

## Process -Technology 3 – Electronic Batch Records

Electronic Batch Records (EBRs) refer to digital documentation and records that are used in the manufacturing and production processes of goods, particularly in industries such as pharmaceuticals, biotechnology, food and beverage, and chemicals. EBRs serve as a replacement for traditional paper-based batch records and provide a more efficient and streamlined approach to managing batch-related information. Electronic Batch Records streamline processes, reduce the risk of errors, and provide a comprehensive and traceable record of each batch produced.

Pros	Cons
<ul style="list-style-type: none"> <li>• Improve time to market.</li> <li>• Reduce production costs by automating QA functions and reducing human error.</li> <li>• Drive compliance through automated workflows and in-process reporting.</li> </ul>	<ul style="list-style-type: none"> <li>• Multiple solutions available from multiple vendors.</li> <li>• Can be difficult to implement successfully.</li> <li>• May require changes to business processes.</li> <li>• Requires an MES or integrated workflow system.</li> </ul>

**Technology Cost range:** \$50,000 - \$200,000, depending on the complexity of the use case, number of manufacturing and quality processes being scheduled and Operational Technology maturity.

**DMC Technology Cost:** \$100,000

### DMC Cost Assumptions:

- Limited to 1 Manufacturing process plant with limited product variation.
- Existing MES with EBR workflow ability.
- Internal costs for end user staff involvement have not been included.
- Single design and build iteration.

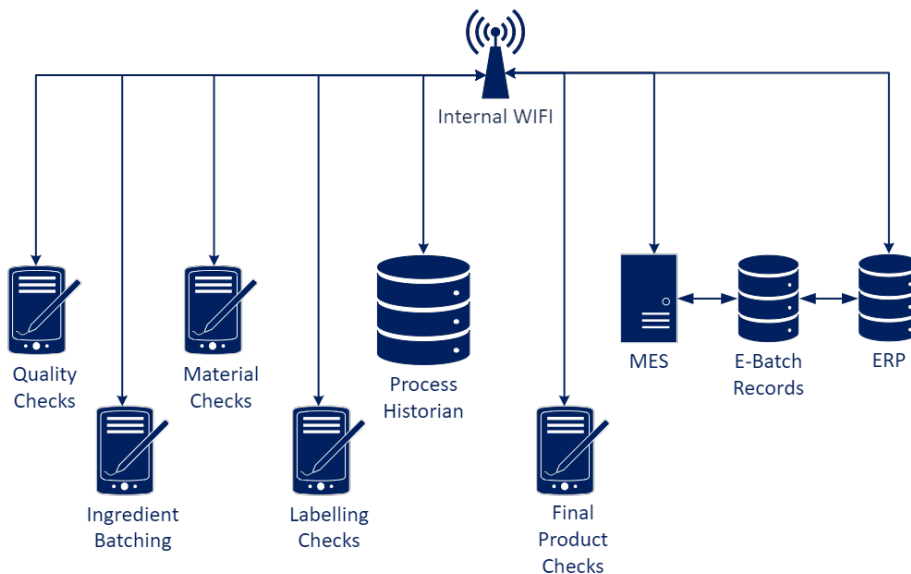
**What situation would this technology usually be adopted in?** Manufacturing Execution Systems (MES) and electronic batch records (EBR) streamline production processes by capturing, managing, and analysing real-time production data. These systems provide visibility into manufacturing operations, facilitate compliance with regulatory requirements, and improve process efficiency. MES and EBR are adopted in manufacturing plants to enhance production control, ensure product quality, and achieve regulatory compliance.

**RoI Considerations:** Costs may include MES software licensing, implementation, and integration expenses. Benefits may include improved production efficiency, reduced compliance risks, and enhanced product quality contribute to ROI.

**What skills are required to implement & run this tech?** Staff should be trained in MES operation, EBR usage, and regulatory compliance procedures. The ability to delay with exceptions is essential for where parameters have not been met. Critically analysing why the batch wasn't released and being able to interrogate systems and other data sources to validate whether these exceptions can be released.

**Pre-requisites for successful adoption:** Preparation involves assessing production control needs, identifying compliance requirements, and selecting suitable MES and EBR solutions. Understanding of the current batch release process and relevant data that is assessed prior to release will allow a new Electronic Batch Record system to be tested rapidly.

### Typical Tech Stack



**Who can help with this technology?** System Integrators, MES consultants, software vendors, and regulatory experts can provide guidance on MES and EBR implementation.

**What to google when researching this technology?** Research topics include MES functionalities, EBR software platforms, and regulatory compliance standards.