A systematic approach for identifying and reducing gaps between the pharma and software industry and transforming quality through digitalization in the pharma industry

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Digitalization of data into electronic formats can transform the efficiency of an organization. Advances in software programming have enabled seamless conversion of manual workflows into electronic processes. We have described our experiences in the development of reliable and robust inter-connected electronic systems. In this article we have addressed the challenges in the development of electronic laboratory notebook software that follows a workflow in a biological laboratory. These challenges include: (i) linguistics: translation of 'language of the scientist' to the 'language of the software designer' and to the 'language of the programmer', (ii) limited knowledge of capabilities and limitations of technologies on either side (scientific and software) and (iii) lack of communication and documentation practices for capturing the requirements. Data integrity is the central regulatory requirement to a quality management system. Digitalization can address this challenge by addressing three major advantages – standardization of processes, increased compliance and enhanced efficiency. The observations made during the development processes of the present study can be applied to scientific software development and increasing requirements for collaboration of diverse cross-functional teams.

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of collaboration among academics, governments and industries. Massive amounts of data, ranging from viral and host genome sequencing, multi-omics, were generated by various labs across the world, and shared seamlessly through electronic digital systems. The ability to collect, analyse, interpret and apply data requires efficient consolidated electronic systems. Electronic quality management systems (eQMS) which can consolidate data have been in existence for several decades[2]. With the advancements in electronic software and hardware technologies, these eQMS systems can transform the biotechnology industry by improving the ability to process data, ensure compliance, in a secure manner, and save large data for long periods of time.

A comprehensive eQMS system comprises of various systems (Figure 1) which are integrated, communicate efficiently amongst themselves, and are secure and easy to use. Some of the systems used in the pharma/biotech industry are listed in Figure 2. We have developed an eQMS system to support digitization of the entire workflow of laboratory and clinical activities for drug development. The process involved defining requirements, software design, production and implementation. A diverse cross-functional team was critical for this collaborative effort, including biologists, software engineers, statisticians, graphic designers and user-experience professionals. The challenges in the development of this system, and the solutions we have described in this article, can enhance efficiency of the entire process.