



**FACTORY 4.0: FROM
PAPER BATCH RECORD
TO ELECTRONIC
BATCH RECORDS**

SIMPLIFY AND STANDARDIZE

The Pharma industry, like other industries is transforming with digital. This Digital Transformation is articulated around 4 main goals:

Optimize chemical and pharma **processes around leveraging data**.

Improve employee (workers and technicians') **efficiency** in a regulated and constrained environment **through specific systems/apps or activity automation**.

Improve supply chain effectiveness enabling traceability, simulating, and optimizing planning & scheduling with powerful **big-data analysis, robotizing storage activities**.

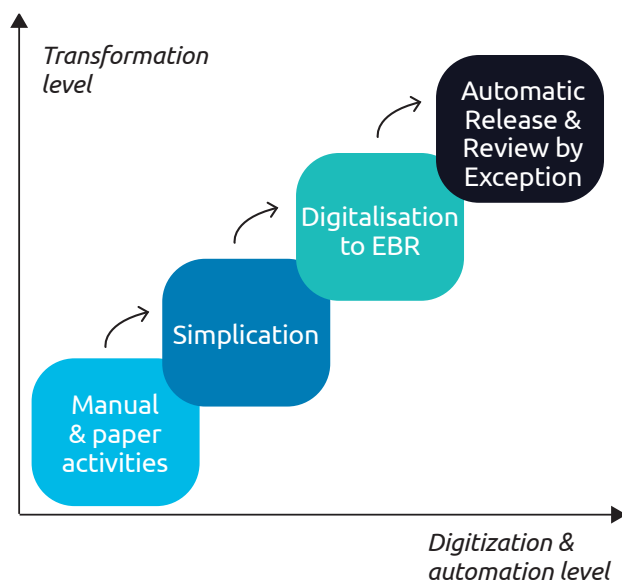
Provide transparency on data and information at all levels of the Industrial organization.

Among the portfolio of initiatives to deliver these objectives, one of the most critical is the implementation of electronic Batch Records (eBR), with the aim of improving compliance, costs, and cycle time performance by switching from paper and manual batch records to digital and partly/fully automated record keeping (up to a release by exception logic).

While already implemented in most digitally advanced industries (Automotive, Manufacturing, Aerospace), the electronic batch record is less common in pharma (at least on a large scale), due to the complexity of regulatory & compliance.

But a big shift is coming. In the coming years eBR **will become mandatory**, firstly, because **Health Authorities will impose** it for regulatory & compliance reasons, and secondly, because it is **a lever of productivity**, and thus competitiveness.

We propose to start by a maturity assessment to define together your starting point and final ambition :



Switching from paper to digital may appear to be a simple IT task, but in reality this digitization only succeeds on a large scale **if the Batch Record process is transformed at its core.**

After years of manufacturing over-securitization, inspection and audits, **batch record templates became too complex, with increasing amounts of data, appendixes and redundancies....** including not just manufacturing data but working instructions, systems and environment data. This made releasing process-heavy, and made batch records heterogeneous within sites and/or between sites.

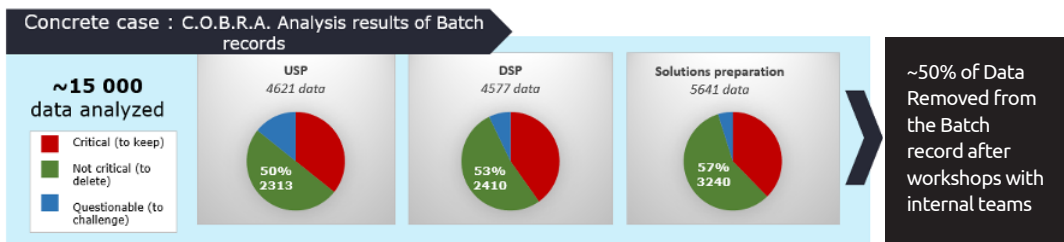
That's why, to accelerate digitization, **our conviction at Caggemini is that batch records MUST first be streamlined and then standardized** as much as possible to facilitate eBR deployment and guarantee a certain level of homogeneity between production lines and sites.

Main gains enabled by Digitization of Batch records

- 75 to 80% less deviations per batch
- ~ 10 to 15% of manufacturing cycle time reduction
- ~ 40 to 80% less data entries and information recorded in the eBR
- ~ 40 to 60% of end-to-end cycle time reduction

A 5-STEPs METHODOLOGY FOR AN IN-DEPTH STREAMLINING OF BATCH RECORDS IS REQUIRED

1. Process mapping with sites knowledge holders
2. Data Criticality analysis for each data point on multiple criteria (see COBRA Methodology)
3. Key principles validation (structure, ergonomics, content, etc.)
4. Target Batch Record Design and validation by sites
5. Functional Architecture definition to prepare the digitization



A transversal team is key for this transformation success, with at least these **3 key stakeholders**:

Local Project leader	Manufacturing representative	Quality Assurance/Release representative
Responsible for identifying key contributors and ensuring attendance to all meetings, representative of digitization project on site.	Contribute to the analysis to make sure the standard will be consistent with local practices.	Contribute to the analysis to ensure that all released data are part of the BR.

Working together sets a crucial example for the group, both within and across sites. In this context, **change management is a great challenge not to be neglected during the implementation phase.**

Benefits of Standardization

- Better compliance and data integrity
- Less data entries
- Less human errors
- Batch Record RFT Improvement
- Less effort and cost in creating and maintaining recipes / validation
- Accelerated MES implementation
- Simpler creation of local recipes
- Less effort and cost in creating and maintaining recipes / validation

A TOP-10 PHARMA HAS BEEN DEPLOYING ELECTRONIC BATCH RECORDS THROUGHOUT ITS INDUSTRIAL NETWORK

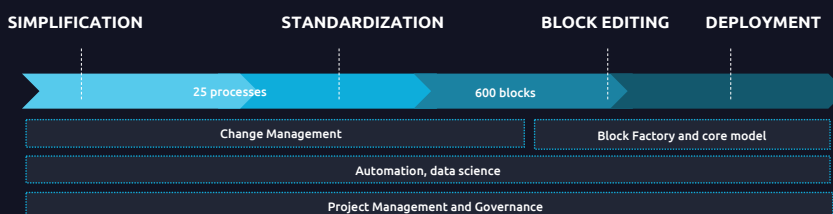
As part of its Industry 4.0 transformation, a top-10 pharma has launched a fast, transformative and global eBR deployment across 52 sites in 2 years. At this scale, this is an industry first. It's also a perfect illustration of the eBR deployment approach.

Beyond its size, this program is remarkable for the following:

- The need to deploy two solutions, with two core models: Siemens and Werum
- The high objective of:
 - Batch Record simplification: 50%
 - Batch Record automation: 60%
 - Batch Record standardization: 70%
- Speed: 2 years



High level approach deployed



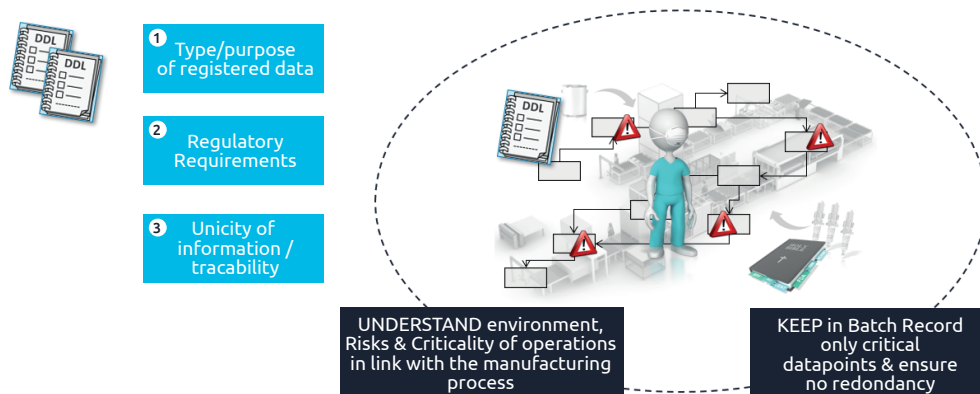
Capgemini is proud to have supported this pharma in its transformation

50+ Sites worldwide
 25 Processes covered
 5000+ users
 2 Technological partners
 3-5 years Payback
 2 years Deployment

CAPGEMINI ASSETS TO ACCELERATE THE OVERALL TIME

Zoom on Cobra Methodology

The Center of Excellence in Life Sciences of Capgemini Engineering has developed a specific Methodology & Tool for Data simplification of Batch Records. This risk analysis ensures to KEEP only critical data based on:



Innovation as a simplification accelerator – From manual data extraction to automation

The Manual processing of one Batch Record can take up to 5 days.

This tool enables to qualify the criticality of thousands of Data, while reducing workload, through:

- An automated import within the tool of data to be analyzed.
- A pre-analysis of data criticality automatically assisted
- A pre-identification of data redundancy in different parts of the BR
- An automated reporting on data criticality per type (Observations, identification, Visa...)

Hence, the automn enables up to **75%-time savings per Batch Record** (or up to 3 working days).

After simplification and standardization... road to digitization

By leveraging our methodology and the accelerating tools developed by Capgemini, we can support our customers to reach a good level of simplification, standardization within / between different sites of production, and be able to reuse MES recipes as much as possible.

This is time for IT to jump-in and work closely with business to transform those simplified paper batch records into digital items on the shopfloor.

This will be the purpose of our next communication.

To know more on Capgemini and eBR offer – please contact:



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