ELN goes GLP

The journey of implementing an ELN system in a regulated environment – experiences at Janssen R&D.

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Pictured above: HIV absorption

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Overview

- Introduction
- Why implement an ELN?
- (The long road of) Implementing the ELN
- QA concerns
- Final Remarks

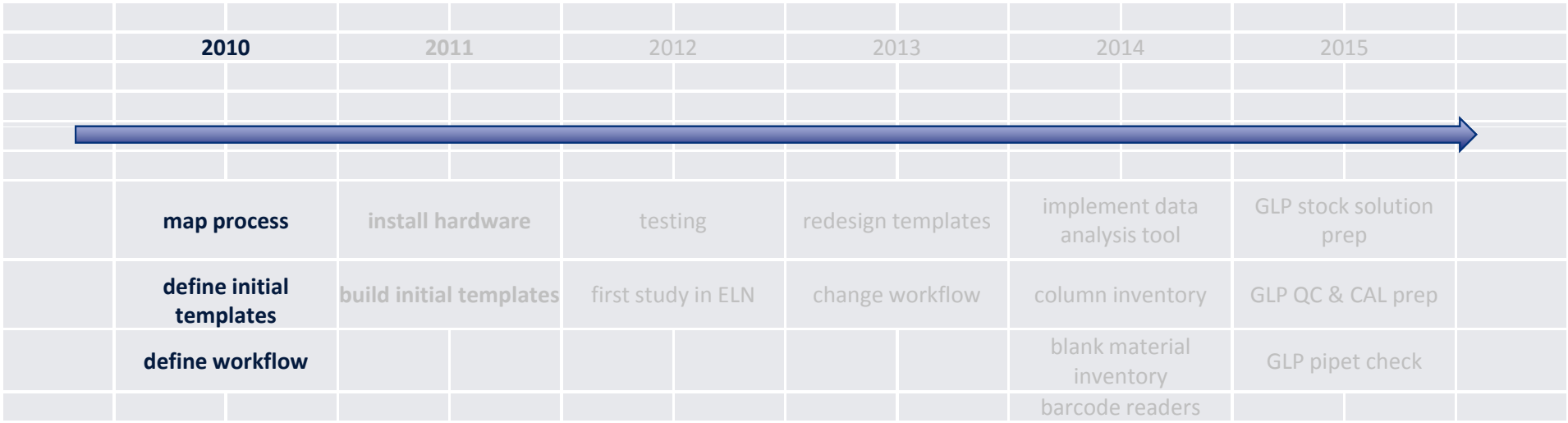
Introduction

- Decision to go for ELN taken in 2010
- One common platform was selected across different groups within R&D for IT consistency
- Consequence: ELN needs to be tailored to specific bioanalytical needs
- Wanted ELN for real time, audit trailed raw data capturing; not a repository for offline filled out forms
- ELN should enable automation of certain tasks: eg QC review

Why implement ELN?

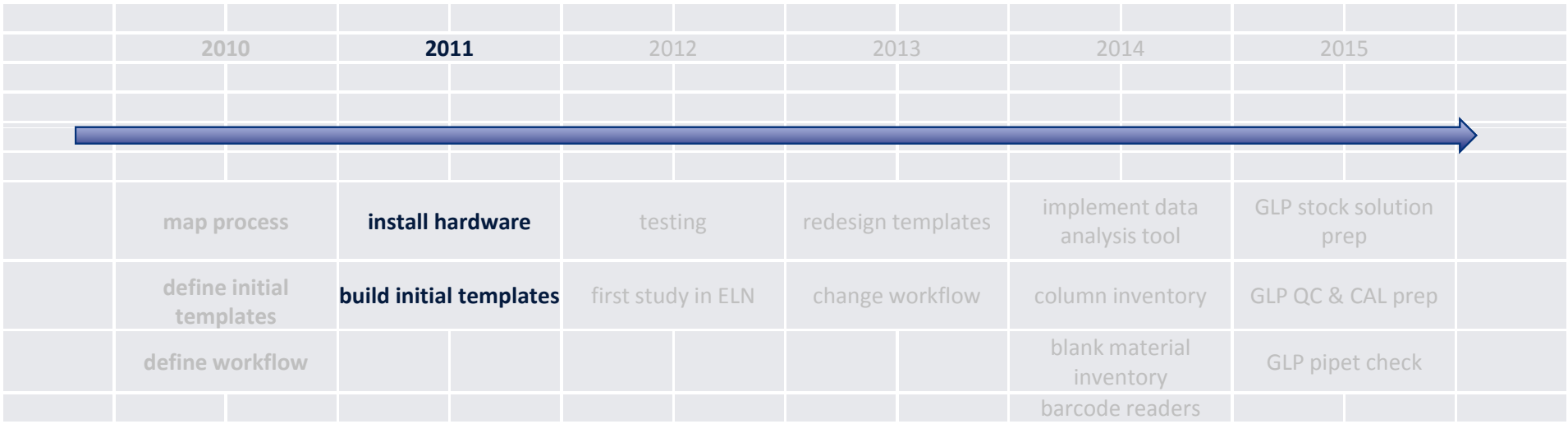
- We had a dream of a “paperless” lab
- Many data already in electronic format (Analyst, Watson, e-mails) but wet lab documentation still on paper
- Quality review in real time (system preventing use of expired reagents or out of spec instruments) rather than after the facts
- Improve data access from all over the world, enable data sharing
- Improve compliance and data integrity (audit trail)
- Reduce risk of data being lost (as opposed to paper)
- Improve efficiency (no more chasing after raw data binders)
- Reduce the space required for physical archiving

From dream to reality: the long road of implementing the ELN



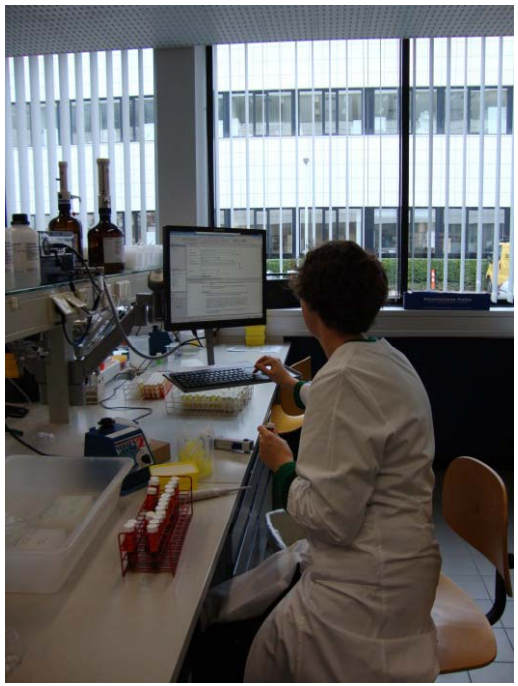
Implementing ELN: translating paper into electronic process

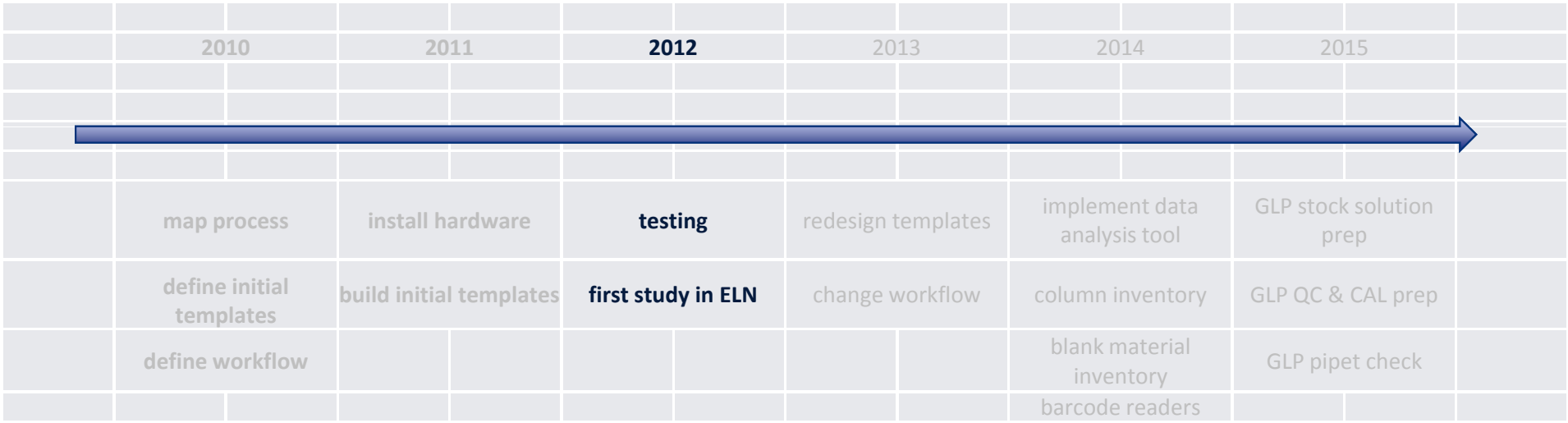
- Formed a team of super users (BA + technology support) to guide the implementation
- Mapped the different steps in the BA process (22 different paper forms for sample prep, analysis & run evaluation)
- Defined templates for ELN
- Started from what we knew: copy available paper forms 1 on 1 into ELN


2010
2011
2012
2013
2014
2015
map process
install hardware
testing
redesign templates
implement data analysis tool
GLP stock solution prep
define initial templates
build initial templates
first study in ELN
change workflow
column inventory
GLP QC & CAL prep
define workflow
blank material inventory
GLP pipet check
barcode readers

Implementing ELN: hardware considerations

- Installed kiosk PCs throughout the lab with remote desktop capability; enable real time data entry and access to info on desk PC
- From experience in other R&D groups this setup is more convenient than tablets

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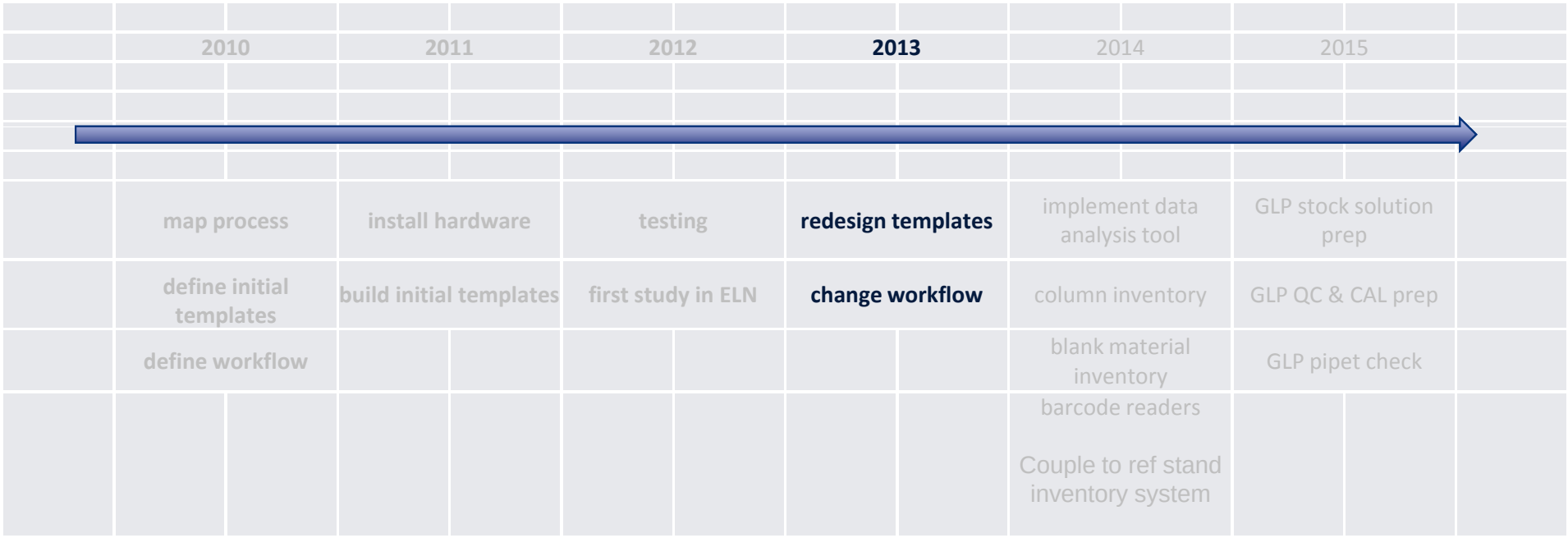
First studies in ELN (non-GLP)

- Feedback from lab technicians not very positive: performance issues hurdle for acceptance
- “Studies take more time to complete than on paper”
- Forms completed after the experiment…not compatible with a regulated environment
- Involved QA from the beginning to avoid unpleasant surprises at the end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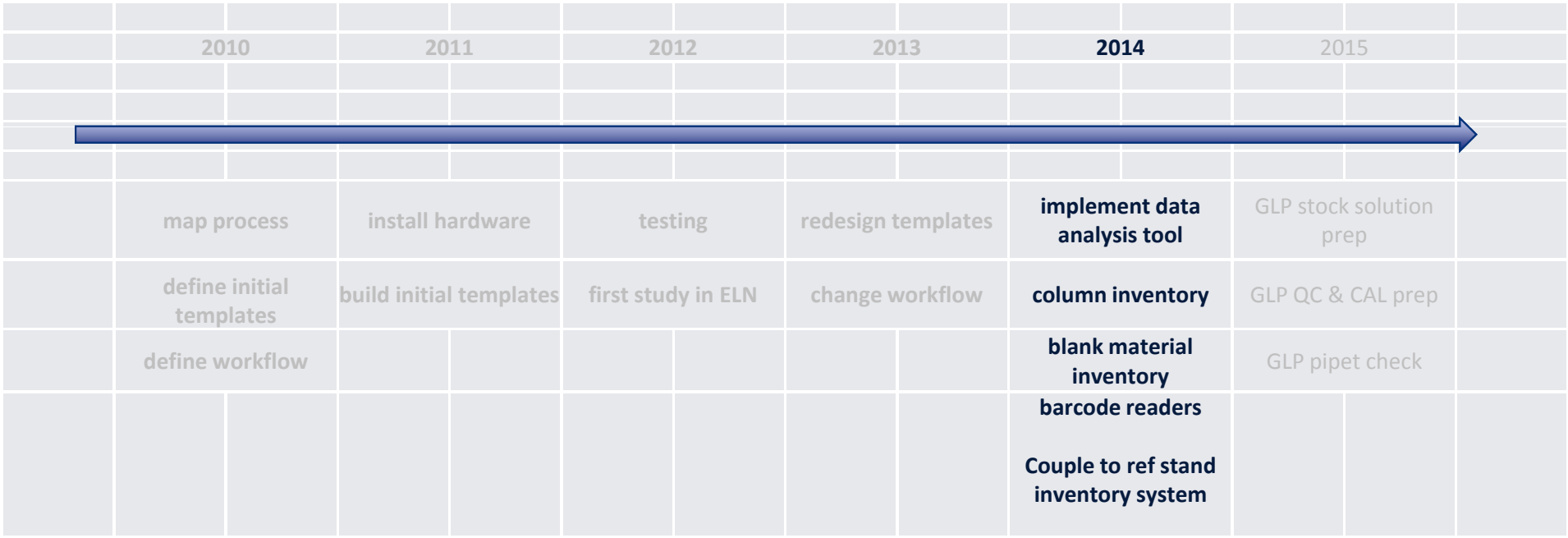
Couple to ref stand inventory system

Back to the drawing board…

- Re-designed templates to reflect chronological flow in the lab
- Reduced number of forms
- Changed setup of studies in the system; each run is experiment of its own i/o master-child setup
- This improved performance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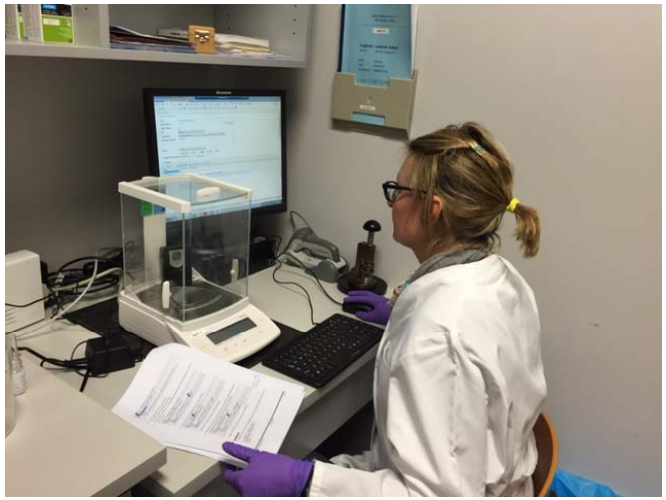
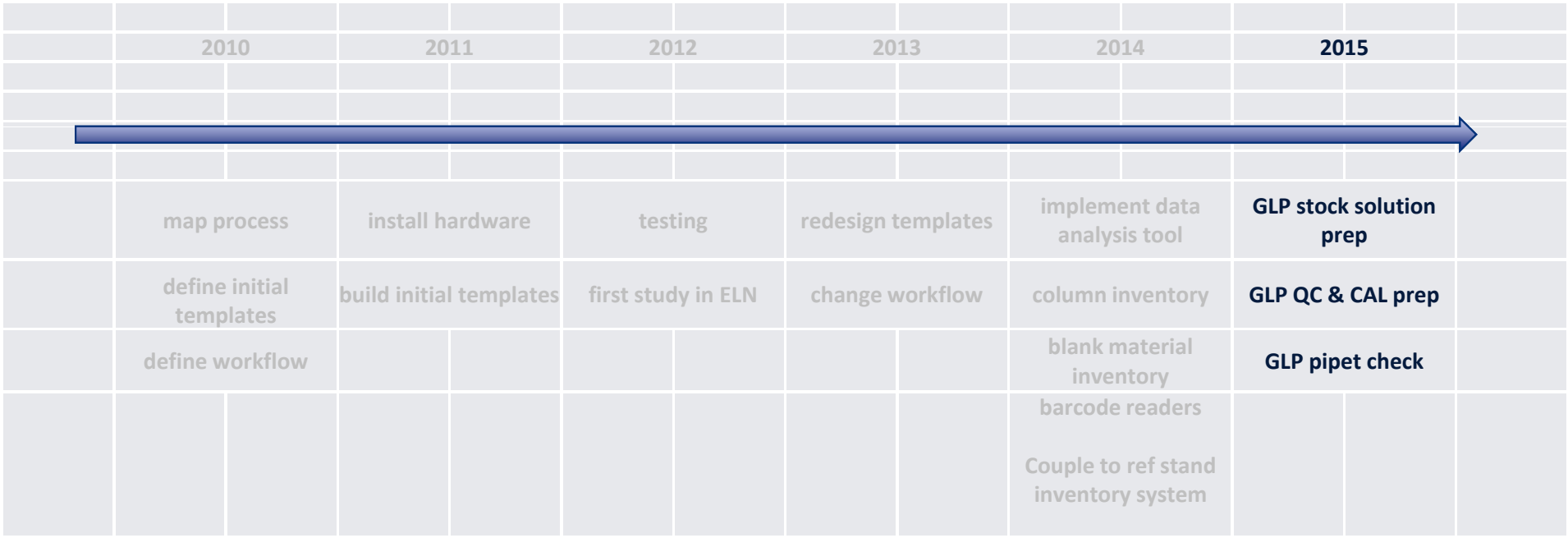
Further improving the ELN

- Implemented data analysis tool to automate some of the QC checks → additional forms become obsolete
- Coupled reference compounds management system to capture balance outputs for stock solution preparations

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Moving into regulated territory

- After testing for 4 years and multiple iterations to design a system that meets our expectations, moved to next level
- In 2015, roll out for regulated work in small steps over a timeframe of several months:
  - Preparation of all stock solutions and dilutions
  - Preparation of CALs & QCs
  - Pipet checks
- Adapted SOPs to reflect use of ELN
- Before full roll-out, QA audited a non-GLP study and flagged some concerns

QA concerns: (Non)-Contemporaneous data entry

- Data are often not entered contemporaneously (every entry is audit trailed and time stamped)
- Defined in SOP what information should be entered immediately and what can be entered on the day of analysis:
  - Immediately: data that should be readily documented to enable re-constructability; eg critical times (time QCs pulled from freezer); balance read-outs (in case of pipet checking)
  - On the day of analysis: eg which equipment did I use ?
- Everyone needs to get adapted to the electronic way of working
- With paper many things will go unnoticed but in the electronic world everything is time-stamped

QA concerns: Paper records

- Part of the documentation is still on paper (eg shipment records, certificates for columns or blank material…)
- Idea was to scan in, upload to ELN and not retain original in paper archive
- QA is hesitant: need QC check to verify copy is conform original to avoid potential loss of data (only one side of the page is scanned, part of the document is not readable…)
- Where to document this QC check?
- Decided to keep paper for now until we find a proper solution

QA concerns: How to document QC review in ELN?

- On paper, check marks indicate what has been verified in QC review
- Not possible for electronic data
- Instead, a QC verification form is used during review, each line representing an individual item that was checked and that is ticked upon completion of that step

QA concerns: Disaster recovery

- What to do in case the system is down?
- Keep a paper based system in place and upload scanned in copies afterwards?
- Need to ensure that every change in the electronic forms is also made to the paper system.
- Decided to not go for this approach and halt activities when the system is down.
- Rely on appropriate IT support.

QA concern: Reason for changes

- Not every change in ELN prompts for a reason, although every change is audit trailed
- On paper reason for changes is “writing error” in 99% of the cases.
- Documented in SOP that “changes without documentation of the reason should be considered as entry error”
- In case the reason is not an entry error, the reason will be documented under additional study information

QA concerns: Double Blind studies in ELN

- ELN set up to enable data access from different locations by different groups
- BA data from DB studies contains unblinding information
- Separate studyfolders with restricted access (limited to BA) must be set up

Final Remarks

- A number of iterations and 5 years of investment were required before getting to an ELN that is adapted to our needs
- Lack of on-site hands-on expert knowledge of the ELN system caused a substantial delay in roll out
- People need time to get used to the electronic way of working and the consequences thereof (audit trail); a paper based process is much more forgiving in terms of documenting stuff after the facts
- Safer to roll out ELN in small steps rather than do it in one big push
- It's only after you have been using ELN for a while that you start to realize the actual benefits
- Lab technicians no longer want to go back to paper

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