Cristian Bogdan DRAGOMIR

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Role:	Senior IT & Aut. Consultant
Dept.:	IT Projects & GxP Compliance

ALPHA WORKFLOWS
Partner up. Go Live!

Summary | Senior IT Consultant focusing on management of IT and Automation Systems within regulated environments such as Pharma, BioTech and MedTech. I have a purposeful approach to working, eagerness to measure myself against new challenges and constantly pursuing personal development and learning. Motivated by working with and engaging skilled team members in finding solutions and breaking down processes into simple, workable products. Enthusiastic about leadership, coaching and cloud-enabled technologies.

Reference clients | **Novo Nordisk, LEO Pharma, Ascendis Pharma**

Specialties | **Project Management:** PRINCE2, SAFe5 (Scum Master)
Life sciences & regulatory: GAMP5, 21 CFR Part 11, ISO 13485 (medical devices)
IT governance & management: COBIT5
Test Management: HP QualityCenter, Azure DevOps
Technological areas: BMS, PCS & SCADA, IT & OT systems, Cloud services (Azure)

PROJECT PORTFOLIO

Dec 2020 – Present

Validation Manager: Responsible for the **quality and compliance of a cloud-based insights platform**. The platform utilized PaaS resources from Microsoft Azure for ingesting data from various areas of interest to Line of Business and then storing, transforming, modelling, and serving the data to end-users via customizable reports. My responsibilities include developing and implementing the quality strategy for the platform and defining the framework for developing new applications on the platform.

Oct 2020 – Jun 2021

IT Project Manager: Responsible for the managing an **Enterprise Search** project for improving the work efficiency of the R&D scientists when searching for data both within and outside the client's data storage landscape. The end solution is a Platform-as-a-Service, offering machine learning capabilities. My responsibilities include managing the vendor selection process, managing the contract with the selected vendor, implementing the solution, training users and handing over to operations.

Jun 2020 – May 2021

IT & Automation PM: (50% workload) This is a capacity expansion project with the purpose to implement automatic visual inspection (AVI) of the products. Responsibilities include the **deployment and integration of the GxP AVI machines** into the customer's product supply network (PSnet), local PAS-X implementation with batch recipes, securing interfaces to the central SQL and Historian servers and POInT integration. Similar integration and deployment is required for the robots handling products at the inlet and outlet of the AVI machines.

Oct 2019 – Jun 2020

IT Project Manager: Responsible for managing three projects in different areas of the client's organization. For Global Business Solution: the implementation of a multi factor authentication (**MFA**) and mobile application management (**MAM**) solution based on Azure and to be rolled out globally to +1800 users. For the Innovation organization: piloting a **cloud-based idea management tool** (Planbox) for increasing employee engagement in innovative thinking. For the Technical Organization: **upgrade and migration of their Document Management System**. The projects required extensive management of stakeholders' expectations and the ability to motivate remote teams.

Sep 2018 – May 2019

IT Compliance Advisor: **Inspection readiness program (SCRUM based)** for strengthening the compliance level of several clinical GxP IT Systems after an inspection. Main tasks: evaluation of customer's **eTMF** (electronic Trial Master File) system based on Veeva Systems SaaS solution and **AEMS** (Adverse Events Management System) from ARISg, definition and implementation of mitigating actions to ensure that all **21 CFR Part 11** requirements were properly implemented, tested and traced.

Jun 2017 – Dec 2018

Project Manager: **Migration and integration** of GMP IT systems (BMS, SCADA, PCS) for enabling the connection of a Business Unit's production IT systems to the customer's product supply network for centralized **deployment of IT services** (backup, antivirus, time management, user management, remote access). The task consisted in migrating

six BMS applications from one IT infrastructure to another and integrating a completely new SCADA system to an existing domain.

OCT 2016 – AUG 2018	<u>Project Manager & Assistant System Manager</u>: **Virtualization and upgrade** of two PCS (Process Control Systems) based on **DeltaV**. Main Tasks: **business case definition** and justification, budget preparation and approval, creation of schedule and scope, **facilitation of decision making** with the steering committee, factory shutdown coordination, contract management, supplier management, supervision of FAT & SAT and qualification, handover to operations. The PCS were used in the automation and supervision of the production processes at the pilot plants, spanning four departments. The task required extensive planning and coordination of the closing window to enable the safe upgrade of the two PCS and the return to operation of the pilot plants.
Mar 2016 – May 2018	<u>Assistant Project Manager and validation responsible</u>: Implementation of a **wireless Facility Monitoring System** based on Testo Saveris. Main tasks: preparation of specifications, validation planning and execution, supplier management and PM support.
Nov 2016 – Dec 2016	<u>Compliance Track Lead</u>: **Inspection readiness project** for ensuring readiness before inspection. Main tasks: definition of data integrity procedures, description and classification of Electronic Records used by a Building Management System.
Aug 2016 – Feb 2017	<u>Project engineer</u>: **Preparation of specifications** for the BMS controllers managing the HVAC systems used in an oral solid dosage plant. The task consisted in defining and approving the user requirements specifications through the interacting with the BMS engineer, Validation Responsible and QA.
May 2016 – Aug 2016	<u>Project coordinator & Tester</u>: **Qualification of freeze storage** using temperature and humidity mappings. The new freeze room are used by the customer to freeze their products before shipping. The task consisted in receiving the freezer for testing, preparation of the qualification protocols, coordination of the temperature and humidity mappings, testing, test reporting and handover.
Mar 2016 – Apr 2016	<u>Tester</u>: **Qualification of BMS controllers**. Main tasks: follow-up on test readiness with the supplier, execution of test protocols, quality control and compliance.
May 2015 – Feb 2016	<u>Assistant Project Manager and Validation Responsible</u>: Implementation of two **Building Management Systems** (BMS) for controlling the environmental conditions in four pilot plants. Main tasks: development of **validation deliverables** spanning the entire V-Model (System Impact Assessment, IT Quality Risk Assessment, URS, Validation Plan, TDS, IQ, OQ, PQ, RTM, CIL, SOPs), communication and change management, review and **approval of supplier deliverables**, coordination of on-site activities.
Jun 2014 – Aug 2015	<u>Assistant Project Manager</u>: Implementation of a **Virtual Infrastructure Platform** spanning two data centers with geographic separation, fully redundant and with high availability. Main tasks: responsible for the **qualification of the data centers** where the IT infrastructure was installed. Support with the development of the user requirement specs. for the IT infrastructure, **negotiation of SLA** terms and conditions, supporting the Project Manager with slides for the steering committee meetings, **coordination of on-site activities** performed by the supplier, interaction with QA for documentation approval.

PROFESSIONAL TRAINING AND COURSES

Jan 2021	Scaled Agile Framework – **"SAFe 5 SCRUM Master"**
Nov 2020	Microsoft – **"Azure Administrator"**
Feb 2020	European Compliance Academy - "**GxP Cloud Computing**"
Oct 2019	Microsoft – "**Azure Fundamentals**"
Oct 2019	European Compliance Academy - "**GMP for Medical Devices**"
June 2019	Scaled Agile Framework – "**SAFe 4 Leading SAFe**"
Jan – Apr 2018	Davis University on Coursera - "**Coaching for Managers**": A coaching specialization focused on Designing Performance Expectations, Setting KPIs and Goals, Diagnosing and Assessing Performance Gaps, Designing and Applying 1:1 Coaching Practices
Nov 2017	World Coaching Organization - "**Coaching - Master level**": Advanced coaching tools for holistic coaching focusing on values, emotions and behavior

Sep 2017	APMG - "**COBIT5**": Certification in Governance and Management of IT Systems framework
Jul 2017	World Coaching Organization - "**Coaching - Basic level**": Introduction to coaching: coaching methodology, tools and techniques, building rapport
Feb - Dec 2017	Illinois University on Coursera - "**Strategic Leadership and Management**": On-line specialization delivered by Illinois University. Covered courses: Applications of everyday leadership, Designing Organizations, Executing Organizations, Business Strategy, Corporate Strategy, Capstone project
Nov 2016	NNE - "**Basic programming in DeltaV**": Programming in DeltaV - 5 day course
Oct 2016	AXELOS - "**PRINCE2 Practitioner**": Project Management certification
Jan – Oct 2016	University of Geneva on Coursera – "**Investment Management Specialization**" – Understanding Financial Markets, Meeting Investors' Goals, Portfolio and Risk Management,, Securing Investment Returns in the Long Run
Oct 2015	Global Knowledge - "**VMware vSphere: Install, Configure, Manage**": Virtual Machines Management, Configuring and Managing Virtual Networks and Virtual Storage, Resource Management and Monitoring
Jul 2015	Zero Generation - "**Leadership Summer School**": Emotional Intelligence, Group Dynamics, Conflict Management, Public Speaking, Facilitation, Coaching
Sept 2014	ECA - "**Virtual IT Systems in a GxP Environment**": Planning of Virtualization Projects, Compliance Requirements for Virtual Systems, Qualification of IT Infrastructures
Nov 2014	ECA - "**The Validation Manager**": Regulatory Requirements, Risk Assessment, Validation Planning, Process Validation, Qualification, Change Management
Aug 2014	Novo Nordisk - **HP QC** - Testing Information and Management System, HP provided software.

COMPUTER SKILLS

General	MS Office	MS Project	MS Visio	VMware, Azure^{Cloud}	HP QC$^{Test\ Management}$	SQL^{DB}	SFC, FB, LD, ST$^{PLC\ Programing}$	C, C++ ^{Algorithms}	Powershell ^{Scripting}

EDUCATION

2011 – 2014 MSc. El. Eng.	**Automation and Robot Technology – Danmarks Tekniske Universitet** Focus areas: Linear Control Design	Fault Tolerant Control Systems	Robotics	Computer Vision	Image Analysis	Computer Control Systems Thesis: 'Modeling and Optimal Control of Hydraulic Systems' – Mark: 10 • Mathematical modeling and simulation of physical systems via Matlab/Simulink. • Diagnosis and assessment of system stability and control objectives. • Design of controllers (PID, LQR/LQG) and Kalman filters.
2007 – 2011 BSc. Comp. Sc.	**Automation and Computer Science – Polytechnic University of Bucharest** Focus areas: Automatic Control	PLC & Micro-controller programming	Home Automation	SW/HW Development	Embedded Control Systems Thesis: 'Sensorless Automated Sun Tracking System': PCB design in Proteus/Isis; Sun-tracking algorithm embedded on a Atmel micro-controller using AVR/C++. • Data structures and programming • Design of automation and control systems

LANGUAGES

ENGLISH	Fluent
DANISH	Working Proficiency
ROMANIAN	Native