

REBECCA THOMPSON, Ph.D.

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EXPERIENCE

Cell Culture Company (formerly Biovest International), Minneapolis, MN

June 2014 – present

Senior Director of Quality:

- Management with Executive Responsibility
- Directs quality control receiving and analytical teams.
- Supports QC activities involving the QMS.
- Provides custom services to support biologics manufacturing.
- Leads technology transfer of analytical methods.
- Prepares protocols and summaries for experiments
- Manages ISO Cleanroom Suite routine environmental monitoring.
- Supervises method development and validation for analytical test methods including A280, SEC-HPLC, SDS-PAGE, IEF, ELISA, antibody isotyping and protein G chromatography.
- Ensures compliance with FDA and ICH guidelines.

Quality Control Manager:

- Provided custom services to support biologics manufacturing.
- Lead technology transfer of analytical methods.
- Established user requirements for purchase and qualification of QC analytical equipment.
- Managed analytical team in a GMP/CMO facility.
- Organized out-sourcing of test methods not performed on-site.
- Monitored ISO Cleanroom Suite with routine environmental monitoring.
- Supervised method development and validation for analytical test methods including A280, SEC-HPLC, SDS-PAGE, IEF, ELISA, antibody isotyping and protein G chromatography.
- Tracked data for trending and determination of OOS and OOT.

Vaccine CMC Quality Control Senior Scientist:

- Organized and managed the development of key analytical release assays for a personalized, therapeutic vaccine for non-Hodgkin's lymphoma.
- Validated and optimized methods for 8 impurity and identification ELISAs on a Tecan robotic system.
- Worked closely with senior management (CEO and CMC/Quality Directors) and multiple departments to design, test and implement validated methods in anticipation of clinical product approval and EMA commercial launch.
- Managed small team of 2 scientists in a GMP facility.
- Developed schedule to manage routine assignments, reagent inventory, stability studies and test results.
- Led the analytical method life cycle efforts by conducting qualification and validation experiments, troubleshooting methods, developing ICH guideline validation protocols, analyzing data, writing final cGMP SOPs, assembling validation reports and training junior staff.
- Performed QC activities with cross-functional development teams to support in-process validation of final vaccine.
- Monitored data for OOS and OOT test results.
- Skilled in SoftMax Pro Data Acquisition and Analysis Software and Veeva Vault content management.

Pharmasan Labs, Inc., Osceola, WI

October 2012 – June 2014

Cellular Immunology Technical Supervisor:

- Received promotion after exhibiting exceptional organizational and analytical skills.
- Supervised expansion of metal allergy and multiplex testing panels.
- Reviewed clinical patient test results for 5 different immunological assays that utilized flow cytometry, B cell proliferation, chromium release, ELISPOT and multiplex immunoassay.
- Managed department team of 1 lab manager and 4 technicians in a GLP laboratory.
- Enforced CLIA and NYDOH regulatory compliance and represented department during CLIA compliance audit.
- Reviewed CAP performance and monitored proficiency testing results from submission to submission.
- Analyzed and established laboratory test performance criteria to ensure quality control and quality assurance of these assays.
- Verified proper specimen handling and collection procedures to ensure proper testing and GLP practices.
- Reviewed immunological test methodologies and advised appropriate clinical use of the test results.
- Provided scientific support to clinical technical support and clinical technical sales teams.

Immunology R&D Manager:

- Received promotion after the expansion of the immunology R&D department and extensive experience with immunoassay development.
- Managed team of 5 scientists.
- Researched current scientific literature to pursue new projects and improve current products.
- Directed and analyzed project data.
- Optimized and established test protocols for commercialization and transfer into production.
- Worked closely with sales and marketing team to provide scientific and technical information for website and promotional material.
- Provided scientific customer support for clinical research studies.
- Communicated with physicians and clinical research team regarding study criteria and compliance.

Immunoassay Development Scientist:

- Recruited to develop new functional B cell and T cell ELISPOT bioassay tests.
- Developed 3 new ELISPOT tests.
- Initiated several ongoing projects for the novel detection of invasive and systemic infections.
- Optimized and expanded the use of multiple cytokine ELISPOTs.
- Introduced the B cell ELISPOT procedure and technology.
- Worked in a BSL2 facility processing human blood samples.
- Experienced in PBMC cell separation and maintaining primary human tissue culture.
- Trained interdepartmentally on assays utilizing Western blot and ELISA.

University of Toledo Health Science Campus, Toledo, OH

January 2007 – October 2012

Postdoctoral fellow:

- Developed technique for fluorescent modification and conjugation of carbohydrates, specifically pneumococcal polysaccharide for extensive use in flow cytometry and B cell subtype analysis.
- Analyzed the B cell response to Pneumovax® in HIV positive and elderly individuals as part of a clinical trial.
- Worked directly with patients via vaccine administration and eligibility interview.
- Managed medical interns, rotation and summer students GLP laboratory.
- Provided insight on study design and development for IRB.
- Analyzed antibody production by Western blot, ELISA and surface plasmon resonance.
- Determined immunoglobulin variable region gene expression.

Ph.D. student:

- Dissertation entitled “Polyreactive and antigen specific B cell antibody response to Streptococcus pneumoniae”.
- Constructed recombinant monoclonal human antibodies through transfection of mammalian cell lines.
- Completed an individual student project involving the study of human antibodies produced in the response to Pneumovax®, a vaccine for the Gram-positive bacteria, Streptococcus pneumoniae.
- Worked in BSL2 laboratory with mammalian and bacterial cell lines.
- Analyzed human samples through B lymphocyte isolation, magnetic enrichment, cell culture and expansion.
- Confirmed antibody specificity to pneumococcal polysaccharides by OPSA and ELISA.
- Produced recombinant antibodies by PCR amplification of the natively-paired variable regions, DNA cloning into Escherichia coli, ligation into expression vector and mammalian cell transfection.
- Analyzed affinity and avidity of recombinant antibodies through antibody purification, BiaCore SPR and ELISA.
- Maintained cell bank inventories.

EDUCATION

Degree: Ph.D. in Biomedical Sciences

Major: Infection, immunity and transplantation

University of Toledo Health Science Campus, Toledo, OH

Degree: B.S. in Pharmaceutical Sciences

Major: Pharmacology and toxicology Minor: Biochemistry

University of Toledo, Toledo, OH

PUBLICATIONS

Leggat DJ*, Thompson RS*, Khaskhely NM, Iyer AS, Westerink MA. “The immune response to pneumococcal polysaccharides 14 and 23F among elderly individuals consists predominantly of switched memory B cells”. J Infect Dis. 2013 Jul;208(1):1018. doi: 10.1093/infdis/jit139. Epub 2013 Apr 1.

Leggat DJ, Khaskhely NM, Iyer AS, Mosakowski J, Thompson RS, Weinandy JD, Westerink MA. “Pneumococcal polysaccharide vaccination induces polysaccharidespecific B cells in adult peripheral blood expressing CD19+CD20+CD3-CD70-CD27+IgM+CD43+CD5+/-”. Vaccine. 2013 Sep 23;31(41):463240. doi:10.1016/j.vaccine.2013.07.030. Epub 2013 Aug 1.

Thompson RS, Khaskhely N, Malhotra K, Leggat D, Mosakowski J, Khuder S, McLean G and Westerink M. “Isolation and characterization of human polyreactive pneumococcal polysaccharide antibodies”. Open Journal of Immunology. 2012 Sept; 2(3):98110.

Khaskhely N, Mosakowski J, Thompson RS, Khuder S, Smithson SL, Westerink MA. “Phenotypic analysis of pneumococcal polysaccharide specific B cells”. J Immunol. 2012 Mar 1;188(5):245563. Epub 2012 Jan 23.