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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date: 3rd April 2025

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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	Waldheim Pharmazeutika GmbH

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- Auditing of Production by Authorities und Contractors

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	IIR, London
	Management and Coaching of Employees	Austrian Res. Center
1999	Statistical Tools in manufacturing, quality control and quality assurance in the pharmaceutical industry	C. Heidelberg
2001	Project Management	Hernstein Inst.
	Time and Task Management	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, 3rd April 2025

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Projects and References Aquene & Olaf Kasemann Consulting GmbH

Projects and References:

Aquene & Olaf Kasemann Consulting GmbH

March 2024 - ongoing
Production Support Project, 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 – ongoing
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.)

Aug. 2020 – Feb. 2021
C & Q Support Project, Sterile Compounding Facility (Small Molecules)
Akorn AG, Hettlingen, Swizerland
Qualification & Validation Unit, EU & US requirements
- Coordination, Planning and Performing of C & Q Tasks
- Qual & Val Documentation, Generation & Review

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Projects and References:

Mar. 2019 – Dec. 2019 **Quality and MFG Project, Comp. & Sterile Filling (Small Molecules)**
Recipharm/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 (Diagostica)**
Bavarian Nordic GmbH, Munich, Germany
Documentation, EU & US requirements
- Generation of Project Validation Master Plan
- Relocation Impact Risk Assessment

Nov. 2015 – Feb. 2016 **Virus Safety Project, Cell Culture Plant, Biotech (Therapeut.)**
Sandoz GmbH, Schaftenau, Austria
Virus Safety Concept, EU & US requirements
- Document and Summarize the Virus Safety Concept of the Cell Culture Plant for Authority Presentation & Submission

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Projects and References:

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

Sept. 2013 - Dec. 2013 **Process Validation Project, Cell Culture Plant (Therapeutic P.)**
Sandoz GmbH, Schaftenau, 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)

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Projects and References:

Feb. 2013 - Apr. 2013 — **Process Validation Project, Cell Culture Plant, Biotech (Therapeutic P.)**
Sandoz GmbH, Schaftenau, 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, Schaftenau, Austria
Stability Report, EU & US requirements
- Generation of Stability Report

Sept. 2012 — **Risk Assessment Project, Cell Culture Plant, Biotech (Therapeutic P.)**
Sandoz GmbH, Schaftenau, 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

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

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Projects and References:

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 Row 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

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

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Projects and References:

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 Tiergesundheit), 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 Tiergesundheit), 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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