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Top Skills

C Level Management
Product Operations
Product Planning

Certifications

Medical Device Regulation
Usability & Requirements
Risk Management ISO 14971
Agile Product Owner(ship)
Masterclass: Advanced Techniques
Artificial Intelligence

Publications

Flotillin-1 is an evolutionary-
conserved memory-related protein
up-regulated in implicit and explicit
learning paradigms

Marvie "Marvs" Demit

Licensed AI Medical Device Manufacturer | Expert within Highly
Regulated Industries (Life Sciences, Defence, Legal, Critical
Infrastructure) | Former Owner of VividSolutions (Exited)
Vienna, Vienna, Austria

Summary

With approximately 12 years of diverse experience in the Life
Science, Medical, and In Vitro Diagnostic (IVD) Technologies
sectors, I have cultivated expertise in both academic and non-
academic environments.

My journey began during my Master's program in Bioinformatics,
where I explored the Medical and IVD-Tech sectors. This led me to
a role as a Data Scientist at mySugr GmbH, a pioneering Medical
Device start-up. Here, I honed skills in cutting-edge data processing
techniques and mining methods, while building and optimizing
machine learning algorithms.

Transitioning to Product Development Manager for an AI-driven
bioinformatics software company, I took on responsibilities in
Requirements/Usability Engineering, Product Design, and Release
Management. This success led to my promotion as Head of
Operations & Processes at Platomics GmbH, where I oversee
departments including Business Intelligence, Product Management,
Design & Prototyping, Data Protection & Security Risk Management,
Quality Assurance, and Process Management.

Building on my expertise in AI Medical Devices, I have decided to
broaden my horizons as an independent consultant. My role involves
supporting Medical Device Manufacturers as an Interim Product
Owner or Head of Product, ensuring successful CE-marking within
deadlines and budgets.

One significant realization through the years has been my unique
ability to serve as an effective bridge between various departments
within an organization. My knack for relationship-building enables me
to unify different teams towards a common goal—making sure our
company flourishes healthily and exponentially.

Adhering to Gary Vaynerchuk's wisdom that "If a company wants to grow from 1 million to 100 million, it's all about people," I believe there's no formula or platform that can successfully nurture or scale a company without people.

Experience

RobotDreams® GmbH
Chief Product Officer
February 2025 - Present (8 months)

ArnoldAI
Co-Founder
January 2024 - Present (1 year 9 months)
Floridsdorf, Vienna, Austria

VividSolutions
2 years 9 months
Advisor
December 2024 - March 2025 (4 months)

Managing Director
July 2022 - December 2024 (2 years 6 months)
Vienna, Austria

- Offer services including UX design, usability engineering (IEC 62366), SDLC (IEC 62304) and Agile SW Development AAMI TIR 45, software safety risk management (ISO 14971), all in compliance with the relevant standards
- Offer comprehensive support in Agile Project Management, tailored framework established for Medical/IVD Device Development, and Clinical Operations, coordination of Product Development Team, streamlining departmental interfaces, and assistance in market research, competitive analysis and product discovery
- Offer range of services including process and operating procedure design and development, automation implementation support, process management system implementation, continuous process optimization (Lean Six Sigma), and performance monitoring and evaluation (OKR, KPIs)
- Offer interpretation of AI Act in conjunction with the MDR/IVDR, support in the development lifecycle of AI models, assistance in requirements and good practices for AI SaMDs, AI data management including collection, annotation,

pre-processing, documentation, and version control, as well as model development including preparation, training, evaluation and documentation

QUAREGIA GmbH - Quality & Regulatory Compliance

AI and DevOps Medical Device Partner

November 2023 - May 2024 (7 months)

Vienna, Austria

My responsibilities as a Partner for Quaregia encompass a wide range of critical areas, including:

- Spearheading AI-driven initiatives to enhance medical device performance and functionality.
- Implementing DevOps practices to streamline software development and deployment processes.
- Leading cross-functional teams in the development and integration of cutting-edge technologies.
- Ensuring compliance with regulatory standards and requirements in the medical device sector.
- Collaborating with stakeholders to drive innovation and achieve strategic business objectives.
- Providing expert guidance on cybersecurity measures to safeguard sensitive medical data.
- Developing and optimizing machine learning algorithms for improved diagnostic accuracy.
- Managing technical documentation and process validation to uphold quality standards.

Exploris Health AG

Head of Product - AI SaMD (Interim) - Contract Based

November 2023 - May 2024 (7 months)

Vienna, Austria

Supporting Exploris Health to ensure that they can CE-mark their AI Medical Device successfully.

- Technical Product Ownership: Lead technical aspects aligning with business goals.
- Agile Project Manager: Drive efficient project execution using Agile methodologies.
- Architectural Design Support: Enhance Cardio Explorer's functionality and performance.

- SW Lifecycle Ownership: Manage software development lifecycle for quality and compliance.
- Verification and Validation Ownership: Ensure product quality through testing and analysis.
- Configuration and Change Management Ownership: Maintain product integrity and streamline change processes.
- Risk Management and Usability Engineering: Identify risks, enhance usability, and optimize performance.
- Cybersecurity Conceptualization Ownership: Develop cybersecurity strategies to protect product data.
- Collaborate with cross-functional teams to define and prioritize technical requirements.
- Implement continuous improvement initiatives to enhance verification and validation processes.

Exscientia

Agile Project Management Consultant - AI SaMD - Precision Medicine
July 2022 - August 2023 (1 year 2 months)

Floridsdorf, Vienna, Austria

- Developed and implemented a product strategy for AI Software as a Medical Device (SaMD) aimed at enhancing precision medicine initiatives.
- Established a comprehensive Quality Management System (QMS) utilizing Confluence to ensure compliance with regulatory standards and improve operational efficiency.
- Implemented an Application Lifecycle Management (ALM) system using Jira, facilitating better project tracking, issue resolution, and collaboration across development teams.
- Created and led the Agile Project Management Office (PMO) tailored for the Precision Medicine Unit, introducing agile methodologies to enhance project delivery and team agility.
- Designed and executed a Project Management Framework specifically for precision medicine projects, incorporating best practices in agile and lean project management to ensure successful project outcomes.
- Fostered a culture of continuous improvement within the Precision Medicine Unit by introducing agile methodologies, leading to increased project efficiency and team productivity.
- Conducted regular training sessions and workshops for team members on agile practices, tools (Confluence and Jira), and the importance of quality management in maintaining regulatory compliance and achieving project success.

- Collaborated closely with cross-functional teams, including R&D, regulatory affairs, and clinical operations, to ensure alignment of project objectives with the overall strategic goals of precision medicine initiatives.
- Monitored and reported on project progress to senior management, providing insights and recommendations to address any challenges or roadblocks encountered during the project lifecycle.
- Played a key role in the successful delivery of AI SaMD projects, contributing to the advancement of precision medicine solutions and improving patient outcomes.

AustrianStartups

Fellow, Entrepreneurial Leadership Program

March 2022 - February 2023 (1 year)

- Participated in an immersive entrepreneurial leadership program that combined rigorous academic theory with real-world practical application.
- Built comprehensive business models and strategic plans for startups under the guidance of experienced mentors.
- Engaged in workshops on various topics such as venture capital funding, marketing strategies, financial modeling, legal requirements for startups, and much more.
- Validated business ideas through customer discovery interviews and market research.
- Worked in cross-functional teams to develop MVPs (Minimum Viable Products) and run beta tests.
- Benefitted from one-on-one mentoring sessions focused on personal growth and leadership development.
- Networked with entrepreneurs, industry experts, investors, and other like-minded peers to learn best practices and latest trends in the startup ecosystem.

Platomics

3 years

Head of Product (interim)

August 2021 - June 2022 (11 months)

Vienna, Austria

- Led the design thinking sessions and design sprints to create and pilot prototypes and MVPs
- Collaborated with business, product management, and software development to define and implement innovative solutions for the product direction, experience, and processes

- Defined and designed interfaces, experiences, and processes across multiple platforms to enhance customer and employee journeys

KEY ACHIEVEMENTS:

- Kickstarted the Minimum Viable Design System. Managed to deliver vision, release and adoption of essential components contained in the library
- Delivered same font, icons and color palette across Platomics Platform, improved legibility, page scalability, visual appeal, and system performance. Led transition to a new development environment (Storybook)
- Orchestrated strategy, roadmap, design for new GSPR Assistant Tool release
- Facilitated quality assurance for all features set to release in the roadmap

Head of Operations & Processes

April 2020 - June 2022 (2 years 3 months)

Vienna, Austria

- Ensured adherence to Standard Operating Procedures (SOPs) in all facets of operation including Product, Software, Sales, Human Resources, and Software Testing
- Fostered operational excellence by effectively managing the organization's accuracy, efficiency, and production targets
- Managed the Operations department; following its expansion, directed and oversaw annual performance management for the operations team
- Collaborated with the Executive Team to make strategic decisions for operational activities
- Orchestrated and monitored daily business operations to ensure seamless progress
- Routinely assessed the efficacy of business procedures relative to organizational objectives and implemented improvements accordingly
- Reviewed financial data and adjusted operational budgets to increase profitability
- Reformed or established policies and promoted their successful implementation
- Managed relationships and agreements with external partners/vendors
- Assessed overall performance via gathering, analyzing, and interpreting data and metrics
- Acted as the primary business lead or Subject Matter Expert (SME) for Regulatory Service Division interactions with Technology partners related to new or existing business applications

- Established objectives, Key Performance Indicators (KPIs), monitoring procedures, along with reporting capabilities to assess overall organizational performance

KEY ACHIEVEMENTS:

- Effected successful establishment of Objectives & Key Results (OKR) alongside Agile Project Management Office (PMO) across the organization.
- Developed a comprehensive Product Development Lifecycle Process for Medical Devices that includes full traceability from high-level requirements through product testing & release.
- Led the transition from paper-based quality management system into an electronic one using Confluence & JIRA.
- Successfully oversaw the launch of an In Vitro Diagnostic (IVD) Bioinformatics Pipeline for Genetic Testing.

Product Manager - PlatoX LAB IVD - AI SaMD

July 2019 - April 2020 (10 months)

Austria

- Led key research for different product features and supported business objectives
- Drove the hands-on investigation of new technologies and novel innovations towards genetic testing
- Managed the entire requirements engineering process starting from the elicitation, analysis and negotiation, documentation and validation
- Conducted user research, usability analysis, usability design, formative and summative evaluation
- Translated business cases into user workflows, wireframes, and prototypes
- Designed and delivered wireframes, user journeys, and mockups optimized for a wide range of interfaces

KEY ACHIEVEMENTS:

- Launched a Minimum Viable Genomics Database
- Established SOP for Data Curation and Integration
- Established all product development related SOPs including, SW Development SOP, QA SOP, Sales SOP, Human-Factor Engineering SOP

mySugr

Product Data Scientist

2017 - 2019 (2 years)

Vienna

- Collaborated with stakeholders across various levels of the organization to pinpoint opportunities for utilizing corporate data to facilitate business solutions.
- Undertook an analysis of patient data to enhance the app's usability.
- Conducted an assessment of the Apps' Diabetes Insights Reporting's data visualization.
- Reviewed various external predictive analytic tools for potential data integration with Continuous Glucose Monitoring (CGM).
- Assisted in creating an A/B testing framework and testing the quality of AI/ML models.
- Established methodologies and tools for tracking, monitoring, and analyzing model performance as well as data accuracy in Glucose Monitoring Systems.

KEY ACHIEVEMENTS:

- Authored a Standard Operating Procedure for Data Curation and Assessment related to CGM.
- Developed conceptual design concepts pertaining to CMG Reporting.
- Wrote a Work Instruction manual for CMG Reporting Visualization.
- Assessed Neura AI tool for possible integration with CGM Report.

University of Natural Resources and Life Sciences, Vienna (BOKU)
 Student Supervisor
 2014 - 2018 (4 years)

Analytical Chemistry: 2014 - 2016

- Advising and consulting students with their mandatory laboratory practices
- preparing the corresponding experiments for the lab
- organizing and supervising exams with professors

Machine Learning: 2016 - 2018

- designing homework exercises
- group-meeting
- supervising students with their exercises

Evologic-Technologies
 Product Analyst
 2016 - 2017 (1 year)
 Austria

Responsible for the entire product approval process within the DACH region and the associated product application and authorization until the relevant admission.

- Supported the product approval process within the DACH region
- Supported the product accreditation process
- Supported the ECO certification of GAIA's Ureterde
- Led the validation of product/market fit and ground key assumptions

KEY ACHIEVEMENTS:

- Achieved ECO-certification of GAIA's Main Product

labors.at

Laboratory Operations Technician

2013 - 2015 (2 years)

Austria

- Planned the work schedule for the Laboratory Support and the Sample Receipt Team
- Maintained and performed the continuous monitoring process of different analytical processes
- Performed frequent validations of different analytical devices
- Prepared and organized device acceptance tests, test assessments of reference materials

KEY ACHIEVEMENTS:

- Improved the workflow of the Hematological testing analyses
- Improved the workflow of all chemical and immunological testing analyses
- Improved the process workflow for sample receipt and archival

Medical University of Vienna

Laboratory Research Assistant

2011 - 2013 (2 years)

Austria

- Prepared samples for testing various laboratory equipment
- Maintained all laboratory records
- Conducted laboratory tests, analyzed and documented the results
- Collected and prepared research materials required for the studies
- Cleaned and sterilized equipment and work area
- Undertook basic administrative tasks such as filing and answering requests

KEY ACHIEVEMENTS:

- Gained skills in PCR testing and immunohistochemistry testing

Education

Saïd Business School, University of Oxford

Entrepreneurship: Venture Finance Programme · (March 2022 - December 2022)

Google Creative Campus

Google Project Management Professional · (December 2021 - June 2022)

University of Natural Resources and Life Sciences, Vienna (BOKU)

Master's degree, Biotechnology - Bioinformatics (Machine Learning) · (2016 - 2018)

University of Natural Resources and Life Sciences, Vienna (BOKU)

Bachelor's degree, Food Science and Biotechnology · (2012 - 2016)