DANIEL A DIXON

Pfizer/Wyeth BioPharma – Andover, MA

Senior Manager, Technical Services, Pharmaceutical R&D 1/11 to current

- Overall lead for all Drug Product-related activities for clinical vaccine
    - Define manufacturing strategy considering clinical trial timelines
    - Lead development, implementation and validation of high-volume commercial manufacturing process
    - Interface with stakeholders, ranging from Vaccine Program Management, Clinical, Regulatory, Upstream Drug Substance and Analytical Development
- Act as technical lead and primary interface between laboratory-based teams and >10 2nd and 3rd party DP manufacturing sites.
    - Author, review, and approve manufacturing documentation, including tech transfer documents, batch records, and validation protocols (as necessary)
    - Act as Pfizer Person-in-Plant during cGMP clinical manufacturing across many programs, modalities and lot sizes (5000-250000 units).
- Member of Pfizer Lyophilization Network Steering Committee. Organization contains >150 individuals spanning R&D and commercial manufacturing.

Senior Process Engineer/Senior Scientist, Pharmaceutical R&D 10/00 to 12/10

- Identified and implemented best practices for clinical process development utilizing Quality by Design compliant principles for steps such as thawing, compounding, mixing, filtration, lyophilization and in-process hold times for Phase I/II projects and Proof-of-Concept through Commercial Launch activities.
- Harmonized practices across multiple legacy Wyeth and Pfizer sites.
- Generated laboratory data to define and support clinical manufacturing processes.
- Acted as a department expert on lyophilization, solid state characterization, process development, and technology transfer.

Northeastern University – Boston, MA

Part Time Instructor, Department of Biotechnology 1/15 to current

- Lead instructor for Master's Level BIOT5640 course "Drug Product Processes for BioPharmaceuticals" during Winter Term

EDUCATION:

M.S. Chemical Engineering. University of Colorado, Boulder, CO
Advisor: Dr. Theodore Randolph

B.S.E. Chemical Engineering, Cum Laude. University of Michigan, Ann Arbor, MI

PUBLICATION SUMMARY:

Talks:

"Lyophilized biotherapeutics: impact of formulation design on process design." Lyophilization Americas Conference, Boston, MA. Feb 2011.

"The Application of QbD/PAT Guidelines at an Early Stage in the Lyophilization Process to Minimize Undesirable Effects." World Lyophilization Summit. Cambridge, MA. May 2011.

Manuscripts:

Dixon, Tchessalov, Warne, Barry. "The Impact of Protein Concentration on Mannitol and Sodium Chloride Crystallinity and Polymorphism Upon Lyophilization." *Journal of Pharmaceutical Sciences.* **98**(9):3419-3429 (2009).

Tchessalov, Dixon, Warne. "Principles of Lyophilization Scale-Up." *American Pharmaceutical Review.* March/April 2007. Pgs 88-91

Posters:

Dixon, Tchessalov, Gudinas, Warne. "Heat Transfer Characterization of LyoGuard trays in Laboratory and Commercial Lyophilizers and Application to Two Model Solutions." American Association of Pharmaceutical Scientists (AAPS) National Conference. New Orleans, LA, November 2010.

Dixon, Tchessalov, Barry, Warne. "Design of Lyophilization Robustness Studies for Clinical Lyophilization Processes." Drying of Pharmaceuticals and Biologicals Conference, Breckenridge, CO, July 2008.

Tchessalov, McGarvey, Dixon, Warne. "Freeze Dryer Characterization as Part of Scale-Up Protocol." Freeze Drying of Pharmaceuticals and Biologicals Conference, Breckenridge, CO, July 2004.

Ho, Linton, Dixon, Tchessalov, Knowles, Kantor, Warne. "Membrane Preference During Protein Sterile Filtration: Adsorption Studies." American Association of Pharmaceutical Scientists (AAPS) Biotechnology Conference. Boston, MA, May 2004.

Dixon, Tchessalov, Warne, Barry. "The Impact of Protein Concentration on Mannitol and Sodium Chloride Crystallinity and Polymorphism Upon Lyophilization." American Association of Pharmaceutical Scientists (AAPS) National Convention. Salt Lake City, UT, October 2003.