

## GEORGE HRISTOPOULOS

PHARMACEUTICAL SERVICES | [intertek.com/pharmaceutical](http://intertek.com/pharmaceutical)

### PROFILE



### OVERVIEW

Seasoned Scientist with more than 10 years of diverse technical background focused on building immunoassays and associated GLP practices to support the development of large molecule therapeutics throughout the drug development process.

### HONORS/AWARDS

*Merck Award of Excellence, 2011* • Validation Notebook Organization Strategy, for increasing audit efficiency

*Merck Award of Excellence, 2011* • Leadership Role Watson (L.I.M.S.) Working Group, for establishing innovative use of Watson

### EXPERIENCE

#### Scientific Director • Intertek Pharmaceutical Services • 2016 – Present

Manage immunochemistry personnel and oversee laboratory. Review and approve critical GLP documentation. Collaborate with Senior Staff to develop and execute high level planning for profitability and staff retention. Work with clients regarding their immunochemistry needs. Identify tactical and strategic marketing practices to attract potential clients and industry partnerships. Mentor and empower professionals to achieve development goals. Interact directly/indirectly with Regulatory Authorities (Scientific Review Lead for FDA scientific focus interactions both through onsite audits and advice/information requests.

#### Senior Scientist • Q<sup>2</sup> Solutions • 2014 – 2016

Worked with clients regarding their immunoassay needs and method development progress. Designed, developed and validated immunoassays in support of large molecule therapeutic programs, spanning fit-for-purpose biomarkers, pharmacokinetic and immunogenicity assays. Streamlined various procedures in GLP environment to assure compliance and consistent practices. Ensured knowledge transfer from method development to various stages of assay life-cycle to achieve reproducibility and low assay failure rate. Executed beta-testing or assist in IQ/OQ/PQ of instrumentation and analytical software towards 21 CFR Part 11 compliance.

#### Senior Scientist • InVentiv Health Clinical • 2013 – 2014

Developed and validated fit-for-purpose biomarkers, PK and ADA immunoassays. Completed projects efficiently using compliance of critical reagent materials. Developed and trained junior scientists in various phases of assay lifecycle. Established new procedures required for exploration of novel assay formats. Resolved documentation issues.

#### Scientist • Merck • 2010 – 2013

Established radio-immuno assay lab in support of various peptide programs. Worked on ADA and PK immunoassay method development, validation and implementation in support of various preclinical and



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L.I.M.S. for significant gains in PK assay validation workflow

## PUBLICATIONS

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Published Articles: 6

clinical biologic therapeutics. Evaluated various technology platforms to enhance departmental capabilities. Executed leadership and membership roles. Authored and reviewed departmental Standard Operating Procedures (SOPs).

### **Research Scientist II • Imclone Systems (Eli Lilly) • 2009 – 2010**

Developed and validated PK and ADA assays utilizing ELISA and Meso Scale Discovery (MSD) Platforms. Performed sample analysis per departmental SOPs. Executed Watson L.I.M.S. Performance Qualification (PQ) scripts. Authored assay qualification and bioanalytical reports.

### **Scientist II • Wyeth Research • 2007 – 2009**

Developed, validated and analyzed samples for PK & ADA analysis utilizing ELISA and Bioveris technology platforms. Performed preclinical and clinical assays as per Laboratory Operating Guidelines and Standard Operating Procedures. Maintained laboratory equipment. Ensured proper documentation for internal audits of assay validation and/or sample analysis. Helped resolve group problem areas to ensure compliance and efficiency of GLP standards.

### **Research Associate • Orentreich Foundation for the Advancement of Science • 2000 – 2007**

Performed research in: *In vitro* and *ex vivo* biochemical techniques, protein expression, histology and immunohistochemistry, and cell culture. Performed cell based and radio-enzymatic assays and established novel experiments with minimal supervision. Contributed to the design and execution of new experimental paradigms.

## EDUCATION / PROFESSIONAL ACCREDITATIONS

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**MS, Microbiology & Immunology • 2007 • New York Medical College • Valhalla, NY**

**BS, Biology • 2000 • Mount Saint Mary College • Newburgh, NY**

**American Association for Pharmaceutical Scientists • 2014 – Present**



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