MARIA NG

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PROFESSIONAL EXPERIENCE

BioMarin Pharmaceuticals, Process Sciences Department – Novato, CA

Senior Scientist I **2017– Present**

SME for a global process transfer of a Phase III CHO upstream process. In addition, a cell culture lead in an early stage drug program.

Notable Contributions:

QUALITY and DATA ANALYTIC PROJECT OBJECTIVES

- **Lead Corporate Initiative** under Product and Pipeline Pillar to apply quality assurance and data science to assess process and method robustness readiness for "Ready at PPQ" stage gate transition by means of quantitative tools and enhance process knowledge.
- **Develop a Methodology** to address small sample size for calculating process capability (Cpk) and performance (Ppk). Additionally, apply Measurement System Analysis to differentiate between process and measurement variabilities.

PROCESS DEVELOPMENT PROJECT OBJECTIVES

- **Serve as Statistical Mentor** to guide Manufacturing Science, Process Science, and Product Quality Leader departments in designing DOE experiments for process characterization risk assessment as well as process improvement for various gene therapy program.
- **Established as Upstream SME** to transfer a Phase III CHO fed-batch process to Cork, Ireland. Also, interact extensively with MSAT, validation, regulatory, and CMC team members to provide essential supporting documents for process characterization risk assessment, and IND filing.
- **Served as Upstream lead** to develop a new fed-batch CHO process by utilizing previous CHO process knowledge for an early-stage drug program and reducing development time by 50% in using in-house feeds.

LAB PROCESSES & PRODUCT IMPROVEMENT

- **Utilize AMBR250, AMBR15, 2L systems, and deep-wells** as scale down tools for gene therapy platform project. Implement definitive DOE screening design for media and feed development to minimize working volume and improve workflow efficiency.
- **Leverage experience in formulating medium/feed** to transfer the CHO knowledge of components in the medium/feed toward gene therapy process.
- **Streamline an Upstream Gene Therapy Platform** by implementing batch process at N-1 stage to increase cell mass for N-stage production while maintaining product quality and reducing process time for a HEK293 process.

INTERDEPARTMENTAL COLLABORATION & LEADERSHIP

- **Manage two-three research associates** in various drug programs.
- **Implement data management** by compiling relevant early to late stage process development data for predictive modeling, simulation, and decision tree analysis.
- **Mentor a team of scientists at Cork, Ireland** by introducing statistical software, JMP, for the purpose of data streamlining across the organization.

SCIENTIST II **2012 – 2017**

Developed in-house media and feeds within the Cell Culture Process Development department to produce enzymes for the treatment of lysosomal storage diseases.

Notable Contributions:

PROCESS DEVELOPMENT PROJECT OBJECTIVES

- **Harnessed a quality-oriented design of experiment (DOE) methodology** toward development, resulting in the efficient, and optimal development of in-house media. Gaining critical process knowledge by having formulation ownership. Also, reduced cost of good by 80% in using in-house medium.
- **Developed media/feed formulations and feed strategies to maximize protein production from cells**, while meeting stringent quality standards. Maintain awareness of the relationship between production quantity and quality.

PROFESSIONAL EXPERIENCE (cont'd)

- **Conducted troubleshooting of product quality** during instances of inability to manufacture on a larger scale, aiming to resolve issues with strategies through root cause analysis.

LAB PROCESSES & PRODUCT IMPROVEMENT

- **Conceived and tested in-house medium and feed strategies at an AMBR15 and 2L batch scales** to be given to biochemical engineers to consider a clinical manufacturing options, with potential to scale-up to 200L bioreactor scale.
- **Contributed to 60% increase in protein production** with comparable improvement in quality, representing an instrumental milestone in project progress.
- **Continuously recognize the value of in-house medium/feed over commercial-grade medium/feed**. Maintain a holistic knowledge of components within the cell culture medium/feed being used throughout research, with each ingredient representing a traceable variable.

INTERDEPARTMENTAL COLLABORATION & LEADERSHIP

- **Manage one research associate and an intern** in various medium and feed development projects.
- **Coordinate annual JMP training and serve as a JMP trainer** supporting the usage of statistical software for Design of Experiment (DOE) and various statistical analysis tools.
- **Collaborate with a diverse team** including scientists, and biochemical engineers. Serve as a reliable mentor and leader, instilling design of experiment methodology and quality management in various process development projects.
- **Served as administrator and coordinator of the department's Electronic Laboratory Notebook**, governing the department-wide transition from paper-based research notes to a digital resource.

SCIENTIST I **2006 – 2012**

Secured this initial role with BioMarin as a subject matter expert on leading-edge CHO cell culture processes, exploring their potential for new product manufacturing.

- **Conducted research toward the development of perfusion and fed-batch processes** in this lab environment. Entered this role to explore the potential of both processes in the pharmaceutical manufacturing life-cycle.
- **Harnessed design of experiment and response surface methodologies** in combination with a suite of leading-edge research methods to develop a component to be screened for insight into improving product quality.
- **Contributed to the successful development of BioMarin's first in-house cell culture medium**, serving as the foundation for future process development work.
- **Drove significant forward momentum toward achieving a manufacturer-ready status** for new therapies, through evaluative investigation of redox components on GALNs, and spin-tubes for cloning and media screening.
- **Served as leader and mentor** to various junior scientists, gaining and applying senior-level leadership skills.
- **Harnessed leading-edge lab resources** including the Millipore disposable 2L Mobius reactor, Applikon BioController, DASGIP, spin tubes, AMBR15 and other instrumentation.

SENIOR RESEARCH ASSOCIATE **2004 – 2006**

- **Joined BioMarin to support the modernization through set up of a 2L cell culture perfusion system**. Secured this role as a subject matter expert on perfusion systems through experience at Bayer Corporation.
- **Gained and applied experience in DoE to build an understanding of the commercial process**, while identifying key parameters (pH) and their impact on drug production quality.

Bayer Corporation, Process Sciences – Berkeley, CA **1996 – 2004**

Acquired and harnessed an advanced skill set in leading-edge cell culturing processes. Earned recognition as a department-wide leader and innovator of new feed strategies to generate breakthroughs in process science.

Scientist (2001 – 2004): Served as DER investigator during a phase II/III clinical campaign, leading pilot plant and process development to ensure the 24-hour monitoring of cell culture and bioreactor operations. Developed an amino acid feed strategy to improve productivity by ~30%.

Senior Associate Scientist II (1999 – 2001): Collaborated with Biowhittaker to enhance CHO medium formulation, and performed cell line selection for optimal cell culturing.

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PROFESSIONAL EXPERIENCE (cont'd)

Associated Process Science Development Scientist (1996 – 1997, 1997 – 1999): Participated a phase II/III process transfer to pilot plant.

INDEPENDENT CONTRIBUTIONS TO SCIENCE

- **Publication:**
  - The "push-to-low" approach for optimization of high-density perfusion cultures of animal cells. Konstantinov K, Goudar C, Ng M, Meneses R, Thrift J, Chuppa S, Matanguihan C, Michaels J, Naveh D. Adv Biochem Eng Biotechnol. 2006;101:75-98.
- **Poster:**
  - Cell Culture Engineering XI 2008 at Sunshine Coast, Queensland, Australia
    Title: Influence of culture conditions on the productivity and quality of a lysosomal enzyme produced in high cell density, continuous perfusion, and CHO cell bioreactors
- **Speaker Presentation:**
  - Non antibody Protein Production Conference 2011 at Berlin, Germany
    Title: A novel methodology for chemically defined production media development
  - Cell Line Development & Engineering 2014 at Berkeley, CA
    Title: An efficient DoE approach for developing in-house chemically defined media
- **Collaboration:**
  - BioMAN BioManufacturing Program team member as part of the MIT Center of Biomedical Innovation
  - East Bay ASQ Program Chair (June

FORMAL EDUCATION

Master of Science-Data Science | Syracuse University **2022**
Master of Science-Quality Assurance | California State University at Dominque Hill **2019**
Certified Quality Engineer | American Society for Quality (ASQ) **2014**
Bachelor of Arts – Integrative Biology and Practice of Art | University of California at Berkeley **1995**