STEM and Engineered BioPharmaceuticals (eBio)

Mark Ketner
Bite of Science
Danville Community College
September 13, 2017
My Background

- North Carolina
- Early Career Path - Charlotte – Banking
- Family Tradition: UNC – Business Majors
- NCSU – Business
- Freshman Year Personal Discovery
- New Path – Medical School
  - Engineering
  - Transfer
My Background

• Accepted to UNC after sophomore year
  
  Another new path – Chemical Engineering

• Graduated B.S. Chemical Engineering – NCSU

• Waitlisted

• Dedicated, Path driven
My Background

The Appalachian Trail, a 2,189-mile trail running from Mount Katahdin, Maine, to Springer Mountain, Ga., is by far the most well-known footpath in the nation. Created through the genius and hard work of a few far-seeing founders and many early collaborators, the trail was brought to completion by dozens of trail clubs and thousands of volunteers. Though almost every foot of the trail is now owned by the U.S. government, it is still maintained by volunteers, coordinated by the non-profit Appalachian Trail Conference, formed in 1925. It is now part of the national park system.
My Background

- UNC Biomedical Engineering
  - Cardiovascular
    - Pediatric congenital heart defects
    - Fluid Dynamics, Energetics, Mechanics
- Poor grad student – Oriel Therapeutics
  - Design dry powder inhalers – Interest in pharmaceuticals
- Ph.D. – Biomedical Engineering
- Becton Dickinson
  - 9/11 – Need for dry powder pharmaceutical counter measures against biological warfare (botulism, plague, anthrax, etc.)
  - Chemical and Biomedical Engineering principles along with dry powder experience to develop a novel dry powder pharmaceutical manufacturing method (Atmospheric Spray Freeze Drying – ASFD)
- Engineered BioPharmaceuticals – Director of Engineering
  - NIST TIP/Tobacco Commission grant – Tech and Pharmaceuticals to US (Southside Virginia)
  - STEM jobs to Virginia
  - Pilot scale manufacturing line
Engineered Solution – Powder Experts

• Liquid-to-powder transformation
  – Retention of active’s properties
  – Use particle morphology and compositional structure to increase therapeutic value

• Delivery technology
  – Match delivery packaging to need
  – Match powder to delivery technology
• Location, Location, Location
  – Proximity to RTP
  – Pharma, Universities, Community Colleges, RCATT, IALR
  – Proximity to Washington and Government labs
• Aggressive Tech Oriented Vision
• Support systems
• Motivated workforce with a manufacturing background
  – STEM – Technology Background
• Dan River Business Development Center (DRBDC)
• Cyber Park
What do we deliver?

Range of Therapeutic Payloads

- Small Molecules
- Lipids
- DNA/RNA
- Vaccines
- Nutraceuticals
- Peptides
- Large Proteins
- mAb
- STEM Cells Therapy
- Consumer Products
Delivery Vehicle

Spherical Particles with Controllable Morphology

Narrow Particle Size Distribution

Radial Pore Structure

Embedded Microparticles

Payload Layering

Mixture of Particles

Particle Coating
Routes of Administration

- Oral
  - Increase Bioavailability
  - Increase solubility
  - Minimize side effects
  - Time released
  - Target specific (Intestine, Colon)
  - Dose Form (tablet, capsule, softgel, liquid, powder, nano)
- Animal Testing
  - Toxicology
  - Dose
  - Formulation Optimization
Routes of Administration

• Nasal
  • Larger Particle Size (Blood Brain Barrier)
  • Excipients (Muco-adhesive properties)
  • NALT (Nasal Associated Lymphoid Tissue)
  • Kids – No Needle
  • Dry Powder or Liquid Formulation
  • Flumist
Routes of Administration

- Pulmonary
  - Avoid first pass metabolism
  - Direct to bloodstream
  - Target specific delivery
    - Asthma, TB, IPF, Lung Cancer
  - Reduce side effects
- Vaccine development (Anthrax)
- Diabetes (Inhaled insulin – Afreeza)
Routes of Administration

- Injection
  - Industry Standard
  - Increase Bioavailability
  - Low dose
  - Shelf Life
  - Stability
  - Immediate Therapeutic Effect
  - Compatible with all payloads and size
    - Cake or Powder
Equipment to Formulate, Dry, Fill, and Characterize Dry Powder Pharmaceuticals

Proprietary and Confidential
P&ID Examples

Proprietary and Confidential
Broad Market Applications

Enhanced stability, shelf-life, and distribution

Targeted drug delivery

Optimizing Point-of-Use Beverage Flavors

Food Applications
STEM Skills and Knowledge

Often Overlooked but VERY Important

- Basic Computer Skills
- Basic Finance (Budget, Estimate)
- Creativity – Think outside the box
- Scientific Method – DOE
- Theoretical vs. Practical
- Hands On Experience – Internships, Workshops
- Writing
- Organizational
- Failure is OK – Fail Fast and Learn
STEM – Soft Skills

• Communication
  • One-on-one
  • Team
  • Writing
• Leadership
• Scope
  • Big Picture - Company
  • Detail - Project
• Vision
  • Individual
  • Company

• Flexibility
  • Many Hats
  • Vision / Scope
  • Team
• Compatibility / Interpersonal
  • Mentor / Boss
  • Team
• Time Management
  • Deadline
• Work / Life Balance
Internship/Employment Opportunities

- **Formulation Development**
  - Pharmaceutical, Consumer, OTC (Nutraceutical)
- **Spraying & Drying Processes**
  - ASFD, Spray Drying, Lyophilization
- **Pharmaceutical & Particle Characterization**
  - UV-Vis, HPLC, Laser Diffraction, FTIR, DSC, Moisture Titration
- **Automation and Design**
  - Solidworks, P&ID, R&D, Prototype, Electrical, Mechanical
- **Programming**
  - PLC, LabVIEW, Arduino, Raspberry Pi
- **Technician**
  - Formulation, Laboratory, Manufacturing
Thank You

meketner@engbiopharm.com
www.engbiopharm.com