Customizing an adaptive case management software in a GMP production lab as a quality management system for clinical trial PET radiopharmaceuticals development and production

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benchsys
Hot Case Cool Manager

Introduction

Case Management is a structured, collaborative, dynamic and information-intensive process driven by outside events that requires incremental and progressive responses from the business domain handling the case. An batch records a good example of case folder (fig. 1).

Adaptive Case Management (ACM) is an information technology that exposes structured and unstructured information (data and content) and allows evolving organizations to execute a routine and emergent processes in a secure but transparent manner.

The Cyclotron Research Centre (CRC) of the University of Liège develops and produces innovative radiopharmaceuticals for research and clinical diagnostic applications in humans. The constraints due to our multiple activities (academic education, research, production of parenteral radiopharmaceuticals, and clinical research) and limited budget impair the use of conventional IT tools available on the market (laboratory information management software, LIMS).

We report our recent experience in the implementation of an adaptive case management software as a tool of traceability and quality management in our GMP[1] facility (fig. 3).

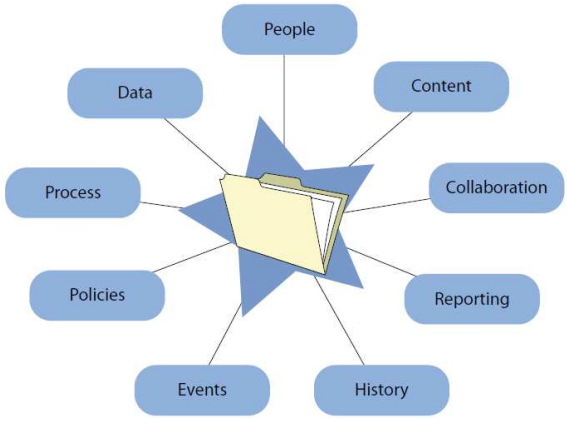

Figure 1 – General structure of a case [source: Forrester Research][4]

Methods & Results

The software[2] is an integrated solution for the quality and traceability management of most laboratory activities: standard operating procedures (SOP) and protocols edition, raw material, intermediates, finished products and samples managements, documents versioning, back-ups, and archiving.

The data base and the core software are installed on a server centralising all information (fig. 2). This allows an easy organisation of revisions and back-ups. Users access the data through a customized interface (fig. 4) available on client pc's connected to the local network. To shift from the previous documentation system to this new quality system, different modules were first identified and gradually implemented in the new environment (users' rights, equipment log-book, resources management, SOPs, protocols…). The documentation structure was based on Eudralex GMP[3].

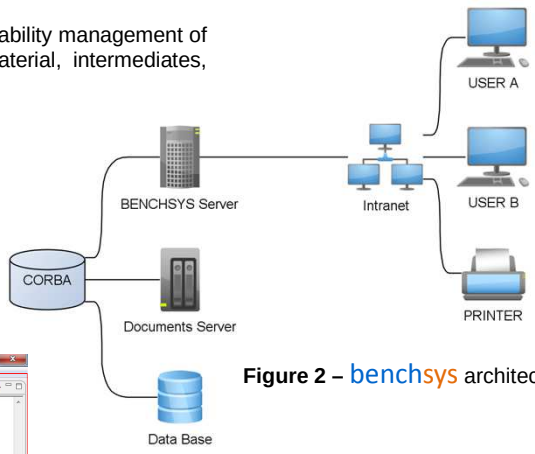

Figure 2 – benchsys architecture

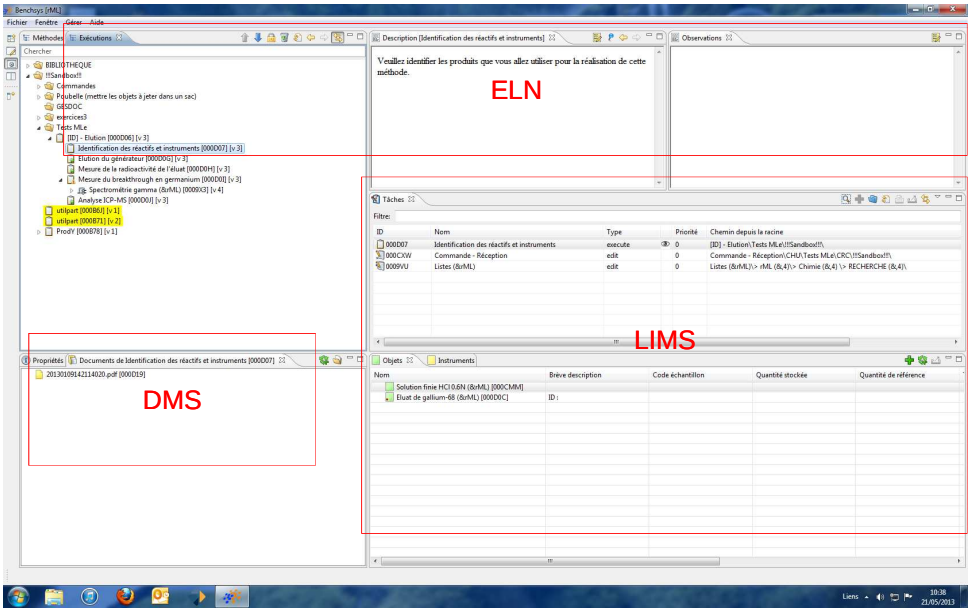

Figure 4 – An example of customizable interface in benchsys

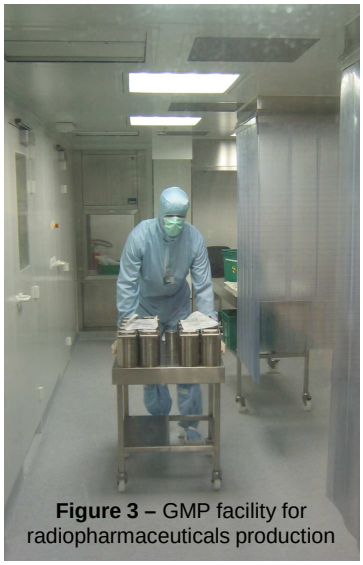

Figure 3 – GMP facility for radiopharmaceuticals production

Conclusions

Based on the integration of our own core know-out and the expertise (software, hardware) of a specialized small and medium enterprise, we implemented a new cost effective quality system for GMP radiopharmaceuticals production in an academic environment. Our decision to use an affordable adaptive case management software instead of a suite of a laboratory information management software (LIMS), an electronic laboratory notebook (ELN), and a documentation management software (DMS) greatly simplifies and speeds the implementation of a traceability and quality management system in GMP facilities.

References

1 EU Legislation - Eudralex Volume 4, Good Manufacturing Practice (GMP)
2 BenchSys, Labage SA http://www.benchsys.com/
3 EU Legislation - Eudralex Volume 4, chapter 4, documentation, 01/2011 http://ec.europa.eu/health/files/eudralex/vol-4/chapter4_01-2011_en.pdf
4 Dynamic case management – An old idea catches new fire, December 28, 2009

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