SUPPLY CHAIN WIZARD SOLUTIONS

DIGITAL PROJECTS

CONFIDENTIAL

Any use of this material without written permission of Supply Chain Wizard, LLC is strictly prohibited!

supplychainwizard   SC_Wizard   supply-chain-wizard-llc   **supplychainwizard.com**

Supply Chain Wizard – Services & Solutions for Digital Supply Chain

SUPPLY CHAIN WIZARD CONSULTING

Management Consulting

TRACK & TRACE

DIGITAL TRANSFORMATION

DIGITAL COLLABORATION

IoT & BIG DATA

BLOCKCHAIN

Serialization (Track & Trace) Consulting

- Program Setup & Strategic Planning
- Project Management & Implementation / Integration
- ROI / Value Beyond Compliance & Sustainability

Supply Chain Consulting

- Supply Chain Strategy Design
- E2E Process Optimization
- Process Automation
- Advanced Analytics
- IoT & Big Data
- Blockchain & SC Security

Strategy | Execution | Transformation

SUPPLY CHAIN WIZARD SOLUTIONS

Software Solutions

DIGITAL PROJECTS
- SERIALIZATION
- PRODUCT LAUNCH
- TECH TRANSFER

DIGITAL SUPPLY CHAIN
- MANAGEMENT DASHBOARD
- SUPPLY CHAIN PORTAL

DIGITAL RETAIL
- LABOR TRACKER
- CUSTOMER TRACKER

TRACK & TRACE
- REGULATIONS DATABASE
- SERIALIZATION SURVEY
- SERIALIZATION WIZARD

DIGITAL FACTORY
- DIGITAL LOGBOOK
- OEE TRACKER
- LABOR TRACKER
- SCHEDULER

DIGITAL TRANSPORT
- SHIPMENT TRACKER

DIGITAL WAREHOUSE
- FORKLIFT TRACKER
- LABOR TRACKER

SUPPLY CHAIN WIZARD

supplychainwizard   SC_Wizard   supply-chain-wizard-llc   **supplychainwizard.com**

3

Digital Projects

Industry Challenge

Managing and executing multiple projects at various stages (i.e., **Project Portfolio Management**) is a vital need for the industry. Especially, new product launches and tech transfers require careful management of all project phases from planning and initiation to execution and closing, but lacking consolidated program level management with **disparate tools** and **people-dependent (instead of process-centric) approach**, makes it very challenging for effective management of resources and budgets, jeopardizing the timely accomplishment of project goals, risking the business outcomes.

What you get?

Cloud-based platform to: *i)* oversee a portfolio of projects and their stages , *ii)* establish structured communication with stakeholders to collaborate, track project status. All with **low cost & highly scalable** with no infrastructure to maintain.

Digital Projects provides **full visibility and control** on all projects / programs and proven digital PMO solutions.

How does it work?

Choose a predefined management template, such as '**Serialization**', '**Product Launch**' or '**Tech Transfer**', all crafted with Supply Chain Wizard's domain expertise and tailored for the Pharma Industry. You can also **customize your own template** & master data and bring multiple parties, e.g. CMOs together to collaboratively use the cloud based Digital Projects. Then, you can use dashboards and reports providing online visibility on the '**project**', '**budget**', '**timeline**' and '**resource**' statuses, assisting you to give the optimal management decisions.

Why you need it?

Achieve regulatory compliance through cross-functional, global collaboration on a single platform.
Launch products into market through a streamlines process.
Enable **repeatable**, **collaborative** & **cost-effective** product technology transfer capabilities.
Reduce your project risks, budget, resources, while maximizing the communication & collaboration.

Digital Projects 3D Transformation Journey

Project Management Office (PMO)

Impact to Business:

- All products
- All functions
- All master data
- Resource / SME avail.
- Part-time resources
- Business Decisions
- Investment Decisions

DATA

- **Activities:** What are the on-going activities across projects near and longer term

- **In-scope Assets:** High-speed line, low speed lines, sites, products & markets impacted

- **Resources:** Individuals involved in projects either full or part time

- **Budget:** Project budgets, CAPEX / OPEX, cost categories

DASHBOARD

- **Status Management:** Global status management of active projects / programs & reporting

- **Resource Visibility:** Deployment of part-time and dedicated resources

- **Collaboration Platform:** One-stop shop to visualize the multi-dimensional aspects of a project (e.g. products, sites, resources, external partners, risks, budget)

- **Project Trends:** Dashboards, Benchmarks, Trends, Insights, Patterns, Exceptions

DECISIONS

- **Launch Date:** Visibility toward status of launching products in markets, regulatory, art work, etc.

- **Resource Allocation:** Active monitoring of resources toward the multiple in-flight projects

- **Go-live Decisions:** Review of major elements and risks toward a go-live date based on sensor updates from equipment and software

- **Budget Allocation:** Project budgets, program budgets, project extensions, budget approvals

SUPPLY CHAIN WIZARD

Digital Projects SCW's Technology Transfer Process

Establishing a robust, repeatable & scalable technology transfer is critical to on-time/on-budget delivery

Gate 1 Product Source Change Approved	Gate 2 Team Assigned & Execution Mobilized	Gate 3 Supply Chain & Validation Batches	Gate 4 Filings Approved, Supply Planned	Gate 5 Technology Transfer Completed
1.1 Strategic Imperative	2.1 Sending/Receiving Site Team Selection	3.1 Technology & equipment transfer	4.1 Tech transfer activities continue	5.1 Summary report completed
1.2 Business Case	2.2 Definition of roles and operating model	3.2 Physical & Financial Flow	4.2 Regulatory entity feedback received	5.2 Source Recommendation Issued
1.3 Source/ Destination Decision	2.3 Primary change control and SOPs	3.3 Definition of logistics plan	4.3 At risk manufacturing decision	5.3 Lessons learned documented
1.4 Change Control Initiated	2.4 Timeline, status, Governance	3.4 Current registration and filing	4.4 Monitor inventory & supply for decisions	5.3 Change control closed
	2.5 Market and Regulatory kicked-off	3.5 Produce validation batches	4.5 Market-by-market approvals received	

← Executed over a 6 to 12 months period →

SCW built the Tech Transfer process to enable Pharma to plan, communicate, monitor and successfully execute the highly collaborative and multi-dimensional process

supplychainwizard SC_Wizard supply-chain-wizard-llc **supplychainwizard.com**

Digital Projects SCW's New Product Introduction Process

NPI solution offers a robust and structured methodology to meet regulatory requirements

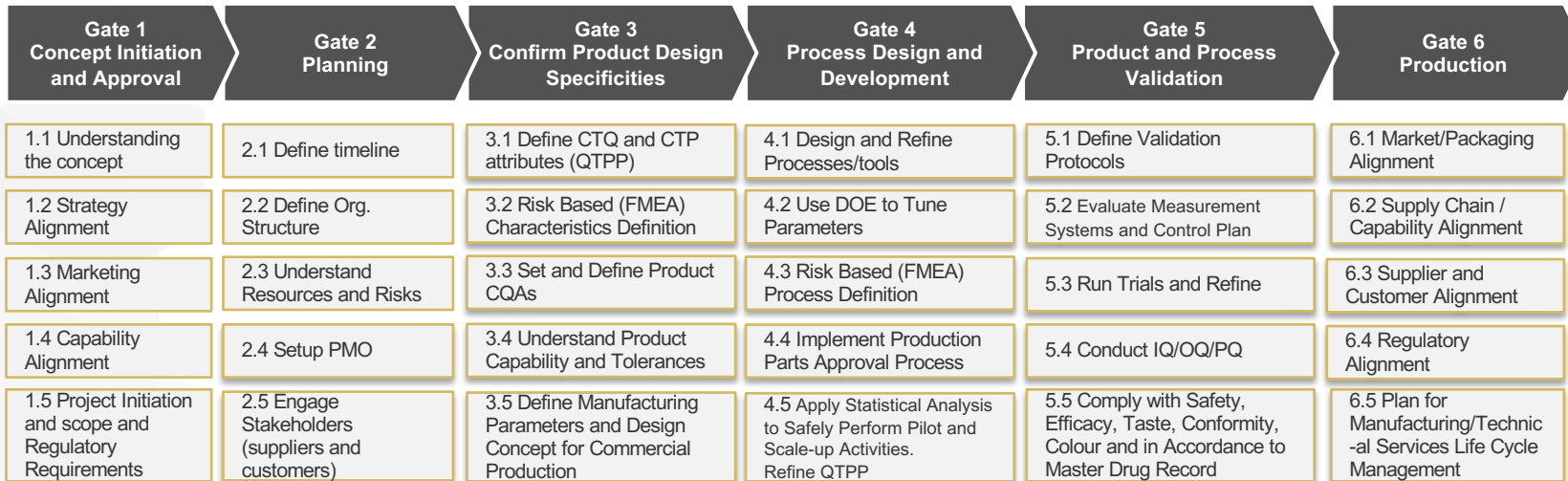| Gate 1 Concept Initiation and Approval	Gate 2 Planning	Gate 3 Confirm Product Design Specificities	Gate 4 Process Design and Development	Gate 5 Product and Process Validation	Gate 6 Production
1.1 Understanding the concept	2.1 Define timeline	3.1 Define CTQ and CTP attributes (QTPP)	4.1 Design and Refine Processes/tools	5.1 Define Validation Protocols	6.1 Market/Packaging Alignment
1.2 Strategy Alignment	2.2 Define Org. Structure	3.2 Risk Based (FMEA) Characteristics Definition	4.2 Use DOE to Tune Parameters	5.2 Evaluate Measurement Systems and Control Plan	6.2 Supply Chain / Capability Alignment
1.3 Marketing Alignment	2.3 Understand Resources and Risks	3.3 Set and Define Product CQAs	4.3 Risk Based (FMEA) Process Definition	5.3 Run Trials and Refine	6.3 Supplier and Customer Alignment
1.4 Capability Alignment	2.4 Setup PMO	3.4 Understand Product Capability and Tolerances	4.4 Implement Production Parts Approval Process	5.4 Conduct IQ/OQ/PQ	6.4 Regulatory Alignment
1.5 Project Initiation and scope and Regulatory Requirements	2.5 Engage Stakeholders (suppliers and customers)	3.5 Define Manufacturing Parameters and Design Concept for Commercial Production	4.5 Apply Statistical Analysis to Safely Perform Pilot and Scale-up Activities. Refine QTPP	5.5 Comply with Safety, Efficacy, Taste, Conformity, Colour and in Accordance to Master Drug Record	6.5 Plan for Manufacturing/Technic-al Services Life Cycle Management

NPI process offers a structured methodology in defining and establishing the steps necessary to assure product and processes satisfies customer requirement within a regulatory setting

supplychainwizard   SC_Wizard   supply-chain-wizard-llc   supplychainwizard.com

Digital Projects Before & After

Before Digital Projects

- Lack of project status visibility
- Decisions based on subjective information
- Limited Collaboration among project stakeholders
- Costly, Complex, Project Management

Suppliers

Project Managers

External Partners

After Digital Projects

- Global status management with high visibility
- Data-driven decision capability, e.g. Market status for strategic launch, resource allocation
- Collaboration platform for large number of suppliers & partners
- Highly scalable, cost effective Project Management

supplychainwizard   SC_Wizard   supply-chain-wizard-llc   **supplychainwizard.com**

Thank you

Questions
Comments

Supply Chain Wizard LLC

94 Autumn Lane, Skillman, NJ 08558, USA

[+1] 609 300 2017

Evren Ozkaya

Founder and CEO

Supply Chain Wizard, LLC

evren.ozkaya@supplychainwizard.com

SUPPLY CHAIN WIZARD