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Translating Science to Medicine

Workflow Automation in a regulated BA CRO environment

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Requirement Phase

- **Why** did we want to automate?
  - Increase throughput
    - Deliver results faster without increasing headcount
  - Increase reproducibility
    - Quality of data
    - Decrease of human errors
  - Increase traceability
    - Barcodes
    - Trace Files

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Requirement Phase

- **What** did we want to automate?
  - PK and ADA
    - sample preparation & processing & measurement
  - LCMS and EIA & RIA & ECL& AlphaLisa Assays
    - different workflows (bioanalytical assays)
    - different complexity / labware
  - Preclinical to Clinical Late Stage Studies
    - study size 500 to 20’000 samples
    - different tubes / sample labelling

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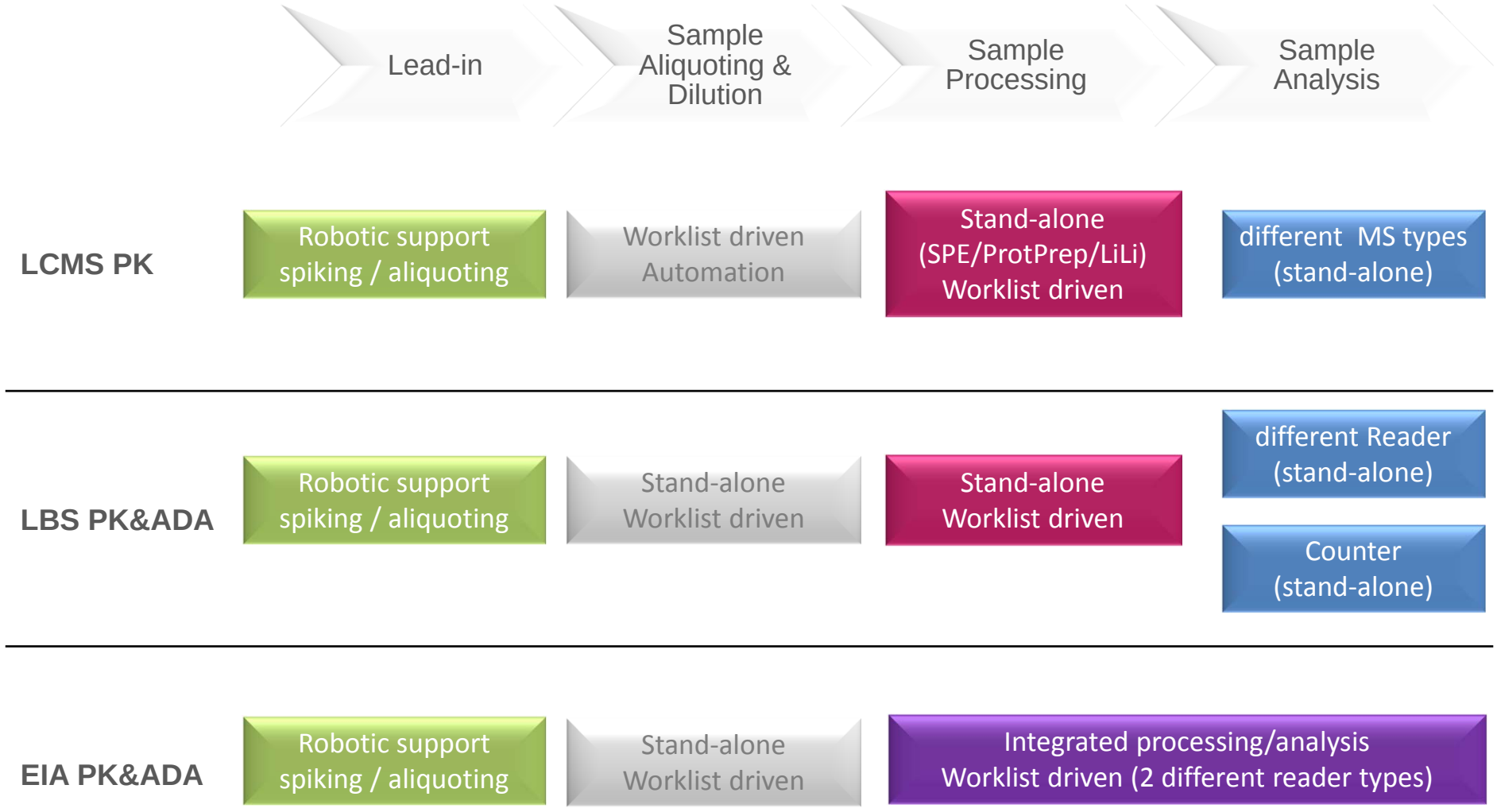
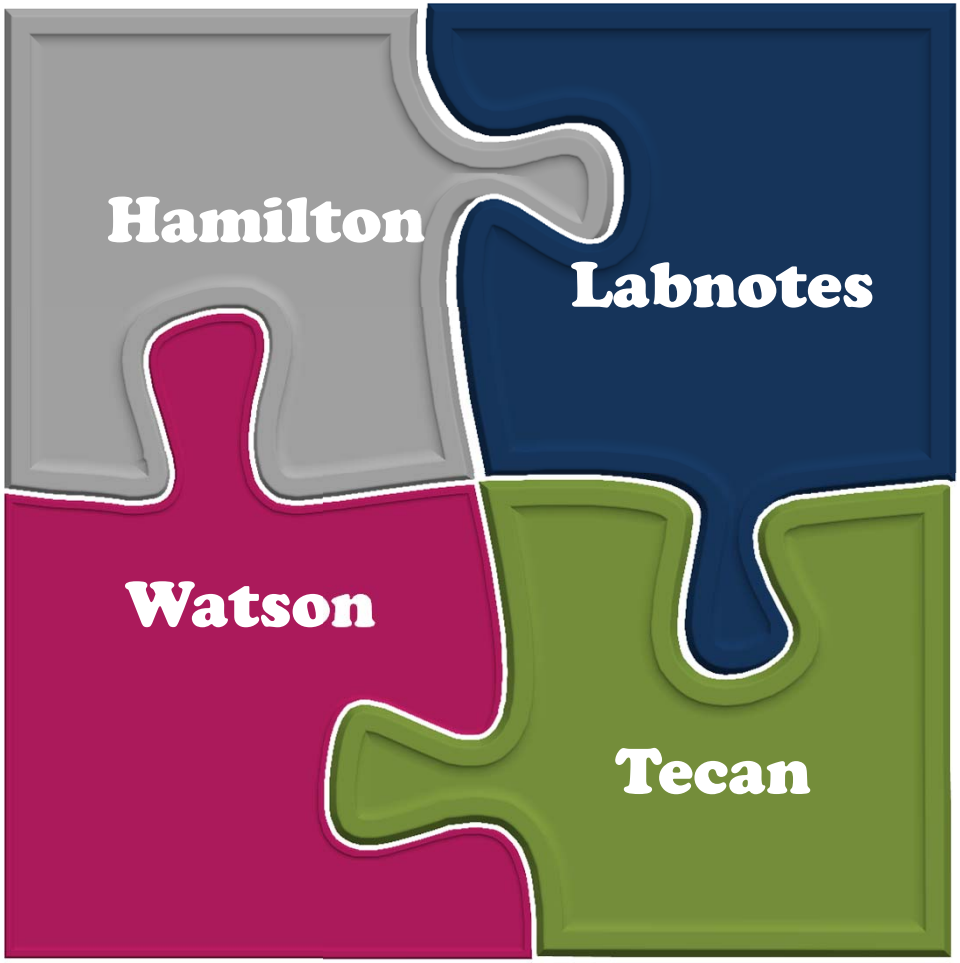
Handle different workflows assays



Interaction of Databases and Equipment



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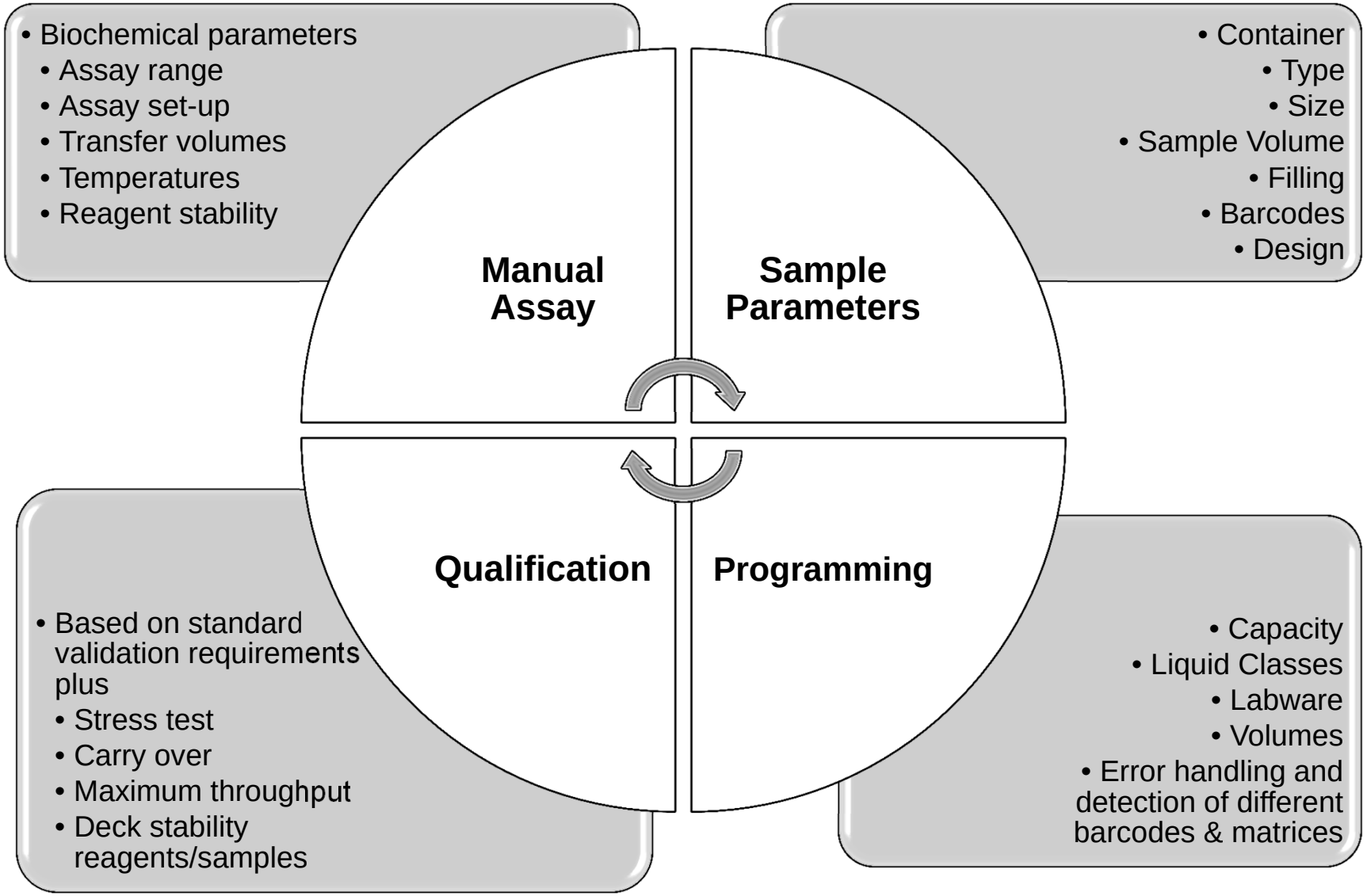
Implementation Challenges

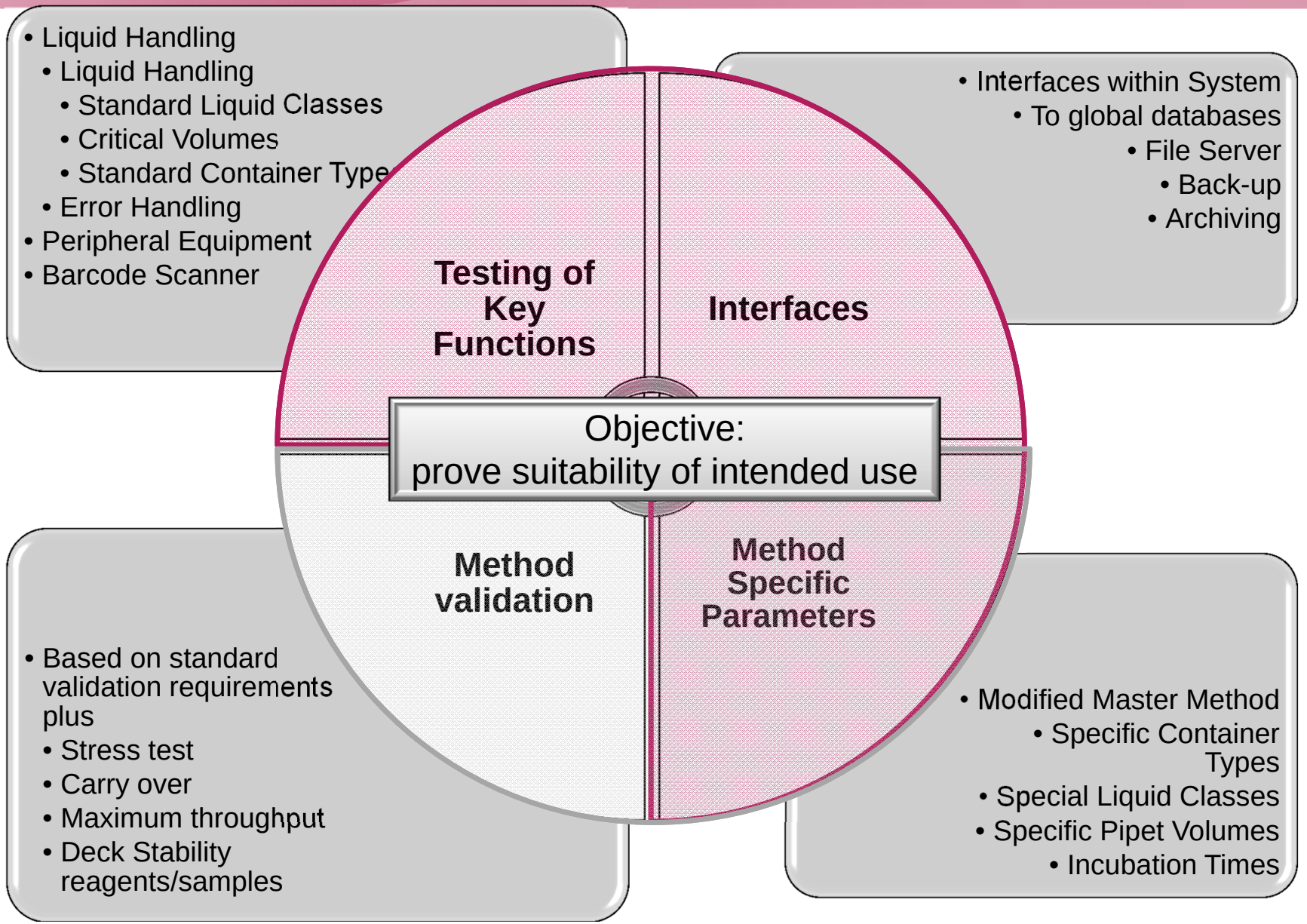
- Overcoming barcode differences between Watson™ and Labnotes™
  - Two barcodes on same label
  - Standardizing plate labeling (interface between 2 platforms)

- Handling different scanning / Barcode readability
- Develop methods to allow increased throughput
  - incubation times, reagent stability on deck
- Increased complexity in methods
  - acid dissociation, temperature critical steps
- Handling different labware
- Handling different scanning / Barcode readability

Adopted Process Flow Method Development



Automation Validation Approach



Current Status

- All Systems validated and majority of all PK & ADA work is based on robotic support (>80% of all PK/ADA samples)
- Depending on the method the output per person increased by a factor 2 to 5
- Increased traceability throughout the process
  - Alerts related system status via light and email
  - Error logs / barcode reading
- Increased batch success rate
- Ensure proper training of employees
  - e.g. Deck layout check, loading of samples and disposables, filling volumes
- Have a manual/semi-manual process as back-up in case of system failure or limited system capacity included in the validation

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Challenges – Lessons learned

- 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
- «Expect the unexpected», reminder automation does not mean everything will be faster! Therefore, allow sufficient time for lead-in
- Develop flexible systems that will have multiple uses over time.
- Talk to your IT!

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