

Annex Questionnaire

A: Questionnaire: Survey Evaluation Electronic Batch Recording Solutions

Dear Experts,

First, let me thank you for your willingness to support my dissertation as partial fulfilment of the PhD award at the University of Duisburg-Essen. It is highly appreciated.

The dissertation examines **‘AN EVALUATION MODEL FOR ELECTRONIC BATCH RECORDING SYSTEMS IN THE PHARMACEUTICAL INDUSTRY’**.

The study aims to analyse the advantages and limitations of electronic batch recording solutions in MES- operated production in the pharmaceutical industry and to develop an evaluation model for system implementation.

It would be wrong to claim that there is one electronic batch recording solution to provide optimal support for the various types of pharmaceutical productions. My goal is therefore to develop a classification metrics with multiple batch recording solutions and to evaluate them based on a set of specific criteria. This classification can then be used to define the different benefit levels and lead to different implementation concepts for a particular pharmaceutical production. Ultimately, this study shall help companies to select and decide about the most effective electronic batch recording solution and implementation strategy for their needs.

With the help of this survey, five different batch recording solutions (Stage 1 to 5) shall be compared and evaluated based on pre-defined evaluation criteria. The solutions differ in the degree of integration of the batch recording solution in the production modules, production equipment and other software systems (i.e. LIMS).

The results from this survey will provide one source of primary data of my research and is an essential part of the entire dissertation.

Please be assured that the information will be used only for this study. Your name will be kept confidential.

Instructions:

1. Please fill in your contact and answer the attached question list (pg.2)
2. Review the introduction and description of the different Electronic Batch Recording solutions (pg. 3-4)
3. Please evaluate the different Electronic Batch Recording solutions from Paper Batch Record (Stage 1) to Electronic Batch Documentation (Stage 5) in the excel sheet
4. Please email the excel file with your scoring back to me by June 13, 2014.

In case of any questions or concerns please don't hesitate to contact me.

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Company and participants profile

Please provide names, job function and experiences of survey participants:

Company name:

Country (your site location):

What is your email address:

Do you work for a central organization:

Do you want to receive to outcomes of this study:

Analysis of the organizational structure and Electronic Batch Recording System deployment

1. Which pharmaceutical products are manufactured in your company (pharmaceutical drug substance, drug products, packaging)?
2. Which experiences does your company have with Electronic Batch Recording Systems?
3. What is the number of EBRs/MES user in your company?
4. How many sites in your company are using Electronic Batch Recording Systems? Which and why?
5. Please describe which Electronic Batch Recording Systems are used in your company within the different sites and why?
6. If you have implemented any of the described Batch Recording stages can you briefly summarized the change efforts for the first implementation (duration, budget, required resources etc.)?
7. Please describe the evaluation criteria used in our company for Electronic Batch Recording Systems implementation decisions? Which aspects do you typically consider for decision making and why?

Evaluation of Batch Recording solutions

Please evaluate the Batch Recording Steps relatively to each other based on the criteria provided below:

Paper Batch Record

"Paper on Glass" Batch Record
(Review on Screen)

"Paper on Glass" Batch Record
(Review by Section)

Automated Batch Record
Machine data integrated

Automated Batch Documentation
Machine/ equipment data integrated

Connected-IT systems

MES Layer w. EBRs

Connected elements (SCADA)

Training

LIMS

Others (e.g. PDMA/PMU)

MES

MES

MES

MES

MES

MES

Data Historian

Data Historian

Data Historian

Machinery

Machinery

Machinery

Equipment

Equipment

Equipment

cat.	comparison criteria	Scoring							
Quality	Amount of paper per batch	high...5 none...0							
	Number of operator entries per BR	high...5 none...0							
	Amount of data to be reviewed per BR	low...0 high...5							
	Human error rate	low...0 high...5							
Information exchange	Inprocess monitoring rate	full inprocess control ...5 partial inproc. control ...2 no inprocess control ...0							
	Ease of trending critical BR parameter	all parameters possible...5 partially possible...2 no parameter...0							
	Safety in equipment management rate	high...5 low...0							
	Investigation efforts	high...5 low...0							
	BR access time	slow (>15min)...5 within 15 min accessible...3 immediately...0							
Process time (speed)	Time for creating new MBR	long...5 short...0							
	Review time for new MBR	long...5 short...0 #...no impact							
	Release time for new MBR	long...5 short...0							
	Time for execution BR	long...5 short...0							
	Review time BR	long...5 short...0							
	Release time BR	long...5 short...0							
	production cycle time of a single batch	long...5 short...0 no impact...#							
	overall cycle time of batch record documentation process	long...5 short...0 no impact...#							
Flexibility	Operations Flexibility (in executing operational processes)	easy...5 hardly flexible...0							
	Flexibility in producing different batch sizes	easy...5 hardly possible...0 no impact...#							
	Availability of production equipment	low...0 high...5 no impact...#							
	Time needed for cleaning & setting-up of equipment	long...5 short...0 no impact...#							
Implementation	Initial investment costs	> 1 Mio...5 > 500K < 1 Mio...2 < 100k...0							
	Initial validation costs	> 1 Mio...5 > 500K < 1 Mio...2 < 100k...0							
	Initial User Training efforts	high...5 mid...2 low...0 no difference...#							
	Initial implementation time	12-36 months...5 6-12 months...2 < 6 months...0							
	Prerequisite integration efforts	high...5 low...0							
	Magnitude of change mgmt required before/ with implementation	high...5 low...0 no difference...#							
cost and resources	Annual operations running costs	> 1 Mio...5 > 500K < 1 Mio...2 < 500k...0							
	Change costs (improvements)	high...5 low...0							
	Inventory costs WIP	high...5 low...0							
	Inventory costs finished products	high...5 low...0							
	No. of required operators	high...5 low...0 no impact...#							
	No. of required quality control staff	high...5 low...0							
	No. of required IT support & admin staff	high...5 low...0							

Definition of performance criteria

Performance objective	Comparison Criteria	Evaluation method	Source
Quality performance	1.Amount of paper per batch	It is defined as the total number of BR papers that are handled in the production or quality control department for one batch.	LEN08; PAT01; GH012
	2.Number of operator entries per BR	It is defined as the number of required operator entries per BR for one batch.	LEN08
	3.Amount of data to be reviewed per BR	It is defined as the amount of data to be reviewed by Production and Quality personnel.	LEN08
	4.Human error rate	It is defined as the probability of a human error occurring throughout execution of the BR document (i.e. missing entries, wrong calculations etc.) [KIR94].	MESA12; SAV13; RIC13; GH012; MON06;
Information exchange performance	5.In-process monitoring rate	It is defined as the percentage of batch record data that is created throughout the production can be monitored online and in real-time.	MESA12; SAV13
	6.Ease of trending critical BR parameter	It is defined as the time and costs needed to collect data from multiple sources for performing trend analysis of critical BR related parameters.	SAV13
	7.Safety in equipment management rate	It is defined as the percentage of operator tasks and decisions related to equipment that are controlled & automated by a system.	MESA12; LEN08; SAV13; GH012
	8.Investigation efforts	It is defined as the total time and costs needed to investigate root causes to failures and deviations	SAV13; JW08; GH012
	9.BR data access time	It is defined as the time needed to access BR data for a specific batch in case of an inspection	SAV13
Time performance	10.Time for creating new MBR	It is defined as the total time needed for setting up the MBR template for a new product.	PAT01
	11.Review time for new MBR	It is defined as the total time needed for reviewing the MBR template content for a new product.	PAT01
	12.Release time for new MBR	It is defined as the average total time needed from completion of review until releasing.	PAT01
	13.Time for execution BR	It is defined as the average total time needed for collecting/ recording BR data incl. writing, calculating, signing, instrument reading and checking SOPs during production associated with one batch.	PAT01
	14.Review time BR	It is defined as the aver. total time needed to review	PAT01

		the BR of one batch in Production, QC/QP.	
	15.Release time BR	It is defined as the average total time needed for releasing the BR from the completion of the review until the release for distribution through QP.	SAV13; PAT01
	16.Production cycle time of single batch	It is defined as the time between start of production order until completion. It includes time for charging raw materials and transfer of finished products to storage place but without considering (i) cleanup and set-up time for equipment and process machine automation (ii) analytic control time of samples and finished products and (iii) BR review and release time.	BOB88; LEN08; SAV13; KLE07; GHO12
	17.Overall cycle time of batch record documentation process	It is defined as the total elapsed time from start of a batch production order through its release of the batch and associated documentation for distribution and sale. It includes the waiting time until analytical quality results are available and batch documents are released by QP.	MESA11; LEN08; SAV13; KLE07; GHO12
Flexibility	18. Flexibility (in producing different batch sizes)	It is defined as the time and costs needed to adapt the templates to new batch sizes.	MAU13
	19.Operations Flexibility (in executing operational processes)	It is defined as the time and cost needed to adapt to special cause alterations from the standard production process including documentation process.	LEN08; SAV13
	20.Availability of production equipment	It is defined as the percentage of scheduled time that the production equipment is available for operation.	MESA11; LEN08; GHO12
	21.Time needed for cleaning & setting-up of equipment	It is defined as the time needed for cleaning & setting-up required process equipment before start of production [GHO12].	MESA11; GHO12
Cost & resource performance	22.Annual operational running costs	It is defined as the total annual re-occurring costs for license fee renewal, hardware maintenance, 1st, 2nd, 3rd level support excluding change costs for improvements.	MESA11; SAV13
	23.Change costs (improvements)	It is defined as the total annual costs for functional improvement and adjustment changes of the EBRs/MES and interfacing elements. The cost equation compromise of the number of connected systems and process automation to the EBRs/ MES, the average annual number of changes per system and layer and the average costs per change.	MESA11; SAV13
	24.Inventory costs (WIP)	It is defined as capital costs of Work-In-Process (WIP) materials and semi-finished products inventory utilized during the production of one	MESA11; SAV13; GHO12

Implementation aspects		batch.	
	25.Inventory costs finished products	It is defined as the capital costs of finished products stocked in the warehouse and waiting for the BR to be released.	MESA11; SAV13
	26.No. of required operators	It is defined as the total number of employees needed in production for the execution of the BR.	MESA11; LEN08
	27.No. of required quality control staff	It is defined as the total number of employees needed in quality control to review & release the Complete Batch Documentation.	LEN08
	28.No. of required IT support & admin staff	It is defined as the total number of employees needed as support for administration, IT incidents and IT maintenance for the EBRs/MES.	MESA11; LEN08
	29.Initial investment costs	It is defined as the total costs for EBRs software license, hardware, engineering including design and development, installation and user training.	MESA11; BD98
	30.Initial validation costs	It is defined as the total costs for EBRs system validation and interface validation. The main aspects driving the validation costs are outline below [IOV03; BD98]: –High customization of EBRs functionalities increase costs –Use of off-the shelf products reduce the validation costs –High number of interfaces to process automation and systems increase costs –Add-on functionality to EBRs increase costs –Testing costs (IQ, OQ, PQ)	MESA11; BD98
	31.Initial User Training efforts	It is defined as to the total training time and cost required for all system users in a certain time period. It reflects the efforts and degree of change management and the company's developing ability.	LEN08
	32.Initial implantation time	It is defined as the total project time from planning through completion of the EBRs implementation.	LEN08; BD98
	33.Pre-required integration efforts	It is defined as the efforts for integrating other information technology sources to EBRs/ MES and is summarized as the total time and costs for integration. The higher the number of process automation and other IT systems that need to be integrated to EBRs/ MES the higher the integration efforts.	MESA11; BD98
	34.Magnitude of change management required before implementation	It is defined as the level of required changes necessary for system deployment. It is an important aspect that refers to an organization's capability to streamline processes and apply lean practices. It measures the time and costs for necessary changes in processes, SOPs and training before implementation.	MESA11

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