-line HPLC
 - Fluorescence (patches for pH, DO)
 - Metabolic flux analysis
- Harvest/Centrifugation
 - Ultrasonic reflectometry for membrane integrity
 - TMP control
- Purification
 - On-line HPLC (pooling conc., pooling decisions, SEC)
 - Flow injection analysis
 - Transition analysis, HETP, acoustics for packing/re-packing decisions
- Formulation & Filling
 - Humidity
 - NIR
 - Manomeric temperature measurement
 - Automated visual inspection
 - Vacuum and headspace gas testing



Technology Gaps Topic - Sampling

- Typically in-line and at-line sampling systems need to ensure the sample is homogeneous and representative of the bulk. Depending on the application other criteria must be met, including:
 - Small volume, including line flush (distance from instrument may be greater issue in commercial)
 - Sterile or aseptic
 - Free of carryover from prior sample
 - Ability to clean/sterilize system if contamination
- Is this issue hindering the adoption of technologies?
- Solutions?



Technology Gaps Topic – Whole Package

- Vendors supply sensor or analytical technologies, but often lack a clear picture of the hurdles to implementing it in a lab or production facility.
- Academics often generate novel ideas, but lack the resources or know-how to bring a product to market.
- We supply the need and the perspective of what it takes to implement a new technology, but often lack the resources or champion to bridge the gap between vendors and academics to the lab or production environment.
- Is anyone working with vendors and/or academic institutions to leverage what each brings in a more effective way?



Technology Gaps Topic – MVA

- A common approach to using complex data sets into something functional for real time analysis is to use data conditioning and/or MVA. Examples include spectra from UV, NIR and Raman; HPLC chromatograms; etc.
- Are there concerns about calibration of the probe/signal after cleaning/sterilization, especially in a commercial environment, when dealing with an output that may be generated based on a complex algorithm rather than a single value that can be corrected with a 1 or 2 point standardization?