

Services Catalogue

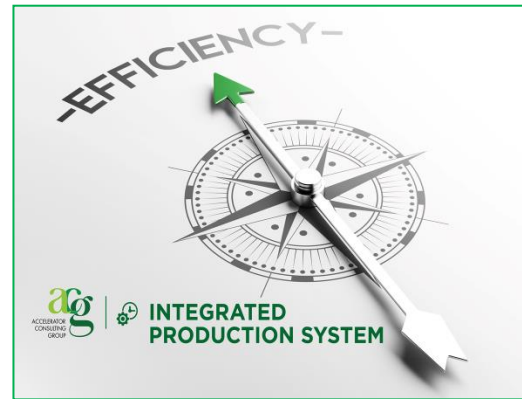


2022

“Ready to Implement” Programs



Overview





QUALITY EXCELLENCE PROGRAM

New processes

New Mindset

New Capabilities Development

New Performance



Quality Excellence Program (QEP) - Overview

- ✓ Based on a structured and systematic approach supported by accelerated change management principles, Quality Excellence Program aims to deliver a sustainable transformation of the quality management system performance, aligned with the business strategy and requirements.
- ✓ A focus on people capability, mindset and engagement will be applied along with the transformation of the QMS elements in order to ensure a robust handover and to reach a continuous improvement maturity.
- ✓ QEP has been designed by ACG based on several successful Quality Remediation and Improvement programs conducted by its Managing Directors and Partners, in MENA region and high regulated markets.
- ✓ QEP is based on the most recent international standards and fits for Global, Regional and Local Supply Companies.

Objectives

Quality Excellence Program aims to:

- Ensure cGMP basics & fundamentals in place and in use
- Ensure QMS compliance with targeted markets regulation and standards (e.g EU, US FDA cGMP, WHO guidelines, local standards, ...)
- Build quality culture, mindset and leadership
- Build related skills and competencies (Staff and SME capability)
- Build Robust Quality governance and performance management
- Build Systematic Audit & Inspection Readiness process
- Identify the required facility and equipment investments (Facility Master Plan)

Key steps for QSE* Review

Transformation Steps	Prepare	Diagnose	Design	Implement	Sustain
Key Activities	<ul style="list-style-type: none"> - Data Collection - Logistics and resources setup - Planning 	<ul style="list-style-type: none"> - Current state definition - Gap analysis vs targeted standards 	<ul style="list-style-type: none"> - Future State definition - Action plan and road map established 	<ul style="list-style-type: none"> - Action plan execution - Capability building 	<ul style="list-style-type: none"> - Post Implementation Review - Performance Monitoring
Key Deliverables	<ul style="list-style-type: none"> - Resources in place - Data collected and organized - Detailed plan 	<ul style="list-style-type: none"> - Diagnose report including gaps, root causes and key areas for improvement 	<ul style="list-style-type: none"> - New process map - Targeted staff identified (SME, users) - KPIs & governance 	<ul style="list-style-type: none"> - New process (SOP, Std Work, forms, ...) - Impacted staff trained - PM aligned 	<ul style="list-style-type: none"> - Sustainability reports - Process adjustments - Autonomous SME
Maturity Level	Ready for transformation	Gaps and root causes known and integrated	Organization aligned on future state Ready to change	In place	In use / Continuous improvement

QEP = Transformation

Transformation of:

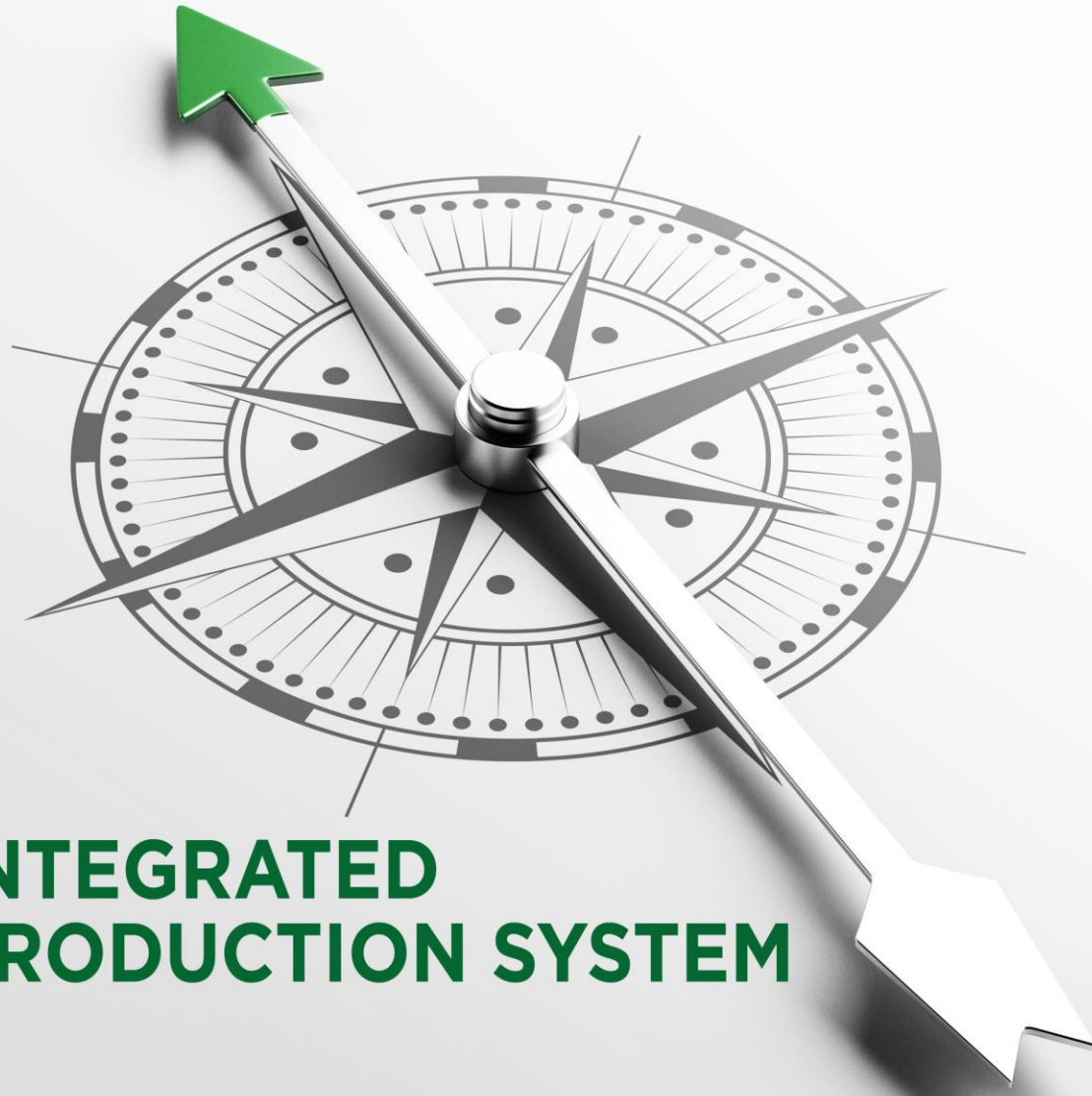
- ✓ Processes and way of working
- ✓ Capabilities, processes understanding and control
- ✓ Mindset and Culture

A structured and systematic Accelerated Change Management (ACM) process will be used in order to:

- ✓ Deliver the transformation within a constrained **timeline**
- ✓ Build **autonomous** and **engaged** staff and SMEs
- ✓ Ensure **sustainability** and **continuous improvement**

QEP will integrate by design the ACM principles and a formal Change Management training / Workshop will be done for leaders (Leadership team, middle management and First Line Leaders during the program)

-EFFICIENCY-



**INTEGRATED
PRODUCTION SYSTEM**

Definition

- ✓ The Integrated Production System (IPS) **IS**:
 - A standard way of working to develop and improve people capabilities, processes and overall business performance.
 - A continuous improvement mindset, and hence moving out from fire fighting status by solving continuously the top problems at all levels of the organization.

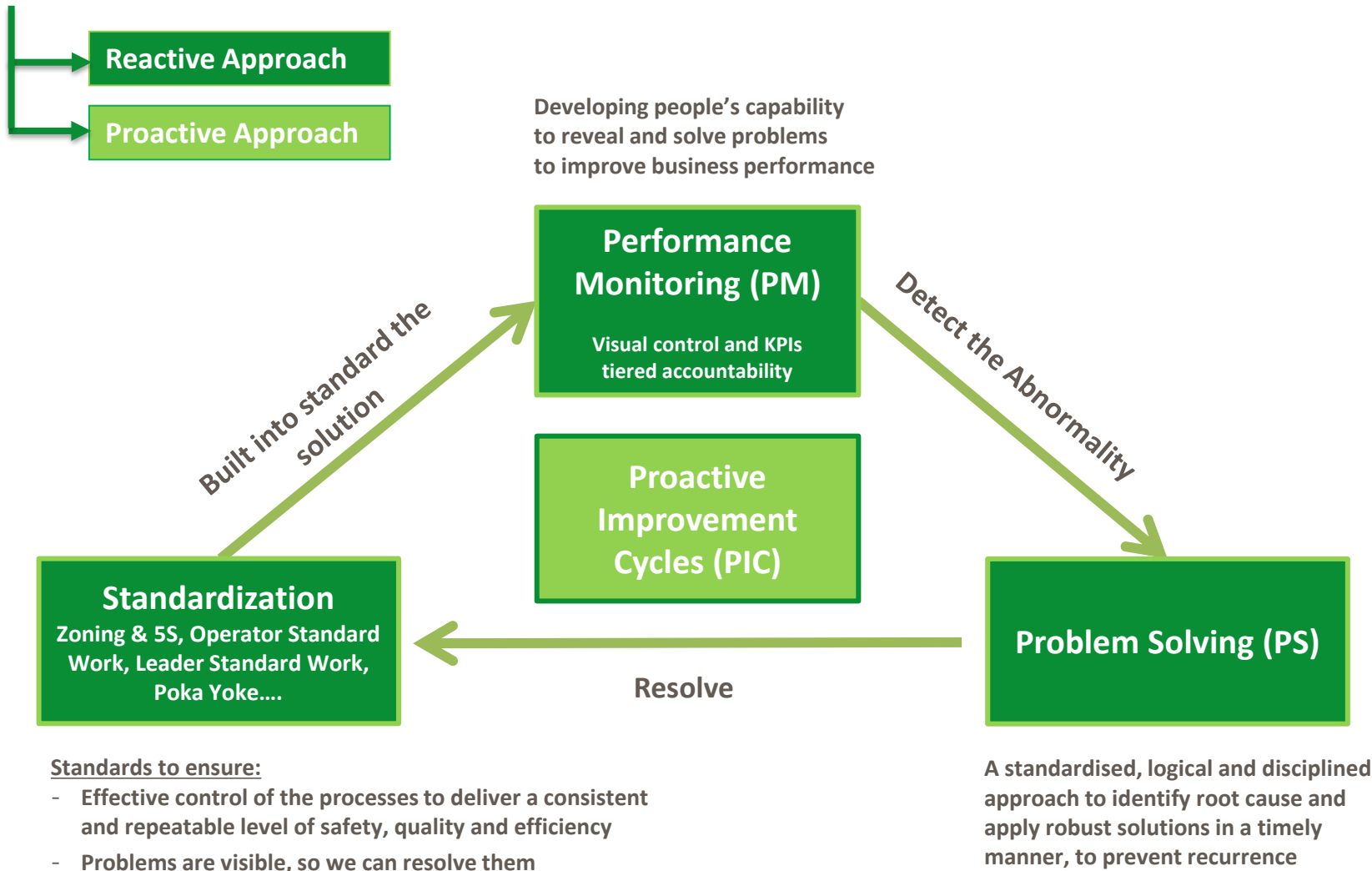
- ✓ The Integrated Production System **IS NOT**:
 - A Lean / 6 Sigma toolbox (IPS = System using Lean and 6 Sigma tools and principles)
 - A project (IPS = new and sustainable way of working)

Objectives

Improve the overall business performance by:

- ✓ Ensuring proper cascading of the company strategy to all levels of the organization and hence alignment on company objectives.
- ✓ Developing capable and engaged employees and leaders, able to reveal, identify and solve the business problems at the appropriate level.
- ✓ Providing a standardised, logical and disciplined approach for problem solving and applying robust solutions in a timely manner to prevent recurrence.
- ✓ Standardizing the processes and tasks to ensure delivery of consistent and sustainable level of performance, and to make problems visible.
- ✓ Monitoring and controlling visually the key performance indicators, trends and improvement actions delivery.

Integrated Production System Overview





Lab Excellence Overview

Lab Excellence is an optimization and standardization program focused on Quality Control operations combining quality improvement and operational excellence principles, aiming to improve the overall Lab quality, compliance, productivity and service performance.

The transformation will be supported by a structured and people oriented change management approach.

Lab Excellence is based on 8 pillars:

Lab organization & Layout	Lab staff capability & mindset	Analytical methods robustness	OOS / OOT / Lab Investigation processes	Testing reduction and simplification	Capacity management	Equipment obsolescence & replacement strategy	Performance management
Team roles	Lean capability	Trending	Problem solving	Sampling rationalization	Capacity modeling	DI compliance	Lead time
Layers & Span of Control	GLP capability	Methods capability analysis	Lab errors / human factors	Risk- based testing reduction	Demand management	Automation	Productivity
5S, layout, flow	Leaders capability	Methods standardization		Specifications optimization	Scheduling	Digitalization	Batch tracking

**OPERATING
LICENSE**

Regulations

**BUSINESS
CONTINUITY**

**CRITICAL /
MAJOR CAPA**

**MANAGING
TRANSITION**

BACKLOGS

REQUIREMENTS



SWAT Intervention - Overview

- ✓ The ACG SWAT Intervention helps companies and sites facing a high risk or a fire fighting situation requiring short terms external support to return to a standard situation and restore control.
- ✓ Example of situations might require SWAT Intervention:
 - Significant backlog in Quality System processes
 - Challenging Customer Audits or Regulatory Inspections requiring significant short terms improvements (CAPA) or step change.
 - Major or Critical product incident or recall
 - Sudden and significant change of regulatory or customer requirements.
 - Transition phase accompanied with high staff turnover (managing transition)

Objectives

- ✓ Ensure business continuity.
- ✓ Treat and resolve the quality systems backlog.
- ✓ Close the critical and major CAPA and respond to the short terms requirements of the audit or inspection body.
- ✓ Avoid regulatory or customer sanctions
- ✓ Maintain the operating license.



FLL DEVELOPMENT PROGRAM



Overview

First Line Leaders are a key component of an efficient organization where they are in charge of translating and executing the business strategy, objectives and changes at operational level, building the capability and engaging their teams while solving short terms operational problems.

The ACG FLL Development Program is designed to equip newly appointed and experienced First Line Leaders with the tools, techniques and mindset necessary to lead High Performing Teams.

The required Leadership and Business skills will be built through different learning and development approaches, including formal training, coaching and practice.

Objectives

This program enables First Line Leaders to:

- Understand their role and its importance
- Establish team goals aligned with the organization's Strategy
- Develop robust development plan for themselves and their teams
- Tailor Coaching strategies to the style preferences of their team members
- Motivate teams to achieve goals with maximum productivity
- Analyze team and individual performance to provide feedback & recognitions effectively
- Communicate effectively, improve the listening skills and develop the capability to conduct effectively a challenging conversation
- Delegate team responsibility appropriately
- Understand how to manage Conflict & Change effectively
- Develop the ability to influence others

Framework

Steps →	Pre Workshop	Workshop	Post Workshop
Key Activities	<ul style="list-style-type: none"> - Self and Team Assessment (Surveys) - Collect Feedback & Expectations from line managers and HRBP - Homework (articles, books, videos, ...) 	<ul style="list-style-type: none"> - Formal training sessions covering Leadership and Business Skills - Learning, Team building and Engagement activities (Games, Simulations, breakout sessions, ...) 	<ul style="list-style-type: none"> - Workshop feedback (Survey) - Group Coaching and follow up on reflection of the formal training on day to day business. - Periodic Refreshers - Individual Coaching*
Key Objectives	<ul style="list-style-type: none"> - Get ready for an efficient workshop - Self and Team Awareness 	<ul style="list-style-type: none"> - Learning & Development - Team Building & Engagement 	<ul style="list-style-type: none"> - Program improvement - Build bases for Sustainability & Continuous Development - Autonomous FLL, using workshop learning in day to day business
Duration	1 month	4 days	3 months

*: not included in the FLL Development Program.

Leadership & Business Skills covered during the program

Type of Learning	Topics Covered*
Formal Training Sessions	<ul style="list-style-type: none">- Leadership Fundamentals (including: Setting Goals, Influencing others, Delegation, Managing Conflicts, ...)- Motivating and Engaging employees- How to build a Robust Development Plan (for me and my team)- Feedback & Coaching- Communication (Engaging & Efficient Conversation)- Personal & Team Resilience (Managing the Energy)- Finance for Non Finance Leaders- Accelerated Change Management- Problem Solving
Games, Simulations and Other Activities	<ul style="list-style-type: none">- Leadership- Team work / HPT (High Performing Team)- Team Engagement- Communication- Feedback & Coaching- Personal Resilience

*: could be customized based on organization needs and priorities

Post FLL Program Services

Following the FLL Development Program, some key talents within the organization might require additional personalized support in order to complete and accelerate their development.

The below services are also proposed for Middle Managers and Senior Leaders.

- 1) **On-boarding support (90 days plan)** for internally promoted talents or newly hired leaders, including 90 days plan generation, monitoring and coaching sessions. End of On-Boarding period report will be provided to line manager and HRBP.
- 2) Individual talent **Coaching Program**, including 360° Survey report, Development Plan generation and monitoring, periodic Coaching sessions, personalized teach points, feedback to line manager and HRBP.

Training & Consultancy



GMP Fundamentals & Quality Systems

Learning & Development

Area	Training Modules
GxP	Introduction to Good Manufacturing Practices
	Introduction to Good Laboratory Practices
	Introduction to Good Distribution Practices
	Periodic GMP Refresh Training Sessions and Workshops
Quality Systems	ICH Q10 Quality Systems
	Deviation & Investigation Management
	Out Of Specification (OOS) and Out Of Trend (OOT) results Management
	CAPA Management
	Change Control
	Internal Audit & Self Inspection
	Risk Management
	Complaints Management
	Periodic Product Review
	Batch Release
	Major Products Incident & Recall
	Quality Management Review
	Quality Systems Full Package Training / On Demand Modules design and execution
Contamination Control	Penicillin / Cephalosporin Contamination Control, highly Potent materials handling and control (Cytotoxic, ...)

Consultancy & Support

Scope	Service category	Key deliverables
GMP & Quality Management Systems	Diagnose	Diagnose report including: Compliance status, Gaps and root causes, improvement recommendations
	Design & Implementation	Documentation architecture (Quality Manual SOP, forms, ...), system management (SME, governance, KPIs, ...), Staff Training
	Inspection & Audit Readiness	Assistance in audit preparation & management, including: Documentation review and preparation, Mock audit and simulation, Fronters (auditees) Training & Coaching
	Auditing	Audit plan, Audit report of Third Parties or Suppliers, Support in CAPA definition and follow up

Sterility Assurance

Learning & Development

Area	Training Modules
Sterility Assurance	Basics of Sterile Operations and Sterility Assurance
	Basics of Microbiology (Microorganisms)
	Contamination Control
	Disinfection agents, methods and Qualification
	Aseptic Simulation (Media Fill Test)
	HVAC & Utilities
	Water Systems
	Sterilization methods and validation
	Environmental Monitoring Program
	Sterility Testing
	Endotoxin testing and Bioburden
	Sterility Assurance Full Package Training
	Audit Checklist for Sterile or Aseptic Operations and Facilities

Consultancy & Support

Scope	Service category	Key deliverables
Sterility Assurance Processes	Diagnose	Diagnose report including: Compliance status, Gaps and root causes, improvement recommendations (CAPA)
	Design & Implementation	Documentation architecture (SOP, forms, ...), system management (SME, governance, KPIs, ...), Staff Training
	Inspection & Audit Readiness	Assistance in audit preparation & management, including: Documentation review and preparation, Mock audit and simulation, Fronters (auditees) Training & Coaching
	Auditing	Audit plan, Audit report of Third Parties or Suppliers, Support in CAPA definition and follow up
Media Fill Test	Execution	Risk Assessment, Protocols & Reports for Initial (New project) & Periodic Aseptic Qualifications
Microbiology Lab	Testing Methods Standardization	<p>Bioburden, Endotoxin, Sterility testing, Growth promotion test, Media preparation,</p> <ul style="list-style-type: none"> - Development of methods. - Validation of methods. - Analysts Qualification.
Aseptic & Sterile PMO	PMO – Project Management	<p>Production equipment and lines / Microbiology lab equipment</p> <p>Design & Planning (URS, FMEA, suppliers selection, design qualification, ...)</p> <p>Execution & follow up (FAT / SAT / IQ / OQ / PQ including initial Media Fill Test, etc)</p>

Audit & Inspection Readiness

Learning & Development

Area	Training Modules
Auditing	Auditing
	Certified Quality Auditor
Audit Readiness	Audit & Inspection Preparation
	Audit & Inspection Management
	Post Audit & Inspection activities

Consultancy & Support

Scope	Service category	Key deliverables
Audit & Regulatory Inspection	Inspection & Audit Readiness	Inspection & Audit Readiness Process (SOP), Staff Training, Assistance in audit preparation, including: Documentation review and preparation, Mock audit and simulation, Fronters (auditees) Training & Coaching
	Audit Management	Audit Logistics and Organization, Control room Management
Auditing	Third party or supplier Audit execution	Audit plan, Audit report of Third Parties or Suppliers, Support in CAPA definition and follow up.

Validation Life Cycle, CSV & Data Integrity

Learning & Development

Area	Training Modules
CSV	CSV - Process overview
	CSV - Governance
	CSV - Automation
	CSV - Analytical systems
	CSV - Information Systems (SAP, BPCS, LIMS, ...)
	CSV - Spreadsheets
	CSV - Run & Operate
	CSV - Audit (Audit Checklist, Audit Readiness)
	CSV Full Training Package
Validation Life Cycle	Validation Life Cycle - System overview
	Validation Planning (URS, Risk Assessment, VMP, VP, supplier assessment)
	Design Qualification (DQ)
	FAT & SAT
	Qualification (IQ, OQ)
	PQ & Process Validation
	Cleaning Validation
	Maintain the validated status (Validation Review, Change Control)
	Legacy Systems
	Decommissioning & Data Migration
	Validation Life Cycle Full Training Package
Data Integrity	DI - Electronic Systems: Data Integrity Assessment
	DI - Electronic Systems: Data Analytics
	DI - Electronic Systems: Audit Trail Review Frequency
	DI - Electronic Systems: Access Management & Conflict of Interest
	DI - Paper based Systems: ALCOA principles
	DI - Paper based Systems: Documentation Design
	DI - Paper based Systems: Good Documentation Practices
	Data Integrity – Full Training Package

Consultancy & Support

Scope	Service category	Key deliverables
Validation Life Cycle Processes & systems	Diagnose	Diagnose report including: Compliance status, Gaps and root causes, improvement recommendations (CAPA)
	Design & Implementation	Documentation architecture (SOP, forms, ...), system management (SME, governance, KPIs, ...), Staff Training
	Inspection & Audit Readiness	Assistance in audit preparation & management, including: Documentation review and preparation, Mock audit and simulation, Fronters (auditees) Training & Coaching
	Auditing	Audit plan, Audit report of Third Parties or Suppliers, Support in CAPA definition and follow up
Validation & Qualification	Execution	Validation Plans, Risk Assessment, Protocols & Reports for Initial (New project) & Periodic Qualifications (Production and Laboratory Equipments, HVAC, Water Systems , Classified Areas, ...
Cleaning Validation	Execution	Validation Plans, Risk Assessment, Protocols & Report for Initial Cleaning Validation and Periodic Cleaning Verification and Monitoring
Data Integrity, Electronic Systems & documentation	Diagnose	Diagnose report, including: Electronic systems assessment, Documentation assessment, Compliance status, Gaps and root causes, Improvement recommendations (CAPA)
	Design & Implementation	DI Control Process, Process Management (SME, governance, KPIs, ...), Staff Training
	Inspection & Audit Readiness	Assistance in audit preparation & management, including: Documentation review and preparation, Mock audit and simulation, Fronters (auditees) Training & Coaching
	Auditing	Audit plan, Audit report of Third Parties or Suppliers, Support in CAPA definition and follow up

Product Life Cycle, Product & Process Robustness

Learning & Development

Area	Training Modules
Product Life Cycle	Introduction to Product Life Cycle Management
Product & Process Robustness	Technical Risk Assessment (TRA)
	Product Transfer
	Analytical Method Transfer
	Material Risk Assessment (MRA) for Material qualification (API, Excipients, Primary Packaging Materials).

Consultancy & Support

Scope	Service category	Key deliverables
Product, Process, Technology Transfer	Technical Risk Assessment	TRA report including: risks definition, classification and mitigation. Process and Product critical parameters definition, transfer and validation strategy
	Product transfer execution	Project delivery
	Analytical Method Transfer execution	Assistance in audit preparation & management, including: Documentation review and preparation, Mock audit and simulation, Fronters (auditees) Training & Coaching
Troubleshooting & Process Robustness	Technical Problem Solving	Root cause analysis, DOE (Design of Experiment).
	Product Optimization	Optimized product and/or process

Operations Management :

- ✓ Lean & Operational Excellence
- ✓ Integrated Production System
- ✓ Supply Chain Management

Learning & Development

Area	Training Modules
Integrated Production System	IPS – System Overview
	IPS – Performance Management
	IPS – Problem Solving
	IPS – Standardization
	IPS – Continuous Improvement Cycles
Production Performance and Capacity Utilization	Capacity Utilization & Management
	Overall Equipment Effectiveness (OEE)
	Change Over Optimization (SMED)
Flow Management	Value Stream Mapping (VSM)
Lean & Six Sigma Toolkit	L&SST – Types of Waste
	L&SST – Process Observation (4M)
	L&SST – Process Mapping
	L&SST – Time Value Mapping
	L&SST – Value Stream Mapping
	L&SST – Spaghetti Charts
	L&SST – 7 cycles analysis
	L&SST – Pareto
	L&SST – FMEA
	L&SST – Layout Improvements
	L&SST – Kanban
	L&SST – SMED
	L&SST – Poke Yoke
	Lean & Six Sigma Toolkit Full Training Package

Learning & Development

Area	Training Modules
Integrated Supply Chain Management	ISCM – Integrated Supply Chain Overview
	ISCM – Effective Sales & Operations Planning (S&OP)
	ISCM – Effective Forecasting and Demand Management
	ISCM – Effective Supply Planning including (RCCP)
	ISCM – Effective Production Scheduling
	ISCM – Effective Material Scheduling
	ISCM – Inventory Management

Consultancy & Support

Scope	Service category	Key deliverables	
Integrated Production System (Reactive & Proactive)	Execution of reactive or proactive IPS	Integrated Production System in place including: Translation of the Strategy Deployment into Plant/Site Objectives cascaded top down through performance management, problem solving for top problems, standardization of the solutions and continuous improvement cycles and staff training.	
Productivity	Man	Diagnose & Analyze	Diagnose report including : Headcount mapping as an outcome of the process observation of the current state, gap analysis vs ideal state / benchmark and root causes, improvement recommendations.
		Design, Execution & benefits measurement	Prioritized improvement plan execution based on the expected benefits, Process Standardization Process Management (SME, governance, KPIs, ...), Staff Training.
		Data Gathering	YoY Machine Performance & availability for the past 3 years, & 1 year historical detailed data, process observation and operators and staff interviews.
	Machine	Diagnose & Analyze	Diagnose report including: Machine Efficiency Status and waste matrix, Gaps and root causes, improvement recommendations.
		Design, Execution & benefits measurement	OEE, SMED, Process Standardization, Process Management (SME, governance, KPIs, ...), Staff Training.
		Data Gathering	YoY Performance for the past 3 years, 1 year historical detailed data, process observation and operators and staff interviews.
	Material (Yield, Material Usage & Write off)	Diagnose & Analyze	Diagnose report including: Material Efficiency Status and waste matrix, Gaps and root causes, improvement recommendations.
		Design, Execution & benefits measurement	Prioritized improvement plan execution based on the expected benefits, Process Standardization, Process Management (SME, governance, KPIs, ...), Staff Training.

Consultancy & Support

Scope	Service category	Key deliverables
Capacity Management Process	Execution	Capacity Model.
Process Management / Optimization	Diagnose & Analyze	Diagnose report including: current E2E process flow, Gaps and root causes, improvement recommendations.
	Design, Execution & benefits measurement	Batch Tracker/ VSM, Process Standardization, process Management (SME, governance, KPIs, ...), Staff Training.
Inventory Management	Data Gathering	YoY Performance for the past 3 years, 1 year historical detailed data, process observation and staff interviews.
	Diagnose & Analyze	Diagnose report including: Current Stock Analysis, gaps and root causes, improvement recommendations including needed stocks clean up.
	Design, Execution & benefits measurement	Process Standardization, Process Management (SME, governance, KPIs, ...), Staff Training
COGs & Profitability Improvement	Data Gathering	Profitability per SKU, Cost Structure, Material Spend, 3-5 years BIS, PPV, Yield, Material Usage, OPEX trending & data.
	Diagnose, Analyze & Benchmark	Diagnose report including: D2D process mapping, Profitability analysis & status, Cost Structure, TOP material spend, YoY PPV Performance, YoY Yield Performance, YoY Material Usage Performance, YoY BIS, benchmark vs competitors, improvement recommendations.
	Design, Execution & benefits measurement	Execution of prioritized action plan, Process Management (SME, governance, KPIs, ...), Staff Training

Consultancy & Support

Scope	Service category	Key deliverables
Integrated Supply Chain Management	Diagnose & Analyze	Diagnose report including: Supply Chain maturity status, Gaps and root causes, improvement recommendations.
	Design, Execution & benefits measurement	Effective S&OP, Effective Forecasting & Demand Management, Effective Supply Planning & Scheduling, Inventory Management including Process Standardization, Process Management (SME, governance, KPIs,.....), Staff Training.

Medical Devices

Learning & Development

Area	Training Modules
Medical Devices	Medical Devices – Introduction to EU Medical Device Regulation 245/747
	Medical Device Vigilance System in US, EU and other regions
	Post Market Surveillance – Requirements and Process

Consultancy & Support

Scope	Service category	Key Deliverables
Medical Devices	QMS Implementation (ISO, MDSAP)	GAP Analysis – Procedure review / Creation – Internal training
	Complaint Handling Unit and Vigilance Systems	Build up of a functional CHU dedicates to all class of medical devices - Process of incoming complaints – registration – reportability assessment – follow-up with complainant – Submission of vigilance reports
	Post Marketing Surveillance	Implementation of a methodic operational process – PMS plan and PMS report (PSUR)
	Act as Authorized representative	Represent medical device manufacturer nearby EU Regulatory Authorities – Ensuring compliance of the device
	Act person responsible for regulatory compliance	Act as the person responsible for regulatory compliance according to EU requirements

People

Learning & Development

Area	Training Modules
Business and Leadership Skills	Development Plan
	Performance Management
	Talent Management
	Change Management
	Effective & Engaging Communication
	Effective Coaching
	Project Management
	Finance For Non-Finance Leaders
	First Line Leader Development Program – Leadership L1
	Leading for Success Program – Leadership L2
	Professional Trainer
	Presentation Skills
	Business Writing Skills
	Negotiation skills

Consultancy & Support

Scope	Service category	Key Deliverables
People's Functions outsourcing	Hiring & Selection Execution	Searching and Selection of candidates on behalf of the customer
	Performance Management	Process (SOPs, forms,...), Training & Governance Implementation
	Talent Management & Retention	Process & Governance Implementation, Talents Mapping,
	HR Policies & Documentation	Policies, Process and SOPs (Benchmark, implementation, audit,)
	Training Management	Management of Training System including SOP, maintenance of training records, audit preparation, Period review, etc.
Benchmark	Salary Survey	Sectorial benchmark, standard template, reports, etc
On-boarding	On-boarding process (90 DAYS PLAN)	90 days plan preparation and follow up
Organizational Design	Diagnose	Diagnose report, key gaps and root causes, improvement recommendations
	Design & Implementation	Design of the future organization based on organizational standard (Layers & Span of Control) and support the implementation in terms of change management
Employees Engagement & Team Building	People Engagement	Employees Satisfaction / Engagement Survey (Design and Execution) Employees Engagement Plan
	Personal & Team Resilience program	Process, Training & Governance Implementation
	Leadership Teams building and events	Events design, preparation and execution.

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