

Kasemann Consulting

Consulting Services for Pharmaceutical & Biotech Industries
Validation / GXP / Quality / Project / Interim Management

Services Provided by Aquene & Olaf Kasemann Consulting GmbH

Project Management Services:

- Project Management
- Project Execution Planning
- Schedule Development
- Fast Track Validation/Qualification Scheduling

Interim Management Services:

- Interim Department/Team Management
(Sterile Fill & Finishing, Compounding, USP & DSP, small molecules & large molecules/biotech & vaccines)
 - Validation and Qualification Department/Teams
 - Quality Assurance Department/Teams
 - Manufacturing Department/Teams
 - Process and Plant Engineering Department/Teams

GXP-Compliance Services:

- Business/GMP Process Analysis
- Process Development and Improvement
- Documentation Structure Analysis, Development and Update
- Standard Operation Procedure, Generation and Update Services
- Quality Manuals, Contamination Control Strategies, Generation and Update Service
- Support on EU/FDA Requirements and Expectations Assessments
- GXP Training & Workshops

Validation Services:

- Process Validation
- Cleaning Validation
- Analytical and Sampling Method Validation
- Qualification of Equipment & Utilities
- Commissioning of Equipment
- Re-validation and Re-qualification
- Verification & Validation
- Traceability Matrices and Risk Analysis
- Validation Documentation, Reviews, Reports, and Summaries
- GAP Assessments

Quality Assurance Services:

- Q-Systems Reviews, Development, and Optimization
- Validation Master Plans, Generation and Update Service
- Risk Assessments (GXP, Raw Material, Process, Cleaning, Utilities, Equipment, etc.)
- Virus Safety Assessments
- Process Safety Assessments
- Procedures and Documentation, Review and Upgrade Service
- Audit Preparation & Support
- Auditing Services

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Curriculum Vitae

Personal Data:

Name: Dipl.-Ing. Dr. Olaf Kasemann
Company Address: Hetzendorfer Straße 128
1120 Vienna/Austria
Mobil: +43 / 699 / 11 53 10 11
E-Mail: office@olafkasemann.com
Date of Birth/Nationality: 09.07.1965 / German

Occupations and Expertise:

since October 2004	Validation / GXP / Quality / Project Consulting & Interim Management - General Manager - Executive Consultant and Project Manager (for Details see Reference List)	Aquene & Olaf Kasemann Consulting GmbH
Jan. 2002 - Sept. 2004	Head Validation Department, Quality Operation - Process Validation, Cleaning Validation, Method Validation, Validation of Aseptic Filling Processes, Down-Scale Validation Definition of Requirements for Validation Documentation, Development of Validation Master Plans, Risk Assessments and corresponding further documentation - Qualification of Production Equipment, Utilities, Critical Systems (HVAC, WFI, PW, CS, CA), Computer Systems, Analytical Equipment - Project Management / Manager of Validation and Qualification Tasks in various Upgrade and GMP-Projects - Project Management of Technology Transfer- und Registration Projects, Writing of corresponding documents - Interface Function to Departments of the Major Facilities - Budget Responsibility of approx. 1.000.000,- € (Cost Center & Projects) - Management of 10 Employees & Consultants	ZLB Behring (Aventis Behring GmbH)
July 1997 - Dec. 2001	Head Process Validation - Development of Process Validation Concept for Vienna Facility, Establishment of Statistical Process Control (SPC) - Management of Cleaning Validation - Establishment of harmonized production processes at the Vienna facility and major production facilities - Management of Technology Transfer und Registration Projects, Development of corresponding documentation - Interface Function to Departments of the Major Facilities (Regulatory Affairs, Process Evaluation and Validation, Manufacturing, Virus Validation, Down Scale Validation) - Project Manager of „FVIII Products, Batch Enlargement Project“ (Budget 850.000,- €) - Project Manager „Technology Transfer Sub-Fractionation Immunoglobulines“ - 1999-2001 Substitutional Head of Production according to Austrian Drug Law (AMG), responsible for quality assuring measures within production department - Budget Responsibility 170.000,- € - Management of 2 Employees	Aventis Behring GmbH (Centeon Pharma GmbH)
April 1993 - June 1997	Assistant Head of Production - Production Manager, Production and final packaging of granulates, tablets and coated tablets, sterile und non-sterile ointments, sterile und non-sterile solutions und suspensions, approx. 40 employees - Main Responsibility for sterile Products (Liquida & Ointments) - Management of Technology Transfer Projects - Responsible for Contract Manufacturing and Auditing, Production - Auditing of Production by Authorities und Contractors	Waldheim Pharmazeutika GmbH

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Sept. 1989 - Dec. 1989	Junior Scientific Officer - Evaluation of Sampling Errors and Homogeneity of Standards of the AQCS-Program Analytical Testing of AQCS-Standards	IAEA, United Nations Vienna
Education:		
Jan. 1990 - March 1993	Doctorate Study / Organic Chemistry	Technical University Vienna
Sept. 1984 - June 1989	Diploma Study / Organic Chemistry	Technical University Vienna
Further Skills and Certificates:		
Languages Skills:	German, native speaker English, fluently	
EDV-Skills:	Standard Office - very good user skills (Word, Excel, Access, Power Point, MS Project, Visio, Concept Draw) Windows/OS 10 - standard user skills	
Software User-Skills:	Trackwise, MasterControl, Veeva/Quality Docs, SAP, Power BI, Thingworx, ValGenesis, etc.	
Further Training:		
1995	GMP-compliant Documentation in the pharmaceutical production	C. Heidelberg
1996	Supply Chain Management in the pharmaceutical industry	C. Heidelberg
1997	Current aspects of Cleaning and Disinfection in the pharmaceutical industry	C. Heidelberg
1998	Technology Transfer in the Pharmaceutical Industry & Workshop: Achieving success in Technology Transfer by Working through a Simulated Project Management and Coaching of Employees	IIR, London Austrian Res. Center
1999	Statistical Tools in manufacturing, quality control and quality assurance in the pharmaceutical industry	C. Heidelberg
2001	Project Management Time and Task Management	Hernstein Inst. Hernstein Inst.
2002	Aventis Behring Manager Advantage (Business Acumen, Social Styles for Manager, Managing Conflict, Coaching for Performance, Negotiation skills)	Wilson Learning
2003	„Fish“ - an unusual Motivation Seminar FDA & the Current Challenges of GMP's - Europe	Pharma Conference
2009	Statistical Tools for Method Validation	Novia
2010	Method Validation	Novia
Personal Interests:		
	- Classic Music - Fencing (Epee, Foil) - Individual Traveling - Reading	

Vienna, 26th July 2026

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Projects and References Aquene & Olaf Kasemann Consulting GmbH

Projects and References:

Aug. 2025 - ongoing	Quality Assurance Project, Compounding & Sterile Filling (Therap. & ADCs) Simtra Germany GmbH, Halle (Westphalia), Germany Quality Assurance, EU & US requirements - New Manufacturing Area, Validation Compliance & Quality Support - Inspection Remediation Program (Work Stream Lead & Quality Support & Execution) - GXP Support, Assessments & Review Services	Aquene & Olaf Kasemann Consulting GmbH
Mar. 2024 - Aug. 2025	Production Support Project, Compounding & Sterile Filling (Therapeut.) Ferring Germany GmbH, Kiel, Germany Manufacturing, EU & US requirements - Filling Process Risk Assessment - Process Inventory and Flow Diagrams (Define Standard & Execute) - New/Updated Document Structure - GXP Update Support, Review & Update Service	
July 2023 - June 2024	Quality Assurance Project, Sterile Filling & Visual Inspection (Therapeut.) Ferring Germany GmbH, Kiel, Germany Quality Assurance, EU & US requirements - Establishing Particle Contamination Control Strategy - Standardize Particle Incident Risk Assessment & Escalation Schemes - Risk Assessments for Particulate Contamination Pathways - Analyze and Optimize Sites overall Trending Concept	
Feb. 2022 - June 2023	Quality Assurance Project, USP & DSP, Biotech (mAb) WuXi Biologics Germany GmbH, Wuppertal, Germany Quality Assurance, EU & US requirements - Interim Head QA Operations (USP & DSP, 6 FTE) - Qualification Compliance (Utilities, USP & DSP Process Equipment, CSV, QC, Clean Rooms) - QA Operations & Engineering Support, Setup of GXP compliant Processes and Documentation	
Sept. 2021 - Jan. 2022	Manufacturing Project, Comp. & Sterile Filling, Biotech (Vaccines) WuXi Biologics Germany GmbH, Leverkusen, Germany Technical Operations, EU & US requirements - Interim Head Technical Operations (Comp. & Filling, 80 FTE) - Production Planning (Material Mgt, Batch Docu, Comp. & Filling & VI/Packaging)	
Jul. 2021 - Sept. 2021	Quality Support Project, USP & DSP, Biotech (mAb, Vaccines) WuXi Biologics Germany GmbH, Wuppertal, Germany Quality Unit, EU & US requirements - Risk Assessment Cross Contamination - QA Support Qualification & Validation Compliance	
Mar. 2020 - Aug. 2021	Quality Support Project, Comp. & Sterile Filling, Biotech (Vaccines) WuXi Biologics Germany GmbH, Leverkusen, Germany Quality Unit, EU & US requirements - QA Support Qualification Validation Compliance - Project Support Process & Documentation - Audit/Inspection Preparation (QRAs, CCS, APS-report, etc.)	

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Projects and References:

Aug. 2020 - Feb. 2021	C & Q Support Project, Sterile Compounding Facility (Small Molecules) Akorn AG, Hettlingen, Switzerland Qualification & Validation Unit, EU & US requirements - Coordination, Planning and Performing of C & Q Tasks - Qual & Val Documentation, Generation & Review
Mar. 2019 - Dec. 2019	Quality and MFG Project, Comp. & Sterile Filling (Small Molecules) Reciphaarm/Wasserburger Arzneimittelwerke GmbH, Wasserburg, Ger. Quality Unit, Manufacturing Depart., EU & US requirements - QA Operations Support, Batch Record Reviews & GMP-Assessments & Closure of Deviations - QA Systems Support, Assessment Qualification (Fill & Finishing, Packaging) & Deviation Management - Manufacturing Support, Update of Master Batch Records, Closure of Deviations & CAPAs
Sept. 2017 - Feb. 2019	Capacity Expansion Project, Comp & Sterile Filling, Biotech (Therapeut.), Bayer AG, Leverkusen, Germany Quality Assurance Biotech Department, EU & US requirements - QA Project Support, Commissioning & Qualification (Compounding plant, Auxiliary Equipment, Small Equipment) - Validation-, Qualification- & GMP-Compliance - Cleaning Validation Support
July 2017 - Aug. 2017	Manufacturing Project, Logistic & Distribution (Small Molecules) Linz, Austria Documentation, EU & US requirements - Generation of Transport Validation Protocol and Report
Jan. 2017 - June 2017	Manufacturing Project, Comp & Sterile Filling (Small Molecules) BIPSO GmbH, Singen, Germany Compounding & Sterile Filling, EU & US requirements - Interim Head Sterile Production, Line Function (Comp. and Filling) - Full Budget and Personnel Responsibility (4.2 Mio € & 150 FTE)
Dec. 2016 - Jan. 2017	Virus Safety Project, Cell Culture Plant, Biotech (Therapeut.) Novartis AG, Basel, Switzerland Virus Safety Concept, EU & US requirements - Evaluation & Assessment of the Virus Safety Concept of the Cell Culture plant
Feb. 2016 - Dec. 2016	Manufacturing Project, Comp & Sterile Filling (Small Molecules) BIPSO GmbH, Singen, Germany Compounding & Sterile Filling, EU & US requirements - GXP Support (DRs, CAPAs, CCAs), SOP Updates, Training - FDA Preparation Team Lead, Summaries and Presentations for Audit
Feb 2016	Area Concept in API Production, Support Project (API Mfg) Boehringer Ingelheim International GmbH, Ingelheim, Germany Documentation, EU & US requirements - Generation of Interim Transition Report
Dec. 2015 - Sep. 2016	Process Validation Project (Therapeutic Proteins) CSL Behring GmbH, Marburg, Germany Documentation, EU & US requirements - Generation of Process Val., Stability and Impurity Profiling Reports
Dec. 2015	Laboratory Relocation Project (Diagnostica) Bavarian Nordic GmbH, Munich, Germany Documentation, EU & US requirements - Generation of Project Validation Master Plan - Relocation Impact Risk Assessment

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Projects and References:

Nov. 2015 - Feb. 2016	Virus Safety Project, Cell Culture Plant, Biotech (Therapeut.) Sandoz GmbH, Schafftenau, Austria Virus Safety Concept, EU & US requirements - Document and Summarize the Virus Safety Concept of the Cell Culture Plant for Authority Presentation & Submission
Nov. 2014 - Oct. 2015	Engineering Project, Biotech Plant (Vaccines) Dynavax GmbH, Düsseldorf, Germany Recombinant Vaccines, EU & US requirements - Interim Head Preventive Maintenance, Corrective Maintenance, Calibration Group - Engineering Line Function, Work & Personnel Management - Project Management & GMP-Support (CAPAs, DRs, CCAs)
May 2015 - June 2015	Process Validation Project (Therapeutic Proteins) CSL Behring GmbH, Marburg, Germany Documentation, EU & US requirements - Generation of Process Validation and Impurity Profiling Reports
Feb. 2015 - July 2015	Conditioning Concept Closed Equipment, Support Project (API Mfg) Boehringer Ingelheim International GmbH, Ingelheim, Germany Documentation, EU & US requirements - Summary of a Concept for Conditioning of Closed Equipment in API Production
Jan. 2015 - Mar. 2015	Process Validation Project (Therapeutic Proteins) CSL Behring GmbH, Marburg, Germany Documentation, EU & US requirements - Generation of Process Validation and Impurity Profiling Reports
Oct. 2014	Process Validation & Cleaning Validation Project (Small Molecules) Linz, Austria Documentation, EU & US requirements - Generation of Submission Summaries for Process Validation & Cleaning Validation Projects
May 2014 - Sep. 2014	Area Concept in API Production, Support Project (API Mfg) Boehringer Ingelheim International GmbH, Ingelheim, Germany Documentation, EU & US requirements - Generation of an Evaluation and Change Over Master Plan
Nov. 2013 - Feb. 2014	Particulate Contamination in APIs, Support Project (API Mfg) Boehringer Ingelheim International GmbH, Ingelheim, Germany Documentation, EU & US requirements - Docu. of Concept in regard to Particulate Contamination in APIs - Generation of Final Report for FMEA Risk Assessment for Particulate Contamination in APIs
May 2013 - Feb. 2014	Process Validation Project (Therapeutic Proteins) CSL Behring GmbH, Marburg, Germany Documentation, EU & US requirements - Generation of Process Validation, Cleaning Validation, and Impurity Profiling Reports
Nov. 2013 - Jan. 2014	Process Validation & Cleaning Validation Project (Small Molecules) Linz, Austria Documentation, EU & US requirements - Generation of Submission Summaries for Process Validation & Cleaning Validation Projects

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Sept. 2013 - Dec. 2013	Process Validation Project, Cell Culture Plant (Therapeutic P.) Sandoz GmbH, Schafftenau, Austria Raw Material Risk Assessment, EU & US requirements - Conceptual design and Generation of Raw Material Risk Assessment
July 2013 - Aug. 2013	Manufacturing Project, Biotech Plant (Vaccines) Dynavax GmbH, Düsseldorf, Germany Recombinant Vaccines, EU & US requirements - CCA Performance Qualification (Docu., Management & Report)
Feb. 2013 - Apr. 2013	Process Validation Project, Cell Culture Plant, Biotech (Therapeutic P.) Sandoz GmbH, Schafftenau, Austria Virus & Scale Down Validation Report, EU & US requirements - Generation of Process Virus & Scale Down Validation Report
Nov. 2012 - May 2013	Manufacturing Project, Biotech Plant (Vaccines) Dynavax GmbH, Düsseldorf, Germany Recombinant Vaccines, EU & US requirements - Interim Head Manufacturing, Line Function, Work & Personnel Management - Validation & Qualification Responsibility, Concept & Documentation - Project Management & GMP-Support, Product & Process Risk Ass.
Dec. 2012 - Feb. 2013	QC & QA Support Project, Cell Culture Plant, Biotech (Therapeutic P.) Sandoz GmbH, Schafftenau, Austria Stability Report, EU & US requirements - Generation of Stability Report
Sept. 2012	Risk Assessment Project, Cell Culture Plant, Biotech (Therapeutic P.) Sandoz GmbH, Schafftenau, Austria Cross Contamination, EU & US requirements - Generation of Risk Assessment in regard to Cross Contamination
Nov. 2011 - Sept. 2012	Process Validation Project, Parenteral Products (Cytostatic D., Small M.) Sandoz GmbH, Unterach am Attasee, Austria Parenteral Products, EU & US requirements - Process Validation, Concepts & Requirements, Support - Sterile Filter Validation, Concept & Documentation Support - Generation of Process Validation Protocols & Reports - Execution of Process Validation Projects
Jan. 2011 - Oct. 2011	Site Expansion Project (Small Molecules) Intervet GesmbH (MSD Tiergesundheit), Vienna, Austria Quality Assurance Department, EU & US requirements - QA Project Support, Review and Revision of Quality Systems, Documentation, Processes and Procedures - Validation Master Plan, Validation Project Plan - Validation-, Qualification- & GMP-Compliance
Oct. 2010	IMPD Submission Project Support Soldan Regulatory Consultancy, Biedenkopf, Germany Biotech Product, US requirements - Review & Summary Method Validation, IMPD-Submission
Sept. 2009 - Dec. 2010	Business Process Optimization Project (Therapeutic Proteins) Biotest AG, Frankfurt, Germany Quality Control Department - Business Process Optimization, Quality Control Department: Evaluation, Analysis, Action Plan, Implementation, and Follow up

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Projects and References:

- Feb. 2009 & Mar. 2009 **Process Validation Project Support (Therapeutic Proteins)**
Biotest Pharmaceuticals Corp, Boca Raton, USA
Product Downstream, US requirements
- Review and Assessment of Process Validation Documentation, Concept and Requirements Support
- July 2008 - Dec. 2008 **Regulatory Project Support(Therapeutic Proteins)**
Biotest AG, Frankfurt, Germany
Downstream & Filling Processes, EU & US requirements
- Review & Assessment of Final Reports for Submission, Qualification & Validation Documentation
- Mar. 2007 - Dec. 2010 **cGMP - FDA, EU Compliance Project (Therapeutic Proteins)**
Biotest AG, Frankfurt, Germany
QC, Downstream & Filling Processes, EU & US requirements
- FDA-Compliance Upgrade in Quality Control Unit
 - Project Management Support, Sub-Project Manager QC
 - Review and Assessment of Quality Systems, Documentation, Processes and Procedures
 - Validation / Verification Quality System Definition, Establishment, Documentation and Performance Support
 - Qualification Analytical Equipment, Documentation, Performance and Performance Support
 - Raw Material Testing, Specification and Testing Documentation
 - Review and Update of Testing Procedures for Final Products
 - Method Validation for Raw Material and Final Product Testing
 - Bioburden Control Strategy, Concept and Requirements Support
 - Cleaning Validation, Concept and Requirements Support
 - Internal Audits (QC Laboratories, LSO Recall-Process)
- Nov. 2007 - May 2009 **Cleaning Validation Project (Small Molecules)**
Intervet GesmbH (MSD Tiergesundheit), Vienna, Austria
Solida Production, EU & US requirements
- Cleaning Validation Concept and Documentation
 - Analytical and Swab Sampling Method Validation
 - Project Management Support, Sub-Project Manager CV
- Apr. 2006 - Dec. 2006 **GMP Support Project: Production Plant and Utilities (Vaccines)**
Zeta GmbH, Vienna, Austria
Downstream Processing, Utilities, EU & US requirements
- Project Management of Commissioning and Qualification Tasks
 - Risk Assessment GMP, Product, Environment, Health and Safety
 - FAT, SAT, Qualification Documentation
 - Deviation Management: System Definition and Management
- Dez. 2005 - July 2006 **Process Validation Project, Lyophilization (Therapeutic Proteins)**
CSL Behring GmbH, Marburg, Germany
Lyophilization, EU & US requirements
- Process Validation Concept and Requirements Support
 - Generation of Process Validation Plans & Reports for Authority Submission
- Oct. 2005 - Dec. 2005 **Qualification Project: Packaging Machine (Small Molecules)**
Intervet GesmbH (MSD Tiergesundheit), Vienna, Austria
Solida Production, EU & US requirements
- Qualification Concept and Docu., Performance and Final Report
 - Review and Assessment of Vendor Documentation

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- Oct. 2005 - Nov. 2005 **De-Bottlenecking Project, Biotech**
Roche Pharma AG, Basel, Switzerland
- Assessment of potential Yield Improvement Capabilities in regard to Regulatory and Inventory Impact, Business Risk and Phasing
 - Estimation of Costs and Benefits
- June 2005 - Dec. 2005 **Contract Filler Technology Transfer Project, Biotech (Therapeutic P.)**
Delta Biotechnology Limited, Nottingham, GB
- Aseptic Contract Filling, EU & US requirements**
- Technology Transfer of Aseptic Filling Process
 - On Site - Project Management Support
 - Establishment of Compliant Process Documentation
 - Review and Assessment of Qualification and Validation Docu.
 - Review of Quality Systems, Evaluation of general GXP-Compliance
- June 2005 **Documentation Review Project: Granulation Equipment (Small Molecules)**
Intervet GesmbH (MSD Tiergesundheits), Vienna, Austria
- Solida Production, EU & US requirements**
- Review and Assessment of Vendor Documentation, GAP Analysis
- Oct. 2004 - Feb. 2007 **Cleaning Validation Project (Small Molecules)**
Intervet GesmbH (MSD Tiergesundheits), Vienna, Austria
- Solida Production, EU & US requirements**
- Project Management, Project Manager
 - Cleaning Validation Concept and Documentation
 - Analytical and Swab Sampling Method Validation
- Oct. 2004 & Nov. 2004 **FDA Pre Approval Inspection Support Project (Therapeutic Proteins)**
Delta Biotechnology Limited, Nottingham, GB
- API-Manufacturing and Filling, EU & US requirements**
- Audit Preparation & Support (FDA PAI)
 - General GXP-Compliance Status
 - Review of Quality Systems

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