 Vistin Pharma	RFI, Request for Information on Electronic Batch Record (EBR) 2025		
	Document Number: MISC-2018	Effective Date: 19.09.2025	Revision: 1.0

Approval History(Document electronically signed)

Step	Job Function	Approved By	Date Approved
Approval Step 2 QA Approval	QA Approval	Ademir Dzuzdanovic	19.09.2025 8:13 AM
Approval Step 1 Technical Approval	Vistin All	Vegard Heggem	18.09.2025 2:49 PM

Revision History


Revision Number	Description of Change
1.0	

Review History(Document electronically signed)

Reviewer	Approved By	Date Approved
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Related Documents

Document Number	Title
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# **RFI – Request for Information** **Electronic Batch Record System** **(EBR)**

Current

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Current

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# 1 Introduction

## 1.1 Description of Vistin Pharma

Vistin Pharma (Vistin) is a Norwegian pharmaceutical company producing Metformin Hydrochloride (API). Our Metformin is also available as Direct Compressible lubricated granules (drug product intermediate).

For further information about the company, please see <https://www.vistin.com/>

## 1.2 Short description of our current quality system

Vistin has to comply with the pharmaceutical “current Good Manufacturing Practices” (cGMP) standards during all stages of its product development and manufacturing. Complying with cGMP means that a range of Quality systems has to be established and maintained. Detailed batch record is a fundamental part of the manufacturing and release of product. Currently our Master Batch Records (MBR) are handled as a controlled document in our EQMS, printed out for each batch, and filled in manually by the operators. The filled in paper-record together with some printed reports and curves from our Process Control System (PCS), Siemens WinCC (SCADA ver 7.5 SP2), constitutes our batch record to be reviewed by QA prior to release. Vistin manufactures more than 2000 batches of the above mentioned products, which are further broken down to approximately 10 different product variants with different/separate batch records.

Vistin has a strategy to digitalise our processes where it is justified, in parallel with an ongoing growth in our production volumes. Based on the huge amount of paper-records, tedious control and double control of data, we see a potential for a more accurate and effective batch review with focus on the more critical parts of the manufacturing process related to critical alarms and exceptions. Therefore, we have initialised a project with the target of implementing a system for Electronic Batch Records to replace our current paper based system.


## 1.3 The purchase process

Vistin has decided to divide the purchase of the EBR system in several steps. The first step is to distribute a Request for Information (RFI) to several suppliers. We will then perform an evaluation and pre-qualification of the different suppliers based on the incoming RFIs.

In the next phase, Vistin will create a more detailed User Requirement Specification (URS) and distribute it to selected suppliers as part of a Request for Proposal (RFP).

The plan for the purchase-process is as follows:

Activity	End date	Responsible
Distribute RFI to relevant suppliers	22.09.2025	Vistin

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Due date for the suppliers to return RFI	20.10.2025	Supplier
Evaluation of the incoming RFI with feedback to the suppliers	Q4-2025	Vistin
Distribute final Request for Proposal (RFP) with User Requirement Specification (URS) and Supplier Qualification Questionnaire (SQQ) documents to selected suppliers	Q4-2025/Q1-2026	Vistin
Evaluation of the incoming RFP	Q1-2026	Vistin
Presentation of the selected suppliers' solution, including live demo.	Q1-2026	Supplier/Vistin
Final decision	Q2-2026	Vistin

Expected project start for implementation will be Q2/Q3 2026 with a target of going live by 01.01.2027 for the first product.

## 2 The scope of the RFI

The scope of the project is to **replace the current manual paper records** with a digital record that fulfils our requirements for GMP and will give an improved accuracy and efficacy of our release-processes.


As other digitalisation projects may be relevant in the future, we also would like to gather information about other relevant systems/process which may be added on to the relevant system. The RFI will give valuable input for a short-list of relevant suppliers based on the given information from the RFI.

## 3 IT infrastructure at Vistin

- Vistin has two main locations (**Oslo and Sannidal**) with separate network and **fibre lines operating on the same LAN**.
- **Microsoft Azure is used** for operation of centralised services giving a flexibility in set-up, configuration and specifications.
- Clients are currently using Windows 11 and Office 365.
- Our **PCC is installed in a closed local system**.
- Data from the PCS may be exported to a suitable database at our LAN for further importation to a MBR system.

## 4 Information required from the supplier

See attached file for required information (RFI EBR 2025).

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## 5 RFI response

The final answering of the RFI document must be available to us no later than October 20<sup>th</sup>, 2025 sent by mail to [hilde.merete.hagen@vistin.com](mailto:hilde.merete.hagen@vistin.com)

If you have questions that are important to be clarified before completion of the RFI response, please send them by mail to the above mail addresses.

If you prefer to let a partner respond to this RFI, please forward the documents and notify Vistin.

If you do not find it relevant to answer our RFI, we would appreciate to be informed as soon as possible.

We also feel the need to emphasise that the price estimates are not to be considered as a binding offer. Based on the suppliers' experience with projects of our scale, we think it will give a realistic picture of the expected cost of the project.

The supplier is free to make precautions regarding the understanding of specific issues.