

# James Greene, PMP

Birthdate: September 1964



79418 Schliengen  
Germany

Mobile (D): +49 1525 392 5691  
[james.greene@outlook.com](mailto:james.greene@outlook.com)



## PERSONAL PROFILE

An information systems consultant with more than 25 years of international experience in Life Science industries. Certified in several project management methodologies, auditing of Quality Management Systems, Information Security Management Systems and Computerized Systems Validation. I am a project and program management practitioner, a validation and compliance consultant, a business analyst, a team leader, coach and mentor, a teacher and an author.

## CAREER OBJECTIVE

A role that integrates my varied interests and experience, where I can continue to learn while helping others to achieve their full potential.

## PROFESSIONAL EXPERIENCE

10/2015 → present

**Significon AG**, 55130 Mainz, Germany

[significon.de](http://significon.de)

### Senior Manager

- > Senior Manager for the Business Areas Validation, Quality Management and Project Management.
- > Validation Manager for the GxP Change Request Management (ChaRM) process, based on SAP Solution Manager.
- > Validation Manager for various projects: Retirement of a Change Control system; Validation of a bulk data entry/upload tool; Qualification of an Intranet Application Portal; etc.
- > Consulting and coaching for the establishment of a new PMO.
- > GAMP®5 Awareness Trainings.
- > Webinars (in German): IT Project Management in a GxP Environment (2016); System Retirement (2017)

07/2014 – 09/2015

**Rescop GmbH**, 79379 Müllheim (Baden), Germany

[rescop.com](http://rescop.com)

### Director Business Development & Operations, Germany; Managing Director of Rescop GmbH

- > FDA Audit Preparation for a medical device manufacturer (Switzerland / Germany / United Kingdom)
- > Compliance analysis for a GxP-relevant software provider
- > Service Management Request Fulfilment Process design and review for a global chemicals manufacturer

02/2013 to 06/2014

**D-ploy (Schweiz) GmbH**, Kaiseraugst, Switzerland

[d-ploy.ch](http://d-ploy.ch)

### Senior Project & Program Manager

- > Program Manager in IT Infrastructure carve-out (corporate divestitures)
- > Team Leader with 7 direct and 2 indirect reports
- > Account Manager, responsible for > 1.5 mio CHF annual turnover

04/2012 to 01/2013

**DHC Dr. Herterich & Consultants GmbH**,  
Bülach, Switzerland and Saarbrücken, Germany

[dhc-gmbh.com](http://dhc-gmbh.com)

## Senior Manager

- > Program Manager, IT Infrastructure Integration (corporate merger)
- > Presentation and Webinar on Validation of Cloud-Based Systems

09/2008 to 03/2012

**Arcondis AG**, Reinach, Switzerland

[arcondis.com](http://arcondis.com)

## Manager, Computer Systems Validation

- > Program Manager for IT Infrastructure technology transition program
- > Validation Responsible for a Cloud-Based system delivery project
- > CSV- and GxP Audits for various customers

07/2006 to 08/2008

**ims Health / M&H Informatics**, Allschwil, Switzerland

## Senior Consultant

- > Project Manager in Clinical Development IT, implementing new features in the (GxP-relevant, validated) Clinical Trial Management System
- > Project Manager leading the on-site migration of end-user devices with CSV-compliant documentation (integration following a corporate acquisition)

07/2004 to 06/2006

**redtoo AG** a.k.a. **caatoosee AG**, Reinach, Switzerland

[redtoo.com](http://redtoo.com)

Senior Consultant

- > Project Manager in the PKI organization of a global pharmaceuticals company

02/2000 to 06/2004

**innobit AG**, Basel, Switzerland

[innobit.ch](http://innobit.ch)

Managing Director

- > Responsible for Consulting, Project & Quality Management, Software Package Engineering and Training.
- > Lead a team of up to 12 direct reports and responsible for > 2.5 mio CHF annual turnover.

07/1996 to 04/2002, 07/2014 – 10/2014

**James Greene Informatics Consulting**  
Lörrach, Germany / Schliengen, Germany

[informatics-consulting.de](http://informatics-consulting.de)

Owner

*For my work history between 1986 and 2000, please contact me.*

## EDUCATION

1987 Bachelor of Science, Computer Science  
California Lutheran University, Thousand Oaks, Calif., USA

## CERTIFICATES

2015 Quality Management Systems Auditor (QMA-TÜV, ISO 9001:2015)  
2013 PRINCE 2 Foundations  
2012 Foundations for Information Security Management Systems  
2011 Quality Management Systems Representative (QMB-TÜV)  
2009 Project Management Professional (PMP®)  
2005 Computerized Systems Validation Representative  
(CSV-Beauftragter)

## VOLUNTEER ACTIVITIES

### Association of Software Professionals (ASP)

2016 – present ASP Director

### Tammazla Kampfkunstschule e.V., Müllheim (Baden)

2014 – present Aikido Training

2015 – present Director (Chairman since 01/2017)

### Volunteer Fire Fighter

2004 – 2012 Ramlinsburg / Wildenstein, Switzerland

PFC, SCBA-certified, Machinist, Pioneer, Fire Inspector

2013 – present Schliengen / Niedereggenen, Germany

SCBA-certified, Advisory Board Member 2014-present

### PMI Switzerland Chapter

2001 – 2009 Board of Directors, VP Special Projects,  
VP Communications, Chapter President (2007)

2001 – 2014 Webmaster [pmi-switzerland.ch](http://pmi-switzerland.ch)

## SKILLS

- > Business Analysis, Business Consulting, Requirements Analysis and Modelling, Communications, Training
- > Computerized Systems Validation, Infrastructure Qualification per US FDA cGMP / QSR and 21 CFR; Eurdalex Volume 4, Annex 11 & 15
- > Published Author (English & German) of technical/professional articles
- > ISO EN 9001:2015 Quality Management Systems (Auditor)
- > ISO 20000, ITIL V3/2011, IT Service Management
- > ISO EN 27001 Information Security Management Systems, PROTECT
- > Risk Management, ISO 31000, FMEA, Ishikawa Root-Cause Analysis
- > Methodologies: PMI PMBoK® Guide, PRINCE 2, Lean SixSigma, Novartis ICE, GAMP® 5, V-Model, BI LeVA, Agile SDLC Methods

## 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.

— **2012.** Winter 2011/2012. Number 8.

— **2013.** Winter 2012/2013. Number 9.

**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. *Pharmaceutical Engineering*, Vol. 32, Nr 1, Jan/Feb 2012, pp. 17-24. ISSN 0273-8139

**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, pp. 143-154 (German) ISBN-13: 978-3-87193-412-4

**Greene, James and Adamovsky, Stefan. 2012.** Project Risk Management and a Risk-Based Approach to Testing. (English) *PM@CH - The Swiss Project Management Review*, Number 8, 2012, PMI Switzerland Chapter, pp. 9-19.

**Greene, James und Adamovsky, Stefan. 2012.** Projektrisikomanagement in der Life-Science-Industrie. (German) *Management komplexer IT-Projekte*, Symposium Publishing, Düsseldorf, 1. Auflage, 2012, pp. 271-292. ISBN-13: 978-3-86329-438-0

**Greene, James. 2013.** Program Management from the Perspective of a Project Manager. PMI Switzerland Chapter. *PM@CH* Number 9, 2013, Vol. 9, 9, pp. 16-19. (English)

**Greene, James; Müller, Dr. Stephan; Zimara, Jessica. 2015.** Cloud Computing: Ein Validierungsansatz für Cloud-Basierte Systeme. [ed.] Concept Heidelberg. *IT-Trends im GxP-Umfeld*. 1st Edition 2015, 2015, Bd. Pharma Technologie Journal, pp. 28-38 (German) ISBN-13: 978-3-87193-302-8

**Greene, James. 2016.** IT-Projekt-Management im GxP-regulierten Umfeld [Webinar]. (German) Significon AG, 28. Jan. 2016

**Greene, James. 2017.** System Retirement: Der Anfang vom Ende [Webinar]. (German) Significon AG, 27. Apr. 2017

*References available on request.*