

Management Software for the Elaboration of an Electronic File in the Pharmaceutical Industry Following Mexican Regulations

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Abstract : For certification, certain goods of public interest, such as medicines and food, it is required the preparation and delivery of a dossier. For its elaboration, legal and administrative knowledge must be taken, as well as organization of the documents of the process, and an order that allows the file verification. Therefore, a virtual platform was developed to support the process of management and elaboration of the dossier, providing accessibility to the information and interfaces that allow the user to know the status of projects. The development of dossier system on the cloud allows the inclusion of the technical requirements for the software management, including the validation and the manufacturing in the field industry. The platform guides and facilitates the dossier elaboration (report, file or history), considering Mexican legislation and regulations, it also has auxiliary tools for its management. This technological alternative provides organization support for documents and accessibility to the information required to specify the successful development of a dossier. The platform divides into the following modules: System control, catalog, dossier and enterprise management. The modules are designed per the structure required in a dossier in those areas. However, the structure allows for flexibility, as its goal is to become a tool that facilitates and does not obstruct processes. The architecture and development of the software allows flexibility for future work expansion to other fields, this would imply feeding the system with new regulations.

Keywords : electronic dossier, cloud management software, pharmaceutical industry, sanitary registration

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