Digital Transformation Roadmaps to achieve Operational Excellence and Compliance to Regulations

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LifeBee
DIGITALIZING LIFE SCIENCES
A ProductLifeGroup Company

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She works in LifeBee as Partner and Labs & Consulting Director, with a wide experience of more than 10 projects and studies on an international basis.

Vice President of ISPE Italy Affiliate Board of Director.

Co-Author of the recently published ISPE Pharma 4.0™ Baseline Guide.

AGENDA

- ❑ Digital Trasformation in Pharma
- ❑ Digital to support Regulations
- ❑ «Annex 1 and Quality Metrics» Use Case
  - Scenario
  - Requirements
  - Digital Roadmap Design
  - Benefits and Risks

4.0 or … 5.0 or Digital Transformation in Pharma: the WHY*

WHY

- providing the **right information** at the **right time** and in the **right place**
- **supporting decisions**, increasingly in a **predictive** manner
- not only for **Managers**, but also for **Operators**, **Regulatory Agencies** on to … **Patients**
- consistency in **full compliance**
- to **timely** deliver **innovative**, **quality**, **effective** and **safe drugs** at **fair costs**
- in a **sustainable environment**

The WHY of the WHY

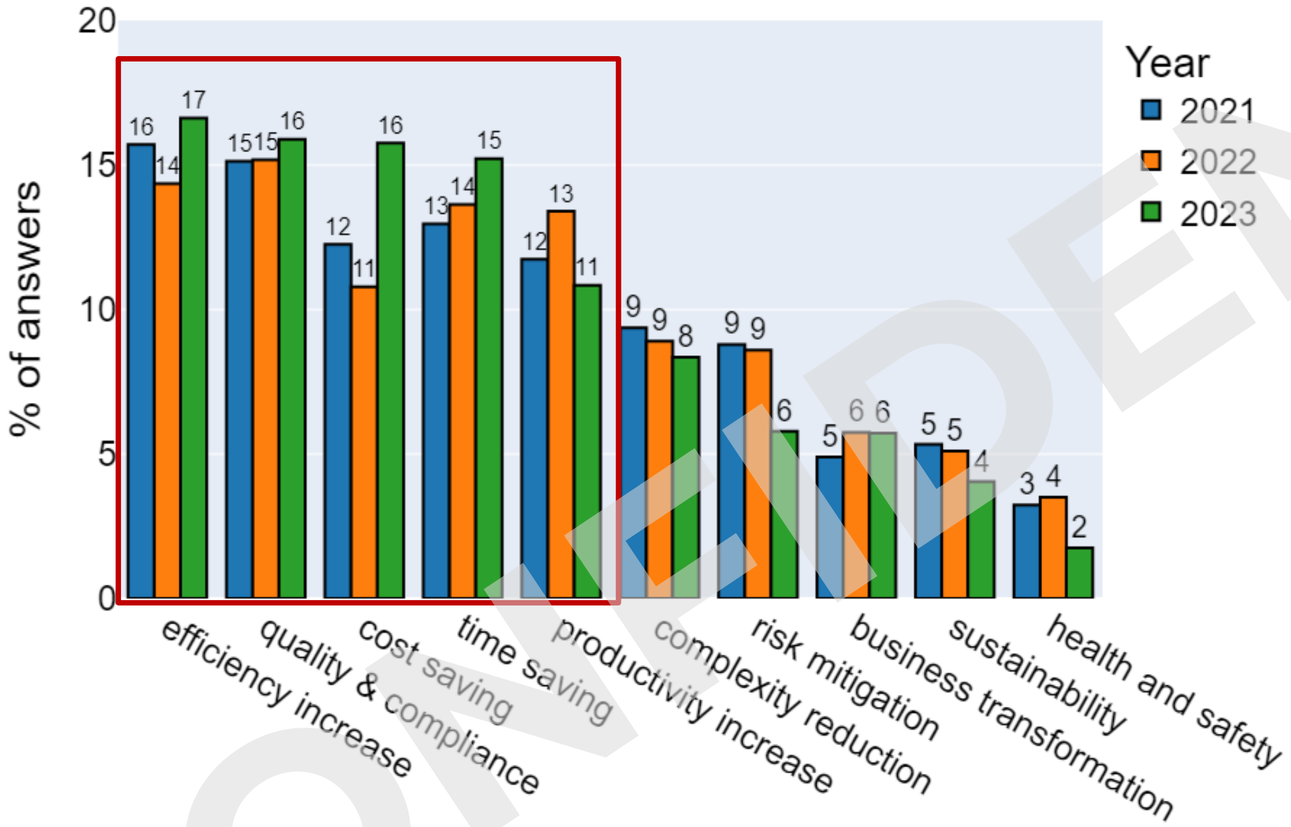
* *One of the many definitions …*

Qualità nel Life Science
QUALI I TREND?

I trend in ambito di qualità nel pharma sono guidati dalla **necessità di garantire la sicurezza, l'efficacia e la conformità normativa** del prodotto finale.

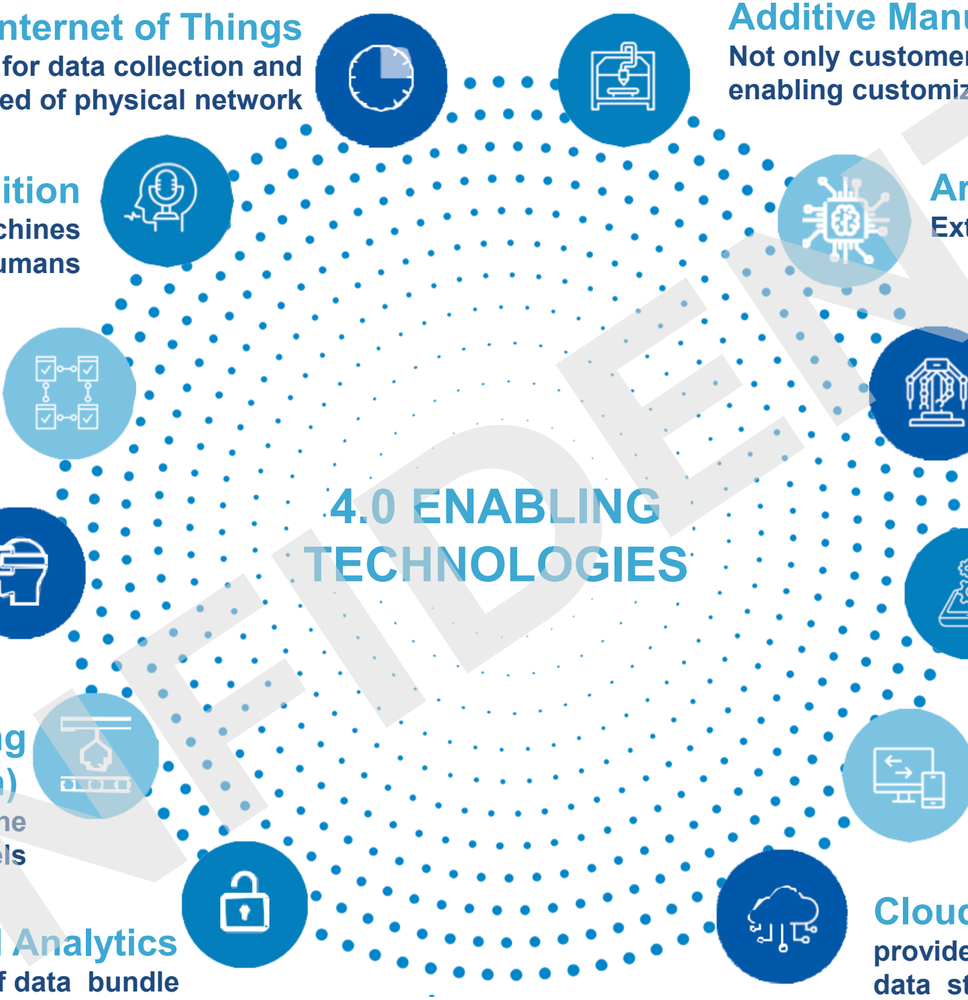
- **Approccio alla qualità basato sui pazienti**
- **Approccio Risk Based**
- **Approccio basato sui dati**
- **Tecnologie innovative**
- **Tracciabilità e autenticazione**
- **Sostenibilità**

4.1 Economic benefits are the main drivers, but quality & compliance among top 3.



- **Quality & Compliance remains among top 3** along with economic benefits
- More or less static across the last 3 years
- Increased awareness of **cost saving**

Enabling technologies are key tools for Digital Transformation …



Internet of Things
connect devices & sensors for data collection and control without the need of physical network

Additive Manufacturing
Not only customer spare parts but also enabling customized drug production

Speech & Sign Recognition
allow a better interaction between machines and multi-cultural humans

Artificial Intelligence & Machine Learning
Extend the human reach, allowing machines to learn and decide

Blockchain
provide the much-needed trust, security and auditability for data exchange

Advanced Robotics
Introduce robots with superior perception, integrability, agility and mobility

Augmented & Virtual Reality
improve workforce efficiency & efficacy and reduce training efforts

Wearable & Smart Devices
Enable objects to exchange data over the internet with a manufacturer, operator, and/or other connected devices, without requiring human intervention

Advanced Modelling (Digital Twin)
foster predictive data-driven decisions with the creation of living simulation models

Collaboration Platforms
enable the modern workplace supporting virtual meetings and knowledge sharing

Big Data & Advanced Analytics
unlock the potential of data bundle to support - also - 'GxP critical decisions

Cloud
provide virtually unlimited power and data storage in a pay-per-use approach

But … key is Information, not tech!

Digital Transformation in Pharma

Life Sciences companies require to be driven by a **foresighted, pragmatic and flexible roadmap**:

- ✓ Step by step, yet visionary
- ✓ Prioritized on real needs, risks and current & upcoming compliances
- ✓ Sustainable: in term of financial, resources and green
- ✓ Fostering proven best practices
- ✓ Enabling the cultural change

NOTE that there is:

- ✓ more than one peak to be reached
- ✓ more than one path to reach your own peak

LATEST AND UPCOMING REGULATIONS SUPPORTED BY DIGITAL TRANSFORMATION

Regulations supported by Digital

Patients and Authorities require continuous Pharma improvement

LATEST OR UPCOMING GLOBAL REGULATIONS

PHARMA REGULATORY REQUIREMENTS

- **Annex 1 – for sterile products**
- **Knowledge improvement and Quality Risk Management – ICH Q9 (R1)**
- **Product Lifecycle - ICH Q12**
- **Continuous manufacturing - ICHQ13**
- **Analytical Procedure Lifecycle - ICH Q14 / Step 2**
- **Continuous Process Verification**
- **Supply Chain Management - GDP**
- **Serialization & Track and Trace Regulations**
  Compliances In place: EU FMD, UAE, Saudi Arabia, China, Korea, US;
  DSCSA, Russia, Uzbekistan, Bahrain Upcoming Compliances: Italy (as EU FMD); Russia (BAFS);
  Indonesia; Kazakistan and more to come
- **Quality Metrics Monitoring & Quality Maturity**
- **Drug Shortages prevention**
- **ePI – electronic Product Information**
- **IDMP – Identification of Medical Products**

Pharma Industry can only comply with Digital in PHARMA !!!

DIGITAL to support REGULATIONS *A few examples 1/4*

PHARMA REGULATORY REQUIREMENTS	"HOW TO" WITH 4.0 IN PHARMA
Annex 1 **7.3** This training should include (…) the specific focus on cleanroom practices, contamination control, aseptic techniques and the protection of sterile products	***Virtual Reality based solutions can effectively and experientially support training sessions, without interfering with processes and facilities, including full tracing and control.***
Annex 1 **2.1** special requirement to minimize risks of microbial, particulate and endotoxin/pyrogen contamination	***The use of appropriate technologies (e.g. RABS, Isolators, Robotics) and Digital Solutions (CMMS, MES, EMS Environmental Management System) allowing an increase in product protection.***
Annex 1– point 8.123 coming into operation: 25 August 2024 Eliminate direct human critical intervention…(lyophilizer loading) UPCOMIG Aug 2024	***Robotics and processes automation can reduce direct human critical interventions (e.g. automatic lyophilizer loading, MES, EMS).***
Continuous manufacturing **ICHQ13** Continuous manufacturing of drug substances and drug products to increase in efficiency, flexibility and safety NEW ADOPTION Jul 2023	***The use of Digital Solutions (like IIoT, MES, AIL) enables in-line/online PAT capabilities and continuous monitoring in support of a real time release testing strategy.***
ANALYTICAL PROCEDURE LIFECYCLE **ICHQ14** Analytical procedure development UPCOMIG Jun 2024	***The use of Laboratory Information Management System ensures immediate availability of data (including historical data) and enables the conduct of correlation studies between variables promoting the adoption of QbD principles to improve the quality and efficiency of analytical procedures and simplify post-approval changes.***

Note: This content was created by LifeBee professionals for use during a specific workshop on March 2023 and following updates, it does not have the intent to be exhaustive

DIGITAL to support REGULATIONS *A few examples 2/4*

PHARMA REGULATORY REQUIREMENTS

Product Lifecycle
ICH Q12 Technical and regulatory considerations for pharmaceutical product lifecycle management

US in force, EU upcoming soon?

Knowledge improvement and Quality Risk Management
ICHQ9 (R1) Quality Risk Management

NEW ADOPTION Jan 2023

Continuous Process Verification
Cap 1 Part I Volume 4 - Good Manufacturing Practice (GMP)
ICH Q10 Pharmaceutical Quality System
Annex 15 EU-GMP
World Health Organization (WHO) - Supplementary guidelines on Good Manufacturing Practices: validation, appendix 7
FDA Guidance Process Validation: General Principles and Practices (January 2011)
EMA Guideline on Real Time Release Testing (formerly Guideline on Parametric Release)
Annex 17 EU GMP
21 CFR 11, 211.68, 211.110, 211.165, 211.180
ICH Q8(R2) Pharmaceutical Development
ICH Q11 Development and Manufacture of Drug Substances

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"HOW TO" WITH 4.0 IN PHARMA

Digital Solutions like MES , AIL & LIMS through the availability of process data and analytical results ensures the suitability of knowledge required for the definition of established conditions and the simplification of post-approval changes.

Digital Solutions for acquiring, analysing, storing and disseminating scientific information are essential for generating knowledge, which in turn informs all quality risk management activities.

IIoT, Automation and Automation Integration Layer to collect and store data from the field to effectively keep production processes under control.

Interfacing production and quality control processes via digital solutions allows the correlation between process data and control data, a must for real time release.

Laboratory Information Management System (LIMS) to collect, connect, and identify analytical trends and support the creation of the PQR (Product Quality Review).

DIGITAL to support REGULATIONS *A few examples 3/4*

PHARMA REGULATORY REQUIREMENTS

Supply Chain Management - GDP

Guidelines on Good Distribution Practice of medicinal products for human use (2013/C 343/01)
AIDE - Memoire inspection of GDP for medicinal products in the Supply Chain (PI 044-1)
Questions & Answers regarding the PIC/S GDP Guide (PE 011-1)

NEW !!! Feb 2023

Quality Metrics Monitoring & Quality Maturity

ICH guideline Q10 on pharmaceutical quality system
FDA - Submission of Quality Metrics Guidance (November 2016)
FDA Notices 2023-N-5706 Voluntary Quality Management Maturity Prototype Assessment Protocol Evaluation Program

Distant Assessment

EMA Q&A on regulatory expectations for medicinal products for human use during the Covid-19 Pandemic
WHO Technical Report Series, No. 1010, Annex 9, 2018
PIC-PI_048_1_Guidance_on_GMP_Inspection_Reliance
EFPIA Alternative GMP/GDP Inspection Practices in a pandemic Situation (COVID-19) and Beyond

ePI – electronic Product Information

EMA-MHA-EC electronic Product Information for human medicines in the EU - 2022

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"HOW TO" WITH 4.0 IN PHARMA

Digital solutions enable wholesalers to ensure adequate control of storage operations, location and environment conditions (ERP, WMS, EMS) and support them in maintaining adequate control over their Quality System (QMS).

Digital solutions support quality assurance processes (like Changes, Deviations, CAPA) allowing the company to monitor key quality system performance indicators, for the benefit of the Industry and the Authorities. This could enable solid risk-based inspection plans.

Digital solutions to transparently share and communicate among all the actors involved in remote assessments and inspections, with adequate robustness and compliance.

Digital solutions ensure a secure, traceable, and continuous transfer of information regarding pharma products to Health Care Professionals, Customers and Patients. Going ahead with the paper Product Information leaflet, but avoiding the risk of a decrease in security and control.

DIGITAL to support REGULATIONS *A few examples 4/4*

PHARMA REGULATORY REQUIREMENTS

Serialization & Track and Trace Regulations

Compliances In place

- EU FMD, UAE, Saudi Arabia, China, Korea, US DSCSA, Russia, Uzbekistan, Bahrain
- Russia Food Supplement (BAFS)

Upcoming Compliances

EXPECTED 2024

- Indonesia (including Food Supplement)
- Kazakistan

UPCOMING 2025

- Italy GU Serie Generale n.46 del 24-02-2024
- Vietnam
- Other Gulf Country

IDMP IDentification of Medicinal Products

- ISO IDMP standards: ISO 11616, 11615, 11238, 11239, 11240
- EU Commission Implementing Regulation No 520/2012 articles 25/26 : obliges European Union Member States, MAH and EMA to make use of the ISO IDMP standards - EU IDMP Implementation Guide EU IG v2.1.1 28 July 2022
- FDA https://www.fda.gov/industry/fda-resources-data-standards/identification-medicinal-products-idmp

"HOW TO" WITH 4.0 IN PHARMA

Corporate and Site Digital solutions for Master Data Management, Serial Data Generation, Integration with ERP/Packaging Lines/Business Partners (CMO, 3PL, MAH), Compliance with Country Hub reporting Systems.
Packaging Line System and Software for applying variable data, serialization data, data matrix and relevant checks and aggregation capabilities.
Without digital solutions it would not be possible to have real, safe, robust control of the compliance. Manual operations are extremely critical, inefficient and redundant. Moreover, on top of the mere Compliance results, there is the opportunity to leverage serial data for supply chain tracking, analysis and improvement.

Digital solutions are becoming a must for the interaction with both Regulatory Agencies and third party business partners like CROs and CMOs. 4.0 enabling technologies like AI and Natural Language Processing support Text Mining more and more to manage the conversion of unstructured data.

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USE CASE OF «ANNEX 1 AND QUALITY METRICS»
Digital to support Compliance and Operational Excellence

USE CASE “ANNEX 1 + QUALITY METRICS”:
SCENARIO

STARTING POINT

- Multinational Pharma Company
- Quality impact systems in place (ERP, LIMS, QMS, CMMS)
- Systems and Production Fields are not adequately connected (only ERP with LIMS, QMS)

PROJECT SCOPE

Digital Transformation Roadmap for:

1. Compliance for Annex 1
2. Readiness for Quality Metrics

ASSUMPTION

- Annex 1 GAP Assessment

CDER’s Vision for Quality Metrics Program

Quality Metrics Program = quality surveillance tool

Quality Metrics Program ≠ enforcement tool

Short-Term Vision				Long-Term Vision	
Segment inventory	Study relationship between metrics and internal quality outcomes in each segment	Estimate predictive power of each metric for each segment	Enhance collaboration with Industry	Develop signal detection program	Utilize metrics as a component of surveillance program (e.g., integration into models)

www.fda.gov

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Nandini Rakala FDA "Advancing Quality Surveillance"
Office of Quality Surveillance, Office of Pharmaceutical Quality CDER | US FDA
ISPE Europe Annual Conference Keynote – Madrid, 26 April 2022

USE CASE “ANNEX 1 + QUALITY METRICS”:
ANNEX 1 – Requirements

ANNEX 1 - chapter	ITEMS	REF.	REQUIREMENT
9.Environmental & process monitoring	Environmental and process monitoring	9.1	The site’s environmental and process monitoring programme forms part of the overall CCS.
9.Environmental & process monitoring	Environmental and process monitoring	9.2	This programme is typically comprised of the following elements: i. Environmental monitoring – total particle. ii. Environmental and personnel monitoring – viable particle. iii. Temperature, relative humidity and other specific characteristics. iv. APS (aseptically manufactured product only).
5. Equipment	Equipment qualification	5.2	Equipment monitoring requirements should be confirmed during qualification.
9.Environmental & process monitoring	Environmental and process monitoring	9.9	Appropriate alert levels and action limits should be set for the results of viable and total particle monitoring. Stringent action limits may be applied based on data trending, the nature of the process or as determined within the CCS. Both viable and total particle alert levels should be established based on results of cleanroom qualification tests and periodically reviewed based on ongoing trend data.
9.Environmental & process monitoring	Environmental and process monitoring – alert/action limit	9.10	Alert levels for grade A (total particle only) grade B, grade C and grade D should be set such that adverse trends (e.g. a numbers of events or individual events that indicate a deterioration of environmental control) are detected and addressed;
9.Environmental & process monitoring	Environmental and process monitoring – trends procedure	9.11	Trends procedure should include, but are not limited to: i. Increasing numbers of excursions from action limits or alert levels. ii. Consecutive excursions from alert levels. iii. Regular but isolated excursion from action limits that may have a common cause, (e.g. single excursions that always follow planned preventative maintenance). iv. Changes in microbial flora type and numbers and predominance of specific organisms. Particular attention should be given to organisms recovered that may indicate a loss of control, deterioration in cleanliness or organisms that may be difficult to control such as spore-forming microorganisms and moulds.

USE CASE “ANNEX 1 + QUALITY METRICS”:
QUALITY METRICS Requirements

PRACTICE AREA	QUALITY METRICS	DESCRIPTION
Manufacturing Process Performance	Process Capability/Performance Indices (Cpk/Ppk)	a measure that compares the output of a process to the specification limits and can be calculated as a proportion
	LAR – Lot Acceptance Rate	a measure of the proportion of lots that were accepted in a given time period
	Right-First-Time Rate	a measure of the proportion of lots manufactured without the occurrence of a non-conformance
	Lot Release Cycle Time	a measure of the amount of time it takes for the lot disposition process

PRACTICE AREA	QUALITY METRICS	DESCRIPTION
Pharmaceutical Quality System Effectiveness	CAPA Effectiveness	a measure of the proportion of CAPA plan implemented and deemed effective
	Repeat Deviation Rate	a measure of the proportion of recurring deviation measures
	Change Control Effectiveness	a measure of timeliness and effectiveness of implemented changes to GMP facilities, systems, equipment, or processes
	Overall Equipment Effectiveness	measure of operating productivity, utilizing planned production time
	Overall Equipment Effectiveness	a measure of the proportion of maintenance time that was not planned or scheduled

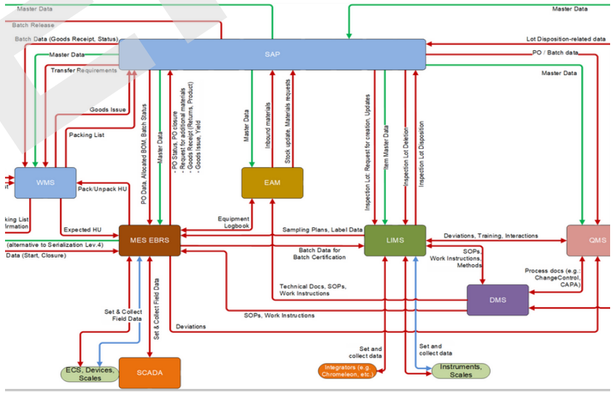
USE CASE “ANNEX 1 + QUALITY METRICS”:
QUALITY METRICS Requirements

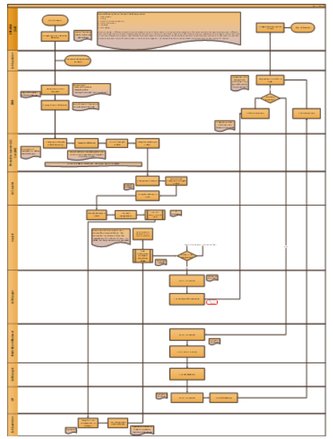
PRACTICE AREA	QUALITY METRICS	DESCRIPTION
Laboratory Performance	Adherence to Lead Time	a measure of the proportion of tests in the laboratory that are completed on time according to schedule requirements
	Right-First-Time Rate	a measure of the proportion of tests conducted without the occurrence of a deviation.
	IOOSR – Invalidated OOS Rate	**a measure that indicates a laboratory’s ability to accurately perform tests**
	Calibration Timeliness	a measure of a laboratory’s adherence to inspecting, calibrating, and testing equipment for its intended purposes as planned

PRACTICE AREA	QUALITY METRICS	DESCRIPTION
Supply Chain Robustness	On-Time In-Full (OTIF)	a measure of the extent to which shipments are delivered to their destination containing the correct quantity and according to the schedule specified in the order
	Fill Rate	a measure that quantifies orders shipped as a percentage of the total demand for a given period
	Disposition On-Time	a measure of the proportion of lots in which the disposition was carried out on time
	Days of Inventory On-Hand	measure of how a company utilizes the average inventory available

USE CASE “ANNEX 1 + QUALITY METRICS”:
DATA and BUSINESS PROCESSES MAPPING - AS-IS versus TO-BE

- Mapping of all the **GxP processes**, with Priority Matrix for intervention
- Mapping of all the **GxP Digital Solutions** with Priority Matrix for Intervention
- **Data flow** mapping
- **Review of processes** considering the Operational Excellence and Compliance prospectives
- **Metrics and Key Parameters definition** (data sources and related elaboration) according to a *risk-based analysis*

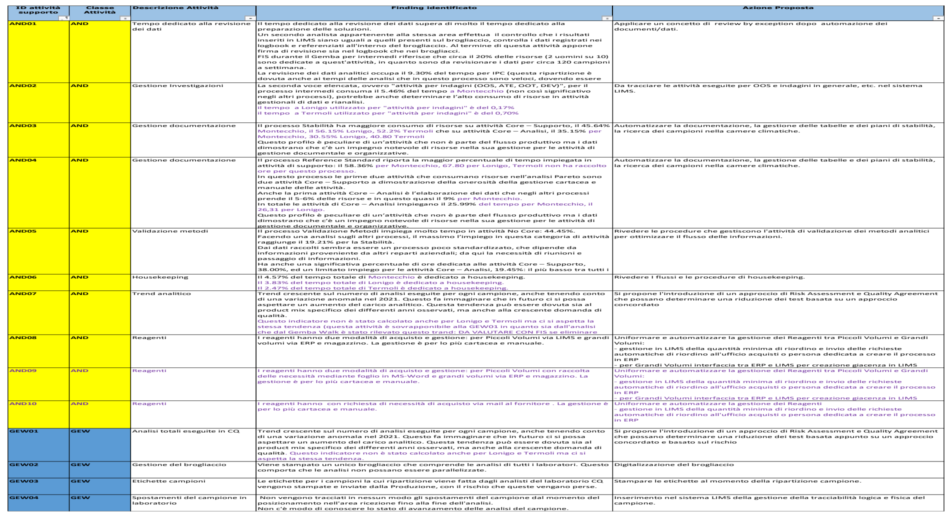




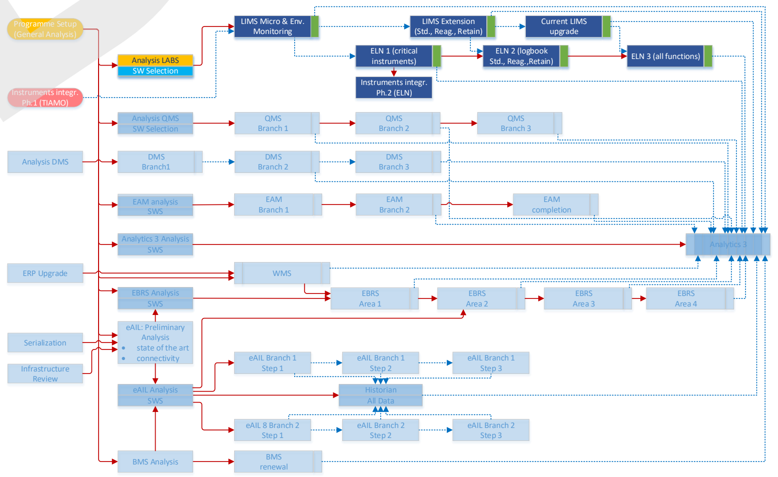
Unità di misura	Tipo KPI	KPI riferito a:	Significato	Analisi risultato	Source Attuale	Source Futura	Commenti
Numero	Storico	Tutti processi	tutti i campioni entrati per analisi in laboratorio Q1 nel periodo di tempo definito (anno) per tutti processi		LIMS	LIMS	potendo ottenere il valore in automatico. In questo modo possibilità di modificare l'orizzonte del tempo di analisi da annuale a mensile o settimanale
Numero	Storico	Materie Prime	tutti i campioni entrati per analisi in laboratorio Q1 nel periodo di tempo definito (anno) per materie prime		LIMS (automatico da ERP)	LIMS	
Numero	Storico	Intermedi	tutti i campioni entrati per analisi in laboratorio Q1 nel periodo di tempo definito (anno) per intermedi		LIMS (automatico da ERP)	LIMS	
Numero	Storico	IPC	tutti i campioni entrati per analisi in laboratorio Q1 nel periodo di tempo definito (anno) per IPC		LIMS (automatico da ERP)	LIMS	
Numero	Storico	Prodotti Finiti	tutti i campioni entrati per analisi in laboratorio Q1 nel periodo di tempo definito (anno) per prodotti finiti		LIMS (automatico da ERP)	LIMS	
Numero	Storico	Stabilità	tutti i campioni entrati per analisi in laboratorio Q1 nel periodo di tempo definito (anno)per stabilità		LIMS (inserito manualmente)	LIMS	Dato manuale
Numero	Storico	Reference Standards	tutti i campioni entrati per analisi in laboratorio Q1 nel periodo di tempo definito (anno) per reference standard		LIMS (inserito manualmente)	LIMS	Dato manuale
Numero	Storico	Reflaid Materie Prime e Intermedi dopo scadenza	tutti i campioni entrati per analisi in laboratorio Q1 nel periodo di tempo definito (anno)		ERP/LIMS	LIMS	Non conteggiati
Numero	Storico	Rianalisi campioni di materiali, ricampionati da analizzare nuovamente	tutti i campioni entrati per analisi in laboratorio Q1 nel periodo di tempo definito (anno) per rianalisi		Manuale	LIMS	Non conteggiati
Numero	Storico	Indagini	tutti i campioni entrati per analisi in laboratorio Q1 nel periodo di tempo definito (anno) per indagini		Manuale	LIMS	Dato manuale
Numero	Storico	Cleaning	tutti i campioni entrati per analisi in laboratorio Q1 nel periodo di tempo definito (anno) per cleaning		Manuale	LIMS	Dato manuale
Numero	Storico	Microbiologia	tutti i campioni entrati per analisi in laboratorio Q1 nel periodo di tempo definito (anno) per		Manuale	LIMS	Dato manuale

USE CASE “ANNEX 1 + QUALITY METRICS”:
ACTION PLAN

- Identification of the **Findings and Improvements** in terms of **Compliance and Operational Excellence**



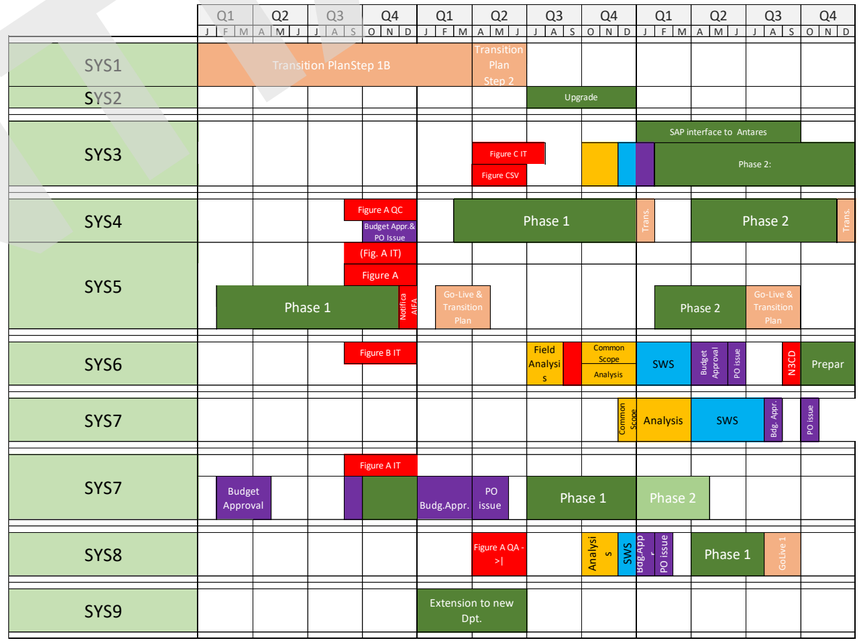
- Proposed **Actions** with **Priority Matrix** for intervention
- High level **Digital Roadmap**



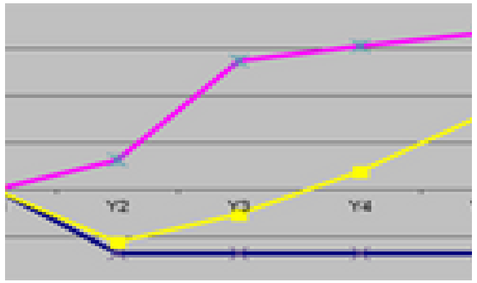
USE CASE “ANNEX 1 + QUALITY METRICS”:
DETAILED DIGITAL ROADMAP

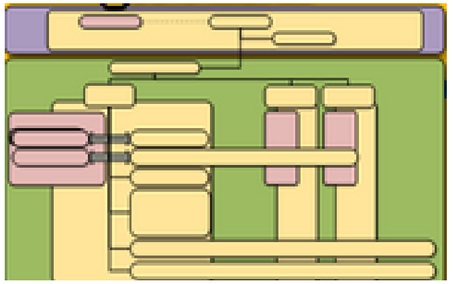
Digital Roadmap Deliverables include:

1. **Execution Map –** identification of the actions and of their sequence
2. **Budget definition –** each identified action has a fork of investment value
3. **Identification of benefits –** qualitative and quantitative benefits
4. **Organization Changes –** according to identified skills and effort



N°	Area	Project	OVERALL (4 years) Project Analysis min	Project Analysis MAX	Project Delivery min	Project Delivery MAX
1	all	Programme Setup	10,000	10,000	N/A	N/A
2	LABS	LIMS + ELN + Instruments integration	10,000	10,000	10,000	10,000
3	QMS	QMS	10,000	10,000	10,000	10,000
4	DMS	DMS (see Note 1)	10,000	10,000	10,000	10,000
5	CMMS	CMMS (see Note 2)	10,000	10,000	10,000	10,000
6	A3-4	Analytics 3-4	10,000	10,000	10,000	10,000
7	WMS	WM (see Note 3)	10,000	10,000	10,000	10,000
8	EBRS	EBRS	10,000	10,000	10,000	10,000
9	eAIL	eAIL, including Production & Utilities	10,000	10,000	10,000	10,000
10	BMS	BMS (see Note 4)	-	-	-	-
		TOTAL	10,000	10,000	10,000	10,000
		TOTAL min (Analysis + Delivery)				10,000
		TOTAL MAX (Analysis + Delivery)				10,000





USE CASE “ANNEX 1 + QUALITY METRICS”:
DIGITAL SOLUTIONS MAPPING - AS-IS versus TO-BE

- **TO-BE Design Output**:
  - Upgrade of the existing systems (**ERP, LIMS, CMMS, QMS**) to cover the new requirements
  - Introduction of an **Integration Automation Layer System**
  - Introduction of a **Manufacturing Execution System**
  - **Interfaces** between the systems according to data flow mapping and KPIs definition
  - Digital Delivery of a **Quality Control Tower** to collect data and trace and monitor KPIs (based on AI customized models)

USE CASE “ANNEX 1 + QUALITY METRICS”:
QUALITY CONTROL TOWER – Drill-down

Golden Bach Comparison

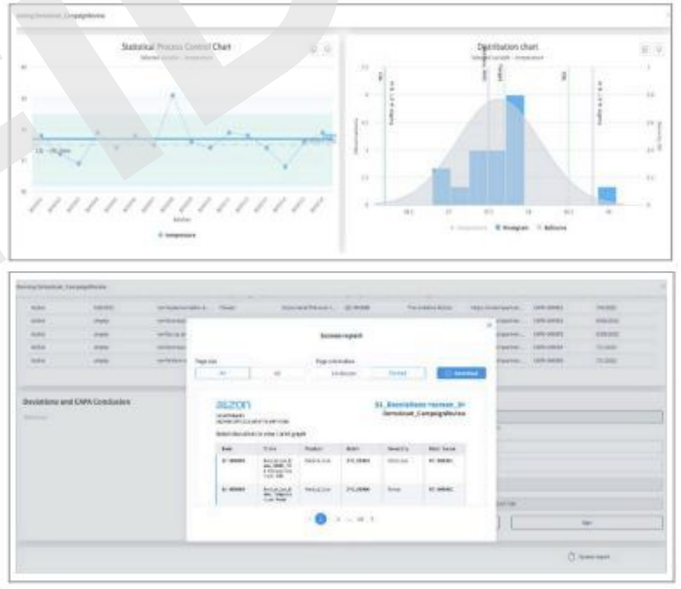
- **Historical and Real-time data collection (**CPP, CQAs and process values from SCADA**)** and data collection from other sources
- **Data contextualization** and correlation of different entities (e.g.: batch, test type, product)
- **Monitor batch performance in real time**, and **predict outcomes** with respect to expected trends
- Batch comparison tools and model performance provide **a self learning solution to promote continuous improvement**

Product Quality Review

Annual PQR generation by automatically searching, filtering, and collecting data from different systems

Be audit-ready with complete campaign information in one place,

View batch results at a glance against expected trends and add required conclusion

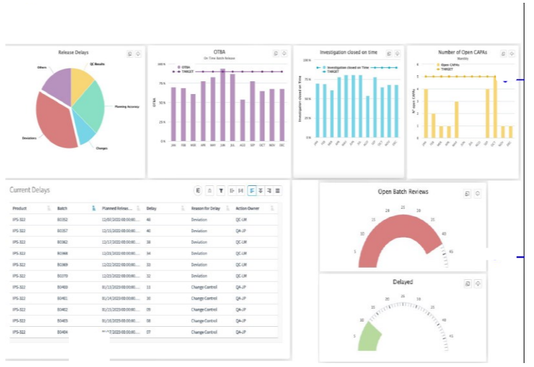


Accelerated Batch Release

Align the stakeholders with the relevant information so they can **optimize each step of the batch release process and compare metrics to targets**

Real-time visibility into total open batch reviews and delays associated with the entire product portfolio

Aggregated historical and real-time data helps **understanding which actions can shorten the time between production and batch shipment**



USE CASE “ANNEX 1 + QUALITY METRICS”:
BENEFITS AND RISKS

KEY BENEFITS

- **Fast data retrieval**, moreover ‘by design’
- **Manual activities reduction**
- **Data Integration** and **Data Integrity** ‘by design’
- **KPIs** availability for **analysis, trending and prediction**
- **Continuous** and **Ongoing Process Verification** support
- Enforce **Compliance**
- Support to **Continuos Improvement**
- Better agility and **adaptability to regulatory changes**
- **Review by Exception** -> Right-first-time

KEY POTENTIAL PROJECT RISKS AND REMEDIATIONS

- Strong Focus on **Change Management** in terms of **Data ownership**
  - (who is the owner of CPP? Who is the owner of analytical raw data?)
  - Digital Culture & System Ownership
  - Process Impacts
- Adequate **Training Strategy and Execution** & Stakeholder Involvement

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