



SAHPRA/2022/REGULATORY INFORMATION MANAGEMENT SYSTEM/RFB002

Questions and answers

Questions	Answers
1. It is assumed that digital signatures are accepted for pages/sections within the response document requiring a signature.	- Yes
2. Is adding a person's initials to the information page sufficient for pages within section B to indicate that we have reviewed and noted the content?	- Yes, fill in information where is required and indicate where it is not applicable.
3. For Requirement SE-22, "Content Reuse Flag - Solution should be able to flag content identical to content used in other submissions based on MD5 Checksums." Can you clarify the requirement and provide a use case for this functionality within a regulatory context?	- MD5 Checksums is the ability to flag identical content and new content on submissions. E.g Submission ref 0000 is missing a letter content reuse flag the re-submitted letter with a new ref 0001.
4. For a foreign supplier who is partnering with a local company, does the foreign supplier need to register on the SARS system for a Tax Clearance Certificate	- Need to complete the SBD 1 in full to be submitted to SARS by SAHPRA.

<p>5. Would reference letters or purchase orders be accepted to satisfy the requirements as evidence or only award letters are required?</p>	<p>- Reference letter provides the required evidence. Include the numbers of year the services were rendered</p>								
<p>6. We would like to get clarification on the image below, the highlighted parts exclude majority of service providers to participate in the tender opportunity, we have relevant experience providing solutions and services based on your requirements and automatically excluded by not having prior opportunity to provide the similar services and solution to Health Products Regulatory Authority, can that condition be waived?</p> <table border="1" data-bbox="203 572 1202 1126"> <thead> <tr> <th data-bbox="203 572 506 684">MANDATORY REQUIREMENTS</th> <th data-bbox="506 572 891 684">Evidence Of Compliance</th> <th data-bbox="891 572 976 684">Provide file location or Page no.</th> <th data-bbox="976 572 1202 684">Yes/No</th> </tr> </thead> <tbody> <tr> <td data-bbox="203 684 506 1126"> <p>BIDDER EXPERIENCE AND CAPABILITY REQUIREMENTS</p> <p>bidder must have provided ICT ware solutions (document management, case management and authors software tools) to any Health Products Regulatory Authority health Products industry during the ten (10) years.</p> </td> <td data-bbox="506 684 891 1126"> <p>The bidder must provide at least 3 award letters of affirmation from other Regulatory Authorities or Health Product Industry to whom the service(s) were delivered. Each letter must be dated, signed and on a letterhead of the customer and indicates:</p> <ol style="list-style-type: none"> The customer Company name and physical address. Customer contact person's name, telephone -number and email address. For a Business customer, the Company Registration Number as registered with Companies and Intellectual Property Commission relevant to the respective territory Service scope of work. Technology scope and Project Start and End Date </td> <td data-bbox="891 684 976 1126"></td> <td data-bbox="976 684 1202 1126"> <ul style="list-style-type: none"> Yes – Proceed No – Do not evaluate further </td> </tr> </tbody> </table>	MANDATORY REQUIREMENTS	Evidence Of Compliance	Provide file location or Page no.	Yes/No	<p>BIDDER EXPERIENCE AND CAPABILITY REQUIREMENTS</p> <p>bidder must have provided ICT ware solutions (document management, case management and authors software tools) to any Health Products Regulatory Authority health Products industry during the ten (10) years.</p>	<p>The bidder must provide at least 3 award letters of affirmation from other Regulatory Authorities or Health Product Industry to whom the service(s) were delivered. Each letter must be dated, signed and on a letterhead of the customer and indicates:</p> <ol style="list-style-type: none"> The customer Company name and physical address. Customer contact person's name, telephone -number and email address. For a Business customer, the Company Registration Number as registered with Companies and Intellectual Property Commission relevant to the respective territory Service scope of work. Technology scope and Project Start and End Date 		<ul style="list-style-type: none"> Yes – Proceed No – Do not evaluate further 	<p>- No</p>
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<p>7. SP-1 Can you please clarify the section for the submission portal: SAHPRA is in the process of developing their own portal:</p> <ul style="list-style-type: none"> - Should we allow for consultation time and engage with the developer on how we will exchange needed information and where we get the submitted dossier? 	<p>- Yes, and for any future developments.</p>								

<p>8. The current Portal has some workflow capabilities that overlap with our software and the information is important for both systems, should we synchronise the information and what will our scope be?</p>	<ul style="list-style-type: none"> - Yes, the preferred bidder's solution will need to complete the regulatory case/document and evaluation management processes' workflow, but it must be able communicate specific process end points to the Portal via an appropriate API.
<p>9. Should our proposal include the SAHPRA portal developers consulting and programming time for the integration?</p>	<ul style="list-style-type: none"> - Yes
<p>10. PA-7</p> <ul style="list-style-type: none"> - The current Portal makes provision for process management and workflow, should we use the portal and communicate all info via there? 	<ul style="list-style-type: none"> - The communication from external parties with SAHPRA will be via the Portal and the Portal will transfer relevant meta data and files to the bidder's solution – all SAHPRA internal processing will be managed in the bidder's solution (with the specific process end points being communicated with the Portal) and communication back with external parties will be via the Portal – In essence the comms will be via Portal and the process management flow on the preferred bidder's solution.
<p>11. The tender mentions a cloud solution and our software complies. You mention AWS and Azure cloud solutions, should we include the SAAS cloud hosting in the tender or must we just be compatible?</p>	<ul style="list-style-type: none"> - Please follow the tenders' functional criteria – which requires a cloud solution that is POPI compliant and will provide hosting of data within the borders of South Africa.
<p>12. Your portal is currently not hosted in AWS or Azure, Is the long-term plan to host in the same environment to prevent large amounts of data moving between to datacentres when the dossier is deposited from the portal to the submission management repository?</p>	<ul style="list-style-type: none"> - SAHPRA will decide in due course on our portal hosting.