



**Michael Ross Goodman**

## **OBJECTIVE**

Seeking a process validation position in a an aggressive and successful biotechnology company

## **EDUCATION**

### **University of Wisconsin – Madison**

Bachelor of Science, **Biochemistry**, August 2002 - May 2006

Masters of Science, **Biotechnology**, In-Process (Currently 3.8 gpa)

## **EXPERIENCE**

**Scientific Protein Laboratories (SPL)** August 2007 to present

### **Validation Specialist**

- Writing protocols to be carried out by operators
- Writing, organizing, and facilitating process validations for various SPL marketed products
- Directing testing required by the FDA for both Active Pharmaceutical Ingredients
- Training in the inner workings of the facility
- Maintaining cGMP regulations within the facility
- Audit outside contract cGMP testing sites

### **Regulatory Affairs related experience**

- Training on FDA regulations pertaining to ICH Q7A (cGMP)
- Extensive experience writing and editing Drug Master Files
  - FDA US#9649 (Pancreatin)
  - FDA US#2616, Canadian #2006-126, FDA US#15973 (Heparin)
- Auditing protocols and reports written by SPL and/or outside contracted agencies

### **Sigma-Aldrich, Madison, Wisconsin**

*Kilo manufacturing* July 2006 – April 2007

- Extensive training in current Good Manufacturing Practice (cGMP)
- Experience working with Category IV compounds
- Performing Installation, Operational, and Performance Qualifications (IOP)
- Upscale manufacturing with an emphasis on process development relating to Active Pharmaceutical Ingredients
- Developed the process to manufacture Tumor Activating Pro-drug for Immunogen Inc.
- Completed A-ring synthesis of Vitamin D derivative first developed by Dr. Hector Deluca

### **Dr. Mike Cox Lab, Biochemistry Department University of Wisconsin – Madison**

*RecA primary research* January 2005 – February 2006

- Wild Type RecA ATP hydrolysis with Viral ssDNA
- Collaborated with Seifort lab (University of Northwestern) on RecX research
- Specialist in Spectrophotometer
- Research specifically involved mapping genome

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**Dr. Linda Graham Lab**, Botany Department University of Wisconsin – Madison

*Research with Synura (multi-celled eukaryote) January 2004 – May 2004*

- Mapping  $\alpha$  and  $\beta$  tubulin in *Synura* for cDNA library
- Specialist in Promega protocol for DNA isolation, PCR, electrophoresis

**LEADERSHIP**

**University of Wisconsin – Madison Intercollegiate Tennis Team**, September 2002 – February 2005

*Career Record of 20-10*

- Competed at #4,5,6 singles
- Most improved player 2003

**Team Colorado**

*Achieving top 5 ranking in tennis in juniors for Intermountain Tennis Association (ITA)*

*Achieving a top 50 National Ranking (USTA)*