ISPE Indonesia Affiliate

Business Case of Electronic Batch Record

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ISPE Indonesia Exhibition
23 Feb 2023

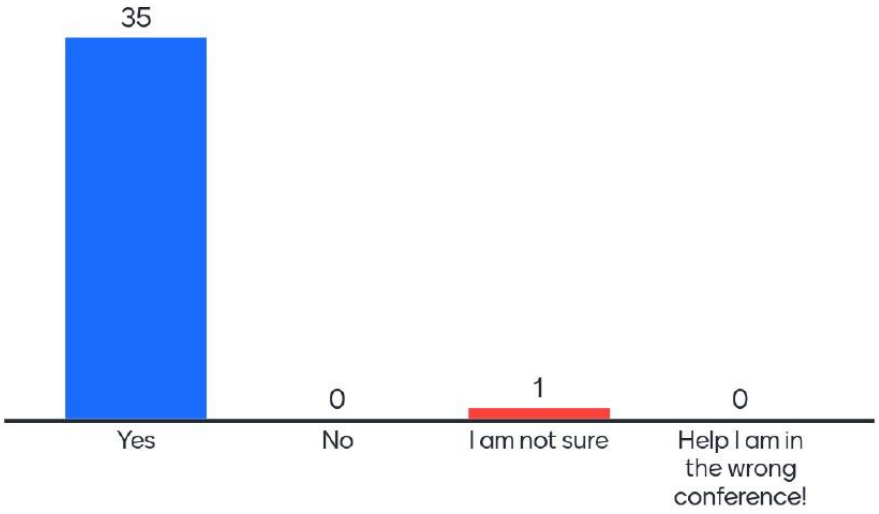
Outline

- **Where were we?**
- Why slow adoption of digital solutions?
- Quantifiable and other benefits of EBR
- New approaches and project examples

our last ISPE Indonesia Event on Digitalisation

Result from our last ISPE Indonesia Event on Digitalisation

Do we want to digitise?!



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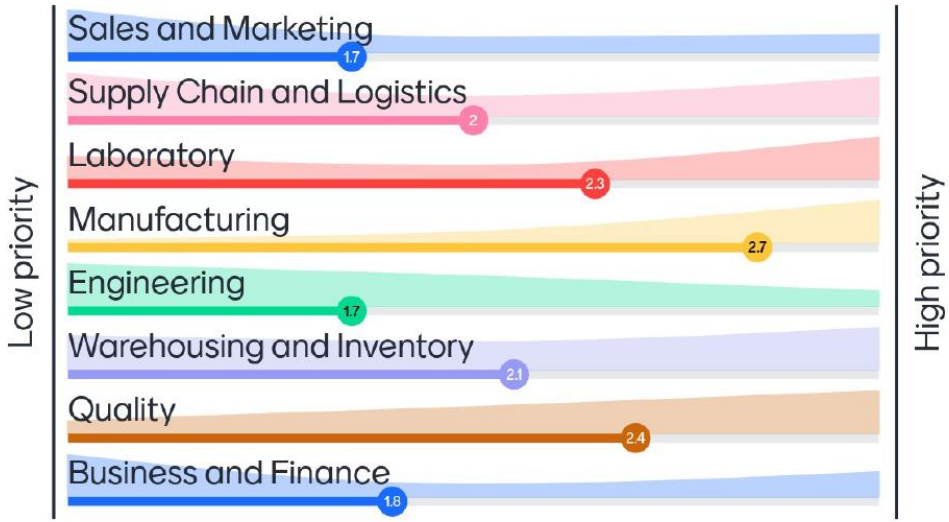
Do we want to digitise?!

Where are your digitisation priorities?

Mentimeter



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Result from our last ISPE Indonesia Event on Digitalisation

Do we want to digitise?!

Where are your digitisation priorities?

Mentimeter

What do you see is holding back digitisation?

Outline

- Where were we?
- **Why slow adoption of digital solutions?**
- Quantifiable and other benefits of EBR
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Why slow adoption of EBR?

Everyone acknowledge common problems caused by operating paper and manual systems

- Slow Batch review/release time
- Data integrity and GMP compliance problems
- Lack of visibility across production and quality operations
- Lack of data required for process improvement
- Inefficient procedures to reduce the risk of human error inherent in manual work

It is well established in Pharma that EBR significantly improves these issues..

Benefits	
Efficiency & Accuracy Improve:	• Automatic Generation of Final Batch Report • Review By Exception (NOT Everything): **large saving of QA time** • Automatic data completeness check • Data entry checked against specification on input
Fewer Document Errors:	• Less Data = Less Errors • Only Approved Batch Spec Can Be Used For Recording • Automatically improve Data Integrity through audit trials and sequence control.
Costs Reductions:	• Print, Distribution, Manage & Storage • No Physical Movements Of Paper • Instant Search - No Time Spent Looking
Automation:	• Automatic Date/Time Stamps • Automatic Reference Values • Automatic Calculations • Automatic Specification control

Why slow adoption of EBR?

For many companies, the benefits of EBR are 100% clear and already accepted, however many of these did not start to implement yet.. For others new to EBR then management need more convincing on the value on the benefits to eliminate paper records:

Why is it difficult to justify investing in EBR?

1. **Data for ROI calculations are not readily available**
2. **GxP and Data Integrity Compliance is still seen as a burden and lower interest to invest beyond a minimum..**
3. **Lack of affordable EBR solution**

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EBR benefits; medium size ASEAN pharma numbers (1)

Facility produces around apprx 4000-6000 Batches per year on a paper batch system

7 QA reviewer personnel

7 Days average release timeframe of each individual non-sterile products.

Among other daily activities, the team spend about 300 hours/week review time contributing to about USD 45.000/ year (using conservative cost rate of 3 USD/hour)

- **EBR is proven in several client studies to reduce by greater than 50% time and effort reduction for batch review using cloud EBR.**
- **Review by Exception features enable QA to focus their scope of review, cut down non-value added review elements such as entry completeness, entry format, legibility, etc. ~22,500 USD/yr saving**

EBR benefits; medium size ASEAN pharma numbers (2)

Operators and supervisors must keep up with the paper batch recording, formula calculations, correctness checks, managing exceptions, completeness checks and escalations to QA intervention

These non-value-added activities take up >3 hours for each batch produced. The time spent on non-value-added production checks is more than 15,000 hours/year (using a conservative cost rate of 2 USD/hour) the total cost of operational checks is $30,000

- **EBR automates completeness and correctness checks to make sure all data required for batch processing is available, QA can work in real time for parallel review and intervention**
- **Client studies with cloud EBR shows operational staff reporting 75% savings on the time & effort spent on non-value-added activities ~ 22,500 USD / year saving**

EBR benefits; example data entry reduction

EBR benefits; medium size ASEAN pharma numbers (3)

Pharma companies spend 3,500 - 5,000 USD / year on the archive storage cost that includes boxes, folders, paper, controlled processes around archive and storage process.

Additional resources time is also consumed on performing APQR entries prior to batch storage, completeness check, moving the documents by pushcart to the designated area and performing batch destruction process. It takes an estimated 4,000 hours (approx. 2FTE, $8,000) annually to perform these activities.

Our clients observe >85% reduction in electronic archival making the data always available for APQR activities ~ 6,800 USD/year saving

Total savings in this area are ~ 6,800 USD/year + 5000 USD/year = 11,800 USD/year

Intangible Benefit of EBR

There are multiple benefits from using EBR, some are tangible and can be justified right away, but there are many intangible benefits which are hard to notice on the paper but it's what make EBR distinct from the paper one.

Right the first-time production approach

Improve operational efficiency and data recording accuracy with the automatic data completeness and correctness check. The error in documentation or batch recording will be reduced with the data entry check against specification input leading to fewer exception and deviation.

Enable strong data integrity principle

Automatically improve Data Integrity through user & time stamp, audit trails and sequence control; e.g only approved batch specs can be used for recording.

Process Visibility

Faster Data-driven Decision Making

Enable Continuous Improvement

Cost of Non-Conformance

How do we measure cost of non-conformance?

Can you take the risk of these happening...

Customer Complaint

Loss of brand reputation and sales

BADAN POM

Regulatory sanctions

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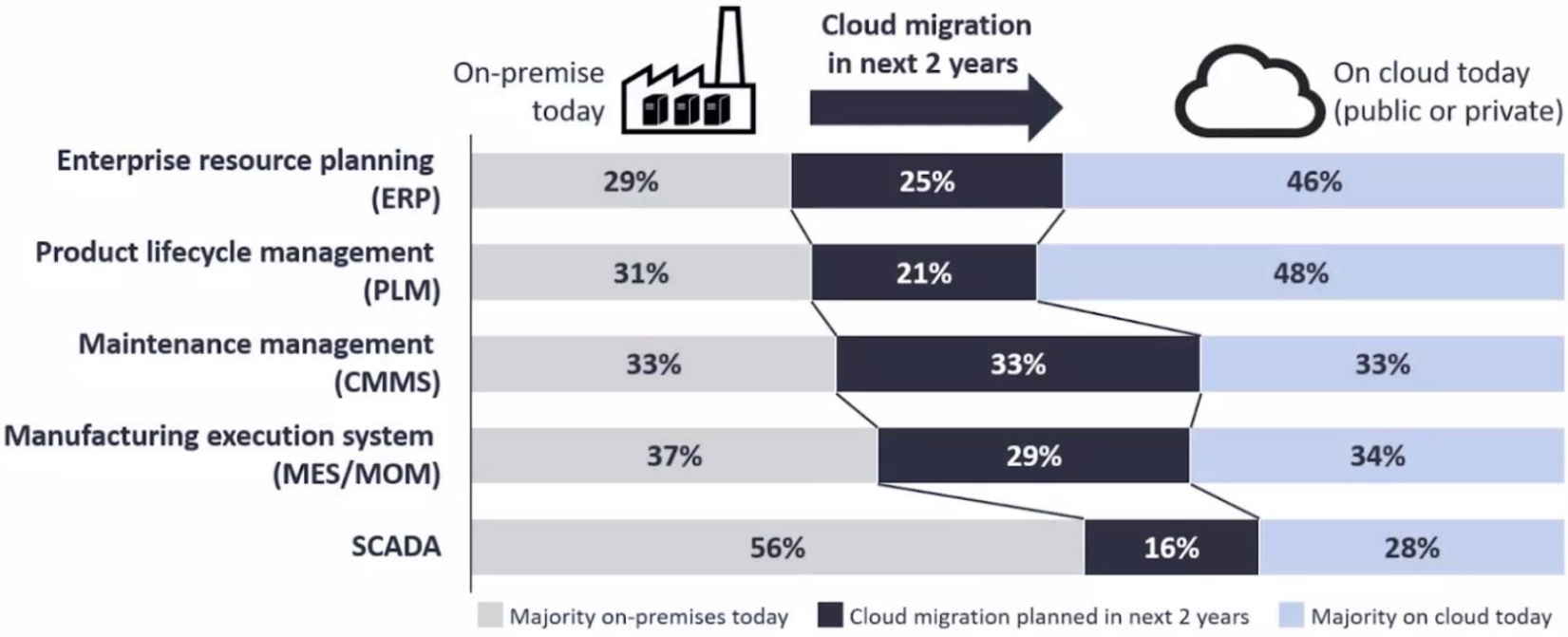
- **New approaches and project examples**

Lack of affordable solutions in Pharma ??

There are significant new approaches for digitisation lowering the barriers for adoption

- IoT based integration
- No-Code incremental vs. Traditional big-bang
- Cloud deployed solutions
- Self-service implementation
- Roadmap focus on improvement not functionality

Manufacturing is moving to the Cloud



*IoT Analysis, March 2021

Cloud contributes to EBR business case

On-premise: can a pharma company fund an IT unit that can compete with cloud service provider?

- Example: Azure offers 99.98% uptime guarantee. How about your internal IT department?
- Can you compete in terms of capability, performance and cost with the large CSP's? (Google, Amazon, Microsoft)
- Risk assessment: A local physical server with own security and administrators or a cloud service?

- Highly available on-premise server infrastructure costs multiple 100's K USD, requires dedicated IT resource and will be replaced in 5yrs..
- Vs. annual SaaS of <10K USD

On-premise and Cloud comparison

Cost is why we are missing the boat to Pharma 4.0?

On-Premises

9%

1. **Software Licenses**
2. Customisation & Implementation
3. Hardware
4. IT Personnel
5. Maintenance
6. Training
7. GxP + CSV services

Ongoing Costs

8.
- Apply Fixes, Patches, Upgrade
- Downtime
- Performance tuning
- Rewrite customizations
- Rewrite integrations
- Upgrade dependent applications
- Ongoing burden on IT
- Maintain/upgrade hardware
- Maintain/upgrade network
- Maintain/upgrade security
- Maintain/upgrade database

Cloud Computing

68%

Subscription Fee

2. Implementation, ~~Customisation~~ & Training
3. GxP + CSV services
4.

Ongoing Costs

- Subscription fee 1

Project / CAPEX cost

Operational / OPEX cost

CAPEX + OPEX costs 10x higher for on-premise than cloud for a 'simple EBR'..

How cloud EBR make it affordable

Modern, cloud-based SaaS Manufacturing Application

5-year total Cost of Ownership

› 50%

More cost effective than incumbents

Project CAPEX

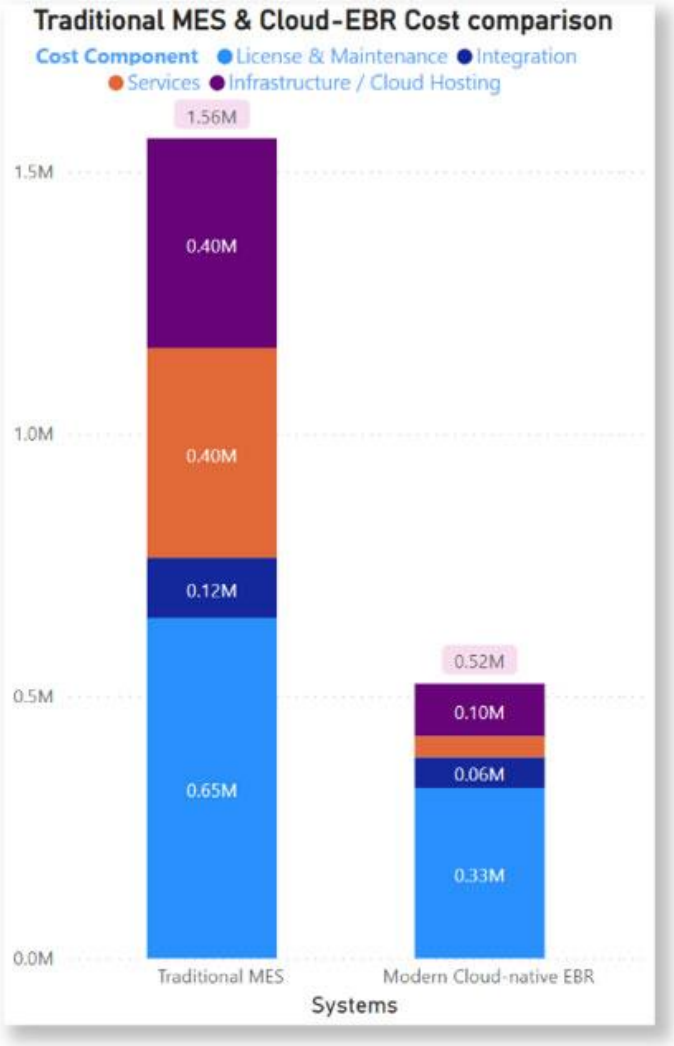
90%

Cheaper cost of implementation & Validation cost compared to traditional MES/EBR

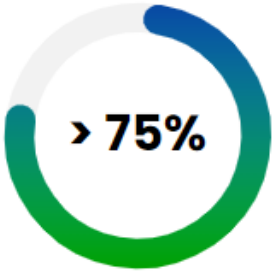
75%

Faster to implement

How cloud EBR make it affordable

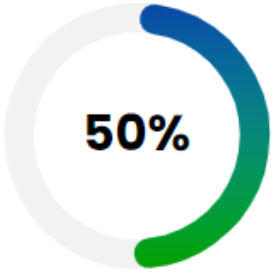


Shift from Server Infrastructure to Cloud hosting



Cost savings

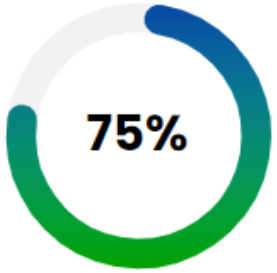
License & Maintenance



Cost savings over 5-year period

Services

Fraction of the cost



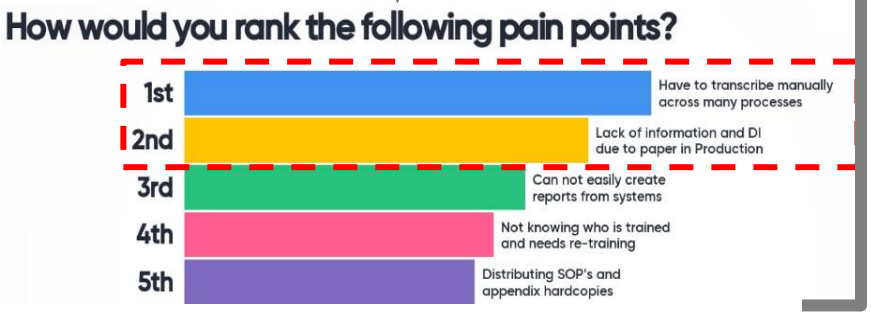
Faster to implement

Cloud EBR Case-Study: GPO-MBP

Regional joint venture between Sanofi & Thai Government manufacturing vaccine products.

Corporate Goals:
- Improve Cycle Time by 15%
- Improve Data Integrity compliance
- Reduce Deviations by 50%

2 weeks study targeting corporate aligned Digitisation goals, resulted in 115 pain-points



Assessment confirmed EBR as a key solution (addressing 10 High priority pain points alone)

49.09% of total cycle time is for Review and Approval activities.. EBR can bring Review by Exception in a short time and get the site on the road to Digitisation.

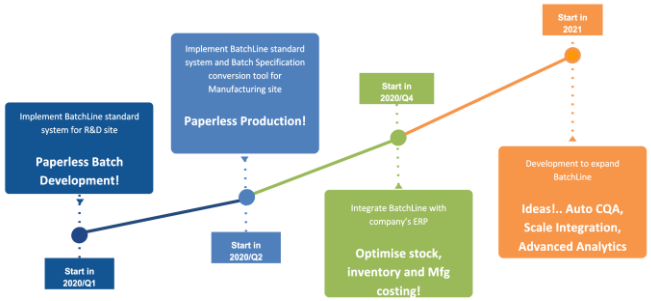
Process/ Area	Current Durations	Estimate CT Reduction
Preparation		0 – 10 %
Packing Process and IPC		20%
Reconciliation (day by day + summary)		30 – 40 %
Production Review		40 %
QA Review and Approve		50 %

40-50% reduction in time and effort to review and approve Batches

Self Service project up and running on EBR in 2 weeks

Thai Cosmetics OEM Company

Client's Vision



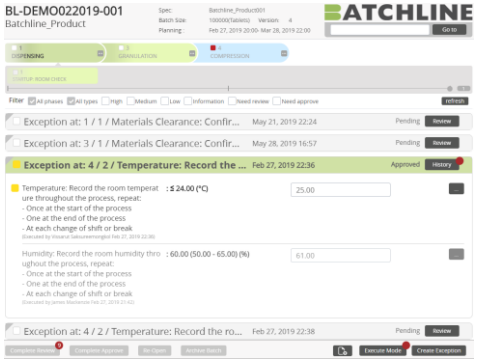
Project Plan, Timeline & Milestones

Topic	Date	Resp.	Location	Remark
Offsite preparation/ System setup	12-13 Mar 20	BL	Offsite	2 days
Operation and Facility Survey	20 Mar 20	BL / PAN	Onsite	1 day
Kickoff meeting and EBR introduction				
Key user training & Workshop + Consulting (1x product specification) *Required: Admin, QAs, Supervisors* • *Materials Management* • *Batch Specifications Management* • *Batches/ EBR Management* • *Dashboard* • *Users Access/ Company information*	23-31 Mar 20		Offsite + TC	7 days
Operator training (half-day) *Require: Operators, Researchers* • *Batches/ EBR Management* • *Dashboard*	27 Mar 20			

All supplier side activities completed during COVID lockdown

Client's R&D Team start building own EBR's

2 FTE's for 2 weeks



Made possible by SaaS EBR

Summary

- Pharma companies are aware of problems caused by paper system and how EBR can solve these problems
- It is difficult to justify investing in EBR because
  - Data for ROI calculations are not readily available
    - **Can quantify tangible savings when the data are available**
  - GxP and Data Integrity Compliance is still seen as a burden and lower interest to invest beyond a minimum.
    - **It is important to quantify savings/tangible benefits of implementing EBR as well as intangible benefits and cost of non-compliance**
  - Lack of affordable EBR solution
    - **Modern Cloud EBR becomes an affordable solution option**
- New approach on digitization and new technology options lowering the barriers for adoption