# Section 1: System Description

Provide a brief description and define the purpose of the system:

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Provide a brief description of the source of inputs and interfaces with other systems:

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Will the system generate records to satisfy record-keeping requirements by any regulatory agency or does the system perform an activity that impacts product quality or that is required by a regulatory agency? Explain

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Provide Validation Relevance Assessment and rationale if validation does not apply. If the system is not Validation Relevant, but the determination has been made to validate the system due to business need, document the rationale:

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# Section 2: Approvals

The signatures below indicate agreement that the contents of this Assessment are accurate and approved for use, and that the decision on whether or not to validate the subject system is consistent with regulatory requirements and company policy.

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| --- | --- | --- | --- |
| **Role** | **Printed Name** | **Signature** | **Date** |
| Author |  |  |  |
| Validation/Quality Assurance |  |  |  |