

## Automation of Sample Traceability at BAXTER European R&D Centre IMPLEMENTATION + GAMP Category 5 VALIDATION

**Partner:** BAXTER R&D Europe

**Industry:** Pharmaceutical

**Turnover:** EUR 6.8 billion

**Employees:** 46,500+

**Website:** [www.baxter.com](http://www.baxter.com)

**Application:** Sample traceability

**Country:** Belgium

**Technology:** HF tag + barcode  
Fixed TAGSYS reader  
Mobile PSION reader  
RFIDEA reading tunnel  
RFIDEA management software

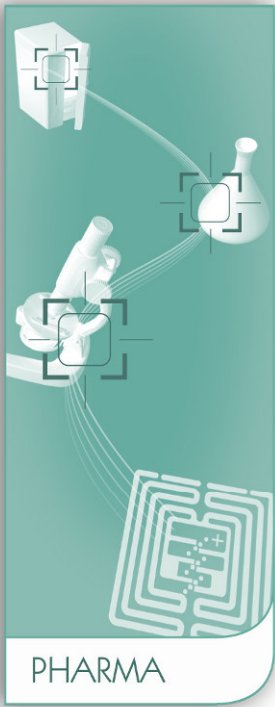
### Client situation and challenge:

- ⇒ BAXTER R&D EUROPE: around 160,000 samples kept in 15,000 boxes in 1,000 locations. These samples (pouches, etc.) are received and then stored in various climatic chambers used to simulate their ageing;
- ⇒ Around 1,500 samples are removed from the stocks each week and prepared to undergo laboratory stability tests. The samples are destroyed at the end of the cycle;
- ⇒ The BAXTER teams must know the number of samples in the various storage zones as well as the number of samples undergoing analysis and their status at all times;
- ⇒ Before implementation of RFIDEA's solution, these operations were long and tedious. They were also associated with a great risk of human error. For this reason, the capacity for use of the information collected was limited;
- ⇒ "GAMP critical" environment.

### Solution:

- ⇒ Preliminary audit by RFIDEA to analyse all parameters (environmental, technological, safety, human, process, etc.) related to the application to identify the technical solution providing the best return on investment;
- ⇒ Implementation of a solution based on mixed identification using both barcodes and the RFID technology (HF);
- ⇒ Creation of RFIDEA's *Samples Identification Management System* (SIMS) based on a client-server IT architecture allowing for viewing and sharing of sample data from and between the "office", "reception", "storage" and "lab" zones with secure identification;

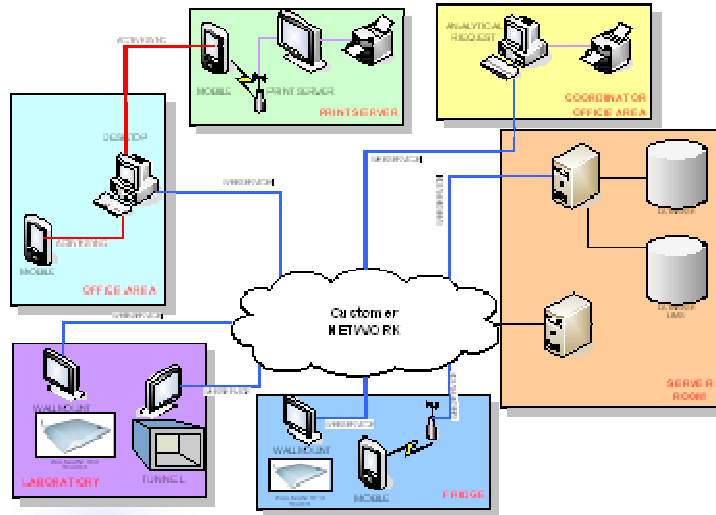




LOGISTICS

EVENT

**Baxter**



- ⇒ Use of mobile readers (supporting both reading of barcodes and HF RFID) and a reading tunnel in the analytical zone for sample reception;
- ⇒ Use of fixed readers connected to the network by Wi-Fi and Ethernet for verification of the reading sequences, selection of actions and error control;
- ⇒ Validation and complete documentation of the final solution based on the recommendations in the GAMP IV guide, category 5 and CFR 21, part 11.

**Advantages:**

- ⇒ Savings of 1 man day/week through automation of the double check procedure;
- ⇒ Development of new analytical capacity;
- ⇒ Optimisation of annual sample processing capacity with the same teams;
- ⇒ Reduced number of errors;
- ⇒ Automation of administrative procedures, dematerialisation;
- ⇒ Automatic verification of stocks;
- ⇒ Increased security;
- ⇒ Perfect conformity with rules of good practice in force in the sector.

**Hardware**

**HF RFID labels + barcode  
Fixed readers  
Mobile readers  
Reading tunnel**

**Software**

**Samples Information Management  
RFIDEA system**

**Database**

**MS SQL Server**

**Client testimonial:**

*"I'd like to thank you for the quality of your work as well as your constant show of honesty and respect throughout our discussions and dealings. Such high-quality communications and open-mindedness are relatively rare in these times. Rest assured that we appreciate it to the fullest extent."*

**Mario Costalungua, R&D and RA Group Controller Europe, Baxter R&D Europe**



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