

Curriculum Vitae



James Greene

B.Sc., PMP[®],

CSV-Beauftragter, QM-Beauftragter)

(CSV Representative, QM Representative)

Kontaktadresse / Contact:

E-Mail: James.Greene@bluewin.ch

LinkedIn: www.linkedin.com/in/jamesgreene

XING: [www.xing.com/profile/James Greene](http://www.xing.com/profile/James_Greene)

James Greene, PMP

**Bachelor of Science, Computer Science
Project Management Professional®
Quality Management Representative TÜV**

Date of Birth: 1964 in Los Angeles, California, USA
Citizenship: USA
Residency: Permanent Resident Permit 'C' (Canton Basel-Landschaft)
Work Permit: Switzerland, USA
Languages: English (mother language), German (Fluent)
LinkedIn: <http://www.linkedin.com/in/jamesgreene>
XING: http://www.xing.com/profile/James_Greene

Professional Publications

Greene, James, [Executive Editor]. 2006. *PM@CH - The Swiss Project Management Journal*. Switzerland: PMI Switzerland Chapter, December 2006. Number 1.

— **2007.** *PM@CH - The Swiss Project Management Review*. PMI Switzerland Chapter, Summer 2007. Number 2.

— **2008.** Spring 2008. Number 3.

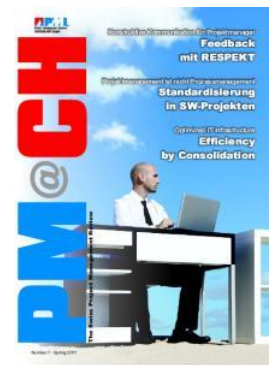
— **2008/2009.** Winter 2008/2009. Number 4.

— **2009.** Summer 2009. Number 5.

— **2010.** Summer 2010. Number 6.

— **2011.** Spring 2011. Number 7.

— **2011.** Autumn 2011. Number 8.



Greene, James. 2008. System Retirement Planning. [ed.] PMI Switzerland Chapter. *PM@CH - The Swiss Project Management Review*. Number 4, 2008, Vol. 4, 4, pp. 8-11. (English)

GAMP D-A-CH SIG ASDMM. 2009/2011. Alternative Software Development Models and Methods. (German). English translation by James Greene. Accepted for publication in *Pharmaceutical Engineering*, the official publication of the ISPE, Jan/Feb 2012.

Greene, James und Häuptli, Patrick. 2010. Validierung von virtuellen Systemen. [ed.] Concept Heidelberg. *Computervalidierung im GxP-regulierten Umfeld*. 1st Edition 2010, 2010, Bd. Pharma Technologie Journal, S. 143-154 (German) ISBN 13: 978-3-87193-412-4



Greene, James und Adamovsky, Stefan. 2011. Project Risk Management and a Risk-Based Approach to Testing. (English) Accepted for publication in *PM@CH - The Swiss Project Management Review*, PMI Switzerland Chapter, November 2011.

Greene, James und Adamovsky, Stefan. 2011. Projektrisikomanagement in der Life-Science-Industrie. (German) Accepted for publication in *Erfolgreiches IT Projektmanagement*, Symposion Publishing, December 2011.

Professional Experience

September 2008 – Present

Arcondis AG, 4153 Reinach, Switzerland



Manager, Computer System Validation. Responsible for the service “information systems validation”, with personnel responsibility for two Junior Consultants and two vacant positions (one Consultant and one Senior Consultant level).

My current customer assignment (since mid-2011) is a program management support role following the merger of two global chemical manufacturers. The IT Infrastructure Integration work-stream includes seven sub-work-streams and five additional working groups, being led in three different regions. The overall budget for the IT integration work-stream is estimated at 8.6 mio CHF (over a program lifetime of 18 months). The IT Infrastructure Integration includes network integration, messaging and collaboration services, data center services, Active Directory integration, IT service management integration and the rollout of a standardized Windows 7 platform.

A previous assignment (2010-2011) was an infrastructure technology migration program management role for a leading global chemicals manufacturer (13,500 users worldwide), included six international project streams with an overall spend of more than 11.2 mio CHF in 2010-2011. The projects and program were managed with the PRINCE 2 methodology, including elements of D4SS (Design for Six Sigma). Much of the technology introduced in this migration provided the foundation for the IT Infrastructure Integration work-stream mentioned above.

Other recent (short-term) projects included a high-level risk assessment for a cloud-based CRM solution used in a global pharmaceuticals company; the qualification of a device for a logistic service company; and a GxP-compliance audit of the Group IT (SAP) service for a medical device manufacturer. Earlier assignments included the planning phase of a global messaging and collaboration migration for a leading pharmaceutical company (80,000 IT users globally); and Vendor and Security Audits for GxP relevant information systems.

July 2006 – August 2008

M&H Informatics / IMS Health, CH-4123 Allschwil



Senior Consultant, Project Manager / Business Analyst. Projects included leading the collection of qualification documents for the corporate network infrastructure as part of a global outsourcing initiative for a leading pharmaceuticals company; managing the development and testing of a series of enhancements and interfaces to a validated clinical trial management system (Project budget 575 KUSD); leading a team of up to 10 technicians performing an in-place technical migration procedure with CSV-compliant documentation on several hundred end-user workstations (Project budget 250 KUSD); and business analysis for the specification of a data warehouse and inventory system for the information security office of the clinical development organization.

June 2004 – June 2006

redtoo ag, (caatoosee ag), CH-4153 Reinach



Senior Consultant. Group leader for the redtoo team providing consulting and services to the global public key infrastructure (PKI) organisation in an international pharmaceutical company. Customer projects include software package engineering for electronic software distribution with enteo's NetInstall; quality assurance testing of PKI-enabled applications on a standardized Windows desktop environment; Project Manager for the international (Switzerland / USA) evaluation and pilot of Passlogix V-GO SSO.

Professional Experience, continued

February 2000 – May 2004
[innobit ag](#), CH-4058 Basel



Managing Director, Project and Quality Management & Consulting. Innobit is an information technology consulting company based in Basel, Switzerland. Responsibilities included leading the groups Consulting, Project & Quality Management, Package Engineering and Training, general management, project and customer acquisition, project and key-account management and leading professional training courses. Personnel responsibility for several teams with up to 12 direct reports and more than 2.5 million CHF in annual turnover.

Customer projects included conception and implementation of standardized desktop environments including electronic software distribution for various industries; concepts for disaster avoidance and recovery for desktop environments; the retrospective validation of a standardized desktop system implementation; design of web-based information systems; secure operational model for Microsoft Active Directory for a city government; software license management; and the service package Proactive Managed Desktop Environment.

July 1996 - April 2002

[J. Greene Informatics Consulting](#), D-79539 Lörrach



Owner. Projects included systems consulting and procurement, local-area network design and implementation, software development and website design and maintenance. Customers included medical device manufacturer, a private high school and a local hand-worker. Development and support of several freeware and shareware programs, including **Auto-Play**, **Plot2EMF**, **NameDate** and **CBText**.

July 1992 - January 2000

[F. Hoffmann-La Roche AG](#), 4070 Basel, Switzerland



Project Manager in Global Informatics. Projects included the development of Pharma Division IT standards and design of the Common Office Environment (COE) for Windows NT 4. COE was the standard desktop configuration for Roche Pharmaceuticals Division world-wide (more than 40,000 desktops) in the early 2000's.

Responsibilities also included leading the Office Software Group of Competence (GoC), and managing parts of the MedNet implementation project, which was installed in 18 Roche affiliates between 1992 and 1995. MedNet was a suite of information systems for the Pharma Marketing group. Other projects included technical support for clinical trials data collection and addressing document management and version control issues.

March 1990 - June 1992

[Hoffmann-La Roche AG](#), 79639 Grenzach-Wyhlen, Germany

LAN-Administrator/Systemprogrammierer. Responsible for the installation and operation of several Novell NetWare file-servers and more than 100 user workstations, as well as user support (help desk) and participation in infrastructure projects.

June 1986 - January 1990

[EEsof, Inc.](#) Westlake Village, California, USA



Systems Programmer. Assistant product manager for ANACAT, a computer-aided-test product designed for microwave and radio-frequency engineering. Responsible for development of new features and enhancements, hardware device interfaces, maintenance and product release procedures. Programming in Pascal and ANSI C on MS-DOS, OS/2, MS-Windows and various Unix platforms.

Formal Education

Bachelor of Science, Computer Science, January 1987
[California Lutheran University](#), Thousand Oaks, California, USA

Volunteer Experience

2001 – Present

PMI Switzerland Chapter, 3000 Berne 13, Switzerland



- 2001 Founding member of the Chapter Charter Steering Committee
- 2002 – 2009 Member of the Chapter Board of Directors (Vice President Special Projects, Vice President Communications, and Chapter President 2007)
- 2001 – present Chapter webmaster (pmi-switzerland.ch)
- 2006 – present Editor-in-chief of *PM@CH – The Swiss Project Management Review*
- 2009 – present Member of the Basel Extended LEC (Local Event Committee)
- May 2010 Presented “ISO 31000 – Risk Management System” as part of a Chapter event on Risk Management

2004 – Present

Feuerwehr Wildenstein, 4416 Bubendorf, Switzerland



- 2004 – 2009 Volunteer Firefighter Feuerwehr Ramllinsburg (PFC, Machinist)
- 2010 – present Volunteer Firefighter Feuerwehr Wildenstein (PFC, Machinist)
- 2006 – present Webmaster feuerwehr-ramllinsburg.ch and fwwildenstein.ch/

Memberships & Certifications

- TÜV Certified Quality Management Representative (QMB-TÜV) (2011)
- PMI Certified Project Management Professional (PMP®) (2009)
- Computerized Systems Validation Representative (CSV-Beauftragter) (2005)
- ISPE GAMP D-A-CH Forum
 - SIG Alternative Software Development Methods and Models (2008 – 2011)
- ASP (Association of Software Professionals) Member

Professional Training

November 2008, November 2011	(CV 20) GAMP5 – Umsetzung anhand eines Real Life Projekts GAMP 5 (Good Automated Manufacturing Practices), presented through a series of practical examples. <i>Role: Lecturer and Moderator</i>	Concept Heidelberg , Frankfurt, Germany (2011) Weinheim, Germany (2008)
September 2011	Information Security (module 2) of the lecture series “Information & Communication Technology” for Executive IT Management students. <i>Role: Lecturer</i>	iimt University of Fribourg, Switzerland
March/May 2011	TÜV-QM-Fachkraft / TÜV-QM-Beauftragter “Quality Management” certifications, focusing on the ISO 9001:2008, ISO 9004 and TQM quality management systems standards.	TÜV SÜD Akademie Freiburg im Breisgau, Germany
March 2009, March 2010, March 2011	Project Risk Management lecture to undergraduate students. <i>Role: Lecturer</i>	iimt University of Fribourg, Switzerland
December 2010	3. Offizielle GAMP® 5 Konferenz Official launch of the German translation of the Good-Practice Guide for Risk-Based Approach for the Operation of GxP-relevant Computer Systems.	Concept Heidelberg , Dusseldorf, Germany
November 2006	PMP PREP + Preparation for the PMI® Project Management Professional (PMP®) examination.	AB&Partner , Basel, Switzerland
March 2005	ITIL in GMP Environments <i>IT Infrastructure Library: ITIL im GMP-Umfeld (CV 3)</i>	Concept Heidelberg , Mannheim, Germany
January 2005	Validating Computerized Systems <i>Validierung computergestützter Systeme (CV 1)</i> Testing Computer Systems in GxP-relevant Environments <i>Testen von Computersystemen in GxP-relevanten Umgebungen (CV 2)</i>	Concept Heidelberg , Mannheim, Germany
December 1999	IT Project Management Management of Information Technology Projects	F. Hoffmann- La Roche AG , Basel
September 1996	Goal Directed Project Management Project planning and management methodology	Coopers & Lybrand, Basel
July 1995	Computerised System Validation Development and implementation of qualified systems	F. Hoffmann- La Roche AG , Basel
September 1994	Leadership in Management Effective leadership and personal performance	Sundridge Park Management Centre , Bromley, Kent, UK
November 1993	SUMMIT-D Systems Delivery Methodology Life-cycle methodology for systems development and delivery	Coopers & Lybrand, Basel

References

UNIVERSITY TRANSCRIPTS AND DIPLOMA

California Lutheran University, B. Sci. Computer Science 1983 - 1987

LETTERS OF REFERENCE

EEsof, Inc., Westlake Village, California 1986 – 1990

Hoffmann-La Roche AG, Grenzach-Wyhlen, Germany 1990 – 1992

F. Hoffmann-La Roche AG, Basel, Switzerland 1992 – 2000

innobit AG, Basel, Switzerland 2000 – 2004

redtoo AG, Reinach, Switzerland 2004 – 2006

IMS Health / M&H Informatics, Allschwil, Switzerland 2006 - 2008

CERTIFICATES

SUMMIT-D Systems Delivery Methodology 1993

Sundridge Park Management Centre – Leadership in Management 1994

Concept Heidelberg – CSV-Authorized Representative 2005

(CSV-Beauftragter)

–, Validating Computerised Systems

(Validierung computergestützter Systeme)

–, Testing Computer Systems in GxP-relevant Environments

(Testen von Computersystemen in GxP-relevanten Umgebungen)

–, ITIL in GXP-Environments

(IT Infrastructure Library: ITIL im GXP-Umfeld)

Concept Heidelberg – Lecturer

(cv 20) GAMP 5 – Umsetzung anhand eines Real-Life Projekts 2008

(cv 20) GAMP 5 – Umsetzung an Hand eines Real-Life Projekts 2011

PMI - Project Management Professional (PMP®) # 1260804 2009

TÜV-Süd – Quality Management Specialist (TÜV-QMF) 2011

Quality Management Representative (TÜV-QMB)

PUBLICATIONS AND SUBMISSIONS

System Retirement Planning 2008

PM@CH – The Swiss Project Management Review

Available at <http://www.pmi-switzerland.ch/pm@ch/index.php>

Validierung von virtuellen Computersystemen 2010

Computervalidierung im GxP-regulierten Umfeld,

Pharma Technologie Journal

Concept Heidelberg, Editio Cantor Verlag, 2010

Available at http://gmp-navigator.com/nav_literatur_1097.html

Alternative Software Development Models and Methods in GxP-Environments 2009-2011

GAMP D-A-CH Special Interest Group

Accepted for publication in *Pharmaceutical Engineering 1/2012*

Project Risk Management and a Risk-Based Approach to Testing. November 2011

PM@CH - The Swiss Project Management Review, PMI Switzerland

Projektrisikomanagement in der Life-Science-Industrie, December 2011

Erfolgreiches IT Projektmanagement, Symposion Publishing.

I will be happy to provide any of these documents upon request.