James Greene

PERSONAL PROFILE

I am a business systems manager and CSV/Quality expert with more than 30 years of international experience in Life Science and manufacturing industries, holding certifications in project management, auditing of Quality Management Systems and Computerized Systems Validation. I am a quality and compliance expert, a project and program management practitioner, a business analyst and systems consultant, a leader, coach, mentor, teacher, author and musician.

CAREER OBJECTIVE

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

PROFESSIONAL EXPERIENCE

11/2020 – present
INNIO Jenbacher GmbH & Co OG, 6200 Jenbach, Austria   innio.com

Group IT, IT Compliance Manager & Auditor (07/2025 -)

▸ Establish a new IT Compliance and internal auditing function.

Group IT, Head of IT PMO (11/2020 – 06/2025)

▸ Member of the Group IT Leadership team, reporting to the Group VP Information Technology.
▸ Head of Group IT **Project Management Office**: Continuous improvement of project and portfolio delivery.
▸ Contributed to the ISO 27001 Certification for INNIO Group IT and Digital. INNO Group received their certification in December 2023. Preparation for ISO EN 27001:2022 recertification ongoing.
▸ Responsible for the configuration and deployment of **ServiceNow** ITBM/SPM (Strategic Portfolio Management) and IRM (Integrated Enterprise Risk Management) across the INNIO Group.
▸ **Training**: Created and presented a series of Project Management training sessions (German/English) organized by the INNIO Quality Dept. (Project Cost Management, Project Risk Mgmt., CtQ/Requirements Engineering).
▸ Responsible for "Talent Development" projects in Group IT in cooperation with INNIO HR (2021 & 2022)

10/2015 – 10/2020
Significon AG, 55130 Mainz, Germany   significon.de

Senior Manager / Partner

▸ Senior Manager for Computerized Systems Validation and Compliance, Quality Management and Project Management.
▸ **Validation Manager** for the implementation and operation of various business applications and services, including **SAP Solution Manager 7.2** (ChaRM, Test Management), **ServiceNow** as a global IT Service Management tool, and **Veeva QualityDocs** as a Document Management System, and **UiPath** for Robotic Process Automation.
▸ Consulting, Workshops and Publications: System Retirement; Qualification of an IaaS infrastructure; PM Methods in a GxP-relevant Environment.
▸ Webinars (in German): IT Project Management in a GxP Environment (2016); System Retirement (2017), Documentation of SAP Roles (2017); Paperless Validation Systems (2019).

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07/2014 – 09/2015
Rescop GmbH, 79379 Müllheim (Baden), Germany   rescop.com
**Director Business Development & Operations,
Germany; Managing Director of Rescop GmbH**

▸ FDA Audit Preparation for a medical device manufacturer (Switzerland, Germany and in the United Kingdom)

02/2013 to 06/2014
D-Ploy GmbH, Kaiseraugst, Switzerland   d-ploy.ch
Senior Manager / Key Account Manager
▸ Program Manager, IT Infrastructure Integration (corporate divestitures)
▸ Key Account Manager / Team Lead responsible > CHF 1.5 Mio. turnover.

2008 – present (once annually)
Concept Heidelberg, 69123 Heidelberg
Trainer, CV 20 – GAMP 5 2nd Edition – praktisch angewendet

04/2012 – 01/2013   **Senior Manager**
                       DHC Dr. Herterich & Consultants GmbH,
                       Bülach, Switzerland and Saarbrücken, Germany

09/2008 – 03/2012   **Manager. Computer Systems Validation**
                       Arcondis AG, Reinach, Switzerland

07/2006 – 08/2008   **Senior Consultant**
                       ims Health, Allschwil, Switzerland

07/2004 – 06/2006   **Senior Consultant**
                       redtoo AG a.k.a. caatoosee AG, Reinach, Switzerland

02/2000 – 06/2004   **Senior Consultant / Managing Director**
                       innobit AG, Basel, Switzerland

EDUCATION

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

CERTIFICATES

2018   telc Deutsch B1 (German language certificate)
2015   **Quality Management Systems Auditor (QMA-TÜV**, ISO 9001:2015)
2013   **PRINCE 2** Foundations (Project management methodology)
2012   **ISO/IEC 27001**:2012 Foundations for Information Security Mgmt. Systems
2011   **ISO 9001:**2008 Quality Management Systems Representative (QMB-TÜV)
2009   **Project Management Professional (PMP®)** (05/2009 – 05/2018)
2005   **Computerized Systems Validation** Representative (CSV-Beauftragter)

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SKILLS

- **Business Leadership and Management**
  - Leadership & Communication
  - IT Finance – CAPEX/OPEX, tangible & intangible assets
- **IT Project and Program Management** (IT business application implementation, upgrade and retirement; IT infrastructure renewal, data centre consolidation, global end-user device upgrades; Mergers, acquisitions and divestitures (organizational and technical),
  - Generic Project Management Methodologies: PMI PMBoK® Guide, Prince2, Lean SixSigma, GAMP® 5, V-Model, Agile Methods (e.g., Scrum)
  - Company-specific PM Methodologies: Novartis ICE, Boehringer Ingelheim LeVA (Lean Validation Approach) and Hybrid-Agile LeVA.
  - ServiceNow SPM (Strategic Portfolio Management)
- **Computerized Systems Validation** and Infrastructure Qualification per US FDA cGMP (current Good Manufacturing Practices) / QSR (Quality Systems Regulations) and 21 CFR (Code of Federal Regulations); EudraLex Volume 4, Annex 11 & 15
  - Risk Management, ISO 31000, FMEA, Ishikawa and 5-Why Root-Cause Analysis
  - Change Request Management
- **IT Service Management** (Change Request & Change Control Management, Test Management, Document Management, Service Request Management, Incident and Problem Management, etc.)
  - ISO 20000 / ITIL IT Service Management
  - ISO/IEC 27001 Information Security Mgmt. Systems
  - DevOps
- Business Analysis, Business Process Design, Management Consulting, Requirements Analysis and Modelling, Communications, Training
- ISO EN 9001:2015 Quality Management Systems (Auditor)
- Published author (English & German) of technical/professional articles.

References available upon request.

BACKGROUND INFORMATION

- Birthplace: Los Angeles, California, USA
- Citizenship: German / EU (naturalized 04/2019)
- Languages: English (mother language), German (fluent, B1-certificate)

- LinkedIn: https://www.linkedin.com/in/jamesgreene/
- XING: https://www.xing.com/profile/James_Greene/

James Greene

PROFESSIONAL PUBLICATIONS

References / Copies available on request

Greene, James, [Executive Editor]. 2006. *PM@CH - The Swiss Project Management Journal*. Switzerland: PMI Switzerland Chapter, December 2006. No. 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, 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,* Symposion 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, 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

Greene, James; Ludt, Béatrice; Reitz Alexander. 2017. Good Documentation Practices für SAP Rollen [Webinar]. (German) Significon AG, 24. Nov. 2017

Greene, James; Rombach, Niklas. 2019. Papierlose Validierung - Anforderungen und Lösungen [Webinar]. (German) Significon AG, 29. Mar. 2019

Greene, James, [Executive Editor]. 2018. *ASPects - The Official Newsletter of the Association of Software Professionals*. Association of Software Professionals, April 2018. Volume 29, Number 1.
—. **2018.** The Key to Productivity. *ASPects*. Association of Software Professionals, April 2018, Vol. 29, 1, pp. 5-6.
—. **2018.** You've got the Killer App...Now What? (Part 1)
ASPects. Association of Software Professionals, July 2018, Vol. 29, 2, pp. 4-5.
—. **2018.** You've got the Killer App...Now What? (Part 2)
ASPects. Association of Software Professionals, October 2018, Vol. 29, 3, pp. 4-5.
—. **2019.** You've got the Killer App...Now What? (Part 3)
ASPects. Association of Software Professionals, January 2019, Vol. 30, 1, pp. 4-5.
—. **2019.** You've got the Killer App...Now What? (Part 4)
ASPects. Association of Software Professionals, April 2019, Vol. 30, 2, pp. 3-5.
—. **2019.** You've got the Killer App...Now What? (Part 5)
ASPects. Association of Software Professionals, July 2019, Vol. 30, 3, pp. 5-8.

Greene, James; Kappis, Paul. 2020. System- und Prozessstilllegung in der Pharmaindustrie. *TechnoPharm* 10, Nr. 4, ECV – Editio Cantor Verlag, D-Aulendorf, pp. 216-223 (German). ISSN 2191-8341.