Where are we and Where are we going

James R. Bruno

Chemical and Pharmaceutical Solutions

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Yesterday

- MCC approved by the FDA
- Drugs being Developed and launched using MCC Technology
- Increased use in development leads to more production
- Greater acceptance for the use of Chromatography in general

Today

- Thinks seem to come to a stop relative to the use of traditional MCC technology
- Super Critical Fluid Technology increases significantly
- Greater drive toward for Continuous production

Today

- More products under development
- More applications at the smaller scale
- Better Selection of solvents due to stationary phase improvements
- Non-Pharma applications
- Chiral Purifications
- Better Solvent recycling (99%)

Today

- Chase Production (loading versus throughput)
- Packing is more Analytical Mindset
- Synthetic Process linked to Purity
- HPLC systems improving
- Process support in India and China

Today

- SFC
  - Natural Products (larger molecular weight in general)
  - Co-Solvents (heptane and hexane)
  - 5cm column units are work horses
  - Potential for multiple suppliers (Thar and Jasco)
  - 20 cm column unit shipped
  - “Multi-purposed”

Today

- Genentech large molecule purifications and single use
- Continuous purifications (peptide production)

Today

- Shorter Development Times
  - Delay development as long as possible
  - Quicker fixes
- Employment Shifts
  - Small pharma and R&D centers absorbing big pharma cut backs
  - The “Message” is moving more into small pharma and development

Today

- Green is Good
  - Higher Solvent Recovery
  - More energy efficient systems
  - Less waste in general
  - More efficient in general

What's the Problem

- Process Chemist versus Chromatography Chemist
- Existing Batch Equipment
- Reluctance to have continuous processes
- Capacity Uncertainties and drive to dedicated processes with shorter life

Process Chemist versus Chromatography Chemist

- Chromatography Chemist
  - Current Process requires a chromatography step
    - We have multiple tools at our disposal to do this
    - Production equipment available
    - Recent improvements in equipment allows for greater efficiencies and longer stationary phase life
    - Regulatory acceptance
    - “No problem”

Process Chemist versus Chromatography Chemist

- Process Chemist
  - Current Process requires a chromatography step
    - Send it back for additional development and get that step out.
    - Production units have limited experience in large scale process
    - “If we can not remove it we failed”

We are we going

- SFC is becoming more acceptable
  - Novasep plans to deliver 20 cm column unit
  - Thar has increased their application labs and see increased number of analytical separations
- Non-Pharmaceutical Applications
  - Could lead to greater acceptance across the board
  - Pharma could develop greater comfort level

Non-Pharmaceutical Applications
Organic light-emitting diodes

- **Synthesis, Separation, and Circularly Polarized Luminescence Studies of Enantiomers of**
- **Iridium(III) Luminophores**
- **Frederick J. Coughlin,† Michael S. Westrol,† Karl D. Oyler,† Neal Byrne,‡ Christina Kraml,‡ Eli Zysman-Colman,† Michael S.**
- **Lowry,† and Stefan Bernhard*†**
- *Department of Chemistry, Princeton University, Princeton, New Jersey 08544, and Lotus Separations, LLC, 201 Frick Laboratory,*
- *Princeton, New Jersey 08544*

Tomorrow

- Believe over 100 compounds currently under development using Chromatography
- Smaller more complicated molecules could lend more to MCC type purifications
- High Containment may fit better in MCC type systems
- Greater improvements in Stationary Phases give better more efficient separations

Tomorrow

- Energy becoming a greater line item in production costs
- Waste becoming a greater line item in production costs
- Some day we may actually eliminate chlorinated solvents
- Shorter Development times
- Increased purity specifications

Tomorrow

- Emerging Pharma gets the message
- Big pharma goes continous