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Translating Science to Medicine

Implementation of laboratory automation in a CRO environment

– from basic steps to advanced solutions –

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A few general considerations

Lab automation is commonly used in clinical routine laboratories for standard damands:

- High sample numbers
- Day-in, day-out the same analysis

In Pharma, in-house analysis is performed with robotic systems, if/since projects are scheduled for long periods and outsourcing is not foreseen

But in CROs, with short to midterm projects, sample numbers/study 100-5000?

In the beginning…

(7 years ago)

Tomtec and Tecan Genesis: Short and simple scripts for liquid transfer, no handling of worklists, no integration of peripheral instruments (only semi-automated)

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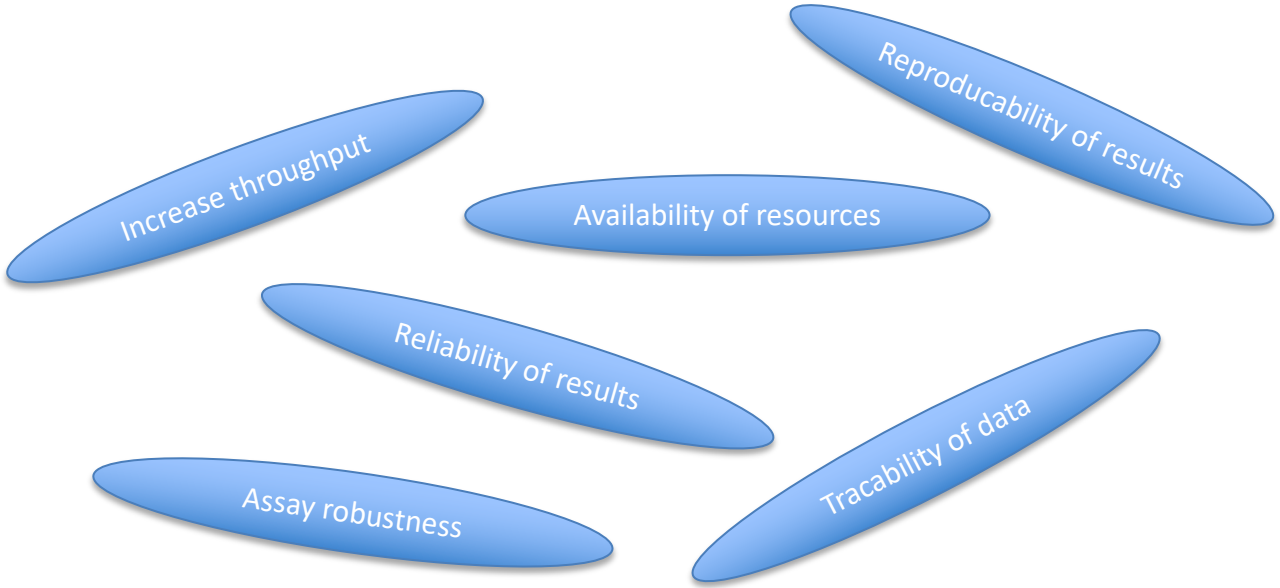
Introducing state of the art automation

What did we want to achieve?



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Take time and care for your user requirements

- Software security: 21CFRp11 should be standard for any modern lab automation
- Liquid transfer: accuracy & precision, error detection, handling and reporting, stress test under maximum capacity
- Peripheral instruments: drivers/compatibility with robot software
- Throughput (instrument size and capabilities)
- Consider flexibility and user-friendliness

And test it repeatedly !!

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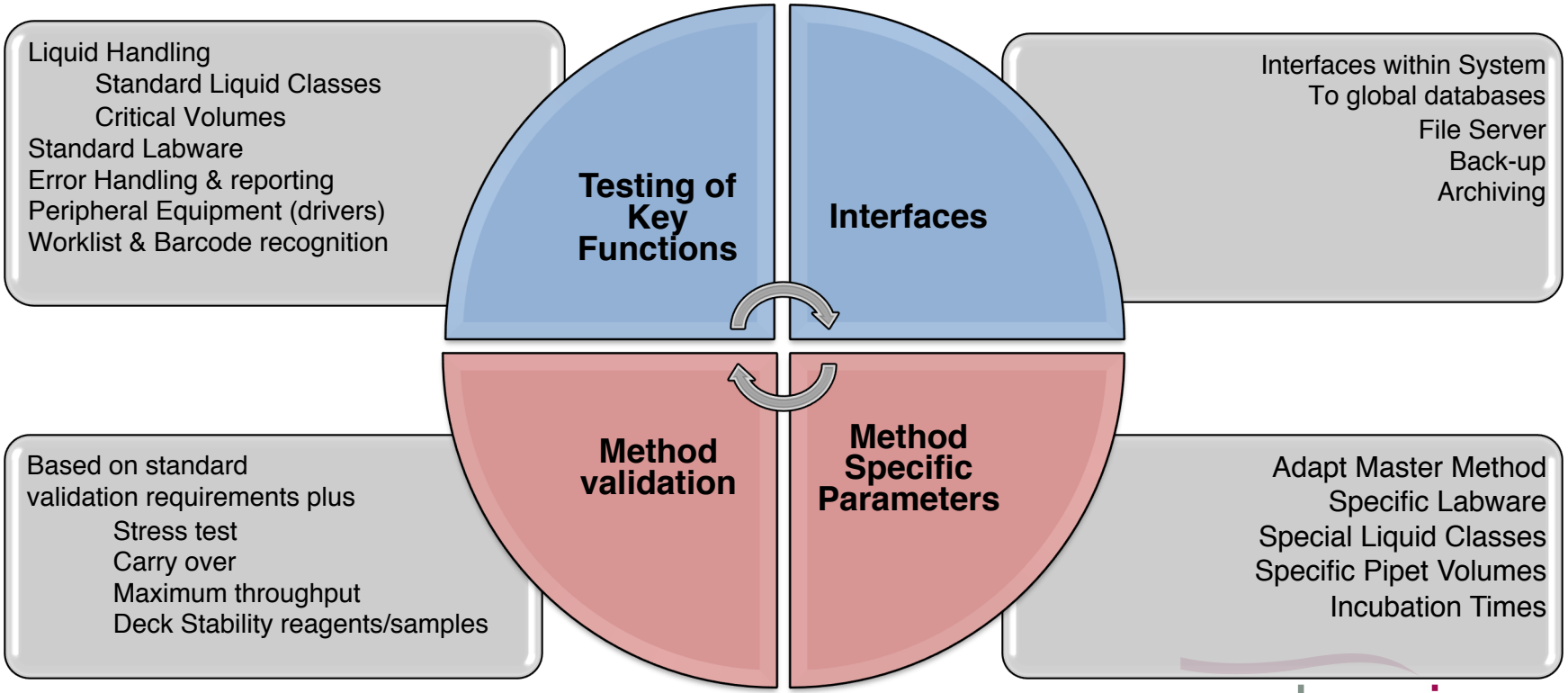
Automation Validation Approach
Prove suitability for intended use



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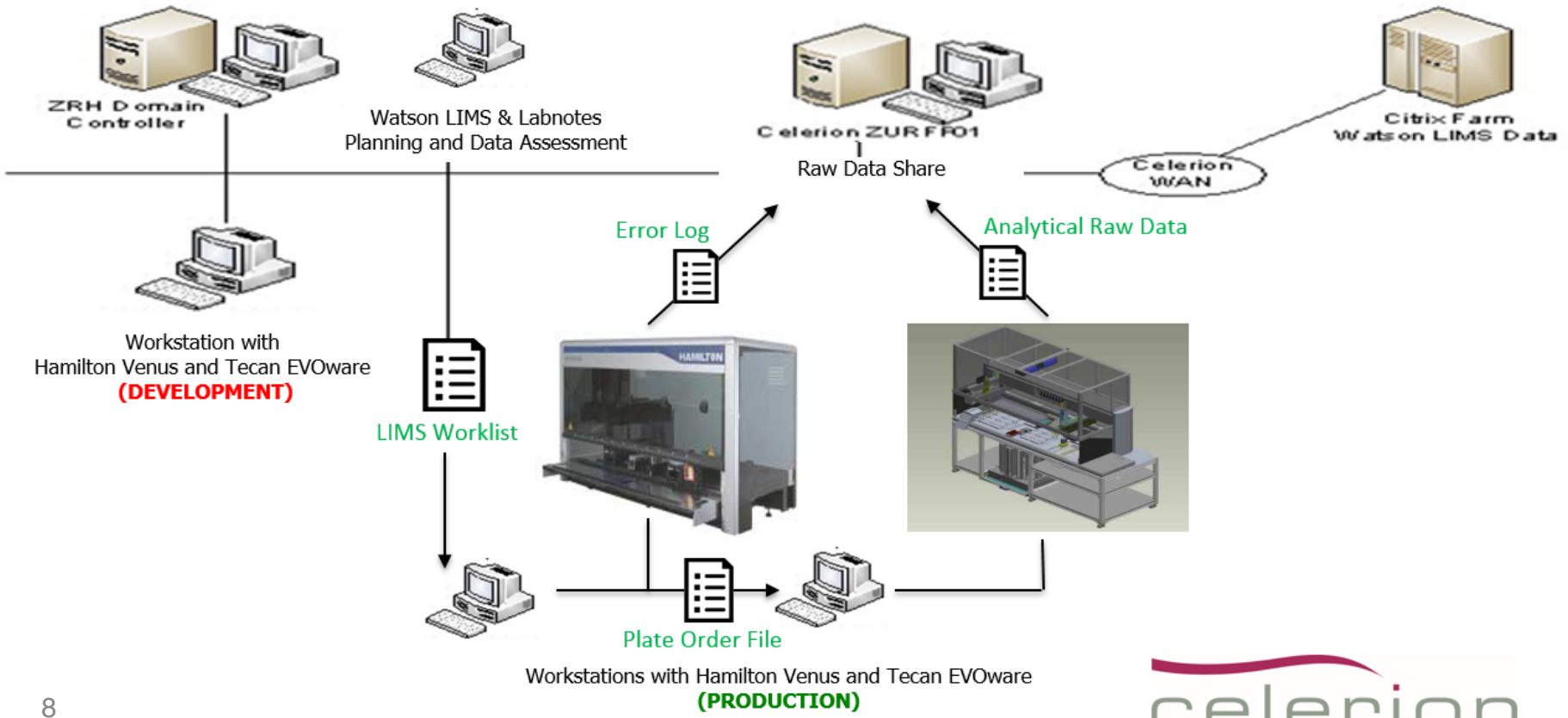
Data flow within your IT-infrastructure

Out of the LIMS – Into the LIMS



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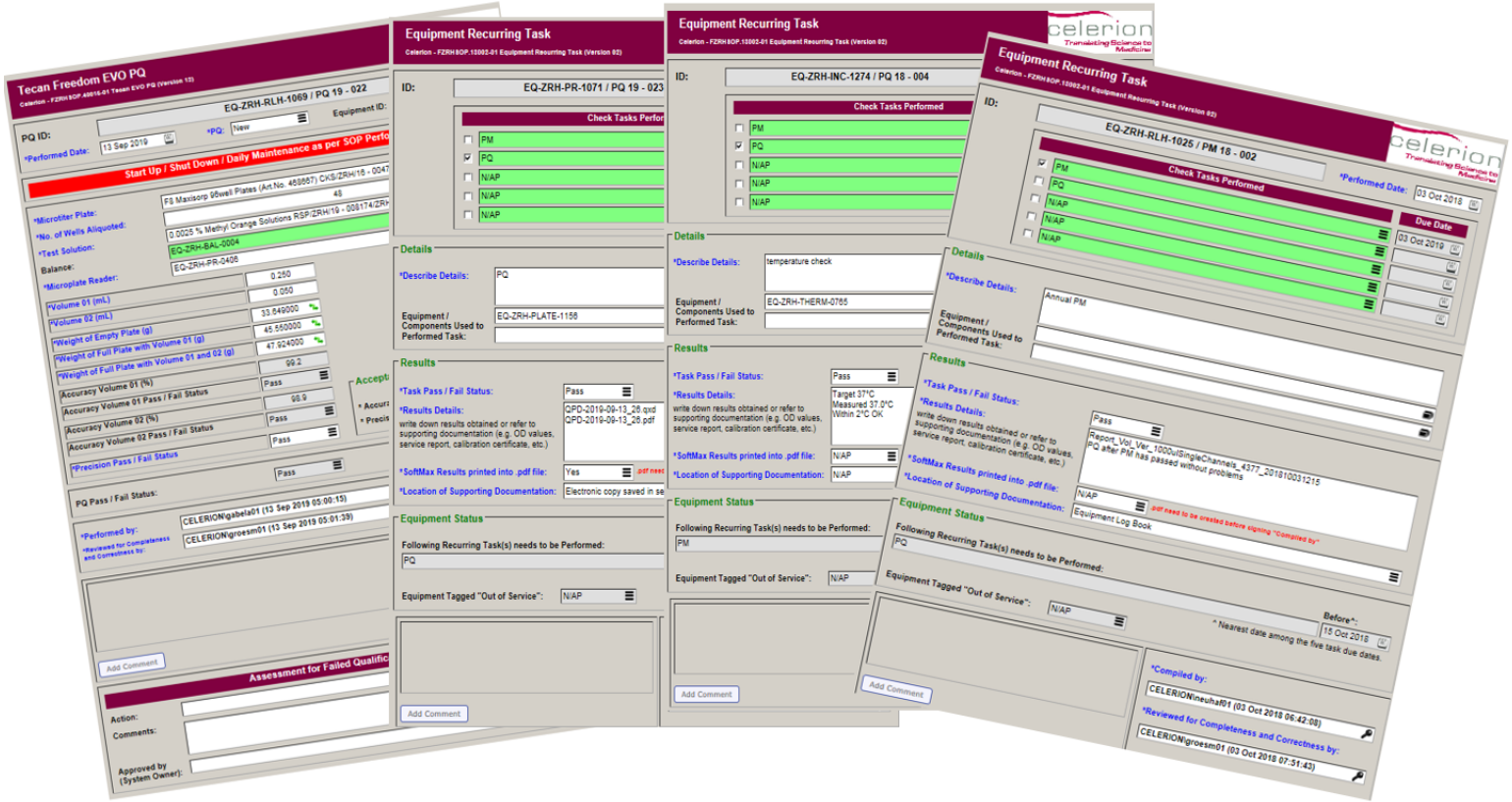
Continuous routine checks

What is practical and reflects the purpose of the system



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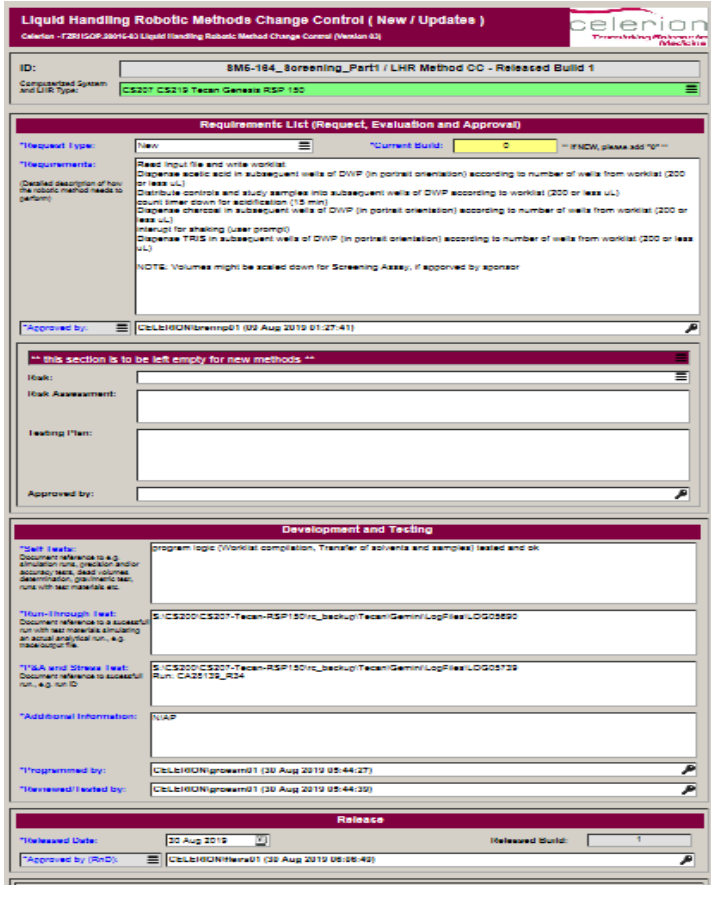
Method specific development and qualification

Request for a new method to be approved by TFM: no/samples, timeframe etc.



- Approval and Release
- Implementation in SOP
- Validation
- Productive usage

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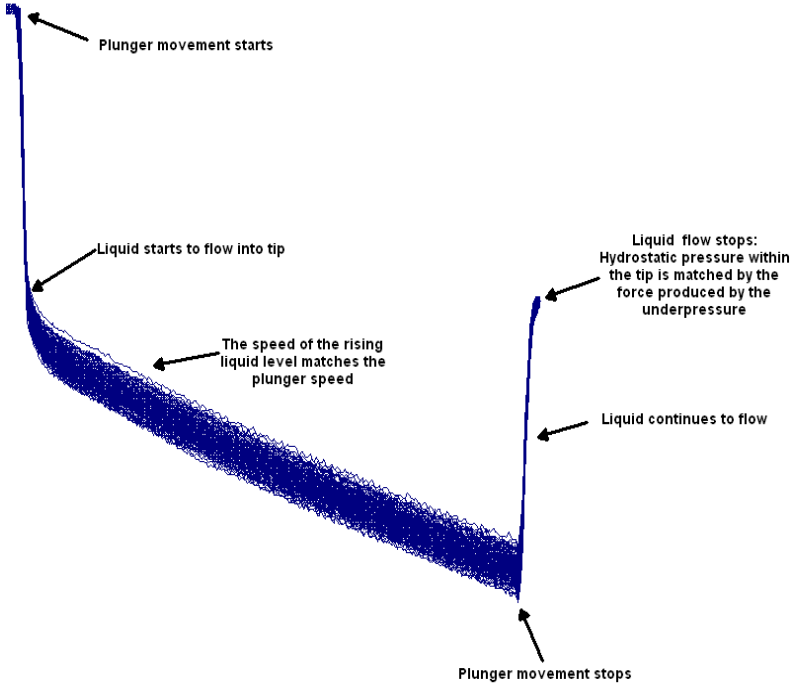
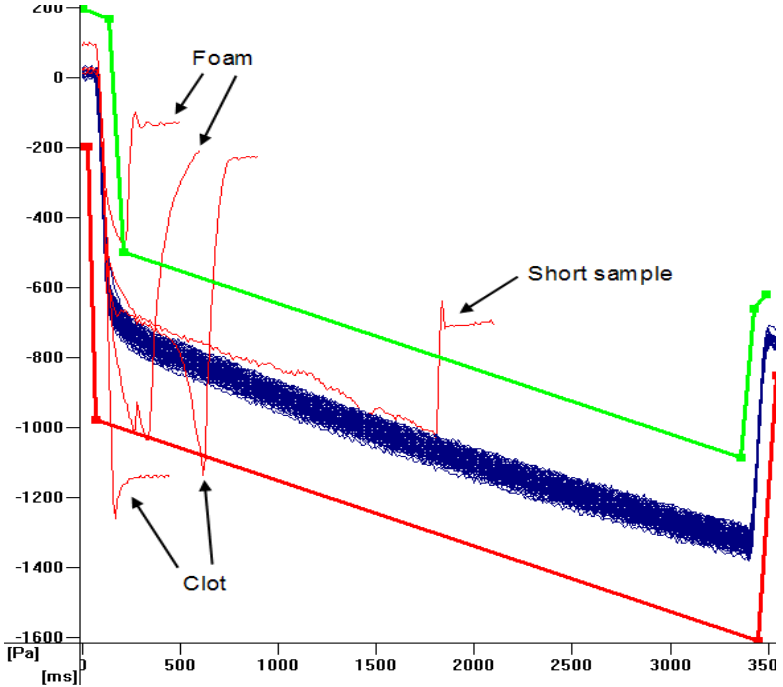
Liquid Handling and Error recognition

Total Aspiration and Dispense Monitoring





Recording and monitoring of complete pressure curve during aspiration and dispense
User defined tolerance band. If measured value leaves the tolerance band, pipetting stops immediately and error handling is executed"
Requires recording of pressure curves for each liquid class and volume

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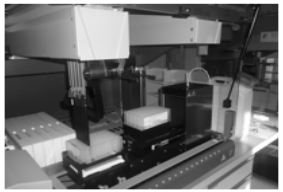
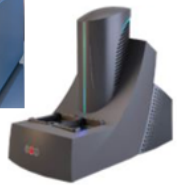
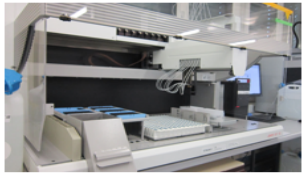
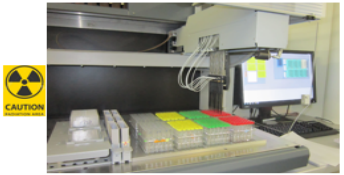
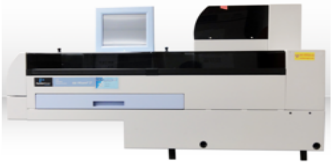
Examples

Current level of Laboratory Automation

	Lead-in (Spiking)	Tube to plate reformatting	Plate processing	Read-out
LCMS PK				
EIA PK & ADA				  integrated
RIA PK & ADA				

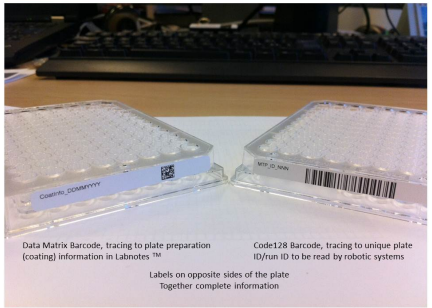
The biggest challenge…..

… and how to overcome

- Inadequate labels on tubes sent from central labs: limitation of tracability, relabeling might be necessary

No «white space» for start/end of barcode

Horizontally affixed label – not readable (even not with handhold scanners)



- Different labware used for sample storage within study: leads to false determination of filling status

→ **Request tester of «kit» (readily labelled sample tube) for central lab/clinic**

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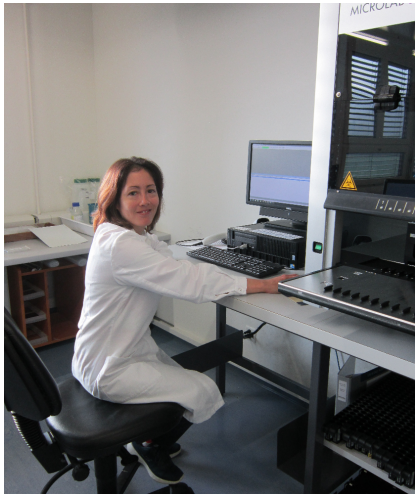
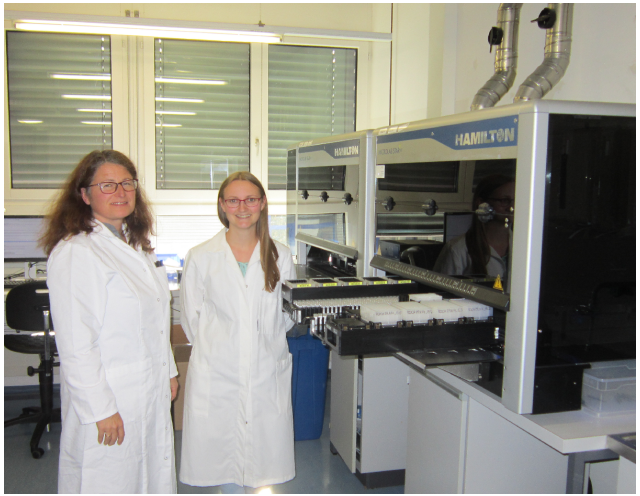
Last but not least

Build a team of dedicated people

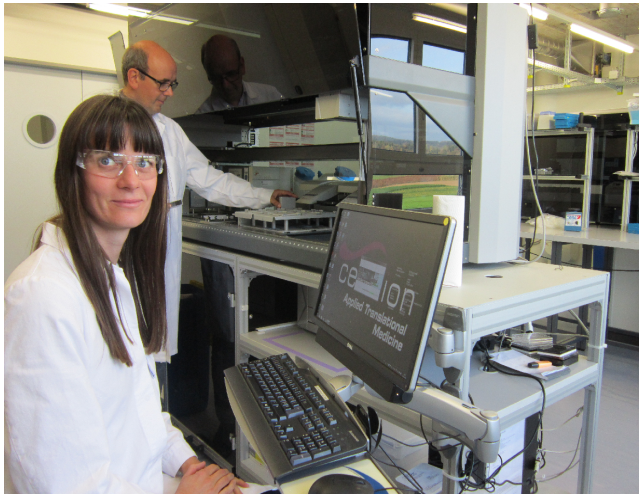


Rebeca
Robot and Labnotes Programming



Simone
Beta-User

Anke
Instrument Responsible
(Programming and Hardware)



Irene & Frieder
Instrument Responsibles (Programming and Hardware)

→ Lab staff needs to understand robotics as fellow, not as rival

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Summarized overview

- No System can accomplish all tasks: define your needs, configure the system and keep it to a dedicated functionality
- CS validation: Cover all basic, standard, daily aspects of the system, also including induced errors

Reliability of results

- Depending on the method the output per person increased by a factor 2 to 10
- Have a manual/semi-manual process as back-up in case of system failure or limited system capacity included in the validation

Increase throughput

- Increased traceability throughout the process
  - Alerts related system status via light and email
  - Error logs / barcode reading

Tracability of data

Reproducability of results

- Increased batch success rate

Assay robustness

- Ensure proper training of employees
  - e.g. Deck layout check, loading of samples and disposables, filling volumes

Availability of resources

- Early Communication with internal & external partners regarding container types and volumes, bring everyone on-board early in the process
- Purchasing control for disposables, like for like is not always the case

Thank you for your attention