

## Helmut M. Rector

Quality- / Risk- & Compliance Management Consultant with validAID  
Brueder-Grimm-Str. 26a

35039 Marburg



phone: +49 163 246 29 78

eMail: [helmut.rector@validAID.de](mailto:helmut.rector@validAID.de)

## Curriculum vitae

### Career Profile

Highly motivated, analytically thinking Quality- / Risk- & Compliance Management Consultant with 14+ years experience in the Pharmaceutical- / Life-Science and Medical Device Industry, a degree in natural sciences and proven expertise in Project Management. Expert in Compliance Regulation, incl. EU GMP, PIC/S, 21CFR part 11, part 210, part 211, part 820, GAMP5 (computerized systems)

### Personal

Date of Birth	02.10.1967
Place of Birth	Neuss a. Rhein
Personal Status	married

### Education

1997	<b>Diploma Degree in Chemistry</b> Philipps-University Marburg, Germany
1990	<b>Bankkaufmann (IHK)</b> Deutsche Bank, Düsseldorf
1988	<b>Abitur</b> Th. Schwann Gymnasium, Neuss a. Rhein
1985	<b>US High School Diploma</b> Hodgdon High School, ME, USA

### Language Skills

German (mother tongue)  
English (fluent)  
French (Basic)

## Helmut M. Rector

Quality- / Risk- & Compliance Management Consultant with validAID  
Brueder-Grimm-Str. 26a

35039 Marburg

phone: +49 163 246 29 78

eMail: [helmut.rector@validAID.de](mailto:helmut.rector@validAID.de)



### Professional Experience

<b>2014 - today</b>	<b>Quality- / Risk- &amp; Compliance Management Consultant - (Founder / Owner)</b> validAID, Marburg <ul style="list-style-type: none"><li>- Ensuring quality by counseling on regulatory compliance</li><li>- Analyzing and streamlining business processes and mitigating risks</li><li>- Performing Computer System Validation (CSV)</li><li>- Project Management</li><li>- Training</li></ul> (see Projects section for additional details)
<b>2010 - 2014</b>	<b>Sr. Manager Quality Assurance (eSystems)</b> CSL Behring, Marburg <ul style="list-style-type: none"><li>- Global Quality Responsible for the development of the risk-based enterprise IT Quality Management System (ITQMS), incl. development, consultation, review and approval of all documents.</li><li>- Responsible for Business Process Optimization (QMS)</li><li>- Responsible for all Changes/Deviations/CAPAs related to GxP-Systems, incl. DMS, LIMS, SAP, eQMS, ITSM, MES...</li><li>- User Responsible eQMS (TrackWise)</li><li>- Global Project Lead Customer Batch Documentation System</li><li>- Global Project Lead TrackWise-SAP-Interface</li><li>- Project Lead TrackWise-Upgrade (Version 8.3.1)</li><li>- Project Lead BI Quality/Manufacturing Data Warehouse</li><li>- Project Lead TrackWise CAPA Process / Workflow</li><li>- Co-Auditor for GxP Systems</li></ul>
<b>1999 - 2010</b>	<b>Quality- / Risk- &amp; Compliance Management Consultant - (Founder / Owner)</b> MoccaNet Systems, Marburg <ul style="list-style-type: none"><li>- Conceptual support as well as automatization and qualification of Albumin Ultrafiltration plant (production)</li><li>- Multiple Implementations of Manufacturing Execution Systems (MES) at pharmaceutical companies</li><li>- Leading risk-based Computer System Validation (CSV) activities</li><li>- Software concepts, engineering and development (JAVA)</li><li>- Process analysis (Variance analysis, Fit/Gap analysis)</li><li>- Development of training material</li><li>- Conducting of IT Systems Validations (Pharma) incl. development of Validation Plans / Reports, test scenarios and procedures for system, validation / verification (FAT / SAT)</li><li>- Project planning and execution</li><li>- Conducting customer and staff trainings</li><li>- Support of project teams during supplier evaluation</li></ul>

## Helmut M. Rector

Quality- / Risk- & Compliance Management Consultant with validAID  
Brueder-Grimm-Str. 26a

35039 Marburg

phone: +49 163 246 29 78

eMail: [helmut.rector@validAID.de](mailto:helmut.rector@validAID.de)



1999 - 1999	<b>Manager Development and Projects (eCommerce)</b> KC Data Systems AG, Pohlheim <ul style="list-style-type: none"><li>- Pre-sales consulting</li><li>- Variance analysis</li><li>- Concept development</li><li>- Preparation of proposals / offers</li><li>- Project planning and execution</li><li>- Conducting customer and partner trainings</li></ul>
1998 - 1999	<b>Internal Consultant (Internet &amp; electronic Banking)</b> HSBC Trinkaus & Burkhardt, Düsseldorf <ul style="list-style-type: none"><li>- Staff development (Training)</li><li>- Concept and planning of the internet site (eBanking)</li><li>- Implementation, design and programming</li><li>- Administration of the site</li><li>- Corodination of the contribution of different specialty departments</li><li>- Implementation of interfaces to legacy Systems (e.g. Stock Quotes)</li></ul>
1997 - 1998	<b>System Administrator</b> Physiological Institute, Dept. of Neurophysiology, Philipps University, Marburg <ul style="list-style-type: none"><li>- Installation, configuration and support, incl. backup / restore</li><li>- Networkand Printer Installation</li><li>- Conducting staff trainings</li></ul>

### Extra-Professional Training / Committee Work

- GAMP DACH	Special Interest Group (SIG) Audit Trail Review Special Interest Group (SIG) Raw Data
- PMO:	Project Management
- Leadership:	Internal Leadership Training, CSL Behring
- GMP:	ISPE GAMP5 Training, PTS
- Process Modelling:	UML Training, Rational Rose, Signsoft
- Data Modelling:	XML Training, Signsoft
- Programming:	Java Enterprise Training, Signsoft Java Advanced Training, Signsoft Java Beginner Training Signsoft
- Product Training:	Crystal Reports (Reporting), IAD Werum PAS-X (MES) Werum AG Intershop enfinity Training (eCommerce), Intershop Intershop Cartridge Development Kit (eCommerce), Intershop Intershop 3 & 4 Advanced Training (eCommerce), Intershop
- Train the Trainer:	Train the Trainer Training, Intershop

## Helmut M. Rector

Quality- / Risk- & Compliance Management Consultant with validAID  
Brueder-Grimm-Str. 26a

35039 Marburg

phone: +49 163 246 29 78

eMail: [helmut.rector@validAID.de](mailto:helmut.rector@validAID.de)



### Projects

2017	<p><b>Project Lead / Sr. MES Consultant</b></p> <p>CSL Behring, Marburg Responsible for the business process design, of the new MES Werum PAS-X for the CSL Behring NBF245 Base Fractioning facility, incl.</p> <ul style="list-style-type: none"><li>- Project Management</li><li>- User Requirement Specification</li><li>- Review of Functional Specification</li></ul>
2015 – 2017	<p><b>Project Lead / Sr. MES Consultant</b></p> <p>CSL Behring, Marburg Responsible for the business process design, validation and training of the new MES Werum PAS-X 3.2 "Sunrise" for the CSL Behring H69 Packaging</p> <ul style="list-style-type: none"><li>- Project Management</li><li>- User Requirement Specification</li><li>- Review of Functional Specification</li><li>- Quality Plan / Risk Analysis</li><li>- MBR Modelling</li></ul>
2015 - 2017	<p><b>Sr. MES Consultant</b></p> <p>Boehringer Ingelheim, Biberach a.d.Riss Responsible for MBR design, validation and training of the new BioMES 7 (Werum PAS-X 3.1.6 / 3.1.8) incl.</p> <ul style="list-style-type: none"><li>- MBR Modelling</li><li>- Support and Troubleshooting of MBRs</li><li>- MES Validation</li></ul>
2016	<p><b>Quality Management Consultant (CSV)</b></p> <p>CSL Behring, Marburg Responsible for the regression qualification of the extended central weighing system MES M300 at CSL Behring, Marburg, incl.</p> <ul style="list-style-type: none"><li>- Change Control preparation</li><li>- Risk Analysis</li><li>- Qualification- and Test Planning</li><li>- IQ / OQ / PQ</li><li>- Test- and final Validation Reporting</li></ul>
2016	<p><b>Quality Management Consultant (CSV)</b></p> <p>CSL Behring, Marburg Responsible for the validation (QlikView) for the manufacturing monitoring of recombinant Factor VIII (for Test Data at different product stages and KPIs )</p> <ul style="list-style-type: none"><li>- User Requirement Specification (URS)</li><li>- Functional Risk Assessment (FMEA)</li><li>- Validation – and Test Planning</li><li>- Test Case creation and execution</li><li>- Test- and final validation reporting</li></ul>

## Helmut M. Rector

Quality- / Risk- & Compliance Management Consultant with validAID  
Brueder-Grimm-Str. 26a

35039 Marburg

phone: +49 163 246 29 78

eMail: [helmut.rector@validAID.de](mailto:helmut.rector@validAID.de)



2016	<b>Quality Management Consultant (CSV)</b>  CSL Behring, Marburg Responsible for the Computer System Validation of the TrackWise EQM Upgrade, incl. <ul style="list-style-type: none"><li>- Change Control preparation</li><li>- Functional Risk Assessment (FMEA)</li><li>- Qualification- and Test Planung</li><li>- Test Case creation</li><li>- IQ / OQ / PQ</li><li>- Test and final validation reporting</li></ul>
2015	<b>Sr. Consultant Business Process Re-Engineering</b>  Merck Serono, Darmstadt Responsible for new Quality Processes, incl. <ul style="list-style-type: none"><li>- Change Control</li><li>- CAPA</li><li>- Audit</li><li>- Deviation</li></ul>
2014	<b>Sr. CSV Consultant (Equipment / Medical Devices)</b>  DePuy Synthes, Zuchwil/Bettlach Responsible for equipment re-validation, incl. <ul style="list-style-type: none"><li>- Inventory</li><li>- Compliance Analysis</li><li>- Legacy Review</li><li>- Remediation (retrospective creation of CSV documentation)</li></ul>
2014	<b>Consultant Global Customer Batch Documentation System</b>  CSL Behring, Bern / Marburg Project Manager and Business Process Responsible <ul style="list-style-type: none"><li>- Global Business Project Lead</li><li>- Business Process Engineering / Optimization</li><li>- Global Workshop Lead for Business Requirements gathering</li><li>- Implementation of a lean process for Customer Batch Documentation compilation</li><li>- Creating a separate reporting layer to generate global Customer Batch Documents from various source systems like SAP, LIMS, TrackWise, ...</li></ul>
2013 - 2014	<b>Consultant Global TrackWise – SAP – Interface</b>  CSL Behring, Bern / Marburg Project Manager and Business Process Responsible <ul style="list-style-type: none"><li>- Global Business Project Lead</li><li>- Business Process Engineering / Optimization</li><li>- Development of a concept for a webservice-driven interface for bi-directional data exchange between TrackWise and SAP</li><li>- Global Workshop Lead for Business Requirements gathering</li><li>- Implementing an integrated bi-directional solution incl. user feedback</li><li>- Computer System Validation Lead</li></ul>

## Helmut M. Rector

Quality- / Risk- & Compliance Management Consultant with validAID  
Brueder-Grimm-Str. 26a

35039 Marburg

phone: +49 163 246 29 78

eMail: [helmut.rector@validAID.de](mailto:helmut.rector@validAID.de)



<b>2011 - 2014</b>	<b>Global IT Quality System Lead</b>  CSL Behring, Marburg Responsible for Quality Oversight of the IT Dept. globally <ul style="list-style-type: none"><li>- Quality / Regulatory oversight during the complete project life-cycle</li><li>- Global Team Lead</li><li>- Conceptual work on document hierarchy</li><li>- Process analysis</li><li>- Creation and approval of Policies / Procedures</li></ul>
<b>2011 - 2012</b>	<b>Business Project Lead &amp; User Responsible</b>  CSL Behring, Marburg Implementation of a system for reporting Process- and KPI-Data <ul style="list-style-type: none"><li>- Business Project Lead</li><li>- Business Process Engineering / Optimization</li><li>- Workshop Lead for Business Requirements gathering</li><li>- Implementation of an integrated platform for reporting joint Quality Data (e.g. KPIs) from various source systems</li><li>- Testcase engineering</li><li>- Validation of the functionality of the new BI dashboards</li></ul>
<b>2010 - 2011</b>	<b>Business Project Lead &amp; User Responsible for IPP</b>  CSL Behring, Marburg BI Project Quality & Manufacturing Data Warehouse <ul style="list-style-type: none"><li>- concept creation</li><li>- initial project planning</li><li>- resource allocation</li></ul>
<b>2010 - 2011</b>	<b>Business Project Lead &amp; User Responsible</b>  CSL Behring, Marburg TrackWise Expansion <ul style="list-style-type: none"><li>- Business Project Lead (Project Management)</li><li>- Business Requirements Engineering</li><li>- Upgrade (V7.4.6 =&gt; V8.3.1)</li><li>- Implementation of the new CAPA Module</li><li>- Testcase engineering</li><li>- Validation of the functionality of the new CAPA module</li></ul>
<b>2007 - 2010</b>	<b>Sr. MES and Automation Consultant for the new Albumin Ultrafiltration</b>  CSL Behring, Marburg <ul style="list-style-type: none"><li>- Requirement analysis, development of concept for the implementation of the requirements while making use of a standard MES software (PAS-X)</li><li>- Checking and assuring the quality and accepting the software and documentation deliveries supplied by vendors</li><li>- Training staff in system usage (Werum PAS-X, Siemens Simatic Batch)</li><li>- Assisting in the development of the automation logic</li><li>- Validation / Verification (FAT / SAT) and assistance in putting the new Albumin Ultrafiltration H68 into operation</li><li>- Process analysis, including simulation and optimization to increase facility productivity to 5 lots per week</li></ul>

## Helmut M. Rector

Quality- / Risk- & Compliance Management Consultant with validAID  
Brueder-Grimm-Str. 26a

35039 Marburg

phone: +49 163 246 29 78

eMail: [helmut.rector@validAID.de](mailto:helmut.rector@validAID.de)



2006	<b>Business Process Consultant (Filling H69)</b>  ZLB Behring, Marburg Responsible for the Requirements- and Gap-Analysis for the implementation of a new Manufacturing Execution System (Werum PAS-X Systems) at the Filling facility H69 <ul style="list-style-type: none"><li>- Requirement management / Interviews / Observation</li><li>- Workshops with Group- and Department Heads</li><li>- Creation of a requirements database</li><li>- Documentation / reporting of results</li></ul>
2005 - 2006	<b>Computer System Validation Consultant (CSV)</b>  ZLB Behring, Marburg Responsible for the validation and training of the new Manufacturing Execution System (Werum PAS-X) at the packaging facility H69 <ul style="list-style-type: none"><li>- Risk Analysis</li><li>- Test creation / execution / documentation</li><li>- Creation and finalization of Validation documentation (Test Report)</li><li>- Tracking of the requirements ( traceability within the database)</li><li>- Development of training material / conducting staff trainings</li></ul>
2005 - 2006	<b>Computer System Validation Consultant (CSV)</b>  ZLB Behring, Marburg Responsible for the validation of the extension of a Manufacturing Execution System (Werum PAS-X) at the Immunoglobulins facility H67 <ul style="list-style-type: none"><li>- Requirement Analysis / Requirement Management</li><li>- Test creation / execution / documentation</li><li>- Creation and finalization of Validation documentation (Test Report)</li></ul>
2004 - 2005	<b>Computer System Validation Consultant (CSV)</b>  ZLB Behring, Marburg Responsible for the Risk analysis and system documentation for LIMS <ul style="list-style-type: none"><li>- Risk analysis for project Monitoring (LIMS)</li><li>- Development of System- / Master Data Management Manual</li></ul>