

Validation Services

Validation philosophy

- risk analysis → critical parameters/functions → DQ/IQ/OQ activities
- cost effective
- EMEA/FDA compliant and inspection-proof

Validation planning

Scope

- preparation of master plans, risk assessments, SOP's
- preparation of qualification plans for DQ, IQ, OQ

Application

- validation in reconstruction or new erection projects
- re-qualification/re-validation

Validation execution

Scope

- test execution and documentation or supervision
- description, investigation and resolution of deviations
- review and approval of executed protocols (together with client)
- preparation of summary reports

Application

- validation in reconstruction or new erection projects
- re-qualification/re-validation

Validation management

Scope

- leadership of the validation team
- planning and controlling of validation sequences, mile stones and documents
- transfer of validation requirements to subcontractors
- co-ordination of interfaces between pharmaceutical manufacturer and subcontractors

Application

- validation in reconstruction or new erection projects

Validation consulting

Scope

- GMP-reviews and audits
- consulting for structure of GMP-documentation
- GMP- and part 11 compliance studies

Application

- preparation of inspections
- „Second opinion“

Validation support

Scope

- preparation of a company-specific validation approach, including guidelines and SOP's
- elaboration of validation standards for technical systems (e.g. for HVAC, utility and process systems)

Application

- restart or reorientation of company-own validation matters
- implementation of a company internal validation standard applicable to all subsidiaries

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Selected References Qualification & Validation

Customer/ Location	Project	Scope of supply	Receipt of order
Novo Nordisk A/S, Bagsværd, Denmark	Pilot plant for the production of different peptides	Conceptual design, engineering, procurement, construction management, commissioning, qualification	2006/2007
Novartis Pharma, Schweizerhalle AG, Pratteln, Switzerland	Extension of a facility for the production of chemical API	Engineering services for concept, basic & detail engineering, qualification (IQ, OQ)	2006/2007
Novo Nordisk A/S, Kalundborg, Denmark	Reconstruction of a plant for the biotechnological production of API	Detail engineering, construction management, commissioning, qualification	2006
F. Hoffmann-La Roche AG, Basel, Switzerland	Plants for the production of sterile liquids and semi-solid dosage forms with highly active ingredients	Project coordination, detail engineering for process technology, procurement support, supervision of installation, qualification support	2006
Novo Nordisk A/S, Kalundborg, Denmark	Exchange of crystallization tanks in a process plant	Conceptual design, basic & detail engineering, procurement, construction, commissioning, qualification	2004 to 2006
GlaxoSmithKline, Sächsisches Serumwerk GmbH, Dresden, Germany	Implementation of a new filling isolator line	Basic & detail engineering, procurement, construction management, validation	2005
Galenica Holding AG, Bern, Switzerland	Modernisation and extension of a pharmaceutical plant, phase 3, turnkey-project	Project management, engineering, construction, start-up, qualification	2003/2004
Wyeth Medica, Dublin, Ireland	Multi product campus with 3 separate facilities	Engineering counselling for validation and qualification management	2003
Roche Diagnostics GmbH, Pernzberg, Germany	New cell culture plant on a scale of 5.000 l	Conceptual design, basic & detail engineering, procurement support, design assistance during realisation, qualification support	2003
Octapharma Pharmazeutika Produktionsgesellschaft mbH Wien, Austria	New plant for aseptic filling line with barrier isolator for LVP	Site development conception, concept design, basic & detail engineering, site supervision, validation management	2002

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Customer/ Location	Project	Scope of supply	Receipt of order
Biotest Pharma GmbH, Dreieich, Germany	New plant for the production of blood clotting factors and immunoglobulines	Project management and controlling, site supervision, validation management	2002/2004
AVENTIS Pharma Deutschland GmbH, Frankfurt, Germany	New manufacturing plant for insulin	Basic & detail engineering, procurement (on behalf and on account), civil, construction, commissioning, qualification	2000/2001
Hoffmann-La Roche AG, Basel, Switzerland	Multi-purpose plant for the production of new pharmaceutical agents in kg amounts during the phase of development	Basic engineering, project management for detail engineering and construction, assistance with qualification	1999
Lonza AG, Visp, Switzerland	Retrospective qualification of the process control system of a multi-purpose plant	Assistance with qualification	1999
Bayer AG, Leverkusen, Germany	Revamp of two closed handling plants for solid active ingredients	Concept, basic & detail engineering, supervision of construction, commissioning, qualification	1998/1999
Merckle GmbH, Blaubeuren, Germany	Retrospective qualification of production	Qualification master plan, qualification standards, inspection	1998
Bayer AG, Elberfeld, Deutschland	Multi-purpose plant	Basic & detail engineering, procurement, qualification	1997
Chemical Works of Gedeon Richter Ltd., Budapest, Hungary	Turnkey manufacturing plants in compliance with FDA	General contractor, authority, basic & detail engineering, supervision of construction, commissioning, qualification	1997/2000