

**Marjun Jepsen**  
Validation Specialist



**PROFILE**

More than 19 years of GMP experience, including:

*Software Validation, Data Integrity, IT Risk Assessment, Compliance Review, Qualification of Laboratory equipment, LEAN, QC-lab Management, Project Management, Audit, CR, NC and Q-Documents*

**PROJECT EXPERIENCE, SELECTED PROJECTS**

2018-	QV- Compliance A/S, Training Responsible
<b>Client</b>	<b>Role, project</b>
Fujifilm Diosynth Biotechnologies	Validation Specialist, QA IT, Approval of Global SAP Validation, Review of Validation of Computerized system procedures
ThermoFisher	Senior Validation Engineer, Implementation of Software Validation Procedure, Validation of Applications, Project Management
AGC Biologic	Senior Validation Engineer, Software Validation of Production facilities and Analytical Equipment
Bifodan	Senior Validation Engineer, Support in implementing ERP system
William Cook Medical ApS	Senior Validation Engineer, Software Validation using V-model, according to 21CFR Part 11, GAMP5 and ISO 13485
Pharmakon	Course Leader, facilitation of courses in IT-Validation/Software Validation
Kenn Hygiens	Validation Engineer, assisting in GMP documentation
QV-Compliance	Audit of Eupry

2016-2018	Novo Nodisk A/S, QC-IM2
<b>Responsibilities</b>	
IT responsible	
<ul style="list-style-type: none"> <li>• Identifcation of IT GAPS using Compliance Assessment and subsequently closing IT GAPS.</li> <li>• Execution of IT Risk Assessment.</li> <li>• Execution of Configuration Item List and Configuration Review Report</li> <li>• Execution of User Administration and User Review Report</li> <li>• Execution of IT Periodic System Evaluation</li> <li>• Insurance of Data Integritet</li> <li>• Implementation of Audit Trail Review</li> <li>• Execution of Software Validation of Laboratory Equipment: Protocols, Testing and Reports</li> <li>• Preparation of CR and NC</li> </ul>	

2016-2018	Novo Nordisk A/S, QC-IM2
<ul style="list-style-type: none"> <li>• Preparation of SOP's and User Manuals</li> <li>• Execution of Systematic Problem Solving (A3)</li> <li>• Responsible for resource allocation board.</li> </ul>	

2007-2016	H. Lundbeck A/S
<p><b>Role, Responsibilities</b></p> <p>System Coordinator/administrator</p> <ul style="list-style-type: none"> <li>• System Administration of Empower</li> <li>• Implementation of Empower Software on Site Lumsås</li> <li>• Troubleshooting on LAC/E Acquisition Server</li> <li>• Software Validation using HP Quality Center</li> <li>• Acting as Super User for Labware LIMS</li> <li>• Execution of Laboratory Equipment Qualification, HPLC and GC</li> <li>• Preparation of SOP's and User Manuals</li> <li>• Preparation of CR</li> <li>• Implementation of LEAN in QC-Lab</li> <li>• Resource allocation and plan for daily activities in QC-lab</li> <li>• Analyzation of API and raw material, approval and release of raw material</li> <li>• Participation in Inspections</li> </ul>	

2006-2007	Schafer-N ApS
<p><b>Role, Responsibilities</b></p> <p>Technician</p> <ul style="list-style-type: none"> <li>• Peptide Syntheses</li> <li>• HPLC-MS</li> </ul>	

2002-2006	Novo Nordisk A/S QC-IM1
<p><b>Role, Responsibilities</b></p> <p>QC-Technician</p> <ul style="list-style-type: none"> <li>• Qualification of Laboratory Equipment</li> <li>• Implementation of QC Laboratory</li> <li>• Preparation of SOP's and User Manuals</li> <li>• Preparation of CR</li> <li>• Executing GC analysis</li> <li>• Implimentation of LEAN</li> <li>• Training of Operators in use of simple Analytical Equipment, in Production Laboratories.</li> </ul>	

2000-2002	Novo Nordisk A/S R&D
<p><b>Role, Responsibilities</b></p> <p>Technician, Trainee</p> <ul style="list-style-type: none"><li>• Organic Synthesis</li><li>• Method Development on HPLC-MS</li><li>• Analysis of samples from Fase III</li><li>• Working with Test Animals</li></ul>	

## SELECTED EDUCATION/COURSES

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2019: Data Integrity, ECA  
2016: Data Integrity, GMQA  
2015: Nordic User Training Empower, Waters  
2014: Waters Informatics Users' Conference, Waters  
2013: Nordic User Training Empower, Waters  
2012: Waters Informatics Users' Conference, Waters  
2010: Empower2 Using Administrative Features, Waters

## LANGUAGES

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Danish	Native
English	Full Professional proficiency