

100% EXCLUSIVE
TO LIFE SCIENCE

• 24/7 ACCESS TO SERVICE SPECIALISTS

99.7% ON TIME DELIVERY,
WITHIN SPECIFICATION

• PASSIONATE TEAM MEMBERS WITH MARKET EXPERIENCE

• ONLINE TOOLS FOR FULL
PRODUCT VISIBILITY

E-LABELS – MANAGING VARIABLE DATA EFFICIENTLY

PRESENTED BY

Sascha Sonnenberg, VP Global CTD Sales & Operations

DEPOT SERVICES



GLOBAL PROJECT MANAGEMENT



COMPLETE GMP-COMPLIANT
DEPOT NETWORK



PICK AND PACK



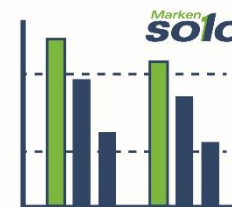
DRUG RETURN AND DESTRUCTION



QP SERVICES
(EU)



LABELING AND
LATE STAGE CUSTOMIZATION



REAL TIME INVENTORY MANAGEMENT



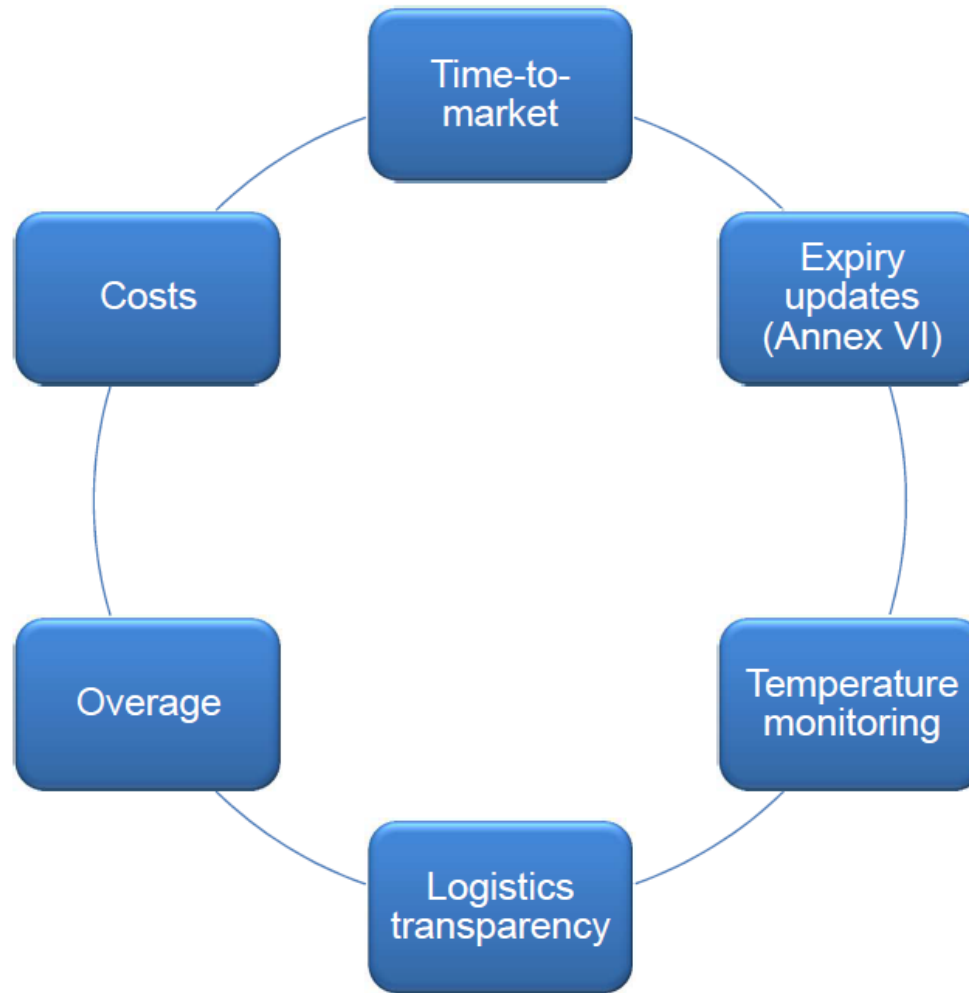
- ✓ Take a piece of paper
- ✓ Write down the amount (your estimate) how much your company spend per year to update expiry/re-test dates

How do you manage re-test dates in your company?

- ✓ Re-labeling at the Investigator Site
- ✓ Re-labeling at the local / regional depot/distribution hub
- ✓ Bringing it back in to a GMP facility
- ✓ Using new central Just in Time concepts
- ✓ Using decentraliued Just in Time (Late Stage Customization)

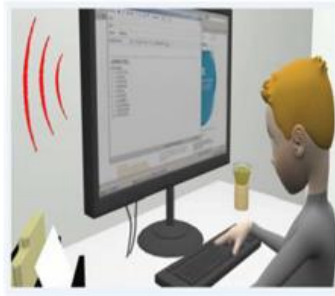


**LABELING AND
LATE STAGE CUSTOMIZATION**



ELABEL

Smart Label Technology



Faubel-Med®Label
Software

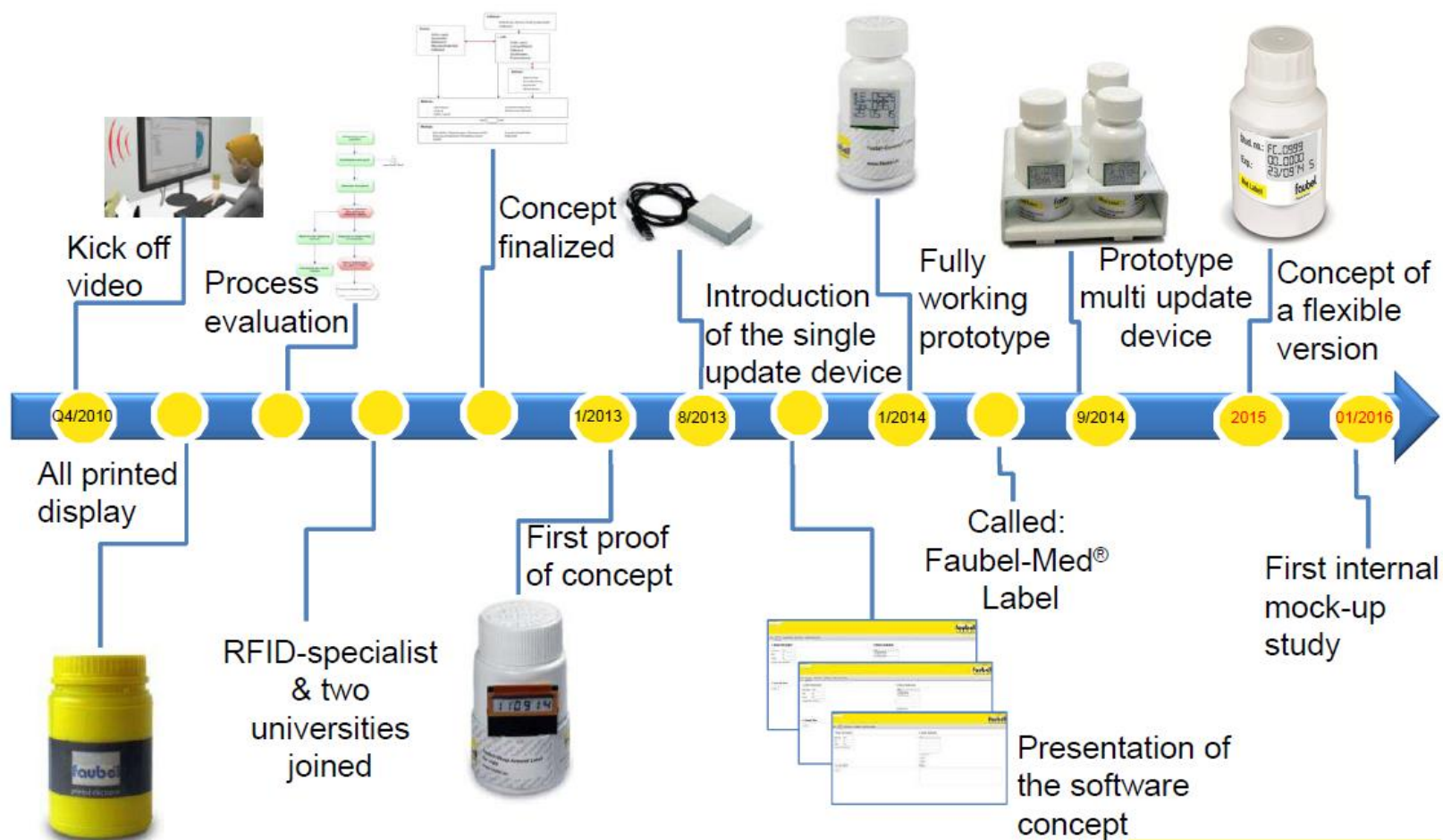


COMPLETE GMP-COMPLIANT
DEPOT NETWORK



Faubel-Med®Label

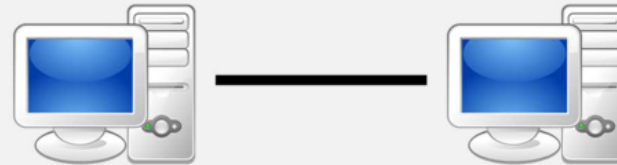
- Update of specific data
 - Expiry updates



Hardware Philosophy

- “One size fits all” due to the technical complexity
 - Cost decrease when upscaling
 - Customization by label concept and / or software

- Use of existing components
 - Approved from other industries
(e.g. nuclear power stations)
 - Mass available standard components
 - More than one supplier per component



faubel[®]
Pharma Services

Infrastructure

› Update device

- › To write data on the Faubel-Med[®]Label
- › Communicate with software
- › Smart Tag
 - › To show variable information
- › (Booklet) Label
- › Software

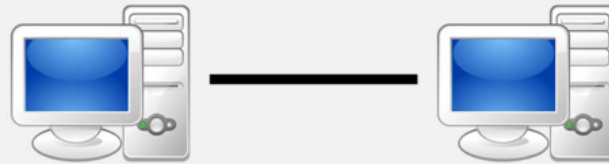


- › **Single-update device**
 - › Proximity-range system (< 5 cm)
 - › Three device types
 - › Desktop device
 - › Handheld device
 - › Smartphone device (NFC)

Hardware Update Device

- › **Multi-update device**
- › To update a kit or box
- › In development
 - › Desktop MUD
 - › Update of 4 units





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Pharma Services

Infrastructure

- › Update device
 - › To write data on the Smart Tag
 - › Communicate with software
- › Smart Tag
 - › To show variable information
- › (Booklet) Label
- › Software

Smart tag

Display information

- › The numbers of characters is limited
- › Clear definition of numeric and alphanumeric digits
- › At the moment



Sponsor – Compound- Protocol

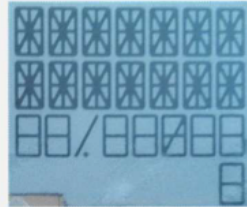


Expiry Date



Counter





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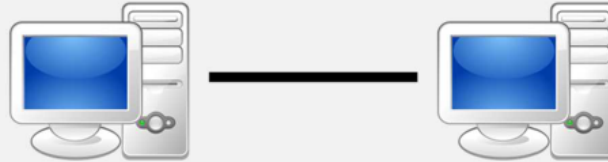
Smart tag

RFID

- › Unique ID
- › To transfer information no visual contact is necessary
- › Transfer data and energy

DISPLAY

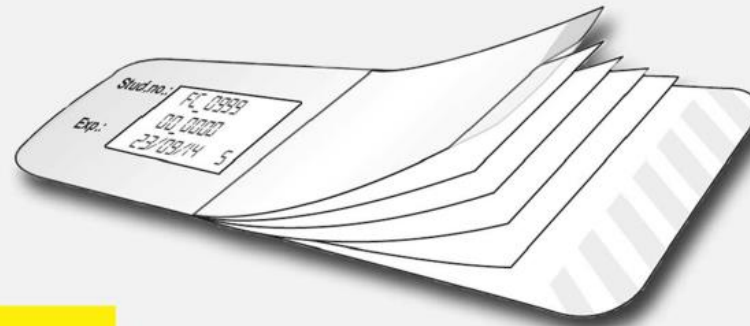
- › Bistable
- › Sunlight readable
- › Robust



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Pharma Services

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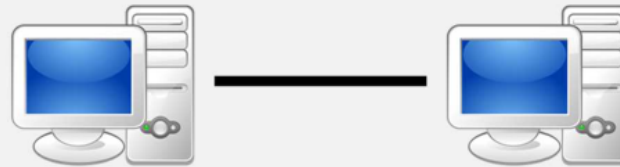


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Booklet Label

- › Faubel-Med[®]Label laminated to booklet
 - › Spine area
 - › Top laminate
 - › Flag label (in development)



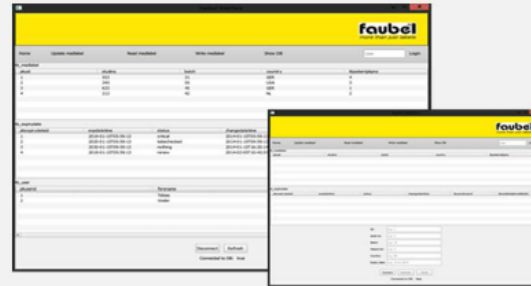


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Software



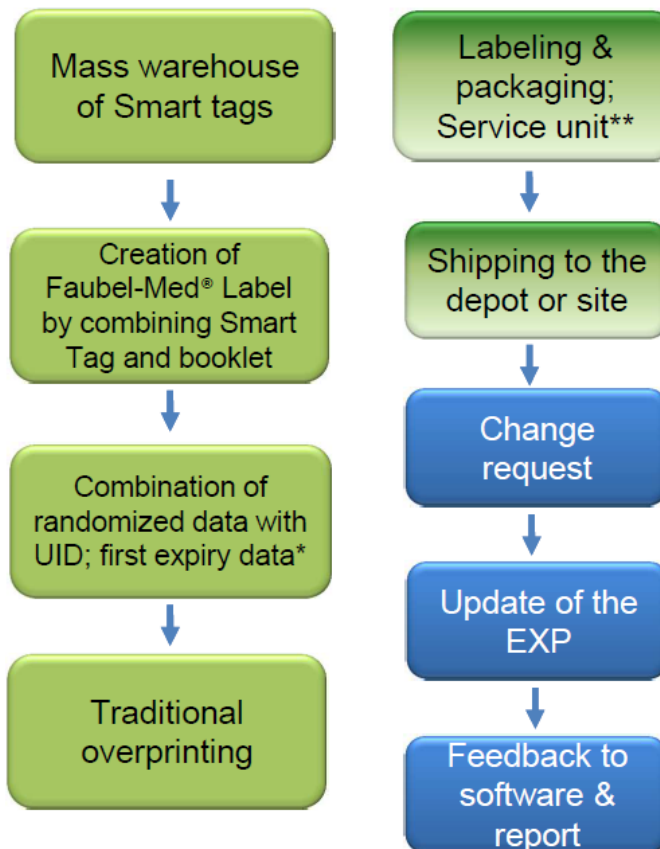
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Pharma Services

- › Built to match GxP requirements
- › Modular software in order to meet all requirements
- › Customization is possible
- › Several trials can be hosted in the system
- › Scaling up is possible
 - › From single dose update to study update

The Prototype

- › Access via login
- › The whole history of changes is stored and documented
- › Sends the data to the update device
- › Update device sends back data to the software

Faubel-Med® Label Process



*Can also be done first time at the depot
 ** Faubel created a GMP facility to facilitate first studies

Potential Impact of Faubel-Med® Labels

Expiry Updates

- Improve Time-to-market
 - Stability data generation and assigning shelf life is no longer a bottleneck for study start
 - Certain stability data are needed to generate sufficient shelf life for a clinical material
 - Would like to start as early as possible with the trial, even with very limited stability data

Potential Impact of Faubel-Med® Labels

Expiry Updates

- › Elimination of labor and resource intensive retest date extensions activities
 - › Writing batch records
 - › Printing and shipping of REDL
 - › Physical application of labels in depots or sites
- › Confirmation of finalized REDL activities (per depot)
 - › Impact on IVR system quarantine and release activities

- ✓ Is this kind of solution allowed? How about compliance with current/upcoming regulations?
- ✓ eLabel or eMeds?
- ✓ Is this technology reliable?
- ✓ How about Manipulation?
- ✓ Isn't this more expensive?



Q&A