


## Consultant's Profile

<b>Name</b>	<b>Thomas Bierling</b> Diploma in Physics Senior Consultant QM/PLM	
<b>Year of birth</b>	1968	
<b>Nationality</b>	German	
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## Summary

Thomas Bierling is SAP consultant in the area of PLM with special focus on Quality Management. Since 2000, he has worked in numerous projects as a Senior or Lead Consultant and subproject manager in all areas of the QM module. His fields of activity are especially process consulting, implementation, specification of Add-Ons, validation, documentation, and training.

## Qualification

<b>Education</b>	1994 Diploma in Physics, University of Karlsruhe
<b>Languages</b>	<ul style="list-style-type: none"><li>- German (native)</li><li>- English (fluent)</li><li>- French (basics)</li></ul>
<b>IT experience</b>	since 1994
<b>SAP experience</b>	since 2000



## Professional Experience

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### Industry experience

#### Process industry:

- Chemical industry
- Pharmaceutical industry

#### Discrete industry:

- Medical products
  - Mechanical engineering/ variants manufacturing
  - Automotive
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### Professional career

- since 10/2004  
Freelance SAP consultant
  - 2000 - 09/2004  
Logistics consultant, j&m Management Consulting AG
  - 1998 - 2000  
Manager of department „Technical Information Management“  
for ALLDOS Dosiertechnik GmbH, a medium-sized mechanical  
engineering company
  - 1994 - 1997  
Technical Writer for the same company
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## SAP Experience

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### Work areas

- Process analysis and consulting
  - Conception
  - Customizing
  - Specification of User-Exits and Add-Ons
  - Migration
  - Subproject management
  - User documentation and training
  - Validation, electronic signature, audit trail (GMP, FDA)
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### Module knowledge

- QM, PLM, PP, PP-PI, PM, MM, SD, BW, LIS
  - Batch management, classification system
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**Detailed knowledge of QM module (> 4.6B)**

- Inspection planning
- Quality inspection
- Test equipment management
- Sample management
- Quality notifications, Stability Studies
- Master data
- Quality certificates
- QM-IDI interface, LIMS integration
- Integration to other logistics modules
- Reporting: LIS, QMIS, QM-Reports using BW
- Data migration using LSMW

**Programming languages** ABAP/4 (Read and specify, but no developer)

**Method knowledge**

- Project management
- Team lead
- Quality management
- Quality assurance
- Validation, FDA 21 CFR Part 11
- Training, Workshops, Moderation

**SAP Project Experience in Detail**

<b>Customer</b>	<b>Helm AG, Hamburg</b>
Duration	02/18
Industry	Chemistry
Project description	- Implementation S/4 HANA

<b>Customer</b>	<b>Henkel AG &amp; Co. KGaA, Düsseldorf</b>
Duration	04/17 - 02/18
Industry	Chemistry/Consumer goods
Project description	- Concept study for optimization of SAP QM Migration of four US plants - Master data migration, training, testing

<b>Customer</b>	<b>OHB System AG, Bremen</b>
Duration	04/17 - 05/17
Industry	Aerospace



Project description    Concept study for optimization of SAP QM

**Customer                    Ciber Managed Services GmbH**

Duration                    12/16 - 03/17

Industry                    Pharmaceutical Consulting, Managed services

Project description    – QM consulting and support for customers of several industry areas  
 – Training for SAP QM and Validation for customers and consultants

**Customer                    Boehringer Ingelheim**

Duration                    09/15 – 12/16

Industry                    Pharmaceutical

Project description    – Ongoing template development of global SAP systems  
 – Rollout on three Chinese plants (with several longer on-site stays)

Role                         Senior Consultant / Validation Manager QM

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**Customer                    Renolit SE, Worms**

Duration                    02/15 – 08/15

Industry                    Chemical/Plastics

Project description    Implementation of SAP QM for incoming goods inspection

Role                         Project Management, Consulting, Customizing, Specification of Add-on developments, Training

**Customer                    Boehringer Ingelheim**

Duration                    09/14 – 05/15

Industry                    Pharmaceutical

Project description    Ongoing validation of global SAP systems

Role                         Senior Consultant, Quality Assurance

**Customer                    DEKRA SE, Stuttgart**



Duration	04/14 – 08/14
Industry	Technical Services
Project description	Implementation of SAP QM
Role	Senior Consultant

**Customer CABB AG, Pratteln**

Duration	10/13 – 12/13
Industry	Chemical
Project description	System migration, implementation of PP-PI
Role	Stream Lead für PP-PI/QM

**Customer Putzmeister Holding GmbH**

Duration	06/13 – 08/14
Industry	Mechanical Engineering
Project description	Maintenance and ongoing development of SAP QM
Role	Senior Consultant

**Customer Bionorica SE, Neumarkt**

Duration	05/13 – 03/14
Industry	Pharmaceutical
Project description	Implementation of a LIMS based on SAP QM
Role	Project Manager

**Customer BASF SE, Ludwigshafen**

Duration	07/11 – 03/13
Industry	Chemical
Project description	QM support and further improvements in the area of crop protection
Role	Senior Consultant

**Customer F. Hoffmann-La Roche AG, Basel**

Duration	03/09 – 04/11
Industry	Pharmaceutical
Project description	Global implementation of SAP-QM as LIMS: Inspection planning, quality inspection, test equipment management, stability studies, quality notifications
Role	Head of Validation



Tasks	Responsible for the validation of the whole project
<b>Customer</b>	<b>Dentsply Friadent GmbH, Mannheim</b>
Duration	12/06 – 02/09
Industry	Medical devices
Project description	SAP implementation
Role	Senior Consultant, Teamlead QM
Tasks	<ul style="list-style-type: none"><li>– Analysis, conception and implementation of QM processes</li><li>– Creation of requirement specifications and functional specifications</li><li>– Risk analysis for GxP-critical processes</li><li>– Specification and test of Add-Ons</li><li>– Creation of validation documents, documented testing</li><li>– Creation of end-user-documentation, end-user training</li><li>– Go-live support</li></ul>
<b>Customer</b>	<b>AREVA ANF GmbH, Lingen</b>
Duration	11/06
Industry	Nuclear fuels
Project description	Spot Consulting
Role	Senior Consultant
Tasks	<ul style="list-style-type: none"><li>– Analysis and evaluation of an existing QM implementation</li><li>– suggestions for improvement</li></ul>
<b>Customer</b>	<b>Vetter Pharma-Fertigung GmbH &amp; Co. KG, Ravensburg</b>
Duration	06/06 – 11/06
Industry	Pharmaceutical
Project description	Conception von SAP R/3 QM (Blueprint)
Role	Senior Consultant, Teamlead QM
Tasks	<ul style="list-style-type: none"><li>– Analysis and conception of QM processes (inspection planning and execution, master data, batch documentation)</li><li>– Blueprint phase: Development of different concept alternatives for LIMS integration or replacement</li></ul>
<b>Customer</b>	<b>Robert Bosch GmbH, Stuttgart</b>
Duration	05/05 – 05/06
Industry	Automotive
Project description	Further development of a company-wide complaint management system based on quality notifications



Role	Senior Consultant/Support of the project manager
Tasks	<ul style="list-style-type: none"> <li>- Project planning and coordination</li> <li>- Deadline- and budget monitoring</li> </ul>
<b>Customer</b>	<b>BASF AG, Ludwigshafen</b>
Duration	01/03 - 10/04
Industry	Chemical
Project description	Implementation of PP-PI and QM for several plants
Role	Senior Consultant
Tasks	<ul style="list-style-type: none"> <li>- Conception and implementation of SAP R/3 QM for several plants (inspection planning and execution, master data, quality certificates)</li> <li>- LIMS integration (QM-IDI) and connection to an external certificates system</li> <li>- Specification of Add-Ons</li> <li>- Testing and documentation of all processes and developments using Mercury TestDirector</li> <li>- Migration of legacy data, roll-out support</li> </ul>
<b>Customer</b>	<b>SIEMENS AG A&amp;D, Karlsruhe/Nürnberg</b>
Duration	03/04 -05/04
Industry	Automation technology
Project description	Comparative study MDM – R/3
Role	Senior Consultant
Tasks	Analysis of integrability of MDM into an existing heterogeneous system landscape (SAP/non-SAP) and comparison of the data models of MDM and R/3, observing especially the classification system and variants configuration, resulting in a recommendation of R/3 as master data server.
<b>Customer</b>	<b>Syngenta AG, Basel</b>
Duration	06/02 - 01/03
Industry	Agro
Project description	Integration of several European plants in several roll-outs into a productive environment
Role	Senior Consultant
Tasks	<ul style="list-style-type: none"> <li>- QM process design and implementation</li> <li>- Specification and testing of several large Add-Ons (LIMS-Interface, Reports)</li> </ul>



<b>Customer</b>	<b>Siegfried Ltd., Zofingen (CH)</b>
Duration	03/02 - 12/02
Industry	Pharmaceutical
Project description	SAP implementation
Role	Senior Consultant
Tasks	Conception von SAP R/3 QM: <ul style="list-style-type: none"><li>– Analysis and conception of QM processes (inspection planning and execution, master data, batch documentation, stability studies)</li><li>– Development of different concept alternatives for LIMS integration or replacement</li><li>– Concept for the implementation of SAP R/3 QM in connection with a LIMS, following cGMP/FDA regulations</li><li>– Concept for GMP risk analysis and system validation</li></ul>

<b>Customer</b>	<b>Bayer AG, Leverkusen</b>
Duration	10/01 - 03/02
Industry	Chemical
Project description	Coordination of QM implementation for several roll-outs
Role	Senior Consultant
Tasks	<ul style="list-style-type: none"><li>– Central responsibility for SAP R/3 QM in the „Customizing Centre“ of the company</li><li>– Coordination of QM implementation for further roll-outs</li></ul>

<b>Customer</b>	<b>Bayer AG, Leverkusen</b>
Duration	08/01 - 01/02
Industry	Chemical
Project description	International Roll-out (4 plants)
Role	Senior Consultant, partial project management
Tasks	<ul style="list-style-type: none"><li>– Conception and implementation of QM processes</li><li>– Batch management, integration to PP-PI</li><li>– Integration of a LIMS</li><li>– Data migration using LSMW</li><li>– Partial project management</li></ul>





<b>Customer</b>	<b>Bayer AG, Leverkusen</b>
Duration	08/00 - 07/01
Industry	Chemical
Project description	SAP implementation
Role	Consultant
Tasks	<ul style="list-style-type: none"><li>- Conception and implementation of SAP R/3 QM for two European plants</li><li>- Analysis, specification, implementation (inspection planning and execution, master data)</li><li>- Specification of numerous Add-Ons (quality certificates, reports)</li><li>- Data migration using LSMW</li><li>- Replacement of a LIMS</li><li>- Training of key-users and end-users, roll-out support</li></ul>