# Kristen Picard, PhD
# Biotechnology Human Performance & Training Specialist

## Personal Profile

Kristen is a highly qualified and experienced professional with two decades of experience in the field of biotechnology. She has designed, developed, and evaluated training programs and performance support initiatives for global biologics networks and universities. In addition, Kristen has extensive hands-on experience with startups, audit and inspection readiness, and Operational Excellence including human performance optimization and the strategic application of lean and six sigma methodologies. She has been involved with the design, implementation, and testing of complex IT infrastructures at multiple locations, offering seamless operation in paperless facilities. Kristen has a broad range of commercial biologics production experience encompassing raw material weigh/dispense, solution preparation, as well as upstream and downstream operations in large and small scale bacterial and mammalian cell culture processes. She also has a background in gene therapy research and development including protein engineering and enzyme design. She is a proven biotechnology specialist who thrives on cross-functional collaboration, brainstorming, and problem solving. She is particularly passionate about the development and application of digital tools to maximize efficiency, safety, and productivity.

## Education

PhD, Adult Learning and Development (Educational Studies), Lesley University, Cambridge, MA

Master of Science, Bioscience Administration, Worcester Polytechnic Institute, Worcester, MA

Bachelor of Science, Communication Disorders, University of Massachusetts at Amherst, Amherst, MA

## Experience

**Prospera Consulting Solutions (Whitinsville, MA)**

Biotechnology Consultant

- Utilize two decades of experience in the field of biotechnology to provide specialized consulting services in the following areas:
  - GMP training and human performance optimization
  - Chemistry, Manufacturing, and Controls (CMC) for gene and cell therapy production
  - Project management for facility start-up and manufacturing process improvements
  - Audit and inspection readiness leadership and support
  - Operational Excellence (OpEx) strategy and application (Lean and Six Sigma methodologies)
  - Management of quality compliance and regulatory initiatives
  - Implementation of cutting-edge digital technologies to maximize efficiency and productivity
- Apply tools, methods, and practices to problem solve, plan, and track project progress while maintaining focus on desired business outcomes.
- Access knowledge and creativity to develop and implement novel and innovative solutions.

**Sanofi (Framingham, MA)**

Global Human Performance & Training Specialist, Biologics Manufacturing

- Successfully managed the on-time delivery of simultaneous mission-critical human performance and training programs
    - Demonstrated strong organizational skills through the planning, design, and development of training courses while maintaining alignment with Good Manufacturing Practices (GMPs) and current industry standards.
    - Designed and developed computer-based trainings as well as in-person instructor-led trainings, working with managers and subject matter experts on the manufacturing floor to support the start-up of the highly innovative *Factory of the Future*.
    - Adapted swiftly when deadlines shifted, developed creative solutions in response to schedule changes, and collaboratively achieved buy-in when adjustments were required to maintain on-time delivery of programs.
    - Worked internationally with French and German Subject Matter Experts (SMEs) to ensure effective global application of training programs
    - Scheduled meetings and provided consistent communication regarding project kick-offs, milestone completions, and project closures.
    - Gathered, sorted, and presented metrics to report on training completions and employee/business success rates (outcomes).
    - Trained employees in Manufacturing, Quality Control, and Quality Assurance.
    - Collaborated and consulted with managers, subject matter experts, and training specialists to determine best strategies for human performance optimization (training and other performance support tools).
    - Actively pursued and implemented avenues to improve operational efficiency through performance support.
    - Ensured instructional integrity of coursework through systematic design methods, including identification of clear learning objectives and incorporation of appropriate learning experiences to achieve desired outcomes.
    - Collected data for program evaluations, including survey development, interviews, and focus groups.
    - Analysed data from program assessments and implemented improvements to enhance program outcomes.
    - Worked with management and leadership to ensure continued compliance with training standards through aptitude assessments and development of skills matrices.
- Developed and implemented a digital learning solution and performance support technology that contributed to the operation of a digitally enabled biomanufacturing facility. This work played a role in Sanofi's Factory of the Future being granted the "2020 Facility of the Year Award" by the International Society of Pharmaceutical Engineers (ISPE).
- Drew upon instructional design experience, doctoral work, coaching education, and mindfulness research to create and facilitate experiential learning sessions for stress reduction and goal attainment among business professionals.
- Large-scale project example: led the development and deployment of EWIs – a digital solution to replace Standard Operating Procedures (SOPs). Prepared Sanofi for global implementation of EWIs through the creation of instructional documentation such a Global Operating Procedure (GOP) and additional supporting SOPs and users guides.

**Lake Pharma (Worcester, MA)**

Project Manager

- Managed the lifespan of projects for contract research, development, and manufacturing which included the development of initial quotes, providing clients with status updates and responses, and completing project closeouts.
- Prepared quotes and proposals based on financial standards combined with knowledge of protein engineering, cell line development, protein optimization, and GMP manufacturing.
- Communicated productively and proactively with clients and members from all levels of the organization.
- Collaborated cross-functionally with sales, accounting, warehouse, and scientific teams to ensure clients' needs were met.
- Consulted with business unit leaders and account managers to increase business revenue and exceed client expectations.
- Nurtured and maintained positive client and vendor relationships.

**Worcester Polytechnic Institute (Worcester, MA)**

Biotechnology Instructor – Biomanufacturing Education and Training Center

- Educated hundreds of adult professionals regarding compliance readiness, quality assurance, biomanufacturing regulations, root cause analysis, CAPA plans, environmental health and safety, upstream and downstream manufacturing processes and equipment preparation and operation [examples include SIP/CIP, mammalian and bacterial inoculation (e.g., roller bottles and bioreactors with and without microcarriers), aseptic processing, various forms of filtration, and single-use technologies].
- Consulted with representatives from biotechnology companies to develop customized employee training programs that addressed training gaps and satisfied unmet needs.
- Coached and mentored adults regarding career development in the field of biotechnology.
- Evaluated training programs through surveys, focus groups, and interviews with stakeholders (students, business partners, industry experts, administrators, and instructors).
- Applied data collected from program evaluations for continuous improvement and further development of robust training programs.
- Active member of International Society for Pharmaceutical Engineers (ISPE), attended local events monthly and contributed to ISPE's blog.
- Volunteered as member of ISPE's Geographic Outreach Committee. Coordinated and hosted monthly educational sessions at Worcester Polytechnic Institute.
- Consulted on the development and production of an interactive educational training video funded by the National Science Foundation. The project was designed to help students and new employees understand the importance of quality procedures when producing biologic medicines.
- Co-created and presented the following posters (note: last name changed from Benoit to Picard in 2015):
    - Bellereive, C., Rashid, K., Mardirosian, D., & Benoit, K. (2014, October). The Utility of Real Time Monitoring of Various Growth Parameters in a Mammalian Cell System. Poster presented at BioProcess International Conference & Exhibition, Boston, MA.
    - Rashid, K. and Benoit, K. (2014, June). The Role of the Biomanufacturing Education and Training Center at Worcester Polytechnic Institute in Workforce Development Efforts for the Biotechnology Industry. Poster presented at 11th Annual Single-Use Applications International Biotechnology Conference, Boston., MA.

**Bristol Myers Squibb (Devens, MA)**

Project Lead – Biologics Manufacturing

- Managed process and automation changes and ensured changes were fully executed on the floor (including proper training for all shifts).
- Compiled and analysed process data, investigated unexpected phenomena, developed and/or assisted in the development of resolution and process improvement plans.
- Delivered clear and articulate presentations and trainings to various levels of the organization.
- Conducted risk assessments for compliance readiness and to mitigate potential failures/hazards.
- Applied knowledge of biotechnology processes, systems, and regulations to the authoring and editing of SOPs, deviation investigations, and CAPAs.
- Responded to deviation investigations on the manufacturing floor to capture real-time reports from employees, photographs, and process data.
- Applied process expertise and technical knowledge to edit electronic batch records and implement associated change controls.
- Ensured accurate execution of recipe modifications/changes through sandbox testing and automation validation runs.
- Maintained electronic batch records in accordance with GxP regulatory requirements and internal standards and ensured change initiatives were driven to timely closure.
- Utilized knowledge of GMP and regulatory requirements as subject matter expert for audit preparation and as an active participant in internal and external commercial audits (FDA/EMA).
- Designed process flow maps to maximize performance success and ensure consistency upon execution.
- Interacted daily with management and functional groups across various departments.
- Presented technical information/projects for knowledge dissemination and to gain cooperation from others.
- Conducted quality review of documentation for errors and omissions on a daily basis.

**Bristol Myers Squibb (Devens, MA)**

Process Lead and Manager of People – Biologics Manufacturing

- System Owner of large-scale solutions preparation process.
- SME in media and buffer formulation processes as well as raw material weigh and dispense operations, and analytical equipment (pH, conductivity, osmolality, and glucose testing).
- Gained strong working knowledge of Cell Culture and Purification processes.
- Directly managed and developed 12 technicians in media preparation and weigh/dispense areas, and indirectly managed 24 technicians in the Solution Preparation Department.
- Educated, mentored, and developed employees, coordinated and led meetings, created and executed changes for improvement projects while maintaining adherence to strict timelines.
- Coordinated various activities across multiple departments to ensure successful completion of complex biomanufacturing processes.
- Completed the following activities during multi-year start-up of the facility:
- Worked in cross-functional teams to complete projects and activities required for the start-up of a high-tech, $700 million dollar, 20,000L biomanufacturing facility.
- Leveraged control standards such as ISA-88 and 95 in the design and development of automated recipes for digital integration of process operations.
- Participated in the integration of Delta-V, Syncade, SAP, and LIMS allowing seamless functionality in a paperless facility.

- Authored an enterprise-critical document supporting site strategy for aseptic processing: Steam in Place (SIP) Strategy White Paper.
- Reviewed CAD drawings (Piping and Instrument Diagrams, General Arrangement Drawings, Piping and Hydraulic Diagrams) for accuracy, errors, and omissions.
- Authored, reviewed, implemented, and tested batch record recipes and electronic work instructions for autoclaves, parts washers, solutions prep equipment (large-scale vessels and associated utility controls), and analytical equipment (pH and conductivity meters, osmometer, and glucose analyser).
- Wrote, reviewed, and executed protocols such as: Factory Acceptance Testing (FAT) Dossiers and Test Matrices, Risk Assessments, and Start-Up Procedures.
- Attended FAT, conducted Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) validation activities (including automation qualification/validation) for large-scale solutions preparation equipment.
- Prepared site for manufacturing approval readiness (FDA and EMEA). Defended personally authored work such as electronic batch records and SOPs when submitted for regulatory review during manufacturing approval audits.

**Abbott Bioresearch Center / AbbVie (Worcester, MA)**

Suite Coordinator

- Assessed manufacturing and business process performance to identify opportunities for improvements:
    - Applied Operational Excellence methodologies (Six Sigma and Lean Manufacturing) to assess/improve operations in terms of cost, cycle time, and inventory.
    - Developed project proposals, charters, and status reports for process improvements and presented to management.
    - Created and executed action plans to achieve strategic goals.
    - Led change activities through the development of transition plans from current to future state, and managed projects to completion.
    - Led people and initiatives to ensure timely completion of projects.
    - Obtained buy-in by gathering, analysing, and presenting metrics such as KPIs and process/equipment data.
- Project example: Created current and future state Value-Stream Maps for process equipment and material flow for large-scale biomanufacturing processes. Identified areas in need of improvement, authored and presented proposals for improvement, and implemented solutions in problem areas.

**Abbott Bioresearch Center / AbbVie (Worcester, MA)**

Continuous Improvement Associate

- Utilized knowledge of systems, equipment, and processes to ensure seamless operation of a 6,000L upstream (cell culture) process.
- Collaborated with management to investigate deviations, determine root cause(s), and develop appropriate CAPAs.
- Project managed CAPAs to reduce or eliminate repeat deviations.
- Authored and edited batch records and SOPs, ensuring accuracy through on-the-floor interaction and collaboration with external vendors, SMEs, and management.

- Managed document review and approval processes to meet project timelines and provided status reports to management.
- Ensured 6,000L suites were always in a state of compliance in regard to the calibration/maintenance of instruments and equipment.
- Coordinated the timely completion of maintenance work orders, equipment calibrations, and preventative maintenance plans.
- Implemented various forms of performance support through the development of job aids and attention activators.
- Upheld safety procedures and safe practices in manufacturing areas.
- Completed calibration coordinator course for certification.

**Abbott Bioresearch Center / AbbVie (Worcester, MA)**

Technical Writer / Administrative Assistant

- Reviewed, edited, and formatted SOPs, batch records, and deviation investigations for cell culture processes (for example: bioreactors, filter trains, and analytical equipment).
- Consulted across various departments to ensure process and equipment operation instructions were clear, accurate, and in accordance with filings, regulations, and industry standards.
- Provided administrative support to manufacturing department (~50 individuals).
- Maintained and managed calendars; proactively identified and resolved scheduling conflicts.
- Coordinated travel arrangements and expense reports for managers and supervisors.
- Conducted onboarding and offboarding activities for employees and contractors.
- Managed office supply ordering and maintenance of computers, photocopiers, and printers.
- Reviewed and processed invoices and purchase orders.

**University of Massachusetts - Graduate School of Biomedical Sciences (Worcester, MA)**

Ph.D. Student, Biochemistry and Molecular Pharmacology

- Completed coursework in research ethics and biomedical sciences, as well as the following laboratory rotations:
    - Biochemistry & Molecular Pharmacology: Supported lead scientist through data gathering and documentation to identify cell cycle characteristics for fission yeast Schizosaccharomyces pombe (S. pombe). Laboratory work included inoculation, DNA labelling, and DNA quantification by scintillation.
    - Gene Function and Expression: Supported lead scientist in the ongoing project to create novel transcription factors that control gene expression. Laboratory work included data gathering and documentation during the following activities: protein purification, molecular cloning by polymerase chain reaction (PCR), and nucleic acid sequencing.

**Publications**


- Picard, K. (2018). An Investigation into Learning and Development Associated with Embodied Mindfulness. Educational Studies Dissertations, 147.
- Picard, K. (2017, January). Gene Therapy 101: Fast Facts & FAQs. WPI's Biomanufacturing Education and Training Center Blog. Retrieved from https://wp.wpi.edu/betc/2017/01/11/gene-therapy-101-fast-facts-faqs/.
- Picard, K. (2017). Gene therapy. In World Book Student. Retrieved from http://www.worldbookonline.com/student/article?id=ar219755. Article available upon request.

- Sivakumar, S., Porter-Goff, M., Patel, P.K., Benoit, K., & Rhind, N. (2004). In vivo labelling of fission yeast DNA with thymidine and thymidine analogs