Michael Calvert, MBA

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US Citizen, Vaccinated

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Qualifications

• M.B.A. – Master of Business Administration 2008	Purdue University
• B.S., Organizational Behavior, Leadership	Purdue University
• PMP - Project Management Program completed, PMbok 2013	Nashville, TN

GxP – Healthcare, Industry Experience

• Ai/ML, SME Leader of Data Analyst	JnJ – Janssen
• Biomarkers, LIMS, ELN, Proteomics	Ray Biotech, Elan, Abbott
• Project Manager, OEM New Products	Pall Corp
• Technical Owner, Business Analyst	AstraZeneca
• Product Owner, Business Analyst	Viatris divestiture Pfizer
• Senior Business Analyst, SDLC	Quest Diagnostics
• Senior Business Analyst, CTMS	BMS/Celgene Merger

SAMD Consulting, an CSO | Contract Service Organization **2019 to present**.

2008 work began on Ai, NLP projects in the Healthcare Ecosystem.
Scoping GxP projects defining boundaries, objectives, deliverables, and requirements.
Omni-channel, Digital Marketing to enlist HCPs and enroll and engage consumers.

Consulting Engagements

Project Leader, 4 data analysts, a Proof of Concept, "Most admired pharmaceutical company," Fortune.
SME, Territory Scan Project, using **Ai / ML**, analytical skills identifying factors driving "Net Sales."
Regulatory, JRoad & EPiiN, using **Ai/ML**, problem solving, identify factors influencing 3 yr. trends.
Compliance, Global PROs, a POC, **AI/ ML** focused on 69 products with a 3 yr. trends, decision tree.
Product Owner, Global Vaccination documentation for C-19 Portal, track & trace, resources.
Regulatory, Business Analyst, Global product launch into 18 countries, Jakafi (Cardiology & Diabetes).
Business Analyst, POPIA | Protection of Personal Information Act, South Africa Parliament.
Business Development, # 1 New Prescriptions, New product launch, Hospital, and field Sales.

Technical Owner/Business Analyst, Top 10 Pharmaceutical dispensed via Medical Devices.
SOW Omnichannel Digital Marketing redeploying ADA compliant Web-to-Mobile assets.

- Regulatory Compliance, realign $1 Billion brands, MLR, vendors, agencies, webinar services.
- AEM, interactive content, focused on awareness of HCPs and digital MLR targeting DTCs.
- MIRO, review Journey designs & commercial objectives, demand refinement, ad-hoc requests.
- MarTech, roadmap, feasibility, demand planning, collaborate with architect on innovation.

Commercialization Assets, industry platform technologies include:

- IQVia, AIM XR, CRM integration for HCPs, new product launches.
- Veeva Commercial, Compliance, RIMS – PromoMats, Medical, Clinical, Regulatory, Quality.
- Adobe & Google Tag Manager, Tealium Audience IQ, Adobe Launch, Rialto, consent manager.
- Content Mgmt., CRM, Master Data Management, Compliance, Commercial Data & Analytics.
- Jira one source of truth, methodologies (Agile, DevOps, CPQ, TQM, Six Sigma etc.).

ITIS-Healthcare, creating innovation disruptive IT technologies. **2014 to 2019**
Clients in Life Science, CROs, Pharmaceuticals, Biotech, Medical Device.
Product Owner, Senior Business Analyst, a US Citizen, able to travel 90%.

- Specializing in the healthcare, clients, stakeholders, vendors, partners.
- Works closely with lead engineers to develop road maps for applications.
- Aligns plans to ensure effective integration within information systems & IT.
- Collaborates with brand managers, agencies, driving, HCP and DTC decisions.
- Elicit requirements, author use cases for project charters, BRDs, URS, FRS, UAT.
- Agile, creates solutions, process improvements, sharepoint, supports growth and scalability.
- Solves problems, plans resource needs, develops prioritizes business strategies to operational changes.
- Governance of MLR commercialization HCPs, digital, eCommerce, omni-channels.

Consulting Projects Include:

Product Owner/Business Analyst, for a Global Laboratory providing diagnostics. NDA in place

SOW: Build an integrated portal, update 30 Million consent forms, engage, and educate patients diagnosed.
Create MLR | Medical, Legal, Reviewed, ADA regulatory compliant Web-to-Mobile assets.
Author BRDs for stakeholder approval and Legal & Compliance addressing use cases.
Present in Visio roadmaps, swim lanes as regulatory acquiescent documents.

Results: Manage Integration of Digital eMarketing, Data Lakes (consumer validated via Health Verity and Research and Development consent documents), One Trust, Dues, Qualtrics-survey, Rally, Sprint,.
DTC |Direct to Consumer, compliant consent forms, engaging in self-enrolled R &D contracts.

- LIMS – bi-laterally informed patients, triggers educational AEM journey and google analytics.
- eCommerce, local Clinical Trial Administrators educated and engaged participation.
- Contracts initiated with R & D, CROs, Life Science, Biotech, pharmaceutical and Medical Device.

NDA in place. **Marketing Director of Salesforce Analytics,** for largest Clinical Trail Organization, UK.
Clinical Research Organization, focused on Life Science R & D, Pharma, ISO 13485, 14971, EU CFR 820.

SOW: Realign Sales & Marketing teams to focus on the top 150 influencing companies.
Data Governance, standardize integrate, migrate to Salesforce CRM creating new data strategy & KPIs.
Leadership of 15 Global Marketing staff and 9 global VPs, 155 CRO sales / business development.

Results: Curated; "Current to Future State by eliciting business requirements via SMEs, VPs, sales staff.
Collaborated MDM, used Informa, ZoomInfo, Cite line, Trial trove, ClinicalTrials.gov, Miller Heiman
Channel collaboration, leads, shapes, develops innovative solutions (Web CMS, mail, social)
Marketing impact on Sales Results: Increase $230 Million on an Annual Target of $100 Million.

NDA in Place. **Senior Business Analyst for M & A three (3) companies** into a Top 10 Pharmaceutical Company.
Life Science, Pharma, CTMS | Clinical Trial Mgmt. Software, ETC | Electronic Data Capture of patient clinical data.
SOW: Data Governance, create framework to ingest quality usable Metadata, auditing integration and preservation.

- Data Strategy, implement a commercial off-the-self software Sycamore Informatics SCE, CDR.
- Integrity and security of metadata is secured via a nonperson account, audited end to end for quality.

Skills: Ingestion of IRT, CDW Clinical R & D, CTMS (Oracle Sibel, Medidata Rave) EDC (Inform Rave, Veeva).

- CTMS, migration of legacy to Sycamore Informatics CDR SCE, R, Tableau visualizations, TLF, DMC.
- ClinSight, Jreview -Spotfire, eCRF, CES -AWS, Oracle Argus -Aware, Watson Pk data, eNarrator, PRISM.
- Author, user stories, URS, FRS, BRDs, bus. layer config., JIRA backlog, convergence, SharePoint - CMS, SAFe.
- R & D, Interview workshops, SMEs, "current vs future state" SDLC analysis and design, MDM, SDTM, ADaM.

- Veeva, Data Lake/Marts, Audit Trail for traceability, Governance, GxP, SDLC, ICSR, 21 CFR Part 11, GDPR.