Ilse I Blumentals

Over 20 years of leadership experience in biopharmaceutical development and manufacturing organizations. Extensive experience leading strategy and execution of regulatory, development and commercialization programs for biologic and vaccine products through department and cross-functional matrix teams. Experienced in implementing global product/process registration and development strategies. Experienced in global health authority interactions and filings for clinical and commercial pharmaceutical products. Business focused and adaptive management leadership style to support shifts in project, program, and portfolio priorities to ensure delivery of business and development objectives.

Skill Highlights

- Global CMC regulatory affairs
- Technical regulatory strategy
- Biopharmaceutical development
- Technology transfer and Validation
- Manufacturing science and technology (MST)
- Biopharmaceutical, vaccine, and biotechnology products
- Management and leadership
- R&D project governance
- Product development strategy
- Organizational skills
- Communications
- Thinking outside the box

Core Accomplishments

Global CMC regulatory Affairs:

- Successfully led global CMC regulatory strategy from mid-stage clinical development to commercial registration including all aspects of drug substance, drug product, and analytical development, technology transfer and process validation. Worked closely with project team, R&D and manufacturing lines and senior management to deliver all process, product, and marketing registration objectives within aggressive project timelines.
- Led successful negotiations on product development and manufacturing strategies with global health authorities (US, EU, Canada, Japan, and Australia) to secure regulatory approval of market registration submissions.
- Led global team in the completion of clinical and registration regulatory submissions in the US, EU, Canada, Japan, and rest of world countries.
- Developed regulatory strategy to introduce post-approval process changes and second generation product.

Biopharmaceutical Development, Technology Transfer, Process Validation, and Commercialization:

- Led cell culture process development, process characterization/validation , scale-up, and technology transfer of monoclonal antibody products to support clinical development and commercial registration.
- Led technology transfer, process characterization, and validation of cell culture manufacturing process that resulted in the successful licensure of RotaTeq, a viral vaccine for the prevention of rotavirus gastroenteritis.

R&D project governance and product development strategy:

- Successfully led the entire GSK biopharmaceutical development and manufacturing organizations through the transformational changes required to implement a new Process Development paradigm to increase productivity, success rates, quality, and robustness of product development output while minimizing errors and decreasing project development timelines while ensuring that product quality targets and patient's needs

were met.

Management and Leadership:

- Successfully led groups and cross-functional teams to deliver timely and high quality results on project and business objectives with an effective, collaborative, and flexible approach.
- Actively promotes integrated team performance to increase productivity, build resilience and potentiate capabilities.
- Consistently strives to build high performing teams focusing on employee strengths, development objectives, organizational development, and individual leadership to ensure a highly engaged, empowered and motivated workforce that is innovative, open to change and fiercely focused on product quality and project objectives.

Professional Experience

Executive Director, Late Stage Biologics Development **July 2015 - present**
Celgene Corporation — Summit, NJ

- Responsible for late stage CMC development of biologic products, including upstream, downstream, formulation, analytical, and drug product development. Current biologics pipeline includes monoclonal antibodies, fusion proteins, and bi-specific antibodies.
- Responsible for building in-house development capabilities and internal governance processes for late-stage biologics products.
- Oversight of multiple joint CMC development programs with external partners and collaborators. Represents Celgene on multiple Joint Scientific Committees and Joint Development Committees.

Director, Global Biopharmaceutical CMC Regulatory Affairs **March 2011-June 2015**
GlaxoSmithKline — King of Prussia, PA

- Responsible for delivering product-specific development and commercialization strategy and regulatory filings for worldwide market registration of biologic products. Worked closely with business partners and customers across R&D, Manufacturing and Global Product Development teams to provide effective advice and strategy to project teams to secure approval for marketing applications.
- Managed direct interface with global health authorities on CMC related matters including formal meetings with regulatory agencies and negotiations of CMC agreements on behalf of GSK's Biopharmaceutical R&D and commercial manufacturing organizations.
- Responsible for developing and implementing global CMC strategies and regulatory submissions for biopharmaceutical products at all stages of development, from early stage (pre Phase I) through marketing approval and lifecycle management. Accountable for all CMC regulatory activities for product and process development, associated technologies, and delivery devices for new biological entities and second generation products.
- Provided CMC regulatory leadership to senior level governance boards including Biopharm CMC Steering team and New Product Supply board.
- Represented CMC regulatory affairs on various cross-functional teams (e.g. development of biopharmaceutical product specifications, raw material and impurity clearance, control strategy, critical quality attribute team, virus and adventitious agent safety, continued process validation for commercial manufacturing).

Director, Biopharmaceutical Product Development **2008 - 2011**
Head of Quality by Design Implementation in Biopharmaceutical Development and Manufacturing
GlaxoSmithKline — King of Prussia, PA

- Led large multifunctional matrix team of senior and experienced biopharmaceutical leaders in the development and subsequent implementation of a new paradigm for product and process development across the global GSK network of Biopharm R&D and commercial manufacture (US, UK, Italy).
- Using the principles of Quality by Design (QbD), developed and implemented a strategic, systematic approach to increase the productivity of the product development pipeline by minimizing errors during candidate selection and defining rationale and quality-driven product/process development objectives and plans.
- Led the organization through the transformational changes required to embed the QbD approaches into the

routine ways of working for biopharmaceutical development and manufacture. The approaches were successfully implemented in every aspect of Biopharm development including, candidate molecule design and selection, drug substance and drug product development, establishment of release and stability specifications, technology transfer, and strategy for process validation and commercial manufacture.

  - For products in discovery stage, developed a rigorous and systematic approach to ensure that product quality and performance targets were built into the design and selection of drug candidates based on drug safety, efficacy and developability considerations. Worked closely with discovery, translational medicine, drug metabolism, clinical immunology, safety assessment, early CMC development groups, and senior management.
  - For products in clinical development and commercial manufacturing stages, developed a science and risk based approach to identify product characteristics that are critical for the safety, efficacy, and quality of the product and understand the aspects of the manufacturing process that impact those product characteristics. The resulting product and process understanding was used to develop approaches for robust manufacturing processes and control strategies to consistently produce product of the desired quality.

- Worked closely with project and line management as well as the senior Biopharm leadership to implement QbD approach across all development projects through integration into the Biopharm development governance process.
- Provided leadership and guidance to senior Biopharm management, project teams and governance boards to ensure that product/process development and manufacturing strategies were integrated to meet product quality and process performance targets.

Manager, Late-Stage Cell Culture Process Development **2004 - 2008**
GlaxoSmithKline — King of Prussia, PA

- Led late stage process development group responsible for all cell culture based products. Responsible for all development activities leading to commercial manufacturing, including Process Development, Characterization, Validation, Scale-up, Technology Transfer, Technology Support to Manufacturing, and preparation of worldwide regulatory submissions.
- Also responsible for management and operations of the R&D pilot scale bioreactor facilities.

Key accomplishments include:

- Led cell culture process development, scale-up, and technology transfer to commercial manufacturing facility, as well as process characterization/validation activities of a monoclonal antibody product to support commercial registration. Led preparation of CMC sections for EU and US regulatory submissions.
- Successfully led the development and scale-up of several monoclonal antibody products, resulting in significantly higher product yields and improved process robustness.
- Led multiple technology development initiatives including, development of new mammalian host cell lines and proprietary media/feeds, improvement of manufacturing platform processes, and development of high-throughput process development approaches. Provided technical leadership for a capital project to upgrade small scale bioreactor equipment and associated instrumentation. Championed IT project to improve data integration and knowledge management systems.
- Developed business processes to integrate and manage process development group and pilot plant schedules, resource planning, and capacity based on R&D product development pipeline and priorities.
- Technical lead for development of functional specifications, design, qualification and startup of process equipment.

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Senior Research Fellow, Group Leader Fermentation and Cell Culture Process Development **2000 – 2004**
Merck Research Laboratories, West Point, PA

- Managed group responsible for cell culture process development, scale-up, technology transfer, and validation of viral vaccine manufacturing processes.

Key accomplishments include:

- Led the technology transfer, process characterization, and validation of the cell culture manufacturing process for the commercial production and licensure of RotaTeq, a viral vaccine for the prevention of rotavirus gastroenteritis.
- Led successful development and scale-up of cell culture processes for production of several adenovirus recombinant vaccine candidates in early and mid-stage clinical development.
- Led the development and characterization of a host cell line to improve productivity and process robustness.
- Led optimization and technology transfer of cell banking processes to the commercial manufacturing facility.

Manager, Fermentation and Cell Culture Process Development and
Manufacturing Sciences and Technology Group **1992 – 2000**
Life Technologies, Inc., Gaithersburg, MD
Leading supplier of products for molecular and cell biology research

- Managed groups responsible for all fermentation and cell culture process development activities leading to manufacturing and launch of new products.
- Also responsible for troubleshooting commercial manufacturing processes and process improvements for existing (catalogue) products.
- Responsible for capital project to design and start-up pilot plant facility; also managed several facility and equipment improvement projects.

Key accomplishments include:

- Developed and/or improved more than 60 commercial fermentation processes for new and existing products, including recombinant proteins (e.g. restriction enzymes), native proteins (e.g. polymerases), nucleic acids (DNA and RNA), and bacteriophages.
- Project lead for the optimization and re-design of upstream and downstream manufacturing processes for the entire *E.coli* competent cell product line, resulting in up to 5X quality improvements, 10X product yield increases, and multimillion-dollar annual savings.
- Project lead for design, build, and start-up of large-scale bioreactors, harvest centrifuges/filters, and kill tank equipment for new commercial manufacturing facility. Led facility startup with a model product and subsequent successful GMP campaigns.
- Project lead for facility and equipment design, build, and start-up of a new R&D pilot plant for microbial and cell culture process development. Started up development facility, developing business operational and documentation systems, and equipment and automation qualification.
- Developed and scaled-up fermentation and harvest processes for more than 10 different thermophilic bacteria and optimized process to prepare genomic DNA libraries. Developed a screening strategy for recombinant thermophilic DNA polymerases; successfully cloned two new polymerases for commercial applications. Co-authored several patents.

Academic Research

The Johns Hopkins University, Baltimore, MD.
Associate Research Scientist and Postdoctoral Fellow, Chemical Engineering Department
Evaluated the feasibility of using thermophilic enzymes and bacteria in processes for industrial waste biodegradation and manufacturing of food components. Developed activity assays for various thermophilic enzymes, including proteases, cellulases, lipases, amylases, pullulanases, hemicellulases and esterases.

National Institutes of Health, NIDDK, Biotechnology Unit, Bethesda, MD.
Conducted research on the regulation of exotoxin A production by Pseudomonas aeruginosa.

Venezuelan Institute of Scientific Research (IVIC), Laboratory of Virology, Caracas, Venezuela.

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Cloned and expressed human rotavirus VP6 in E.coli. Collaborated in several gene-sequencing projects**.**

Education

Ph.D. Chemical Engineering, The Johns Hopkins University, Baltimore, MD.
BSc. Molecular and Cellular Biology (Major), Ecology (Minor), Universidad Simon Bolívar, Caracas, Venezuela

Languages

Fluent in English, Spanish, and Latvian. Basic Italian, German, and French.

Publications and Patents Available upon request
References Available upon request