Pharma IT

A ProductLifeGroup Company

IT Compliance and Project Management

Experienced consultants with specialized IT expertise

peei@pharmait.dk

pharmait.dk

+45 28 68 78 31

We are specialized in domain specific IT consultancy and driven to improve the standards of pharma consulting

Pharma IT prides itself on our subject matter expertise, and know the importance of deep domain specific insight. We have a keen understanding of the life sciences industry, regulatory landscape, latest processes, and innovative tools. Count on us to take responsibility and provide service you can trust.

Peter-Emil Iversen
Partner

We are happy to work together to create a tailored solution to meet your needs

Computer System Validation (CSV) | **Business Analysts** | **IT Project Managers** | **System Architects**

Computer System Validation

We have an experienced team of consultants ready to assist you with services within all areas of Quality and Compliance, including:

- Quality Management System(s)
- Supplier Audits
- Vendor Assurance
- GMP Compliance (Mock) Audits
- Qualification/Validation Services
- Compliance Strategy Development
- 21 CFR Part 11/Annex 11 Compliance & IT Validation
- Standard Operating Procedures

Business Analysts

Pharma IT's Business Analysts can offer assistance in every phase of major changes or basic maintenance of current state on company, department, or system level. This could be larger organizational changes, strategic initiatives, optimization of business processes, preparing, purchasing and implementation of IT systems or daily management and service delivery.

IT Project Managers

Our IT Project Managers all have at least 10 years of experience as PMs within the pharma domain. This means they can support you with a wide range of tasks, ensure on-time delivery, and be trusted partners in your project.

System Architects

Deep insight into domain specific IT Applications make our System Architects specialists in the pharma, biotech, and medical device industries.

Do you want to get in touch? Reach out to Peter-Emil at **peei@pharmait.com** or **+45 2868 7813**

Selected Profiles

Dorte Juul holds more than 15 years' experience within the IT compliance area, working in both the pharmaceutical industry and food ingredients sector. She is highly specialized in GxP and has performed in leading roles, such as Validation Track Lead on projects, as well as Service and Release Manager on production systems. She has SAFe Agilist, SAFe Scrum Master and CISA certifications as well as an ITIL Foundation Certification and certifications as Computer Validation Manager and Lead Auditor. She has also passed the Associate White Belt on Veeva Platform.

Jes Olesen holds 20+ years of experience planning, controlling, executing, and closing life sciences projects, 18 years of which have been within IT. He is highly experienced in Agile IT development and is a Certified SAFe 5.1 Scrum Master & RTE. Jes thrives as a result-oriented Project Manager with a sense of humor, as a supportive and practical Scrum Master, as well as a coordinator, facilitator, and firefighter. He is passionate about delivering solid business benefits in projects involving agile IT system development, integration, and implementation as well as strategic IT management projects.

Maiken Forsberg holds 11 years of experience within IT Quality and IT Security. As a Lead/Principal Advisor, Maiken has implemented, operated and retired IT solutions in line with IT Quality: GAMP 5, 21 CFR Part 11, EU GDPR and HIPAA + HITECH Acts, and IT Security: NIST standards, ISO/IEC 27000 and ITIL4. Maiken has helped several pharma companies establishing or improving IT documentation prior to audits and inspections with good results. As a consultant, Maiken has performed + 30 IT projects as IT Compliance/Validation Lead, Test Manager, IT Project Manager and ITQC.

Mike Astrup Nygaard has 5 years of experience as a Pharma Consultant, working with various compliance and test assignments within GxP. Mike is experienced in taking lead and ownership of all types of compliance tasks from user requirement specifications, to validation plans, testing and reporting. Mike has performed the role as Compliance Consultant, Validation Lead and Test Manager on IT projects and is specialized in GxP. He is a certified SAFe SCRUM Master, and holds further certifications in Azure Tools, DevOps Foundation, ISTQB Foundation, and ITIL Foundation.

Nikolaj Brasen has over 20 years of experience helping large enterprises transform their ideas into technical IT solutions. His main areas of responsibility have been systems and integrations design with a strong focus on data integrity, working both as a Business Analyst and Solution Architect, and participating in RfP activities when required both from a customer and vendor perspective. Nikolaj has also served as the risk and compliance lead for Pharma IT's GxP Initiatives based within the Azure Platform. He holds DevOps Foundations, Veeva Vault Platform, PRINCE2 Foundation, and TOGAF 9 certifications.

Nini Redøhl has worked within IT quality, compliance, and project management for over 15 years. Here she has acquired experience within Project Management, Test and Validation of GxP systems, Quality Management, Customer Relations and Change & Configuration Control. She has acted as Compliance Consultant, Validation Responsible, IT Quality Control (ITQC), Process Consultant and Project Coordinator for multiple IT systems used in the laboratory and production area within the Pharma industry, in collaboration with System Architects, System Management and Quality Assurance responsibles. She holds ITIL Foundation Certification and is a certified SAFEe Agilist.

Meet our Customers

Pharma IT has more than 100 customers consisting of both small and large pharma, medical device, and biotech companies. We value all types of assignments - from small projects to large enterprise solutions.
Here's an excerpt of our customers:

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We looking forward to hearing from you!

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