Todd Kessler

▼ Professional Profile

- Founded PVLMC to support biologics companies.
- Led process validation campaign activities for the US FDA Coronavirus Treatment Acceleration Program (CTAP).
- Provided guidance to PVLMC clients on process validation lifecycle activities and BLA/NDA initiatives, leading to the commercial approval of numerous therapeutic proteins.
- Acted as process validation subject matter expert (SME) for three companies (Amgen, Insmed, and Merck) and additionally for two PVLMC clients.
- Prior to founding PVLMC, directly contributed to the approval of at least 10 commercial drugs in the US, EU, Canada, and Japan including Kineret®, Enbrel®, Iplex™, Ragwitek®, Grastek®, Odactra®, Keytruda®, Lusduna™ Nexvue ™, Zinplava™ and Vaxneuvance™.
- Contributed to more than 40 drug programs.
- Over 20 years of experience commercializing therapeutic proteins/biologics.
- Over 20 years of experience in process validation, including development and management of process validation programs, and ensuring consistency of validation strategies and regulatory commitments across multiple contract manufacturing organizations (CMOs).
- Over 19 years of experience remotely supporting and managing foreign and domestic CMOs.
- Active participant/leader on senior leadership teams for multiple companies, including four Fortune 500 corporations.
- Twice had the US FDA retain a study on resin expiry as a model example for the biologics industry.
- Experienced with authoring and reviewing CTD sections for IND, BLA/NDA, IMPD and APR submissions.
- Proficient at conducting technical, quality, and regulatory compliance audits of domestic and foreign contract manufacturing sites (assessment against regulations, cGMPs, and regulatory commitments).
- Proficient with authoring multiple document types including technical assessments, risk assessments, technical protocols and reports, validation protocols and reports, validation plans, audit reports, sections of regulatory applications and supplements, change controls, and commercial process non-conformances/planned deviations/CAPAs.
- Experienced in supporting US FDA, EMA, and Health Canada pre-approval and biennial inspections.
- Experienced with project management, and with initiating and leading cross-functional teams.
- Exceptional organizational, troubleshooting, and problem-solving skills.
- Strong word processing, database and spreadsheet application skills, communication, and presentation skills.
- Proficient in Microsoft Office applications (Word, Excel, PowerPoint, and Project), and experienced with quality management systems software (i.e. TrackWise, Documentum) and statistical evaluation programs (i.e. JMP, Minitab).

▼ Experience

- **Chief Executive Officer,** *Process Validation Lifecycle Management Consulting Ltd. (PVLMC),* 2016 to present.

  Directed Process Validation Activities for Two Fortune 500 Global Biologics Companies in Support of the US FDA Coronavirus Treatment Acceleration Program (CTAP).
  - Directed process validation campaign to take a phase 3-ready product to process performance qualification (PPQ)-ready in 3 months.
  - Directed PPQ readiness workstream.
  - Provided consultation on BLA initiatives and strategies.
  - Acted as process validation senior leadership team (SLT) representative.
  - Authored process validation documents.

  Consulted for a Major Biologics Manufacturing Company which was Subsequently Sold in a Multi-Billion Dollar Sale.
  - Created and directed a program for the determination of CQAs by quality risk evaluation.
  - Provided consultation on BLA initiatives and strategies.
  - Provided consultation on process control strategy and process validation key initiatives.
  - Provided consultation on process validation quality system development initiatives.

  Consulted for a Major Global Biologics CMO which was Subsequently Sold in a Multi-Billion Dollar Sale.
  - Performed gap analysis on existing process validation systems and provided feedback to address the gaps that were found.
  - Developed process validation global biologics quality standards.
  - Developed and deployed global process validation training module at international manufacturing facility.
  - Developed standard work practices for process characterization and process validation.
  - Collaborated on general subject matter expert (SME) requests/questions relating to process validation and associated regulatory planning and compliance, in support of international and domestic manufacturing facilities.

- **Multiple Process Validation Roles,** *Merck Sharp & Dohme Corp,* 2009 to 2016.

  Process Validation: Senior Specialist, 2010 to 2016.
  - Global biologics process validation subject matter expert within Merck.
  - Managed an annual CMO Budget of ~$5M for process characterization and PPQ readiness.
  - Actively managed PPQ activities for two biologics programs while providing compliance assessments for several additional programs (All programs received US FDA and/or EMA approval).
  - Supported multiple Merck internal manufacturing facilities and external CMOs, including foreign and domestic sites.
  - Supported pre-approval inspections (PAI) at drug substance sites in Denmark, leading to the approval of three commercial products.
  - Authored and/or performed PPQ expert reviews on CTD sections (3.2.S.2.5.2) for six biologics BLA/NDA submissions (leading to US FDA and/or EMA approval of all six). These included the approvals of Keytruda®, Zinplava™, Lusduna™Nexvue, Odactra®, Grastek®, and Ragwitek®.
  - Established and deployed a PPQ readiness program within Merck, leading to the successful completion of at least seven PPQ campaigns.
  - Worked on over 15 biologics, biosimilars, vaccines, and sublingual immunotherapy programs.
  - Created and deployed a global protein biologics PPQ training module across Merck facilities.
  - Contributed to the generation of global Merck quality by design policies and practices.
  - Key contributor for establishing global protein biologics validation policies and best practices in accordance with the revised US FDA process validation guidance.
  - Designed technical study that was retained by the US FDA as a model example.

Process Validation: Senior Engineer, 2009.

- Led process validation integration activities for the Merck Boulder CO site (post-acquisition of Insmed site by Merck).
- Participated on multiple product and project teams including drug substance planning teams, analytical method planning teams, Merck integration teams, and technical operations leadership team.
- Developed and managed the Merck Boulder process validation program.
- Managed process validation timelines and ensured completion of validation prerequisites prior to PPQ.
- Drafted and reviewed IND, NDA and IMPD sections.
- Provided validation impact assessments for change controls and critical deviations.

➢ **Quality Assurance,** *Insmed Therapeutic Proteins*, 2006 to 2009.

QA Validation Specialist, 2006 to 2009.

- Managed equipment qualification, process validation, and cleaning validation projects and activities.
- Provided technical expertise on process characterization, process monitoring, and generation of process validation acceptance criteria.
- Successfully presented and defended validation policies, strategies, and protocols/reports during EMA PAIs.
- Drafted and reviewed NDA and APR sections of US FDA and EMA regulatory filings.
- Performed technical product impact assessments and root-cause analyses for cell culture, purification and fill/finish deviations.

➢ **Multiple Roles,** *Amgen*, 2001-2004.

Contract Manufacturing Quality Assurance: Validation Specialist, 2004 to 2005.

- Remotely managed Enbrel® process validation consistency across multiple domestic and foreign commercial contract manufacturing sites (bulk drug substance and drug product).
- Performed technical, quality and regulatory compliance audits of foreign contract manufacturing sites (regulations, cGMPs, and regulatory commitments).
- Assisted in drafting, reviewing, and gaining approval of BLA regulatory filings.
- Prepared supporting documentation for internal audits and regulatory agency inspections.
- Designed a computer database to manage global contract manufacturer IQ/OQ/PQ, process validation and transport validation documents as well as regulatory agency commitments.
- As QA validation expert, reviewed and approved protocols and reports associated with equipment, process (cell culture and purification), transport, and fill/finish validations.
- Quality assurance technical expert for new commercial manufacturing start-up activities.
- Owned critical cell culture and purification deviation investigations, planned deviations, and corrective/preventative actions.

Process Development, 2001 & 2002 to 2004 (CO and RI facilities).

- Designed and led bench-scale in-process intermediate hold-time validation studies.
- Managed and executed ultrafiltration/diafiltration membrane reuse and liquid chromatography resin reuse studies to support commercial-scale process validation and cost-of-goods reduction.
- Participated in the set-up of a critical high-capacity commercial-scale manufacturing facility (review of unit operations, training of supervisors, and process characterization and validation support).
- Designed and led characterization studies to optimize the primary chromatography step of a commercial process (protein biologics) and improve the clearance of process-related-impurities.
- Technical approver of critical commercial-scale purification process deviations and corrective/preventative actions.
- Initiated, designed, and managed a resin expiration extension project which led to raw material cost-savings of $8.2M.
- Authored numerous technical documents that have been successfully presented to domestic and foreign regulatory agencies.
- Designed technical study that was retained by the US FDA as a model example.

Commercial Manufacturing, 2002.

- Performed product impact assessments and root-cause analyses related to manufacturing deviations.
- Floor-lead for multiple purification production shifts and document owner for production-scale equipment.
- Presented to the US FDA during biennial regulatory inspections.

▼ Education

- **College Degrees**
  - Bachelor's & Master's

▼ Leadership

- Seven years as founder/owner of PVLMC.
- Simultaneously managed process validation activities for six drugs which gained commercial approval from the US FDA and/or EMA (two with both US FDA breakthrough therapy designation and EMA accelerated assessment).
- Over 20 years of experience with biennial and pre-approval inspections.
- Over 14 years participating on senior leadership teams, including four Fortune 500 companies.
- Over 20 years interacting with US FDA, Health Canada, EMA, and PMDA Japan.
- Over 19 years managing multiple CMOs from a remote location.