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SUMMARY OF STRENGTHS & ACCOMPLISHMENTS

With over 18 years of project management and project architecture experience, I bring extensive expertise across the entire SDLC. My strengths encompass proficiency in requirements analysis, solution development, efficient delivery, and ongoing support. I implement project management methodologies within the PMI framework to ensure efficient solution delivery, fostering effective collaboration with Offshore PMOs and IT teams. My core competency lies in translating customer requirements into precise system design specifications, focusing on enterprise applications. I hold certifications, including ITIL V3 Foundation and Six Sigma Greenbelt, and I have presented 18 white papers on SDLC models at national conventions. I have earned commendations for my contributions to renowned organizations such as AT&T, IBM, Lucent Technologies, Ernst & Young LLP, GlaxoSmithKline Pl., and Merck & Co.

KEY COMPETENCIES

Global Program Management	Electronic Legal Discovery
Off-shore/Multi-site Team Management	Data Warehousing
Systems Design/Integration	Business Intelligence
Strategic Systems Planning	Enterprise Data Modeling
Clinical Research & Trial Management	Risk Management
E-Commerce Implementation	Business Analytics
BPMS Design and Automation	Knowledge Management
Six Sigma Processes Improvement	Software Development Life Cycle
GAMP 5 Practice	Pharma Compliance Management

PROFESSIONAL SKILLS

Sharpa eLegal Discovery, Pre-Clinical Software, SAP SD, SAP PP, SAP ATTP Serialization, TraceLink Serialization. PM Tools, Informatica ETL, SharePoint, Azure, AWS, Cognos BI, BPMS, SOAP, DataOps, OOA/OOD, UML, EAI/EII, HTML, XML, XSLT, MDB, MVC, JavaScript, C/C++, Net. Data, Oracle, MS SQL, ODBC, JDBC, Erwin, COBOL, ASP.net, Snowflake, Mobile Computing on Android, Lotus Notes Domino.

BOOK AND JOURNAL PUBLICATIONS

1. Authored a Book: "ENSURING PATIENT SAFETY: A Comprehensive Guide to Implementing Traceability and Pharmaceutical Serialization Guidelines—An Exemplary Approach to TrackNTrace in the Supply Chain." Under review by Notion Press, scheduled for release in May 2024. This book details the challenges faced during Serialization implementation, drawing from consulting experiences with CMOs of Pfizer, Merck, Rising Pharma, and more than 12 other firms. It covers compliance guidelines from FDA, MHRA, TGA, and KFA.
2. Published in the International Journal of Life Science and Pharma Research titled “Design and Implementation of a Track n trace 2D Multi Scanner Bulk Code Reader for Pharmaceutical Packaging International Journal of Life Science and Pharma Research VOLUME 13 ISSUE 2, MARCH 2023 / ISSN 2250-0480.
3. Published in the International Journal Dental and Medical Sciences Research titled “Implementation of a Pharma Enterprise Ecosystem for Medical Drugs Traceability. International Journal of Dental and Medical

Sciences Research Volume 4, Issue 3, May-June 2022 pp 497-504 www.ijdmsrjournal.com SSN: 2582-6018 (UGC CARE, Scopus).

ARTICLES IN LINKEDIN AND KNOWLEDGE REPOSITORY

1. Ensuring Quality and Compliance - The Importance of Batch Manufacturing Records in Pharmaceutical Drug Manufacturing.
2. Strategies for Implementing a Track and Trace System in Pharmaceutical Tracking.
3. SAP Advanced Track and Trace for Pharmaceuticals - Serialization Tasks
4. Steps and guidelines check points for CFR Part 11 Compliance
5. The Drug Supply Chain Security Act
6. Essential Functions and Features Needed in SAP ATTP
7. What is Computer System Validation in Pharmaceuticals?
8. What is 21 CFR Part 11?
9. What are the requirements outlined in 21 CFR Part 11?
10. Questions to ask QA Department during the implementation of SAP ATTP for serialization in pharmaceuticals firms.
11. Questions to ask IT Department during the implementation of SAP ATTP for serialization in pharmaceuticals firms.
12. Implementing SAP Advanced Track and Trace for Pharmaceuticals,
13. Revolutionizing Pharmaceuticals and Life Sciences with AI and Machine Learning.
14. Pharmaceutical Manufacturing and Packaging with Machine Learning.
15. Navigating the Future - Emerging Trends in Pharmaceutical Regulatory Compliance.

KEY ACCOMPLISHMENTS

1. Accomplished project manager with a consistent record of accomplishment of successful project delivery and demonstrated leadership in steering 27 highly visible corporate projects to success.
2. Utilizes a results-driven approach to manage project delivery efficiently, implementing Agile Project Management methodologies to consistently meet sponsor objectives without compromising quality, schedule, or cost.
3. Effective at balancing technical expertise with strategic business goals, resulting in successful project outcomes.
4. Implemented barcode Serialization solutions for TraceLink SAP ATTP platforms for leading pharma firms with integration to multiple third-party line management services.
5. Maintains an impressive 100% success rate with zero project failures throughout my tenure as a Project Manager.
6. Spearheads Pre-Clinical Trials Study management, overseeing recruitment, regulatory reporting, and compliance with FDA, MHRA, TGA, and ANVISA.
7. Managed projects with a cumulative budget exceeding US$86 million since 2001.
8. Earned over 32 service awards and expressions of appreciation, with more continually adding to this tally.

PROFESSIONAL PROFILE

As an experienced Project Delivery expert, specialized in leading enterprise projects within the pharmaceutical and life science industry, addressing budget constraints and prior setbacks. The approach involves assembling dedicated teams, analyzing past failures, and establishing effective strategies to achieve project milestones without compromising quality.

Under this leadership, strict compliance with pharmaceutical manufacturing guidelines was ensured, an Audit Defense System for GAMP 5 compliance was developed, and collaboration with regulatory authorities such as FDA, ANVISA, DGFT, KFDA, TGA, BDA, CFDA, and EMA was initiated to combat counterfeit drug production.

Consultancy services were extended to assist over 28 pharmaceutical firms in meeting the requirements of the US DSCSA (Drug Supply Chain Security Act) regulation. These services were facilitated through close collaborations with prominent pharmaceutical industry leaders, including TEVA, TARO, Breckenridge, Alvogen, Rising Pharma, and Sun Pharmaceuticals, resulting in the delivery of customized solutions.

Technology Used: SAP SD, SAP PP, SAP ATTP, TraceLink, ASP.net, SQL Server 2016, XML, Web Services, Project Management Tools.

January 2014 to To-date **SolutionsMax Technology Services.** **Sacramento, CA**
Principal Project Consultant

In this role, I provided comprehensive support to SolutionsMax customers across various domains. This involved delivering technical services for SAP implementation, ensuring compliance with regulatory practices, and providing quality management services. Additionally, I actively contributed to project management service delivery, ensuring projects were executed within scope, schedule, and cost constraints. I worked on the Drug Serialization Project on the SAP ATTP platform and TraceLink Platform for regulatory agencies such as US FDA, MHRA, and TGA. I authored articles and conducted training on DSCSA Guidelines for the FDA, assisting numerous customer partner sites outside the USA with onboarding.

Responsibilities have encompassed the deployment of Quality Management Systems (QMS), which have been seamlessly integrated with Corrective and Preventive Actions (CAPA) and Customer Complaints Handling (CCF) processes. In addition to this, a pivotal role has been played in the architectural design of Pharma Ecosystem solutions, which are currently in the final stages of implementation.

During my tenure at SolutionsMax, the opportunity has arisen to serve esteemed life science and pharmaceutical companies, including but not limited to Merck, Natco, Rising Pharma, Breckenridge, Sun Pharma, TEVA, TARO, Alvogen, and various others. Implemented Serialization/Track & Trace specifically at these pharmaceutical firms.

The latest implementation occurred at Rising Pharma in Decatur, Ilinois, where I successfully developed the strategy SOP for a Serialization solution on ACG Package equipment utilizing SAP ATTP Serialization.

March, 2011 to August 2013 **Merck Sharp & Dohme Corp** **Whitehouse Station, NJ**
Solutions/Engagement Manager(Consultant)

Active involvement was maintained in the migration of legacy source systems employed during the pre-clinical trial phase of operations. This endeavor posed specific challenges, with a primary focus on the necessity for stringent adherence to Merck's Software Development Life Cycle (SDLC) and Good Laboratory Practice (GLPx) Compliance policies. Risks associated with the project encompassed the need to ensure continued access to and support for the legacy source data formats, in addition to compliance requirements pertaining to these systems.

To effectively address these challenges and mitigate associated risks, an agile project management methodology was introduced. This approach played a pivotal role in maintaining equilibrium among the critical triple constraints of Schedule, Cost, and Scope, ensuring that none of these essential factors were compromised throughout the migration process.

January, 2003 to December, 2008 GlaxoSmithKline Pl Philadelphia, PA
IT Infrastructure Manager/Project Manager

During my tenure at GSK, I held various roles within the Corporate Function and Legal e-Discovery Teams, where I played a pivotal role in supporting and managing diverse initiatives. Here are some of the key responsibilities and achievements I undertook:

Versatile Roles: I had the opportunity to take on multiple roles, including Business Analyst, Technical Analyst, IT Project Manager, and Data Warehouse Tech Lead, demonstrating adaptability and a wide range of skills.

IT Solution Delivery: Managed the IT Solution Delivery process for my business customers, collaborating closely with offshore vendor teams to ensure the timely delivery of solutions. Led the Technical Team at Legal IT Discovery, successfully executing Compliance projects utilizing tools like Cognos and Informatica ETL, while also automating manual processes through ASP.net web interfaces.

Stakeholder Engagement: Engaged in pre-negotiations with senior business stakeholders across various business entities, including Travel & Expenses, Promotion Management for Vendors/Employees, Grants Centrals (MEC), FEMA, Accounts Payables, and Professional Programs.

Central IT Initiatives: Provided leadership, analytical insights, and technical expertise to support the strategy, services, and solutions for Central IT Initiatives, contributing to the organization's overall IT goals.

Throughout my tenure at GSK, I consistently demonstrated my ability to adapt to various roles, effectively manage projects, and contribute to the improvement of IT processes and standards.

PRIOR EXPERIENCE

August, 2001 to January, 2003	IBM	White Plains, NY
July, 1997 to April, 2001	Ernst & Young LLP	Secaucus, New Jersey
December, 1996 to April, 1997	Indotronix International Corporation	Poughkeepsie, NY
October, 1995 to November, 1996	Housing & Development Board	Bukit Merah, Singapore

EDUCATION

- Master of Science in Computer Applications, College of Engineering, Trivandrum.
- Master of Technology in Software Systems; BITS Pilani

CERTIFICATIONS

- Six Sigma Greenbelt Certification Program, GlaxoSmithKline, USA
- Advanced Project Management Program, PMI UK
- Microsoft Certified Professional (on multiple domains).
- ITIL V3 Certified
- Lotus Notes Certified Professional.
- Integrated Quality Management System