Internship Presentation

Kerianne Dobosz
Functional Materials Fellow Intern
TDL: Wei Cai   TOL: Dave Moore
Project Leads: Andrew Burns & Matt Misner
UMass Amherst Ph.D. Candidate
June 5th – August 18th (11 weeks)

Film Development + Extreme Environment Testing → Biopharmaceutical Production

GE Global Research Center
Niskayuna, NY
About Me

• Born in Seoul, South Korea
• Grew up in Rochester, NY
• Cornell University – B.S./M.Eng. Chemical Engineering and German Minor
  Society of Women Engineers (SWE), P&G internships
  Computational Modeling Breast Cancer Research: Prof. Jeff Varner
  Nano Organic Hybrid Materials: Prof. Lynden Archer
• University of Massachusetts, Amherst - Ph.D. Chemical Engineering
  Graduate Women in STEM, Graduate Student Senate,
  NIH Biotechnology Training Program
• Outdoor activities, music
GE Global Research Charter:
“Drive breakthrough technology to give GE competitive advantage”

GE’s First U.S. industrial lab, founded in 1900 in Niskayuna, NY
1800 scientists/engineers, nearly two-thirds PhDs

- One of the world’s most diversified industrial research organizations, providing innovative technology for all of GE’s businesses
Global Research develops technology and product concepts from idea through prototype phase to transition to GE businesses.

High risk, high reward research to accelerate GE business product development.
Evolution of pharmaceuticals

- **Cinchona bark (quinine)**
- **Aspirin**
- **Insulin**

**Natural medicine**
(e.g., herbs, minerals, quinine, opium)

**Synthetic small molecules**
(e.g., penicillin, NSAIDs, opioids)

**Biopharmaceuticals**
(e.g., insulin, hormones, antibodies, vaccines)

**Cell therapies**
(e.g., T-cells, iPSCs, MSCs)

Increasing complexity and evolving production needs

- **Monoclonal Antibody (mAB)**
- **& cytokine treatments for:**
  - Cancer Therapy
  - Autoimmune Diseases

Biopharmaceutical production

Traditional Pharma (Stainless Steel)
- Greater flexibility & scalability
- Smaller footprint

Single Use Disposable (Plastic)
- Lower capital cost
- Lower OpEx cost
- Less water & energy use

Desired properties:

Performance - $O_2/CO_2$ barrier, Flex, RT mechanicals, E&L, Biocompatibility

Manufacturability-Seal strength, Processability, $\gamma$-stability, Optical Clarity
GE Healthcare SUD Portfolio

**Cell culture seed train**
- ReadyToProcess WAVE™ 25 system
- Xcellerex XDR 200L bioreactor
- Xcellerex XDR 500L bioreactor

**Cell culture production**
- Xcellerex XDR 2000L bioreactor
- ReadyToProcess™ filter for CFF

**Harvest operations**
- FlexFactory™ harvest
- BioProcess™ NFF Pump System

**Virus reduction**
- Xcellerex XDUO mixers

**Purification operations**
- AKTA™ ready system
- ReadyToProcess chromatography column
- ReadyToProcess filter for CFF

**Virus filtration**
- FlexFactory™ viral clearance
- BioProcess™ NFF Pump System

**Fluid Management**
- ReadyToProcess portfolio
- ReadyCircuit™ bag and filter assemblies
- ReadyToProcess bins and ReadyCircuit bags
- ReadyMate™ aseptic connectors

**Fast Trak Services**
- Process development
- Bridge manufacturing services
- Training and education

**Bulk formulation and sterile filtration**
- Bulk fill equipment

Second project
Fortem™ to consolidate film portfolio to a single contact surface in current SUD workflows.
Materials Science of Film

- Outer Layer
  - Mechanical robustness (tear, puncture, toughness)
  - Flexibility, Feel
- Barrier Layer
  - Low Oxygen Permeability
- Cell-contact Layer
  - Biocompatibility
  - Minimal Extractables & Leachables
  - Sealing Capability

Ten-layer film architecture

Neutral plane
where tensile and compressive stresses are minimized

Co-extruded film manufactured in Class 8 cleanroom. Supplied as double ply; contact layer exposed only to Class 5 air (Sealed Air Corp. film design patent).
**Goal:** Analyze & understand real-world failure modes to develop bench-scale models and enable rapid, reproducible testing for material capabilities.

- **Flex Fatigue**
- **Bending & Bag Stress Modeling**
- **Oxygen transmission**
- **Extreme Environment Mechanics**

*Test Development & Film Analysis*
Tensile testing

- a) Loaded dogbone sample
- b) Elastic deformation to a yield point
- c) Necking
- d) Failure
Modeling high temperature

Top Hemisphere is the only unsupported film on the bag

Pasteurization at elevated T
Pressure Calculator

Film Thickness 0.013in
XDR 2000
Diameter 53.5in
Pressure 0.1psi

sigma(h) hemi (RT) 0.103ksi
High Temperature performance of Fortem™

Tensile Testing at Elevated Temperature

Temperature-controlled tensile testing enables small scale modeling of film performance in a variety of environments.

Yield Stress: The amount of force the material experience before it deforms.

Graph showing stress-strain curves for different temperatures.
Key learnings

- Learnings from interaction with every day
- Learned more about project life-time at GE GRC
  - Project lifetime, technical performance measures and readiness, manufacturability
  - Tours of other GRC organizations
  - Different roles
- Knowledge about GE GRC in China
- STEM Outreach – Niskayuna Engineering institute panelist
- Joined Newcomer’s club, Adventurer’s club, Women’s network, and Asian Pacific American Forum
- Outdoor activities and local events (race track, Saratoga spring park, rock climbing gym, bumper ball)
Special thanks:

• Functional Materials
  Wei Cai
• Dave Moore
• Films Team
• Andrew Burns
• Bill Alberts
• Jack Howson
• Midstream team

• Matt Misner
• Rachel Gettings
• Christine Morton
• Don Buckley
• Mark Walkowicz and Jeremy Trudell
• Paul Smigelski
• Stanlee Buddle

• Dave Demoulpied
• Women’s Network
• Materials Group
• Asian Pacific American Forum

• All other GE employees that have offered support

Thank you for a fantastic summer!
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