

## JENNIFER OHAYON, PhD

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A LABORATORY LEADER IN THE DRUG DEVELOPMENT, CLINICAL TRIAL EXECUTION, CLINICAL LABORATORY MEDICINE, AND BIOANALYTICAL/TRANSLATIONAL SCIENCES SETTINGS. A SUBJECT MATTER EXPERT IN GXP COMPLIANCE AND METHOD DEVELOPMENT, REGULATED BIOANALYSIS AND TRANSLATION BIOMAKERS STRATEGIES SPANNING THE R&D, PRE-CLINICAL AND CLINICAL DRUG DEVELOPMENT PHASES

### **CORE COMPETENCIES:**

- ◆ A technical expert in the developing fit-for-purpose PK, PD, immunogenicity, and biomarker testing options that span the R&D, pre-clinical, IND-enabling, clinical phases, as well as for post-approval commercialization
- ◆ A subject matter expert in the discovery and fit-for-purpose development/validation of bioanalytical and translational biomarker assays with the goal of incorporating highly correlative clinical endpoints to enrich clinical study data sets and decision making by regulatory agencies
- ◆ Highly skilled at building close partnerships across IVD, RUO and academic diagnostic partners; an expert in the fit-for-purpose development and validation of laboratory methods with hand-on experience across a broad range of technologies, such as: Lc-MS/MS, enzymatic, SPR, RT-PCR, multi-color flow-cytometry; as well as ligand binding assays, such as home-brew ELISA assays, radioimmunoassay, MSD, Luminex, AlphaLISA, Gyrolab, Quanterix Samoa, array-based assays, specialized biosensors and *in silico* assays
- ◆ A constant partner to QA with an understanding and compliance to GxP regulatory guidelines, such as: FDA, EMA, ICH, OECD, CLIA, NYSDH, ISO 15189 and ISO 9001; technical lead on GxP audits performed at external CROs
- ◆ A trusted business, technical and compliance partner to cross-functional internal teams in highly matrixed drug development; a partner to finance in forecasting multimillion dollar budgets, as well as developing real-time monitoring tools to predict and review of pipeline specific P&L and capacity
- ◆ An out-of-the-box thinker and problem solver driven to discover innovative testing solutions, as well as key operational needs in the clinical research setting to insure accurate capture and analysis
- ◆ An experienced scientific mentor that instills a passion for science, core values and commitment to the mission of drug development; as a seasoned leader of large technical teams whom strives to inspire honesty, transparency and trust; committed to career-long support and development of technical teams

### **PROFESSIONAL EXPERIENCE**

May 2021 – Current

**Aeglea Biotherapeutics**; Austin TX

Current Role: **Senior Director of Bioanalytical and Biomarker Sciences**

Type of business: Biopharmaceutical focusing on enzyme replacement therapy for rare metabolic diseases

Serve as the bioanalytical and translational leader for programs spanning the drug development cycle, including: protein chemistry, R&D proof-of-concept disease-state animal model studies (*in vivo* and *in vitro*); GLP pre-clinical toxicology; IND-enabling toxicology, phase 1/2 and phase 3 clinical studies, as well as laboratory testing for post-approval needs

Responsible for the contracting and scope-of-work for all external CRO studies, ensuring that all regulatory and quality recommendations are met; partners closely with finance and accounting teams regarding adherence to pre-defined budgets; partners closely with project managers in the development and adherence to study-specific program-timelines; assists in the development of study-specific and program-specific trackers

Partners closely with the Quality Assurance team; serves as the technical auditor in all external CRO audits; stays abreast to all regulatory guidances; strong commitment to data traceability and clinical study data integrity

Responsible for the drafting (and/or review) of the bioanalytical and immunogenicity sections of regulatory documents, including: IND, IMPD, IB, BLA, and Clinical Laboratory Manual documents

An active participant in discussions with the FDA and MHRA, specifically regarding program-specific strategic immunogenicity methods and assessments; responsible for drafting of the Integrated Summary of Immunogenicity (ISI)

October 2019 – March 2021 (Dual Role – see below):

**Pharmaron Clinical Pharmacology Center**; University of Maryland BioPark; Baltimore MD

Position: **Senior Director of Clinical Labs and Biomarker Strategies**

Type of business: Early-phase clinical research; execution of FIH clinical trials

A member of the Pharmaron senior management team (US)

Clinical laboratory and bioanalytical leader for the execution of all testing endpoints defined in early-phase clinical studies, including phases 0, 1a, 1b, and 2a first-in-human clinical studies

Key internal partner to Pharmaron US in enabling of continuity of services during the COVID19 pandemic; hands-on validation of in-house SARS-CoV-2 RT-PCR LDTs during early pandemic lock-down; led the clinical laboratory during the large-scale Pfizer SARS-CoV-2 vaccine trial

Led the clinical lab and phlebotomy teams from a technical, operational and quality perspective to ensure the timely delivery of all clinical safety data to the PI and medical team to ensure real-time decision making in ongoing first-in-human SAD and MAD studies

Performs clinical, operational and quality risk assessments and gap analysis of business risks; seeks-out and champions new analytical instrumentation and software solutions to mitigation of such risks

Championed and spearheaded the onboarding of the Abbott ALIN-IQ AMS LIMS, a rules-based middleware allowing the automation of specimen labeling and tracking, as well as electronic data capture of biometric and ECK measurements in the research clinic

October 2019 – March 2021 (Dual Role – see above):

**Pharmaron Advanced Bioanalytical and Toxicology Development Sciences (ABS)**; Germantown MD

Position: **Senior Technical Advisor**

Type of business: GLP/GCP/CLIA bioanalytical CRO; and Phase 0 Accelerator Mass-Spec studies

Serve as a bioanalytical method development and validation advisor

Advised Pharmaron ABS on their CLIA/COLA licensure; served as an advisor in the development of a QMS SOP encompassed the fit-for-purpose elements of GLP, GCP, GMP and CLIA compliance

March 2019 – September 2019 (contract position)

**Smithers Avanza Bioanalytical and Toxicology Pharma Services**; Gaithersburg, MD

Position: **General Manager/Technical Advisor**

Type of business: GLP/GCP/CLIA bioanalytical (and toxicology) CRO

Responsible for the operational and scientific oversight of the bioanalytical business during the May 2019 divestiture of

the Smithers Avanza Toxicology business to BASi; active participant in M&A desegregation; responsible for segregation of bioanalytical-specific and toxicology-specific study documentation while ensuring overall study confidentiality during divestiture to a non-Smithers entity (BASi)

August 2016 – February 2019

**Eurofins Pharma Bioanalytical Services US, Inc (EPBS);** St. Charles, MO

Position: **Scientific Director**

Type of business: GLP/GCP/CLIA bioanalytical CRO

Technical oversight of Eurofins method development team regarding the design, optimization, and the development & validation of methods in support of GLP pre-clinical and GCP clinical studies; methods consisted of PK, PD, immunogenicity and translational biomarker endpoints across diverse instrumentation platforms

Served as the scientific face of EPBS Bioanalytical to pharma sponsors

Deep understanding of 21 CFR Part 11 compliance and instrument software validation; expert level user knowledge with WATSON LIMS

Translational Biomarker Lead consultant for Eurofins Biopharma internal consulting business (2017-2019)

June 2015 – June 2016 (contract position)

**Enzo Clinical Labs;** Farmingdale, NY

Position: **Director of CLIA Laboratory and R&D Assay Integration**

(Main Lab: Farmingdale, NY) and (STAT Lab: NYC)

Type of Businesses: Clinical chemistry reference lab

Lab Director for Enzo's CAP-certified clinical reference lab serving the New York Tri-State area; oversaw a technical team of 160 technical staff with eight departments/direct reports, including accessioning; core lab (chemistry, immunochemistry and hematology); immunology & flow cytometry; microbiology; molecular diagnostics; Manhattan-based STAT lab, and a Laboratory Developed Tests (LDT) department, in addition to multiple phlebotomy locations

Responsibilities also included the integration of RUO assays (Enzo Lab Sciences)' for clinical testing at Enzo Clinical Lab; required full analytical and clinical validation as Laboratory Developed Tests (LDTs); directed the validation of Enzo's first NYSDH CLEP-approved LDT for the detection of HCV using Enzo's propriety AmpProbe PCR technology

Served as a resource to physicians regarding concerns and/or understanding of laboratory test results, as well as providing guidance on appropriate follow-up testing

March 2013 – February 2015

**DaVita Labs;** Deland, FL (a division of DaVita Kidney Care)

Position: **Director of Assay Development and Validation**

Type of business: clinical chemistry testing of DaVita Kidney Care's US dialysis population

Primary responsibility was to develop GCLP compliant methods as LDTs for clinical studies contracted by DaVita Clinical Research

Responsibilities at DaVita Labs included the fit-for-purpose verification/validation of IVD assays for DaVita's ESRD dialysis population

Served as the partner to DaVita's Office of Chief Medical Officers (OCMO) on all special projects with a laboratory focus; identified key external collaborators including KOLs, pharma partners regulators, government agencies, vendor partners

Spearheaded the introduction of molecular diagnostics at DaVita Labs for the testing of blood-borne pathogens, including: HBV, HCV, and HIV viral load testing; with support from OCMO and IT, infectious disease algorithms were incorporated infectious disease algorithms across the ~2000 DaVita dialysis clinics; the first US dialysis organization to

have in-house molecular testing for blood-borne pathogens; publicly announced as one of DaVita Healthcare Partners' top-ten corporate milestones of 2014

July 2008–Jan 2013

**Nanolnk, Inc.**; Illinois Science and Technology Park; Skokie, IL

Position: **NanoBioDiscovery Division Leader**

Type of business: emerging technology-based company focusing upon highly parallelized array-based proteomics; Chad Mirkin founder

Non-revenue based emerging technology-based proteomics incubator focused upon Atomic Force Microscopy (AFM) for the fabrication of highly parallelized nano-scale biomarker arrays using cutting-edge chemical biology approaches

Led the commercialization of two 10-plexed RUO pro-inflammatory cytokine arrays to commercialization

July 2006–April 2008

**Monarch Life Sciences** (previously Indiana University Emerging Technologies Center); Indianapolis, IN

Position: **Senior Research Scientist**

Type of business: Lc-MS/MS-based biomarker discovery CRO

Performed Lc-MS/MS-based and MALDI-based biomarker/proteomic profiling and biomarker identification studies; CRO serving academic and pharmaceutical biomarker discovery studies

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2004 – 2006

**The Rockefeller University**. NY, NY 10021

Position: **Postdoctoral Associate**

Area of research: Pluripotency of early-adult derived neural stem cell reprogramming in mice (R&D); focus on flow-cytometry and immunochemistry analysis

Type of business: Academic research institute

2001 – 2003

**Memorial Sloan-Kettering Cancer Center**. NY, NY 10021

Position: **Postdoctoral Fellow**

Area of research: Clinical oncology (clinical laboratory medicine): focus on analysis of growth factor signaling EGF/HER2 receptor pathways

Type of business: Cancer Research Institute

## **EDUCATION:**

1995-2000 (transfer):

**PhD: Harvard University**, Cellular and Molecular Physiology; Boston, MA

PhD research with a focus on the insulin/IGF1 signaling pathways (laboratory of Morris F. White PhD)

1992 –1994

**PhD conferred: Indiana University**; Integrative Cellular & Molecular Physiology & Biophysics

1989 – 1991

**MA conferred: Ball State University**; Major: Biology. Minor: Chemistry. Muncie, IN

**BA conferred: Hanover College**; Major: Chemistry. Hanover, IN

## **ADDITIONAL TRAINING:**

Summer Internship 1999

**Indiana University School of Medicine;** The Alcohol Research Center

Area of research: the regulation of ADH and ADHD in alcohol metabolism.

Summer 1994

The Physiology Course,

**Marine Biological Laboratory;** Woods Hole, MA

## **MEMBERSHIPS:**

American Association for Clinical Chemistry; 2013-2016; 2019-current

American Board Bioanalysis: 2021-current

Clinical Laboratory Standards Institute: 2019-current

American Board of Clinical Chemists 2020-current

Regulatory Affairs Professional Society: 2019-2021

American Association of Pharmaceutical Scientists; 2016-current; 2018-2019

Eligible to sit for HHS-HCLD board exam (ABB and ACCL) – except for genetics

## **ORIGINAL PAPERS:**

Stokes RJ, JA Dougan, Ellrvine, **JR Ohayon**, S Rozhok, T Levesque, B Dudzik, M Nelson and D Graham (2009). DPN writing on non-flat gold surfaces and detection by SERS. *Proc. SPIE* 7207, 720703-12.

McClintick JN, Crabb DW, Tian H, Pinaire J, Jerome R, **Smith JR**, Jerome RE and HJ Edenberg (2007). Global effects of vitamin A deficiency on gene expression in rat liver: Evidence for hypoandrogenism. *J Nutr. Biochem.* 17 (5): 245-55.

Pinaire JA, Chou WY, Morton M, You M, Zeng Y, Cho WK, Galli A., Everett L, Breen H, Dumauval N, **Smith JR**, and Crabb D (2003). Identification of a retinoid receptor response element in the human aldehyde dehydrogenase-2 promoter. *Alcoholism: Clin. Exp. Res.* 27(12):1860-1866.

Pinaire J, **Smith JR**, Cho WK, Crabb D (2000) Effects of vitamin A deficiency on rat liver alcohol dehydrogenase expression and alcohol elimination rate in rats. *Alcohol Clin. Exp. Res.* 24(12): 1759-1764.

Yenush L, Makati KJ, **Smith-Hall J**, Ishibashi O, Myers MG Jr., and White MF (1996) The pleckstrin homology domain is the principal link between the insulin receptor and IRS-1. *J Biol Chem* 271: 24300-6.

**Smith-Hall J**, Pons S, Patti ME, Burks DJ, Yenush Y, Sun XJ, Kahn CR and White MF (1997) The 60 kDa insulin receptor substrate functions like an IRS protein (pp60<sup>IRS3</sup>) in adipose cells. *Biochemistry* 36: 8304-10.

Burks DJ, Pons S, Towery H, **Smith-Hall J**, Myers MG Jr., Yenush L and White MF (1997) Heterologous pleckstrin homology domains do not couple IRS-1 to the insulin receptor. *J Biol Chem* 272: 27716-21.

### **Oral Presentations and Webinars:**

**Ohayon J** (2017) *The interface of the CAP/CLIA and GCLP divide*. CHI Immunogenicity and Bioassay Summit (Podium Presentation); October 26, 2017.

**Ohayon J** and Nann Green (2017) *The dynamic landscape of biomarker validation*. Bioanalysis Zone; October 3, 2017.

**Ohayon, J** (2010) *Minaturized ELISA Arrays - a comparison to the popular solution-based assays*. *Select BioSciences Lab-on-a-Chip conference* (Podium Presentation). Dublin, Ireland. May 24-26, 2010.

**Ohayon J** (2010) *Minaturized Protein Arrays: An ELISA-based sensitivity comparison between Nanoarrays and Microarrays*. Accepted to be presented at the Biomarker World Congress (Podium Presentation); Philadelphia, PA. May 4-6, 2010.

**J Ohayon** (2010) *Enhanced Sensitivity of Biomarker Detection and Identification Using NanoScale Protein Arrays*. The Molecular Medicine Tri-Conference; San Francisco, CA.

**Ohayon J**, Rozhok S, Coen M and N Amro (2009) *Protein nano-arrays: Extending the limit of biomarker detection*. Society of Biomolecular Screening. Lille, France.

## **Posters:**

Mark Abrams, Lenne Martin, Chase Ernsky, Elizabeth Clark, Rob Durham, Jennifer Ohayon (2017). *Qualification of a nano-scale generic IgG assay for the quantitation of two monoclonal antibody drugs*. 2017 WRIB, Los Angeles, April 3-7, 2017.

Sanedrin R, Gubbins E, Amro N and **J Ohayon** (2010) *High Sensitivity Cytokine detection Multiplex Assay using Nanoarrays*. The US HUPO meeting; Denver; March 7-10, 2010.

Amro N\*, **Ohayon J\***, Rusniak K\*, Ooyang K, Sanedrin R, Coen M and S Rozhok (2009) *High Sensitivity Biomarker Detection Using Protein NanoArrays*. Human Proteome Organization; Toronto, Canada.  
\*denotes: These authors contributed equally.

Rozhok S\*, **Ohayon J\***, Coen M, Amro N, Shile R, Fragala J and M Nelson (2009) *Immobilization and detection of proteins on the nanoscale*. Advances in Microarray Technology Lab-on-a-Chip European Congress Molecular Diagnostics Europe; Stockholm, Sweden.  
\*denotes: These authors contributed equally.