

REQUEST FOR INFORMATION

DIGITAL APPLICATION MANAGEMENT SYSTEM

1. **Overview**

The Ministry of Health (hereinafter: "MOH") in its capacity as a regulatory authority operates various kinds of document processes designed for registering and licensing products subjected to regulation: medical devices, pharmaceuticals, drugs, etc.

The MOH is seeking proposals for the assimilation, implementation, development and maintenance of a tool for the processing, editing and viewing of pharmaceutical documents for the State of Israel MOH, which will monitor such document submission processes in accordance to international standards for electronic Common Technical Document (eCTD).

Proposals should relate to the entire process including, but not limited to, the transfer of data outside the MOH and to its assimilation, handling, storage and retrieval within the MOH.

2. **Background**

The MOH, as an authority regulation, processes thousands of applications received each year from organizations all over the world, based on a wide range of products and instruments..

The processing of applications is performed by professional teams and experts.

Each department is responsible for handling, receiving, rejecting or approving various applications.

The MOH is seeking a solution for the automation of said process and for the conversion of paperwork to a paperless digital process.

3. **Required Services and Properties of the System**

3.1 The system should provide support for the entire workflow, must be intuitive and user friendly, i.e. for both MOH users and companies (that send their applications from within the organization).

3.2 The system must be an end-to-end solution which will include a way for transferring, viewing and processing applications, for saving and retrieving applications by professional users, partners and affiliates. The system must support digital events between all parties.

3.3 **Data and file transfer:** The proposal must specify a solution that the software or a cloud service will employ for the secure transfer of metadata and digital information between both internal and external users.

3.4 **Application management:** The system must support various application layouts and structures compliant with the requirements, processes and functions of each department in the MOH.

Regarding this part:

- The system must support international standard applications including but not limited eCTD.

- The system must provide a management tracking system including the capacity to manage comments and versions of documents, metadata sets, tracking of changes, plus revisions of submitted documents, both in Hebrew and English.
- Full log of administrative activity.
- Convenient management of edits.
- Multi-functional viewer for document files.
- Advanced search mechanism that will reduce searching time for information.
- Sharing of information between authorized parties involved in the process, within and outside the office.
- Advanced documentation properties, including but not limited to the property to save documentation history pertaining to the entire application process, and the property to follow-up and send notes to MOH-external parties.

3.5 **Archive** – The solution will enable a way to electronically archive the applications. The offered solution should also enable to find the right documents quickly and easily with an integrated viewer.

4. **About the Response to the RFI**

The response to this request does not commit MOH nor constitutes any obligation to any sort of information, and the responder shall not have any grievances or claims to the MOH in this matter. The MOH reserves the right to save the commercial information received as classified and commits not to transfer it to any other party, except consultants who provide services to the MOH and who signed a confidentiality agreement well in advance.

The response should be sent to the e-mail address listed below. Information sent by other means (snail mail, fax, etc.) will not be considered by MOH and will not be binding in any manner.

The responder should provide the following:

Technical specifications of the proposal

- a. Please explain what the proposed technological solution is.
The response should provide a comprehensive solution including a way for transferring, viewing, processing, saving and retrieving applications.
- b. Architecture – Please describe the recommended architecture (infrastructure diagram).
- c. Please specify what service or module will be provided: on-site service, public cloud, etc.

d. Please fill a markup the questionnaire below regarding the solution to be offered.

NO.	Module	Requirement	Support Yes / No	Customization / Development	Comments
1	File transfer	An embedded solution for sending out digital files from and out to the organization			
2	Applications structure management	Creating application structure based on MOH structure / formats (include the ability to define a chapter or sub-chapter as required)			
3	Applications Reception	Portal solution for applications and other application reception solutions			
4	Applications Validation	Application data validation			
5	Applications Validation	Application document validation			
6	Applications Validation	Application data and documents compliance validation			
7	Applications Review	The option to add inline remarks for each structure, chapters and sub chapters			
8	Applications Review	Flexible search engine, with the option to search for structure and chapter level using key words and a built-in search tool, plus the option to search markups and remarks both in Hebrew and English			
9	Applications Review	The system should manage track changes, have document commenting for each change, note the user responsible for the change and change date			
10	Applications Review	Version management and track version changes by each user			
11	Applications Review	The option to mark paragraphs for inquiry by teams in charge of the application review, i.e. personal remarks and general remarks			

NO.	Module	Requirement	Support Yes / No	Customization / Development	Comments
12	Applications Review	Information documentation – the option of tracking versions of multiple applications in the same subject. For example: the reviewer receives 3 remarks and is requested to fill in data. Data completed will be attached to the original application			
13	Applications Review	The option to create notes, remarks, labels and queries and the ability to email the reviewed application by email or send data from the system, and follow such emails, to save documents and to manually attach files to emails or metadata			
14	Applications Review	Internal and external comment sharing among internal users			
15	Applications Review	Application and document comparison			
16	Applications Management	Creating users via interface with AD and internal users, an option to manage user groups, to assign users to groups, plus management of user roles			
17	Applications Management	The option to assign a manager and team for each structure or chapter (and for the entire application or document)			
18	Applications Management	Managing workflows of review process and approval process, defining personal or team requirements of approvals			
19	Applications Management	Managing SLA scheduling for each stage of the process (sorted by status) – The time allocated for each stage; escalation in case of not meeting deadlines			
20	Applications Management	The system will give an overview of all applications received, sorted by units and statuses			

NO.	Module	Requirement	Support Yes / No	Customization / Development	Comments
21	Applications Management	Each document must be assigned a status, e.g.: being edited, confirmation procedure, invalid, active etc. An option for workflow dependency for each user (there may be a need for another confirmation of a manager). This option will be provided for chapter or document level			
22	Applications Management	Remarks, document, application, chapter (and etc.) approval			
23	Applications Management	Application priority management			
24	Applications Management	Management of licenses and approvals			
25	Applications Management	Reports and logs			
26	Applications Management	Alerts			
27	General	Support in eCTD and other standards structures			
28	General	Implementation of an Israeli regulation set/specifications for eCTD module1			
29	General	English and Hebrew support for data input – RTL & LTR data fields and comments (include multiple languages - Hebrew and English in the same phrase)			
30	General	Several users may work simultaneously on a single application or document			
31	General	Customization options (Workflow definition, fields, etc.)			
32	General	Flexibility in adding new functionality to the system			

NO.	Module	Requirement	Support Yes / No	Customization / Development	Comments
33	General	Flexibility in making regulatory adjustments in the form and structure of the application			
34	General	Permission management (by roles - for creating remarks, for viewing remarks, etc.), for both internal and external users			
35	General	Support desk			
36	General	Interfaces and APIs for exporting and importing information			
37	General	Standalone document review component			
38	General	Ongoing maintenance and support of standard format updates (as eCTD)			
39	Archive	Built-in storage solution			

5. Instructions Regarding General Information in the Proposal

- a. Estimation of the time required to assimilate the entire system.
- b. Estimation of cost / method of pricing for realization should be described.
- c. Number of installations in Israel and the world, where the product is used.
- d. Experience working with authorities.
- e. Responder name, address and contact details, including contact information regarding the response to this request.
- f. Having a representative in Israel or not.

Note: The responder will be asked to give a presentation of the proposal.

6. General Guidelines

This request does not constitute an obligation of any kind on behalf of the MOH to release a tender regarding this request; responding to it will not impart any advantages in such a tender, if released, and it is not sufficient to ensure compliance with the threshold conditions or any other conditions regarding such tender.

Following the RFI stage, the MOH shall decide whether to publish a tender or not and shall determine its terms and conditions. The terms and conditions of this future tender will be determined by MOH sole discretion and subject to law. MOH will not have any obligation to take into account the results of the RFI or any other information arising from this RFI and/or its responses.

If the MOH decides to release such a tender, services other than the ones presented here may be requested, and it will be entitled to add or change the conditions, at its sole discretion.

The MOH reserves the right to request clarifications, completion of information or additional information from anyone responding to this request or any other entity as it deems fit.

Each responder agrees for the MOH to make use of the information provided, in whole or in part, for the purposes of drafting the tender, for the tender specifications and supplements or for any other purpose the MOH will deem necessary.

An applicant who chooses to respond to this RFI will a priori waive any grievance and/or claim and/or appeal to the Ministry of Health and/or to anyone acting on its behalf and/or on behalf of the state and/or to any of the representatives, related to the information, in part or in whole, that the applicant provided in response to this request or to any subsequent requests of clarification, if such are put forward, including, but not limited to intellectual property rights.

It is possible to email questions or requests for clarification regarding this RFI no later than **August 15, 2021 at 22:00** (10 PM Israel Standard Time) to the MOH Tender Committee:
it.tenders@moh.gov.il

The responses to this request must be emailed to the above-mentioned address by August 5th 22:00 (10 PM Israel Standard Time).