

Automation of GMP Validated Processes in Quality Assurance Testing

Automation of
Quality Assurance
processes increasing
efficiency within
GMP guidelines.

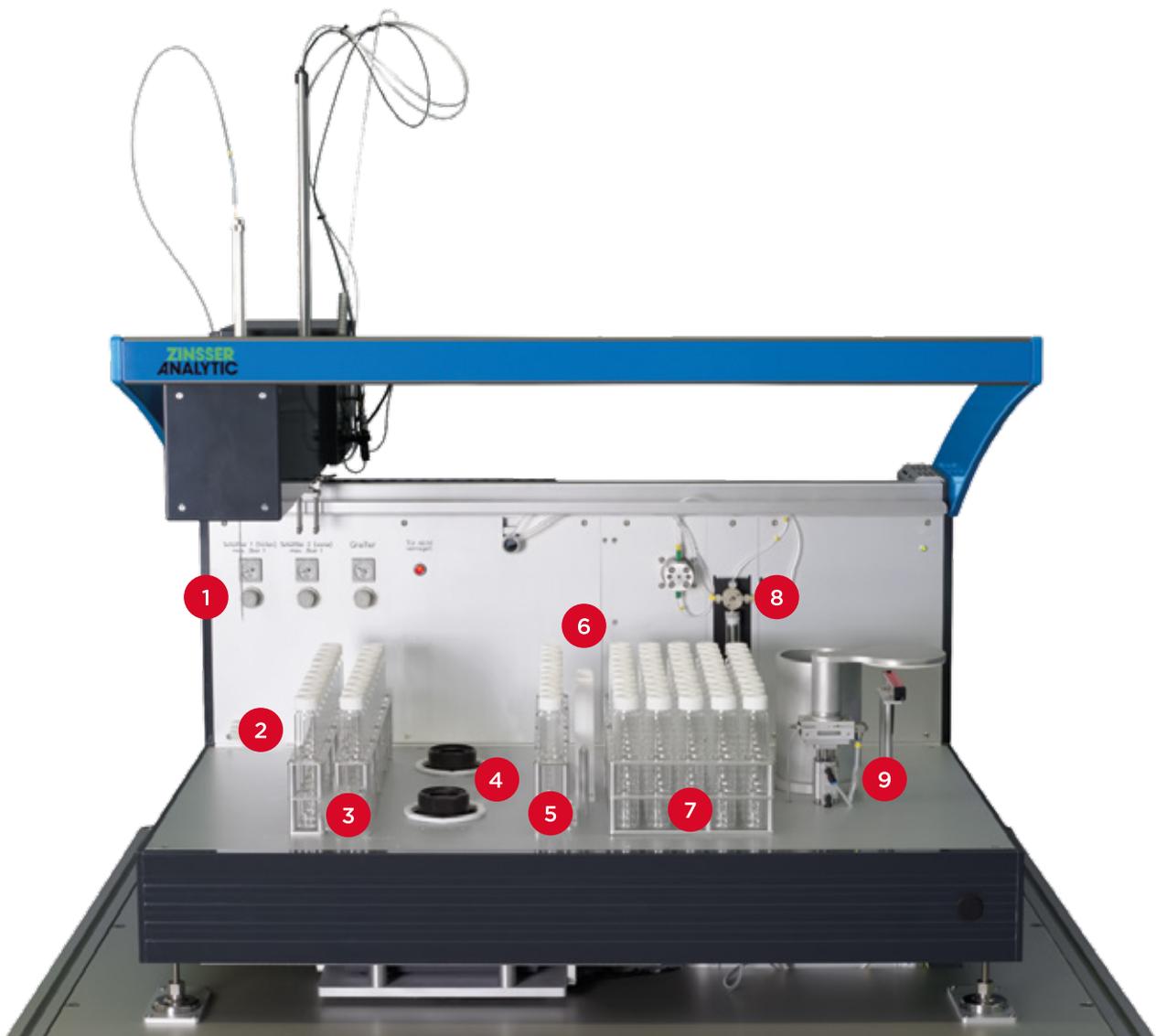


Designed for your processes

GMP regulated processes are time consuming and require accurate documentation in addition to traceable sample processing. Accordingly Zinsser Analytic designed a solution for GMP regulated tests for quality assurance.

- ✓ Precise Dilution of Diverse Target Stock Solutions
- ✓ Well Defined GMP Documentation
- ✓ Reproducible and Reliable Results
- ✓ Customized Software Interface





HARDWARE DESIGN

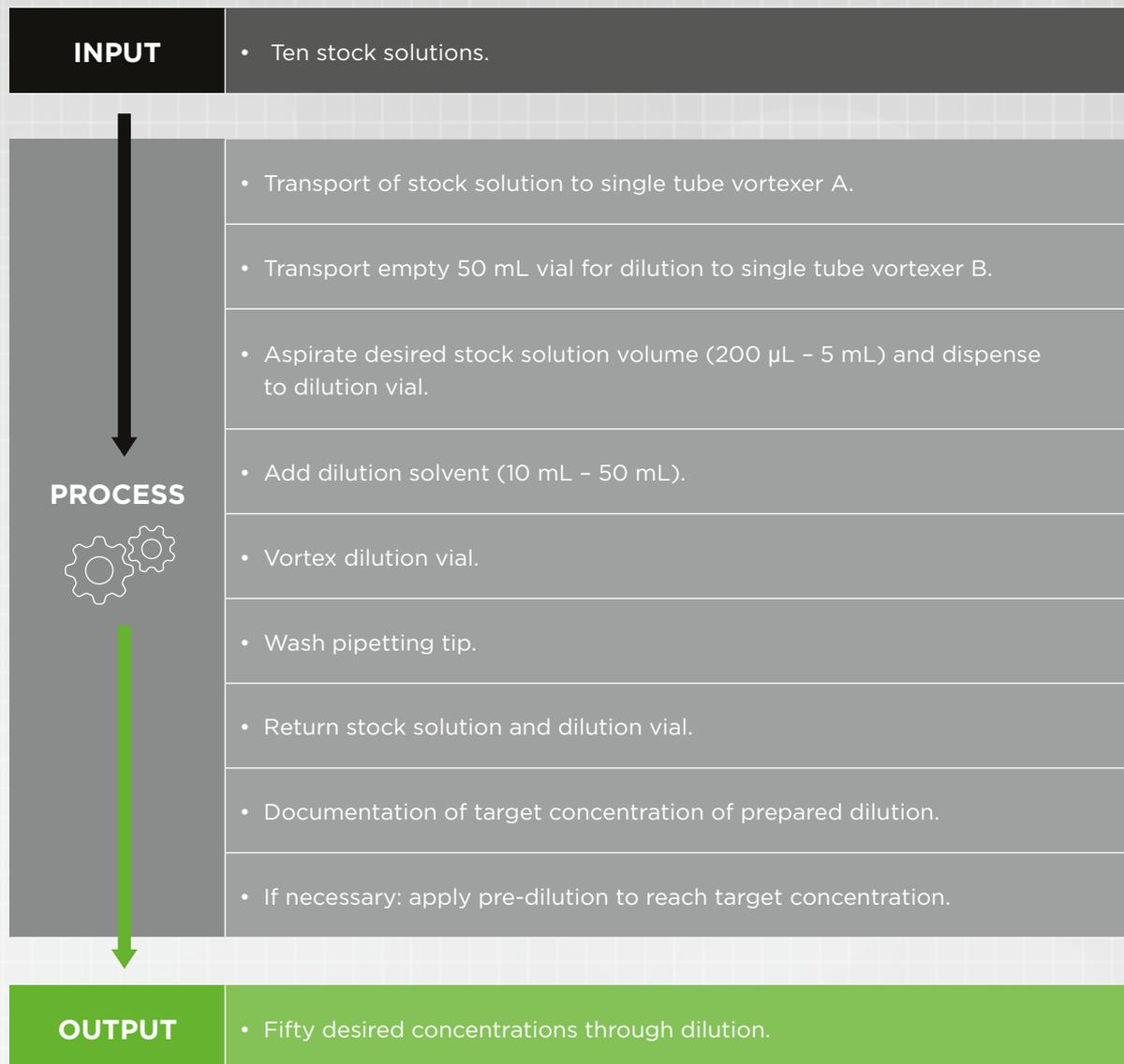
The design color of hardware was desired by the customer to fit their lab.

- 1 Piercing tip to pipette through septum and gripper for 50 mL vials
- 2 Source rack for ten 50 mL stock solution vials
- 3 Rack for ten 50 mL pre-dilution vials
- 4 Single tube vortexer A and B
- 5 Spare ten 50 mL vials as replacement vials if errors appear
- 6 Wash station for tip
- 7 Destination rack for fifty 50 mL vials with dilutions
- 8 6 mL Precision syringe pump
- 9 Balance with housing and ioniser

PERFORM DIVERSE DILUTION STUDIES

For GMP regulated quality assurance laboratories a precise definition of automated process steps is crucial to assure the validation of the workflow. The dilution process steps are designed to be applicable to various stock solutions:

Dilution Process Targets: The variation coefficient for pipetting should range from $\leq 1.5\%$ for stock solution and $\leq 0.5\%$ for dilution solvent.



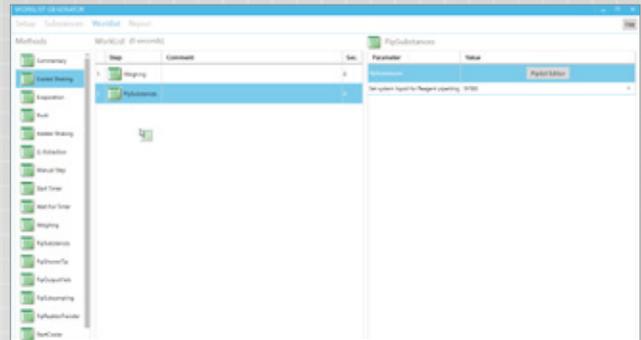
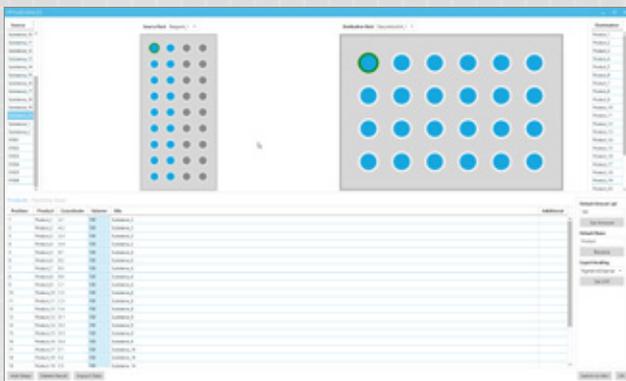
With this process a throughput of **160 dilutions in an 8 h working day** is achievable with a preparation time of maximum **180 seconds per dilution**.

SOFTWARE SOLUTION FOR YOUR SPECIFIC PROCESS

Every process step is designed modularly. Therefore a variety of processes, using differing powders, chemicals and solvents, may be completed. The customised sequential arrangement of the process is composed with a specified MS Excel® file or our Worklist-Generator which is then executed with our WinLissy®-software. With the Worklist-Generator you can create individual processes with many adjustable parameters for sub steps.

Worklist Generator

Drag and drop the needed methods to the desired positions of the worklist.

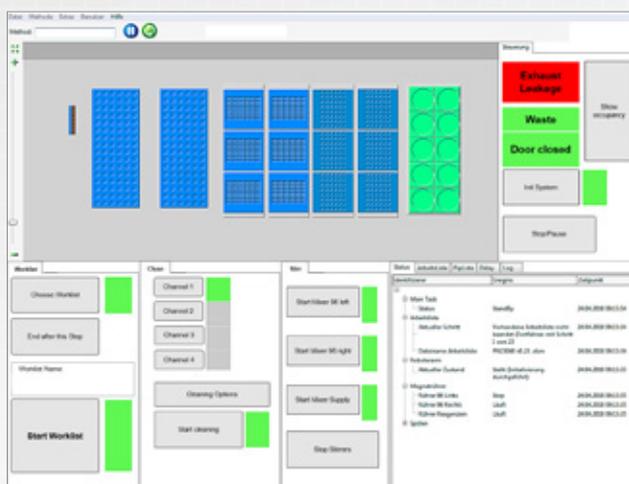
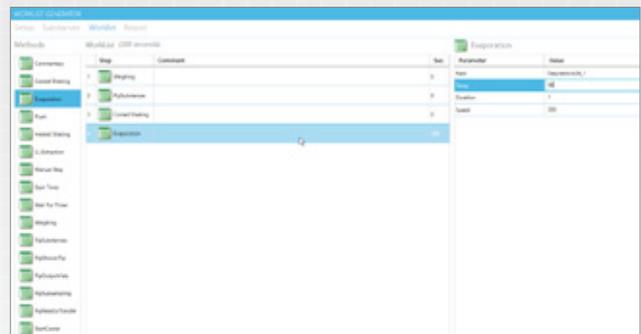


Pipetting Editor

For pipetting steps, the Pipetting-Editor is opened for the definition of racks and number of pipetting steps. Every filled position is indicated blue and the selected positions are highlighted green.

Method Definition

Input the desired time or anything the method requires, while you are defining the process.



WinLissy®-Software

With our WinLissy®-software every prepared worklist of the Worklist-Generator is executable. Communication with customer specific databases or LIMS is easily conceivable.

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